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Faculty Senate Executive Committee
Tuesday, February 13, 2018
10:00a.m. – 12:00p.m., Adelbert Hall, Room M2

10:00 a.m.	Approval of Minutes from the January 16, 2018 Executive Committee Meeting, *attachment*	Juscelino Colares
10:00 a.m.	President Announcements	Barbara Snyder
10:05 a.m.	Chair's Announcements	Juscelino Colares
10:10 a.m.	Conflict of Commitment Policy, *attachment*	Suzanne Rivera
10:25 a.m.	By-Laws Committee: Human Research Protection Policy, *attachment*	Kenneth Ledford
10:30 a.m.	School By-Laws Presentations	Juscelino Colares
10:35 a.m.	Graduate Studies Committee: Incomplete Grade Policy, *attachment*	Paul MacDonald Lynmarie Hamel
10:45 a.m.	Graduate Studies Committee: Proposed Guidelines to Create a University Certificate and Professional Certification, *attachment*	Paul MacDonald Lynmarie Hamel
10:55 a.m.	SOM Representative Report	Jo Ann Wise
11:00 a.m.	MSASS Representative Report	David Miller
11:05 a.m.	Report from the Senate Committee on Minority Affairs	Joachim Voss
11:15 a.m.	Senate Standing Committee Chair Slate for AY 2018-2019, *attachment*	Cynthia Beall
11:20 a.m.	CUE Status Update	Kimberly Emmons Gary Chottiner
11:30 a.m.	FSCUL: Library Content and Resource Review Process Document and Draft Cover Letter	Paul Iversen
11:40 a.m.	Allied Dental Health Programs- Dental Assistant Program	Ron Occhionero Shelly Feiwell
11:50 a.m.	Approval of Faculty Senate Agenda, *attachment*	Juscelino Colares

Faculty Senate Executive Committee
Minutes of the February 13, 2018 Meeting
Adelbert Hall, Room M2

Committee Members in Attendance
Barbara Snyder, President
Juscelino Colares, LAW, chair
Peter Harte, SOM, past chair
Cynthia Beall, CAS, vice chair
Leon Blazey, WSOM
David Miller, MSASS
Kimberly Emmons, CAS
Ibrahim Tulunoglu, SODM
Evelyn Duffy, SON
Jo Ann Wise, SOM
Roger Quinn, CSE

Others Present:
Gary Chottiner, chair, FSCUE
Kenneth Ledford, chair, By-Laws Committee
Maureen McEnery, chair, Nominating Committee
Harihara Baskaran, chair, Research Committee
Paul Iversen, chair, FSCUL
Leena Palomo, chair, Committee on Women Faculty
Joachim Voss, chair, Committee on Minority Affairs
Paul MacDonald, chair, Graduate Studies Committee

Absent:
Bud Baeslack, Provost
Aaron Perzanowski, LAW

Guests:
Suzanne Rivera
Lynmarie Hamel
Ronald Occhionero
Shelly Feiwell

Call to Order
Professor Juscelino Colares, chair, Faculty Senate, called the meeting to order at 10:00 a.m.

Approval of Minutes
The minutes of the January 16, 2018 meeting of the Faculty Senate Executive Committee were reviewed and approved. *Attachment*

President's Announcements

The President reported that the Provost is out of town and unable to attend today's meeting. He is in the process of identifying a consulting firm for the library review. The President reported that the Power of Diversity Lecture will be held today at 4:30 pm in the Tinkham Veale University Center. The speaker is Steve Pemberton, Chief Human Resources Officer for Globoforce and former Senior Executive, Walgreens & Diversity Leader. The President encouraged all faculty to attend.

Chair's Announcements

Professor Colares reported that the co-chairs of the Provost Search Committee, Professor Roy Ritzmann (CAS) and Suzanne Rivera, Vice President for Research, will report on the Committee's progress at the February Faculty Senate meeting. Prof. Colares also mentioned that there will be a Faculty Senate reception following the February meeting and encouraged all to attend.

Prof. Colares invited Professor Jerry Mahoney, chair of the Senate Committee on Faculty Compensation, to report on the committee's activities at today's meeting. Prof. Mahoney requested that he present at a later meeting since he plans to meet with the Provost soon to discuss the committee's work. Professor Joachim Voss, chair of the Senate Minority Affairs Committee, will report today instead.

Prof. Colares said that the report from the ad hoc Committee on the Bias Reporting System was to be presented to the Committees on Faculty Personnel and Minority Affairs and representatives from the ad hoc Committee were to attend the meetings to answer questions. The Faculty Personnel Committee met on January 18th and were satisfied with the report. The Committee on Minority Affairs mistakenly met without representation from the ad hoc Committee and have scheduled another meeting this afternoon where the appropriate representatives will attend. Prof. Colares said that he met with the Provost and the administration supports the ad hoc Committee's recommendations.

Conflict of Commitment Policy

Vice President Rivera presented a faculty conflict of commitment policy which will be incorporated into the university's conflict of interest policy. The policy was reviewed by the Faculty Senate Research and Personnel Committees. With respect to the language requiring prior *approval* of activity by the faculty member's department chair or dean, The Research Committee had requested that the requirement for faculty to receive prior approval from their chair or dean before engaging in non-university activities be modified to require disclosure only. The Personnel Committee had requested that the requirement be eliminated completely, but Vice President Rivera explained that the Faculty Handbook already includes a requirement for prior approval in the section entitled *Non-University Activities of Faculty Members During the Contractual Period* (Chapter 3, Part One, Article III). Another question arose relating to the term *University Faculty* in the policy. The definition of University Faculty in the Faculty Handbook includes special faculty and the conflict of commitment policy does not apply to this category of faculty. The Executive Committee voted to forward this policy to the Senate By-Laws Committee for discussion of these issues with Vice President Rivera and Professor Christine Cano, chair of the Personnel Committee. *Attachment*

By-Laws Committee: Human Research Protection Policy

Professor Ken Ledford, chair of the Senate By-Laws Committee, reported that the committee had considered proposed revisions to the Human Research Protection Policy. Vice President Rivera attended the meeting, and some minor changes were made. The By-Laws Committee approved the policy in its entirety and the Executive Committee voted to include the revised policy on the agenda for the Faculty Senate meeting. *Attachment*

School By-Laws Presentations

Prof. Colares made a motion that in the future when there is a conflict over who should present proposed revisions to school By-Laws, the Executive Committee should forward the proposed By-Laws to the Senate By-Laws Committee and that committee can invite whomever is the appropriate person to answer questions. The motion was seconded and the Executive Committee voted to approve the motion with one vote against and one abstention.

Graduate Studies Committee: Incomplete Grade Policy

Professor Paul MacDonald, chair of the Senate Graduate Studies Committee, presented an update to the Incomplete Grade Policy for graduate students. Students are now required to make up the incomplete work by the 11th week of the semester following the one in which the incomplete was received, rather than by the last day of the semester which is the current policy. The revised policy also includes language on when and how an incomplete grade is to be changed to an evaluative grade.

The Executive Committee discussed the fact that in some schools, such as the Law School, the final exam grade makes up most of the student's grade, and therefore, the language of the policy providing that a student may receive an incomplete when he/she has been passing the course and only has a small segment of the course to complete, might not be appropriate in all situations. The suggestion was to change the language as follows:

T*he student has been passing the course and only a*n ~~*small segment*~~ *evaluative component of the course, such as a term paper, final exam or project, etc. remains to be completed.*

The Committee voted (with one abstention) to include this revision in the policy and to forward the policy to the Senate for review. *Attachment*

Graduate Studies Committee: Proposed Guidelines to Create a University Certificate and Professional Certification

Prof. Paul MacDonald presented the Proposed Guidelines to Create a University Certificate and Professional Certification. Currently there is no officially recognized university definition of what constitutes a certificate program. Certificates vary widely across academic units and there is no university-level process for defining or approving criteria and standards. Certificate completion is generally not noted on the student's transcript. The guidelines define the different types of university certificates that may be offered, and establish the minimum requirements for the certificate to be officially recognized by the university and noted on the student's transcript. The guidelines don't eliminate existing certificates or prevent the development of new certificates that don't meet the university criteria. It was pointed out that the university does not offer undergraduate certificates, but

offers minors instead. The Executive Committee voted to include the proposed guidelines on the agenda for the Faculty Senate meeting. *Attachment*

SOM Representative Report

Professor Jo Ann Wise, SOM representative to the Executive Committee, gave a report from the SOM. She reported that faculty are concerned about the school's finances due to a large amount of debt that is expected to increase due to the new Health Education Campus. They are also concerned because some departments such as Anatomy and Biochemistry do not have chairs and there are no ongoing searches for new chairs. The number of tenure and tenure-track faculty is declining in a number of departments and there is widespread use of salary supplements, which are lost at the same time as the roles for which they were provided, as well as incentives, as opposed to raises in faculty's base salaries. Although rare, the latter can also be taken away. Other schools may be experiencing this also.

MSASS Representative Report

Professor David Miller, MSASS representative to the Executive Committee, gave a report from MSASS. The school has completed its strategic plan and is poised to begin a new planning process to align with a new provost's vision. The online MSSA program is doing well and accounts for nearly 50% of the school's enrollment. 50% of tuition revenue. The school is seeking a new provider for the program and is looking to the university for assistance in making this transition. Some faculty have felt that there wasn't sufficient transparency with regard to the provider contract. Prof. Miller also said that among faculty there is the potential for a number of retirements and/or reductions in status (e.g., from full- to halftime) on the horizon which number of faculty in the school will be retiring and this will create issues with respect to workload. The school will be looking to recruit new faculty.

Report from the Senate Committee on Minority Affairs

Professor Joachim Voss, chair of the Minority Affairs Committee, reported that the committee is working on a number of issues. They are analyzing the results of the 2016 minority faculty survey. 50-60 faculty members responded to the survey. The committee is discussing ways in which the OIDEO office can provide career and professional development for minority faculty. They are also discussing the idea of minority faculty cluster hiring. The committee is looking forward to the results of the Faculty Climate survey. Prof. Colares encouraged Prof. Voss to bring any future recommendations from the Committee on Minority Affairs to the Executive Committee for consideration.

Senate Standing Committee Chair Slate for Academic Year 2018-2019

Professor Cynthia Beall, vice chair of the Senate, presented the slate of Senate standing committee chairs for academic year 2018-2019. The Executive Committee approved the slate of chairs. *Attachment*

CUE Update

Professor Emmons, chair of the CUE, reported that she is working with FSCUE to synthesize feedback received on the CUE recommendations. At the last FSCUE meeting, the school representatives summarized their school's feedback. Prof. Emmons and Professor Gary Chottiner, chair of FSCUE, met after the FSCUE meeting to discuss next steps and they are feeling optimistic about the way forward.

Prof. Colares encouraged Prof. Emmons to continue working with FSCUE and reiterated that the President and Provost support this approach.

FSCUL: Library Content and Resource Review Process Document and Cover Letter

Professor Paul Iversen, chair of FSCUL, presented the Library Content and Resource Review Process document with the revisions approved by the Senate Executive Committee at the January 16th meeting, as well as a draft letter to deans and department chairs regarding the requirements of the review process. The revisions to the document were intended to clarify that the policy applies to undergraduate majors and minors and all degrees/programs subject to Faculty Senate review. Minor changes were also made to the sample template. The Executive Committee reviewed the revised documents and suggested a couple of other minor changes.

Professor Chottiner, chair of FSCUE, said he didn't believe it was necessary for FSCUE to review the revised document. The Executive Committee decided that all revisions to the document were within the scope of what had originally been approved by the Faculty Senate and did not require further consideration by that body. The Committee agreed that the matter should be included in the vice-chair's report at the Senate meeting. *Attachment*

Allied Dental Health Programs- Dental Assistant Program

Professor Ron Occhionero, SODM, discussed a proposal for a dental assistant pre-baccalaureate certificate (for high school graduates and community college students). A similar program had been proposed in 2002 but at that time the student information system software had been unable to incorporate a program of this type. As a result students would have been unable to qualify for Pell grants. Prof. Occhionero said that they are thinking of starting with a pilot program and wondered whether Faculty Senate approval would be required. When asked who would be teaching in the program, Prof. Occhionero said faculty from the SODM and auxiliaries. When asked whether the SODM faculty approved the program, Prof. Occhionero said that they had approved the program back in 2002 but not the new program. Vice Provost Don Feke said that this is a clock-based program not credit-based, and the HLC has specific requirements for this type of program. The Executive Committee recommended that the proponents of the program work with Vice Provost Feke to make any necessary changes required by the HLC and to request approval from the SODM faculty before returning to the Senate for further consideration of the program.

Approval of Faculty Senate Agenda

The Executive Committee approved the agenda for the February 27th Faculty Senate meeting. *Attachment*

The meeting was adjourned at 12:10 pm.

DRAFT 2/6/17

VIII. Policies on individual conflicts of interest and institutional conflicts of interest and faculty conflicts of commitment

Commented [MK1]: Reordered topics to follow the order addressed in the policy. Similarly reordered some paragraphs below.

Introduction

This document establishes policies on individual conflicts of interest, institutional conflicts of interest and faculty conflicts of commitment.

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Research, scholarship, and other creative endeavors have enormous potential to benefit humankind, and the University strongly supports efforts to bring discoveries to society. The purpose of these policies is to protect the University, its faculty, non-faculty employees, students and trainees, and human subjects and animals in research, and to comply with applicable federal laws. The policies seek to accomplish this by striking the proper balance between, on the one hand, the goal of preserving academic freedom and encouraging outside scholarly and entrepreneurial activities by members of the University that enhance the prestige and reputation of the University and benefit society, and, on the other hand, the need to preserve the integrity of the University and its members, and to fulfill the University's responsibilities to the public. In striking this balance, the interests of the public, the integrity of the University and its individual members, and the safety of research subjects always must be given priority.

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Conflict of interest policies apply generally to the members of the Board of Trustees, all University officers, senior officials, faculty (whether or not engaged in research or other scholarly or creative endeavors), volunteer faculty at the School of Medicine engaged in University research, post-doctoral fellows and scholars, non-faculty employees, students, and trainees. The specific policies cover specific types of individuals.

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The conflict of commitment policy applies to University faculty holding full-time faculty appointments (whether tenured, tenure-track or non-tenure-track).

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Availability of the Policies

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The University will maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with applicable regulations, including any federal financial conflict of interest regulations. The policy will be posted and available via a publicly accessible web site. The University will inform covered individuals of the policy and of their responsibilities regarding disclosure. The University will inform covered individuals in the event that the policy is revised and updated.

The University will maintain an up-to-date, written, enforced policy on conflict of commitment applicable to University faculty holding full-time faculty appointments (whether tenured, tenure-track or non-tenure-track) available via a publicly accessible web site. The University will inform covered individuals of the policy and of their responsibilities regarding disclosure. The University will inform covered individuals in the event that the policy is revised and updated.

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I. Individual Conflict of Interest Policy

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The University Conflict of Interests Committee

The members of the Conflict of Interests Committee, including the leadership of the committee, are appointed by the President and include faculty, non-faculty employees, and administrators. The Conflict of Interests Committee includes at least one member of the public who serves as a regular member of the Conflict of Interests Committee, and a second member of the public who serves as an alternate member of the Conflict of Interests Committee. The members of the public must not have any affiliation with the University (including as alumni, faculty, clinical faculty, adjunct faculty, or emeritus faculty) or with its affiliated hospitals (other than as patients). To the maximum extent possible, the members of the public must be independent of the line of authority for institutional oversight of research. A majority of the members of the Conflict of Interests Committee are members of the faculty as defined in Article I, sections (A) and (B) of the University Faculty Handbook, and one of these faculty members is appointed by the Executive Committee of the Faculty Senate. Membership also includes representatives from hospitals affiliated with the University. These members only participate in the resolution of conflicts of interest involving research.

The Conflict of Interests Committee is supported by the Conflict of Interests Committee Staff.

Members of the Conflict of Interests Committee must recuse themselves from consideration of their own conflicts of interest, or institutional conflicts of interest that relate to their own conflicts of interest.

Moved up [1]: I. Individual Conflict of Interest Policy¶

A. Who is covered by this policy?

The conflict of interest policy applies to the members of the Board of Trustees; all University officers; senior ("cabinet-level") officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, Inclusion and Equal Opportunity, and any other individual that the President designates); all University faculty except special faculty members who are not paid by the University, unless engaged in University research; emeritus faculty members who have an ongoing relationship with the University, e.g., who are applying for or engaged in University research; post-doctoral fellows; all employees; students; and trainees. "University faculty" members are those individuals defined as such in the Faculty Handbook.

This policy applies to these individuals regardless of where they conduct activities covered by the policy.

B. What is an individual conflict of interest?

An individual conflict of interest exists when an individual covered by this policy has a financial interest that might adversely affect or appear to a reasonable person to adversely affect the individual's judgment in carrying out University responsibilities, or that might adversely affect or

appear to a reasonable person to adversely affect the University's responsibility to the public, the safety of research subjects, or the integrity of research.

C. Disclosure

The disclosure requirements under this policy are broad, in order to provide adequate protection for individuals covered by the policy, the University and affiliated institutions, and the public interest. It is important to recognize that a disclosure requirement does not indicate that the activity in question is in any way objectionable; indeed, disclosure is required in connection with many activities in which members of the University are expected to engage, such as funded research, or that are otherwise praiseworthy, such as the receipt of honorary awards.

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1. Who must disclose?

The following individuals must disclose under this policy: the members of the Board of Trustees; all University officers and senior officials, as defined in section I(A) of this policy; all University faculty (whether or not engaged in research), except special faculty members who are not paid by the University, unless engaged in University research; emeritus faculty members who have an ongoing relationship with the University, e.g., who are applying for or engaged in University research; and Senior/key personnel and other individuals who contribute to the scientific development or execution of a research project in a substantive way, and any other employees at the request of their supervisor. Individuals who have no disclosable interests must still submit an annual disclosure form to be in compliance with this policy.

Students and post-doctoral fellows and scholars do not have to disclose unless they contribute to the scientific development or execution of a research project in a substantive way.

2. What activities must be disclosed?

Individuals covered by this policy must disclose any financial interest (defined in the attached Definitions) and the acceptance of any gifts, favors, or anything of value, by the individual or the individual's spouse, dependent children, domestic partner, or any other dependent person who is a member of the same household as the individual, that directly or indirectly might influence or appear to a reasonable person to influence the individual's responsibilities as a member of the University.

Individuals covered by this policy who engage in research must disclose any financial interest, no matter how small, that the individual or the individual's spouse, dependent children, domestic partner, or any other dependent person living in the same household as the individual, has in any entity that sponsors or supports the research or that holds a financial interest in the subject of the research, and also must disclose the acceptance of any gift, favor, or anything of value from an entity that sponsors the research or that holds a financial interest in the subject of the research.

Individuals covered by this policy also must disclose whenever a previously disclosed conflict of interest is eliminated.

Whenever an individual covered by this policy has any doubt about whether or not an activity must be disclosed, the individual should disclose the activity.

3. What activities are permitted without disclosure?

Certain activities may be engaged in without disclosure. Typically, these are activities not covered in section 2 above, and in which academics routinely engage and in which an individual's financial interests are not expected to influence his/her judgment. Disclosure is also not required for salary, royalties or other remuneration paid by the University to the individual if the individual is currently employed or otherwise appointed by the University.

Examples of activities in which individuals may engage without disclosure include:

Receiving royalties for published scholarly work and other writings.

Accepting reasonable meals and other customary business amenities (such as pads and pens) that are provided as part of a seminar, course, meeting, or other business-related gathering.

Honoraria for reviewing scholarly manuscripts for publication by academic journals or presses.

Travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Royalties or other payments extending from intellectual property rights assigned to the University, and agreements to share in royalties or other payments related to such rights.

Grants and contracts administered through the University.

Whenever an individual has any doubt about whether or not an activity must be disclosed, the individual should disclose the activity.

4. How is disclosure to be made and to whom?

All members of the University community are covered by the Conflict of Interest policy, but disclosure requirements vary according to the individual's role(s) with the University.

Generally, annual disclosure by faculty and other researchers is made to the Conflict of Interests Committee using the form provided by the University.

Members of the Board of Trustees, the President, and other senior officials disclose using a separate process administered by the Office of the General Counsel.

Those staff members and other individuals who are not required to complete an annual disclosure form must disclose to their supervisors any financial interest that relates to their University responsibilities. Supervisors who determine that an individual may have a conflict of interest must report this to the Conflict of Interests Committee for further review.

Compliance with this policy does not relieve the individual from complying with pertinent regulatory committee disclosure requirements.

5. When is disclosure to be made?

Disclosure must occur at least annually in accordance with the time period prescribed by the University. For those who are listed on sponsored projects, disclosure must occur no later than the time of funding application. Individuals also must disclose, as appropriate, within 30 days of discovering or acquiring a disclosable interest or within 30 days after a financial interest has been eliminated.

Individuals who have been recruited to the University must disclose any conflicts of interest sufficiently in advance of their start date that the conflicts can be reviewed and resolved by the Conflict of Interests Committee prior to their start date.

Disclosure or confirmation/updating of previously disclosed information also is required at the time a research proposal is submitted on the electronic University Review Form, and when a research proposal is submitted to relevant review bodies as required.

D. Review

1. What is the process?

The Conflict of Interests Committee Chair and Staff, or the Office of General Counsel Staff, as appropriate, conducts an initial review of all the disclosures they receive.

If necessary, they obtain additional information from the disclosing individual and from other individuals who possess relevant information. The Conflict of Interests Committee Chair and Staff, or the Office of the General Counsel Staff, as appropriate, notifies the Conflict of Interests Committee or the Board of Trustees, respectively, of those activities that must be further reviewed.

The Conflict of Interests Committee reviews all disclosures to determine whether the disclosed financial interests are significant, whether they are related to the individual's University responsibilities, and whether a management plan is required. Reviews of individual disclosures conducted solely by the Audit Committee of the Board of Trustees are conducted according to the rules of the Board of Trustees.

In conducting review, the Conflict of Interests Committee considers a number of factors, including the value of the individual’s financial interest; and in the case of research, whether the individual is uniquely qualified by virtue of expertise and experience to conduct the research project, whether the research could not be conducted as safely or effectively without that individual, and the degree of risk imposed on research subjects.

Following are some examples of conflicts of interest. In specific cases, individuals may be able to engage in some of these activities with a suitable management plan:

a. While serving as an investigator on a research project that relates to a company's products, an individual is receiving consulting fees from and/or has equity in the company.

b. An individual manages the renovation of departmental offices and participates in the selection of an architectural firm in which his spouse is a partner.

c. A faculty member with a financial interest in an outside company serves as the direct academic supervisor of a university student employed by that company.

d. While serving on the board of directors of a business, an individual acts as an investigator on research sponsored by the business.

e. An individual makes referrals to a business in which he or she has a financial interest.

2. Management

The Conflict of Interests Committee may decide to approve an activity subject to a suitable management plan.

To "manage" means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflicts of interest, and, in the case of conflicts of interest involving research, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

The management plan may include but is not limited to:

a. Requiring the individual to recuse him/herself from particular business decisions.

b. Requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (such as the relevant review bodies, as required; state and federal officials; research sponsors; co-investigators; colleagues; junior colleagues; students; trainees; members and prospective members of the individual's research laboratory; journals to which manuscripts about the research are submitted; and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing).

c. Requiring the individual to refrain from participating in certain activities or aspects of activities relating to the research project (such as requiring IRB members with conflicts of interest in connection with research protocols to recuse themselves from deliberations on those protocols, or, where compelling circumstances exist to allow certain research stages or activities to proceed despite a conflict of interest, restricting the individual's roles to those stages and activities, including establishing a point in time for stopping participation and strategies to keep the individual's involvement at a minimum).

d. Requiring the activity to be approved by additional individuals or entities (such as deans, department chairs, or program chairs).

e. Requiring others to review academic decisions in which the individual participates.

f. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).

g. Requiring the individual to reduce, modify, or eliminate a financial interest (including divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments).

h. Requiring the individual to vacate a position.

i. Prohibiting the individual from disclosing confidential institutional information or channeling discoveries to an outside entity.

j. Prohibiting the research from taking place at the University.

k. Requiring continued oversight of the activity by the Conflict of Interests Committee.

Management plans are developed according to the nature of the significant financial interest and of the related University activity, e.g., whether there is an institutional as well as an individual conflict of interest, and whether the investigator is conducting research.

The Conflict of Interests Committee may involve the individual in the conflict of interest assessment. If the Conflict of Interests Committee determines a management plan is required, then upon finalizing the management plan, the Conflict of Interests Committee will provide the management plan to the individual and inform the individual that the management plan is in effect.

E. Training

Information regarding the University's conflict of interest policy and procedures will be made available to the University community. All individuals required to disclose will receive pertinent information regarding disclosure requirements. The University will comply with federal financial conflict of interest regulations regarding providing training on requirements, including disclosure requirements for investigators applying for and engaged in PHS-funded research.

F. Reporting

The University will comply with federal regulations regarding reporting of financial conflicts of interest, e.g., by submitting financial conflict of interest reports to the awarding component, as required.

The University will comply with federal financial conflict of interest regulations regarding making publicly available information on identified financial conflicts of interest held by investigators and key personnel on PHS-University research.

G. Subrecipient Reporting

The University will comply with federal conflict of interest regulations regarding subrecipient agreements, including for PHS-funded awards.

H. Record Keeping

The University complies with federal regulations regarding maintaining records relating to all disclosures of financial interests and the University's review of, and response to, such disclosures.

I. Appeals

If an individual covered by this policy who is a faculty member is dissatisfied with a determination of the Conflict of Interests Committee, the individual may submit a written appeal to the Provost within 10 days of receipt of the decision. The appeal shall be decided by the Provost or his/her designee. The Provost or his/her designee will make best efforts to render a decision in writing within 30 days of receipt of the appeal. If the Provost upholds the Conflict of Interests Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

A non-faculty employee who is dissatisfied with a determination of the Conflict of Interests Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision. The appeal shall be decided by the Senior Vice President or his/her designee. The Senior Vice President or his/her designee will make best efforts to render a decision in writing within 30 days of receipt of the appeal. If the Senior Vice President for Administration upholds the Conflict of Interests Committee's determination, the decision of the Senior Vice President for Administration is final. If the Senior Vice President for Administration modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

If the individual is the President or senior official, the President or senior official may submit a written appeal to the Audit Committee of the Board of Trustees within 10 days of receipt of the decision.

If the individual is a member of the Board of Trustees, the appeal is conducted in accordance with the policies and procedures of the Board of Trustees.

II. Institutional Conflict of Interest Policy

A. Who is covered by this policy?

This institutional conflict of interest policy applies to the members of the Board of Trustees, the President, the Provost, all senior ("cabinet-level") officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates), vice presidents, vice provosts, deputy provosts, deans, associate and vice deans, department chairs, academic division chiefs, directors of department-level centers, IRB chairs, the chair of the Conflict of Interests Committee, the chair of the Institutional Biosafety Committee, and directors of institutes and centers with department-level status.

B. What is an institutional conflict of interest?

An institutional conflict of interest arises when the financial interests of the University, or of a University official acting within his/her authority on behalf of the University, may influence or appear to influence the research, education, clinical care, business transactions, or other activities of the University. In the case of research, the concern is that the financial interests of the University, or of a University official acting within his/her authority on behalf of the University, might affect—or reasonably appear to affect—University processes for the conduct, review, or oversight of the research.

An institutional conflict of interest also might arise when an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University.

Institutional conflicts of interest may arise when outside activities are inconsistent with an individual's responsibilities to the University. Outside activities include leadership participation in professional, community, or charitable activities, self-employment, participation in business partnerships, employment or consulting arrangements with entities other than the University, either compensated or uncompensated, and service on any private-sector board, including for-profit, non-profit, advisory, or honorary. These activities are inconsistent with an individual's responsibilities to the University when they adversely influence or appear to adversely influence the research, education, clinical care, business transactions, or other activities of the University.

An individual conflict of interest may raise an institutional conflict of interest issue and vice versa.

C. Disclosure

There is no separate individual disclosure under the institutional conflict of interest policy. The information disclosed on individual conflict of interest forms is used in carrying out the institutional conflict of interest policy.

In addition, the Conflict of Interests Committee Staff periodically must receive the following information:

1. From the Senior Vice President of Finance and Chief Financial Officer, a list of the entities in which the University has any financial interest.

2. From the Board of Trustees, a list of the entities in which members of the Board of Trustees and senior officials of the University, their spouses, dependent children, domestic partners, or any other dependent person living in the same household as the individual, have any financial interest. The list of entities provided by the Audit Committee of the Board of Trustees to the Conflict of Interests Committee does not contain the identities of the individuals who have the financial interest in those entities.

3. From the Office of Development, a list of major gifts to the University.

4. From the Office of Research and Technology Management, a list of the University's equity holdings and technology licenses.

D. Review

1. **What is the process?**

Reviews of individual disclosures conducted solely by the Audit Committee of the Board of Trustees are conducted according to the rules of the Board of Trustees.

In the case of all other individual disclosures, the Conflict of Interests Committee Chair and Staff, or the Office of General Counsel Staff, as appropriate, conducts an initial review. If necessary, they obtain additional information from the disclosing individual and from other individuals who possess relevant information.

The Conflict of Interests Committee Chair and Staff utilize information provided by the offices and departments of the institution (e.g., from the Senior Vice President of Finance and Chief Financial Officer, the Board of Trustees, the Office of Development, and the Office of Research and Technology Management) to review potential institutional conflicts of interest received.

The Conflict of Interests Chair and Staff then identify those activities that must be further reviewed by the Conflict of Interests Committee.

The Conflict of Interests Committee will review the disclosures it receives to determine whether the disclosed financial interests of institutional officials or of the University are significant and whether they are related to University activities, and, if so, whether management is required to manage the institutional conflict of interest.

In conducting review, the Conflict of Interests Committee considers a number of factors, including value of the institutional financial interest and the nature of related University activities.

Following are some examples of institutional conflicts of interest. In specific cases, individuals may be able to engage in some of these activities with a suitable management plan:

a. A vice president of the University signs off on a procurement decision involving major purchases from or supply contracts with a commercial entity of which he is a director.

b. A department chairman serves as an investigator in a research project sponsored by a company from which she receives consulting income.

c. As patent-holder, the University stands to gain royalties from intellectual property licensed to a company, and that intellectual property is being investigated under a research contract with the University.

d. A company that has made a major gift to the University has requested special consideration in the bidding process as a vendor. The individual considering the bid is a consultant for the company.

e. A start-up company partially owned by the University has requested a discounted rate in utilizing several University core facilities. The facilities are overseen by an individual who is the chief scientific officer of the company.

2. **Management**

The Conflict of Interests Committee may decide to approve an activity subject to a suitable management plan. The management plan may include:

a. Isolating the individual from involvement in research or decision-making regarding research.
b. Requiring the individual to reduce, modify, defer, waive, or eliminate the financial interest that is the source of the conflict, such as equity holdings, royalty income, stock options and milestone payments.
c. If recusal would preclude the individual from fulfilling the responsibilities of a University position, requiring the individual to eliminate the holdings or vacate the position.

d. Requiring the individual to recuse him- or herself from institutional decisions regarding the outside entity that is source of conflict.

e. Requiring the individual to make periodic written disclosure of the conflict to all administrators, faculty, non-faculty employees, and students under individual's supervision, to Research Administration, IRBs, IACUCs, subjects, state and federal officials, research sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of the individual's research laboratory, journals to which manuscripts about the research are submitted, and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing.

f. Appointing independent individuals or committees to oversee high-level administrative decisions (e.g., financial decisions, space allocations, appointments and promotions) in which the individual participates.

g. Prohibiting the research from taking place at the University.

h. Eliminating, reducing, or modifying the University's financial stake in an outside entity or research project.

i. Enhancing or creating firewalls or other conflict-management systems to separate financial and research decision-making.

j. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).

k. Preventing the individual from serving as the principal investigator, co-principal investigator, or investigator on the research project.

l. Protecting students, trainees, junior colleagues and/or non-faculty employees by preventing or limiting their participation in the research project, preventing or limiting them from working in newly-formed companies involving conflicted superiors, informing them of the potential conflict, giving them access to senior faculty and non-faculty employees to review questions or concerns, having academic decisions outside the research activity made or reviewed by independent individuals, and recusing the conflicted individual from the chain of authority over salary, promotion, and space allocation decisions.

m. Prohibiting the individual from participating in institutional negotiations with the outside entity except as the University directs.

n. Prohibiting the individual from serving on the board of directors of the outside entity, or as an officer, member of the scientific advisory board, member of a speakers' bureau, or consultant.

o. Prohibiting the individual from disclosing confidential University information.

p. Prohibiting the individual from channeling discoveries to the outside entity.

q. Prohibiting the University from accepting research grants from companies founded by the individual.

E. Appeals

The person responsible for ensuring that an individual has complied with the University's Conflict of Interest Policy must report a failure to comply to the Conflict of Interests Committee Chair or Staff, who refers it to the Conflict of Interests Committee, except that a failure to comply by the President or a member of the Board of Trustees must be reported to the Audit Committee of the Board of Trustees.

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The Conflict of Interests Committee determines if the matter can be handled by requiring the individual to comply with a corrective action plan devised by the Conflict of Interests Committee. If so, the Conflict of Interests Committee devises the plan and advises the individual of its requirements. If the Conflict of Interests Committee determines that the matter cannot be handled by requiring the individual to comply with a corrective action plan, or the individual refuses to comply, the Conflict of Interests Committee refers the matter, along with its recommendations about how the matter should be handled, to the appropriate individual or body. In the case of faculty, the Conflict of Interests Committee refers the matter to the Provost. In the case of the Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates as a senior "cabinet-level" official, the Conflict of Interests Committee refers the matter to the President.

If an individual other than a non-faculty employee is dissatisfied with a determination of the Conflict of Interests Committee to impose a corrective action plan or with administrative action by the Vice President for Research to suspend or refuse to approve a University research project, the individual may submit a written appeal to the Provost within 10 days of receipt of the determination. A non-faculty employee who is dissatisfied with a determination of the Conflict of Interests Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision.

If the Provost upholds the Conflict of Interests Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

If the Senior Vice President for Administration upholds the Conflict of Interests Committee's determination, the decision of the Senior Vice President for Administration is final. If the Senior Vice President for Administration modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

Grievance proceedings are conducted in accordance with the procedures provided in the University Faculty Handbook and the Human Resources Policy Manual.

When an individual has an individual conflict of interest and an institutional conflict of interest also exists, the appeal process under the individual conflict of interest policy applies.

In the event that an individual who is charged with executing an institutional conflict of interest management plan but who does not have an individual conflict of interest is dissatisfied with a determination of the Conflict of Interests Committee, the individual may submit a written appeal to the President within 10 days of receipt of the decision. If the individual is the President, the President may submit a written appeal to the Audit Committee of the Board of Trustees within 10 days of receipt of the decision. If the individual is a member of the Audit Committee, the Audit Committee's deliberations and decision is conducted in accordance with the policies and procedures of the Board of Trustees. If the President or the Audit Committee upholds the Conflict of Interests Committee's determination, the decision is final. If the President modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the Audit Committee.

III. Conflict of Commitment Policy

University faculty (whether tenured, tenure-track or non-tenure-track) holding full-time faculty appointments, owe their primary professional commitment to the University. The University recognizes that its faculty may benefit from engaging in professional activities outside of the University (including consulting). Such activities can enrich the faculty member's knowledge and skill base, and benefit the University and its students by establishing relationships that may lead to grants or sponsored research. Faculty members are permitted to accept opportunities for outside professional activities in their fields of specialization subject to this policy and provided that they are able to fulfill all University responsibilities. The amount of a faculty member's professional effort devoted to outside activities should not exceed, on average, one business day per week during the period of their University employment.

A. Who is covered by this policy?

The conflict of commitment policy applies to all University faculty holding full-time faculty appointments (whether tenured, tenure-track or non-tenure-track). "University faculty" members are those individuals defined as such in the Faculty Handbook. This policy applies to these individuals regardless of where they conduct activities covered by the policy.

B. What is a conflict of commitment?

A conflict of commitment involves a situation in which a faculty member's outside activity, or potential outside activity, whether paid or unpaid, involves a commitment of time or effort that may interfere with fulfillment of the faculty member's ability or willingness to perform the full range of responsibilities associated with his or her university position. The issue here is not necessarily financial interest or bias in one's judgment but rather whether one's commitment of time and effort is inconsistent with one's commitment to the University and its interests.

Examples:

1. A faculty member dedicates more than the average one day per week to outside professional activities such as consulting with a company or companies.
2. A faculty member travels excessively in such a manner that interferes with the faculty member's ability to meet his or her university obligations.

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Commented [MK3]: See current CWRU Faculty Handbook page 50 "Non-University Activities of Faculty Members During the Contractual Period". Conflict of Commitment policy will supersede that but we incorporated some of the still relevant language.

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C. **Disclosure**

University faculty holding full-time faculty appointments (whether tenured, tenure-track or non-tenure-track) must disclose potential outside activities to their department chair (or dean if the School in question does not have departments) at least seven (7) days prior to engaging in an outside activity (whether paid or unpaid) to enable potential conflicts of commitment to be identified. Disclosure of a potential outside activity should be submitted by the faculty member directly to his/her chair or dean.

In addition, a faculty member may not hold a faculty appointment in another educational institution without written approval in advance by the Provost. Requests for approval of a potential faculty appointment should be submitted by the faculty member directly to his/her school dean.

Examples of activities that would not require prior disclosure include:

- Participation on federal grant proposal study sections and similar peer review of grant proposals, publications, etc.
- Participation in meetings and conferences of academic and professional societies
- Participation in a governmental commission, board task force or other such working group
- Going to another site to access facilities necessary to perform University research
- Going to another site for accreditation, audits, reviews, etc. in furtherance of University research or a University academic program

D. Review

1. Review of potential outside activities (other than appointment at another educational institution)

The faculty member's chair or dean shall review the disclosure. If the activity is acceptable, no response is required. If the chair or dean has a concern about the activity, the chair or dean shall provide communication to the faculty member within seven (7) days to initiate a dialogue about whether the proposed activity can be managed to avoid a conflict of commitment. If, in the opinion of the chair/dean, the activity cannot be managed, the faculty member must refrain from participating in the activity.

2. Review of potential appointments at another educational institution

The faculty member's dean shall review the disclosure with the Provost. If the appointment is acceptable, the Provost shall provide written approval. A copy of this written approval shall be maintained by the Provost. If the Provost has concerns about the appointment, the Provost and/or dean shall discuss with the faculty member whether the appointment can be managed to avoid a conflict of commitment. If, in the opinion of the Provost, the activity cannot be managed, the faculty member must decline the appointment.

E. Appeals

1. Appeal of chair/dean's decision concerning proposed outside activities (other than appointment at another educational institution)

If a faculty member is dissatisfied with a decision of his/her chair, the faculty member can submit a request for reconsideration to his/her school dean. The dean shall respond to the faculty member within

Commented [SR8]: See Faculty Handbook, p. 50 "Non-University Activities of Faculty Members During the Contractual Period"

Commented [SR9]: Added in response to request by Deans

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thirty (30) days. If a faculty member is dissatisfied with a decision of his/her dean, the faculty member may submit a written appeal to the Provost within 30 days of receipt of the decision. The appeal shall be decided by the Provost. The Provost will make best efforts to render a decision in writing within 30 days of receipt of the appeal. The Provost's decision is final.

2. Appeal of Provost's decision concerning appointment at another educational institution

If a faculty member is dissatisfied with a decision of the Provost not granting approval of an appointment at another institution, the faculty member may submit a written appeal to the President within 30 days of receipt of the decision. The appeal shall be decided by the President. The President will make best efforts to render a decision in writing within 30 days of receipt of the appeal. The President's decision is final.

IV. Confidentiality

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All information contained in disclosures or obtained in the course of reviewing a potential conflict of interest or institutional conflict of interest, is kept confidential, subject to the University's reporting obligations to government agencies, research sponsors and the public. The information is available to the Conflict of Interests Committee and its Staff, and to the individuals charged with the responsibility for review in the particular case. In addition, the disclosures received by the Conflict of Interests Committee are shared with the deans and department chairs or supervisors of the disclosing individuals at the request of the individual's dean, chair or supervisor, or at the request of the Conflict of Interests Committee. The individual's department chair, dean or supervisor will be provided with the management plan. There may be instances when other institutional officials must receive this information (e.g., members or staff of regulatory committees with oversight of activities covered in the management plan).

V. Sanctions

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Failure to comply with these policies includes failing to submit a required disclosure, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with a management plan adopted under these policies.

A failure to comply with these policies may, in the case of University research, result in a decision by the Vice President for Research to suspend the research project or refuse to approve a new University research project for the individual who fails to comply.

A failure to comply also is subject to the full range of University disciplinary procedures, including:

a. Formal admonition.

b. A letter in the individual's file indicating that the individual's good standing as a member of the University has been called into question.

c. Ineligibility of the individual to apply for grants, IRB approval, or supervision of graduate or professional students or trainees.

d. Additional sanctions per research funding agency may apply (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of funding per applicable federal regulations. The University will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action.

e. Non-renewal of appointment.

f. Termination of employment.

VI. Revisions to the Policies

Any revisions to these policies that are required by law or by government agency action will become part of these policies. Other revisions to these policies become effective upon being approved by the President, the Provost, and the Executive Committee of the Faculty Senate.

Definitions

"Conflict of commitment" - A conflict of commitment involves a situation in which a faculty member's outside activity, or potential outside activity, whether paid or unpaid, involves a commitment of time or effort that may interfere with fulfillment of the faculty member's ability or willingness to perform the full range of responsibilities associated with his or her university position.

"Consulting"- In general, consulting is defined as professional activity related to the person's field or discipline, where a fee-for-service or equivalent relationship with a third party exists. Consulting does not include: academic publication or editorial activities; service on national commissions, governmental agencies and boards, granting agency peer review panels, professional societies, visiting committees or advisory groups to other universities, and analogous bodies; and donation of personal time to philanthropic organizations or charities.

"Disclosure" – "Disclosure" means an individual's reporting of financial interests and/or significant financial interests to the University.

"Faculty" – "Faculty," as defined in the Faculty Handbook, comprises tenured or tenure track faculty members, non-tenure track faculty members, and special faculty members. Special faculty members are: 1) those persons holding part-time academic appointments, and 2) persons holding full-time academic appointments, but who have specific, limited responsibilities for the duration of a specific project, or for a limited duration. Examples of special appointments are faculty members hired for one semester, who

Moved up [2]: The person responsible for ensuring that an individual has complied with the University's Conflict of Interest Policy must report a failure to comply to the Conflict of Interests Committee Chair or Staff, who refers it to the Conflict of Interests Committee, except that a failure to comply by the President or a member of the Board of Trustees must be reported to the Audit Committee of the Board of Trustees. ¶
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teach one course on a repeated basis, who engage in clinical supervision only without other responsibilities to the University, or who are engaged in a specific project conducted outside the University.

"Financial conflict of interest report" - In the sponsored research context, this refers to the University's financial conflict of interest report to the awarding component.

"Financial interest" – A "financial interest" means anything of monetary value, whether or not the value is readily ascertainable. Examples of financial interests include the following: income; honoraria; consulting fees; advisory board fees; membership on a speaker's bureau; remuneration; gifts or other emoluments; "in kind" compensation; travel expenses and reimbursement, other than those paid for by the University or its hospital affiliates, or reasonable travel expenses paid for participation in scholarly and academic endeavors and/or those described in the exclusions in Section I.C.3.of this policy; equity such as stock, stock options or other ownership interests, including equity that individuals covered by this policy know they will inherit; royalties; non-university grants; debts; loans; non-university contracts; licensing agreements; inventors' shares. Disclosure of a board membership or other officer position involving advisory or fiduciary duties with any outside entity is required where: 1) the individual receives compensation from the entity (i.e., salary or other remuneration; equity interest, such as stock, stock options or other ownership interest; or other compensation of monetary value); or 2) the board or officer position (whether compensated or uncompensated) is with a for-profit outside entity or with an outside entity (for-profit or non-profit) that has a vendor or sponsor relationship with the University or its clinical affiliates, to the best of the individual's knowledge.

"Individual conflict of interest" – An outside interest that might adversely affect or appear to a reasonable person to adversely affect an individual's judgment in carrying out University responsibilities, or that might adversely affect or appear to a reasonable person to adversely affect the University's responsibility to the public, the safety of research subjects, or the integrity of research. For the purposes of research, a financial conflict interest means a significant financial interest that could directly and significantly affect the individual's University responsibilities, and in the case of research, that could directly and significantly affect the design, conduct, or reporting of research.

"Institutional conflict of interest" -- An institutional conflict of interest arises when the financial interests of the University, or a University official acting within his/her authority on behalf of the University, may influence or appear to influence the research, education, clinical care, business transactions, or other activities of the University; when an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University; and when outside activities are inconsistent with an individual's responsibilities to the University.

"Institutional responsibilities" – "Institutional responsibilities" are defined as those professional responsibilities that are conducted on behalf of the University. Examples of institutional responsibilities include: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

"Investigator" – "Investigator" means the Project Director, Principal Investigator and any other person who is significantly involved in and responsible for the design, conduct or reporting of research, or proposal for such funding, including the person's spouse and dependent children and/or any other collaborators or consultants. The term also includes investigators working for subgrantees, contractors, subcontractors, and collaborators. See also the definitions provided in this policy for "Project Director/Principal Investigator" and "Senior/key personnel."

"Manage" – "Manage" means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflicts of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

"Outside professional activities" – "Outside professional activities" include leadership participation in professional, community, or charitable activities, self-employment, participation in business partnerships, employment or consulting arrangements with entities other than the University, either compensated or uncompensated, and service on any board, including for-profit, non-profit, advisory, or honorary.

"Project Director/Principal Investigator" – These terms refer to the project director or principal investigator of a research project. See also the definitions provided in this policy for "Investigator" and "Senior/key personnel."

"Senior officials" – "Cabinet-level" officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates).

"Senior/key personnel" – These terms are used interchangeably to refer to the Project Director/Principal Investigator and any other senior or key personnel identified by the University on PHS-funded grant applications, progress reports, or any other reports to the PHS by the University. See also the definitions provided in this policy for "Investigator" and "Project Director/Principal Investigator."

"Travel expense disclosure" - Disclosure of travel expenses and reimbursement is required for travel that is not reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosure of the nature of the travel will be accomplished on the annual disclosure form.

**Adopted by the Board of Trustees 10/11/77; amended 5/11/79 and 5/13/81; amended and approved by the Faculty Senate 1/27/09 and the Board of Trustees 2/20/09; revised with the approval of the President on June 19, 2009; amended by the Faculty Senate Executive Committee 4/11/12 and endorsed by the Faculty Senate 4/25/12, as well as the Board of Trustees on June 2, 2012.*

B. University Policy on Human Research Protection

Purpose

The promotion of scholarship and the discovery of new knowledge through research are among the major functions of Case Western Reserve University (CWRU) as an institution of higher learning. If this research is to be meaningful and beneficial to humanity, involvement of human subjects as study participants is necessary. It is imperative that investigators in all disciplines protect the rights and welfare of human subjects.

University policy and federal regulations mandate compliance with all applicable requirements. Moreover, faculty investigators also have a moral obligation to humankind. The interests of society and the rights of individual subjects must be protected as investigators carry out the mandate to advance knowledge. Research may entail risks to human subjects. Therefore, investigators are obligated to weigh those risks in light of potential benefits to the subject and/or to society.

Mission

The mission of CWRU's Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects by ensuring that the oversight of human research is appropriate and in accordance with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.[2]

Scope

The CWRU HRPP covers all human research conducted by any student, employee, trainee, or faculty member (whether paid or unpaid) of CWRU ("CWRU investigator"). It includes any human research conducted at CWRU or cooperating institutions pursuant to a grant, contract, cooperative agreement, or other award to CWRU. Cooperating institutions include: University Hospitals Cleveland Medical Center, the MetroHealth System (MHS), the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and the Cleveland Clinic (CC). Reliance agreements in place allow CWRU to defer to the IRBs at these institutions for protocol review. Hereafter, these institutions shall be referred to as "member institutions" under the CWRU HRPP.

Definitions

Research is defined in 45 CFR 46 as "a systematic investigation designed to develop or contribute to generalizable knowledge." Therefore, any systematic investigation designed to generate results for the purpose of publication (e.g., dissertation, thesis, journal, book, or technical report) or public presentation (e.g. speech, poster, panel, and symposium) is considered to be research.

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[2] Belmont Report (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved February 24, 2015, from hhs.gov/ohrp/humansubjects/guidance/belmont.html

Human subject is defined in 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information."

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information an individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Minimal Risk is defined in 45 CFR 46.102(f) as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Responsible or Principal Investigator is the person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the responsible/principal investigator is the responsible leader of the team. The responsible/principal investigator is accountable for ensuring that the team complies with all rules and regulations and engages with human subjects properly and ethically.

An **Institutional Review Board (IRB)** is a specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects in biomedical or behavioral research [45§46.102(g), .107,.108,.109].

1. Conditions under which Investigations Involving Human Subjects may be pursued under the CWRU HRPP

a. Ethical Principles and Regulatory Mandates

Human research conducted under the auspices of the CWRU HRPP must be carried out in an ethical manner and in accordance with the principles promulgated by The Belmont Report: respect for persons, beneficence, and justice. In addition, investigators must comply with all applicable federal, state and local requirements related to the protection of human subjects, including Department of Health and Human and Services (DHHS) regulations (i.e., 45 CFR 46) and all relevant requirements of other regulatory and funding agencies. CWRU maintains a Federalwide Assurance (FWA) with DHHS. Research must not begin until investigators have

received review and approval or verification by the CWRU IRB or another authorized IRB. CWRU applies its ethical standards to all human research regardless of funding.

All human research, except as explicitly exempted in 45 CFR 46.101(b), must undergo review by an appropriate designated IRB(s). Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, non-scholarly program evaluation, and certain health surveillance activities) do not require review and approval by one of the IRBs within the CWRU HRPP. When CWRU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to the protection of human subjects.

b. Informed Consent

An investigator may involve a human subject in research only if the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, unless consent is waived by an IRB per the regulatory provisions. An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of undue influence. Unless written documentation is waived by an IRB, the investigator must provide the participant with an informed consent document written in language that is understandable to the subject or his/her representative. The investigator cannot include in the consent process, either orally or in writing, any language through which the subject or his/her representative is made to waive or appear to waive any of the subject's legal rights, or which releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent, as described in 45 CFR 46, are as follows:

1) statement that study involves research, explanation of purposes of research and expected duration of subject's participation, description of procedures to be followed, and identification of any procedures which are experimental;
2) description of risks or discomfort to subject;
3) description of benefits to subject or to others;
4) disclosure of alternative procedures, if appropriate;
5) description of the extent to which confidentiality will be maintained;
6) for research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs;
7) explanation of whom to contact if questions arise about the research, the subject's rights or whom to contact if research related injury occurs; and
8) statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time.

c. Confidentiality of Data

Investigators are responsible for protecting the rights of research subjects by safeguarding the confidentiality of all individual data and all data that could be used to identify subjects. Should any investigator be called upon to reveal research data to an outside entity which would in any way endanger confidentiality, it is his or her obligation to refuse to divulge such information as

privileged communication between researcher and subject, unless compelled by law. The investigator should consult with the Office of Research Administration prior to releasing any such information unless compelled by law or university policy.

The University, funding agencies, and regulatory bodies have the right to audit study data in order to ensure that human subjects are being protected adequately, and that the University is in compliance with approved protocols and its FWA. Those individuals who perform audits are bound by the same rules of confidentiality as the investigator.

d. Investigator Non-compliance

All CWRU investigators working with human subjects have a responsibility to comply with federal regulations and university policy. Human research non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal, state or local requirements, or policies established by the applicable IRB. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects; inadequate or non-existent procedures for informed consent; failure to follow the current approved protocol; failure to follow recommendations made by the IRB to safeguard the rights and welfare of subjects; failure to report adverse events or request permission for proposed protocol changes to the IRB; and failure to provide required ongoing progress reports.

Per the applicable regulations, IRBs have the authority to review allegations of human research non-compliance for studies they oversee. An IRB may receive allegations in several different ways, including quality assurance auditing reports, subject complaints, internal allegations, or investigator self-reporting.

The CWRU IRB is required to report serious or continuing non-compliance to federal regulatory entities and to funding agencies or other sponsors. Additionally, CWRU is required to report serious or continuing non-compliance to federal regulatory entities when the research is federally funded and when one of CWRU's affiliated hospital IRBs is the IRB of record.

e. Faculty Advisor Responsibility for Student Research

A faculty member advising student research projects* involving human subjects is responsible for assuring that the rights and welfare of the subjects of student research are adequately protected. CWRU expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of IRB applications. After protocol approval, the advisor should meet regularly with his/her students in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of the student's human subjects. A faculty member's electronic "signature" on the application indicates his/her acceptance of responsibility to comply with all administrative and federal regulations.

* Simulated research activities in a classroom setting for purposes of teaching research techniques typically is not designed to develop or contribute to generalizable knowledge and therefore is not regulated as research.

2. CWRU IRB Review

All protocols, correspondence, notifications, outcomes, and responses to stipulations pertaining to a CWRU research study must be submitted and received via the CWRU IRB electronic system. When CWRU relies on a non-CWRU IRB for approval of a protocol, the CWRU investigator is required to submit to the CWRU IRB a list of the components of the research study that he/she will be responsible for, which is considered a shell protocol. Shell protocols are generally not required for member institutions. Investigators who wish to use a non-CWRU IRB to review a study protocol should contact the CWRU Research Compliance Officer for assistance with the reliance agreement process (https://case.edu/research/faculty-staff/compliance/irb/).

Exempt Determination. All research involving human subjects that is exempt from federal regulation, must be registered with the appropriate IRB. Research may be exempt from IRB review if it meets the criteria described in 45 CFR 46. Determination of exemption must be made in accordance with the policy of the applicable IRB. If a determination of exemption is made, investigators are still responsible for ethical conduct of human research in accordance with The Belmont Report.

Expedited Review. Expedited review is a procedure through which human research posing no more than minimal risk may be reviewed and approved without convening a meeting of the full IRB. DHHS regulations[3] specifically define when minimal-risk research can receive expedited review by an IRB.

Full Review. All research that has not received an exemption determination or an expedited review must be reviewed at a convened meeting of the IRB where a quorum of voting members is present.

Amendments. Changes to a study, including, but not limited to, the enrollment criteria or sample size, recruitment methods, consent form language, procedures for data collection, or study interventions require prior approval by the IRB*. Investigators wanting to change a procedure in a study that has already been approved by an IRB must prepare a written description of the proposed change and the reason for the change. Upon review of the proposed amendment, the IRB will then reassess the balance of risks to benefits.

*In the unusual situation where a protocol change is required to avoid an immediate apparent hazard to a subject, the investigator may make the change prior to obtaining IRB approval but must immediately inform the IRB of the occurrence.

Adverse Events. An adverse event is defined as any undesirable and unintended (although not necessarily unexpected) impact on the subject, as a result of a study intervention.[4] Investigators

must report in writing to the relevant IRB all adverse events in accordance with the IRB's policies and procedures for reporting such events.

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[3] (45§46.110)

[4] http://www.hhs.gov/ohrp/policy/advevntguid.html

3. Studies Eligible for CWRU IRB Review

The CWRU IRB reviews social/behavioral/educational studies and biomedical research not conducted in a hospital setting. The CWRU IRB does not review biomedical research protocols that involve patients, employees, data, and/or equipment at one of the below affiliated hospitals:

- University Hospitals Cleveland Medical Center
- MetroHealth System
- The Cleveland Clinic

Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be the IRB of record for CWRU research. When research conducted at the LSCVAMC is funded through CWRU, a CWRU IRB must be the IRB of record, and that approval must be supplemented by LSCVAMC IRB approval. Investigators planning research to take place at LSCVAMC that will be funded through CWRU, should consult with the CWRU Research Compliance Officer in order to determine which IRB will be the IRB of record.

Any questions about whether a research activity can be submitted to the CWRU IRB should be referred to the CWRU IRB Office (see https://case.edu/research/faculty-staff/compliance/irb/).

4. International Research

All human research, regardless of funding, performed outside the United States must obtain appropriate institutional IRB approval according to federal regulations and the FWA. Typically, this means IRB approval from CWRU or one of its affiliate IRBs plus local approval at the study site. The university recognizes that the procedures normally followed in the foreign countries may differ from those set forth in U.S. federal regulation.

All applicable ethical standards and regulations are applied consistently to all human research, regardless of whether it is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring; quality assurance
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process (when applicable)
- Ensuring all necessary approvals are met

- Coordination and communication with local IRBs

5. CWRU HRPP Components

Institutional Official

CWRU's Vice President for Research is designated as the Institutional Official (IO) for the CWRU HRPP. In addition to oversight of the HRPP, the Institutional Official ensures that CWRU evaluates Conflicts of Interests in research and conducts education on the responsible conduct of research.

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Allocate university resources within the HRPP budget.
- Appoint and remove CWRU IRB members and IRB chairs.
- Approve and rescind authorization agreements for CWRU IRBs.
- Suspend or terminate research approved by the CWRU IRB.
- Disapprove research approved by the CWRU IRB.

Organizational Official

The Associate Vice President for Research is designated as the Organizational Official. The Organizational Official is responsible for oversight of, among other things, policies, procedures, and business decisions related to how research and sponsored project administration are overseen and monitored.

The Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget.
- Make IRB staff personnel decisions.
- Determine upon which IRBs the university will rely[5]
- Place limitations or conditions on an investigator's or research staff's privileges to conduct human research.
- Develop policies and procedures related to the HRPP that are binding on the university.

The Organizational Official has the responsibility to:

- Oversee the review and conduct of human research under the jurisdiction of the HRPP
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that human research will be conducted in accordance with all applicable ethical and legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the HRPP.
- Ensure that the research review process is independent and free of undue influence, and ensure that officials of the organization cannot approve research that has not been approved by one of the IRBs designated by the organization.

[5] The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to rely on another IRB for review and approval of research.

- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in the HRPP.
- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Fulfill federally-mandated educational requirements.

CWRU Investigators and Study Staff

Investigators and research staff have the responsibility to:

- Understand the definition of Human Research.
- Consult the relevant IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by an IRB designated in the CWRU FWA.
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.
- Follow HRPP requirements.
- Follow IRB policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB.

Institutional Review Boards (IRB)

Reliance on an IRB that is not at a cooperating institution requires an Institutional Authorization Agreement for IRB review (IAA) executed by the Institutional or Organizational Official.

The CWRU IRB, as well as any IRBs relied upon by CWRU, has the authority to, for the studies they are monitoring:

- Approve, require modifications to secure approval, and disapprove human research.
- Suspend or terminate approval of human research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process.
- Determine whether an activity is human research.
- Determine whether additional protections are warranted for studies involving vulnerable subject populations.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved. (http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.htm)

IRB members and IRB staff have the responsibility to follow HRPP policies and procedures, including disclosure of outside financial interests and recusal from review of protocols with which the member or staff may have a conflict.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide legal advice upon request to the Institutional Official, Organizational Official, IRB, and other individuals involved with the HRPP.
- Help resolve conflicts among applicable laws.

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Assure scientific review and oversee the conduct of human research in their department or school.
- Forward complaints and allegations regarding the HRPP to the Organizational Official.
- Affirm that each human research study proposed to be conducted in their department or school can be done responsibly by the study team using the resources described in the proposal.

Office of Research Administration

The Office of Research Administration (and similar offices with delegated authority, such as the School of Medicine Office of Grants and Contracts) has the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

6. Education and Training

IRB members, IRB staff, and others involved in the review of human research must complete initial and continuing training on the protection of human subjects.

Investigators and research staff must complete the initial and continuing training on the protection of human subjects.

7. Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Office, the IRB Chair, the Organizational Official, Office of General Counsel, Integrity Hotline, Internal Audit Department, Deans, or Department Chairs.

The relevant IRB has the responsibility to investigate allegations and findings of non-compliance related to conduct of research for studies under its jurisdiction and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed. In some instances, the IRB and the Organizational Official may, for different purposes, both be required to investigate the same matter, or may collaborate or share resources as necessary.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Organizational Official or designee.

To make such reports, contact:

The Office of the Associate Vice President of Research
Sears Library Building, 6th Floor.
2083 Martin Luther King, Jr. Drive
Cleveland, Ohio 44106-7230
216-368-0143

8. Monitoring and Auditing

In order to monitor and assure compliance, auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic not-for-cause audits.

9. Disciplinary Actions

The IRB and the Institutional Official may terminate or suspend IRB approval. In addition, the IRB and/or the Institutional Official and/or Organizational Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the IRB and/or the Institutional Official and/or Organizational Official, such actions are required to maintain the integrity of the HRPP.

B. University Policy on Human Research Protection

Purpose

The promotion of scholarship and the discovery of new knowledge through research are among the major functions of Case Western Reserve University (CWRU) as an institution of higher learning. If this research is to be meaningful and beneficial to humanity, involvement of human subjects as study participants is necessary. It is imperative that investigators in all disciplines protect the rights and welfare of human subjects.

University policy and federal regulations mandate compliance with all applicable requirements. Moreover, faculty investigators also have a moral obligation to humankind. The interests of society and the rights of individual subjects must be protected as investigators carry out the mandate to advance knowledge. Research may entail risks to human subjects. Therefore, investigators are obligated to weigh those risks in light of potential benefits to the subject and/or to society.

Mission

The mission of CWRU's Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects by ensuring that the oversight of human research is appropriate and in accordance with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.[2]

Scope

The CWRU HRPP covers all human research conducted by any student, employee, trainee, or faculty member (whether paid or unpaid) of CWRU ("CWRU investigator"). It includes any human research conducted at CWRU or cooperating institutions pursuant to a grant, contract, cooperative agreement, or other award to CWRU. Cooperating institutions include: University Hospitals Cleveland Medical Center, the MetroHealth System (MHS), the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and the Cleveland Clinic (CC). Reliance agreements in place allow CWRU to defer to the IRBs at these institutions for protocol review. Hereafter, these institutions shall be referred to as "member institutions" under the CWRU HRPP.

Definitions

Research is defined in 45 CFR 46 as "a systematic investigation designed to develop or contribute to generalizable knowledge." Therefore, any systematic investigation designed to generate results for the purpose of publication (e.g., dissertation, thesis, journal, book, or technical report) or public presentation (e.g. speech, poster, panel, and symposium) is considered to be research.

[2] Belmont Report (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved February 24, 2015, from hhs.gov/ohrp/humansubjects/guidance/belmont.html

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Human subject is defined in 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information."

- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information an individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Minimal Risk is defined in 45 CFR 46.102(f) as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Responsible or Principal Investigator is the person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the responsible/principal investigator is the responsible leader of the team. The responsible/principal investigator is accountable for ensuring that the team complies with all rules and regulations and engages with human subjects properly and ethically.

An **Institutional Review Board (IRB)** is a specially constituted review body established or designated by an entity to protect the rights and welfare of human subjects in biomedical or behavioral research [45§46.102(g), .107,.108,.109].

1. Conditions under which Investigations Involving Human Subjects may be pursued under the CWRU HRPP

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a. Ethical Principles and Regulatory Mandates

Human research conducted under the auspices of the CWRU HRPP must be carried out in an ethical manner and in accordance with the principles promulgated by The Belmont Report: respect for persons, beneficence, and justice. In addition, investigators must comply with all applicable federal, state and local requirements related to the protection of human subjects, including Department of Health and Human and Services (DHHS) regulations (i.e., 45 CFR 46) and all relevant requirements of other regulatory and funding agencies. CWRU maintains a Federalwide Assurance (FWA) with DHHS. Research must not begin until investigators have

received review and approval or verification by the CWRU IRB or another authorized IRB. CWRU applies its ethical standards to all human research regardless of funding.

All human research, except as explicitly exempted in 45 CFR 46.101(b), must undergo review by an appropriate designated IRB(s). Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, non-scholarly program evaluation, and certain health surveillance activities) do not require review and approval by one of the IRBs within the CWRU HRPP. When CWRU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to the protection of human subjects.

b. Informed Consent

An investigator may involve a human subject in research only if the investigator has obtained the informed consent of the subject or the subject's legally authorized representative, unless consent is waived by an IRB per the regulatory provisions. An investigator shall seek such consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of undue influence. Unless written documentation is waived by an IRB, the investigator must provide the participant with an informed consent document written in language that is understandable to the subject or his/her representative. The investigator cannot include in the consent process, either orally or in writing, any language through which the subject or his/her representative is made to waive or appear to waive any of the subject's legal rights, or which releases the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent, as described in 45 CFR 46, are as follows:

1) statement that study involves research, explanation of purposes of research and expected duration of subject's participation, description of procedures to be followed, and identification of any procedures which are experimental;
2) description of risks or discomfort to subject;
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4) disclosure of alternative procedures, if appropriate;
5) description of the extent to which confidentiality will be maintained;
6) for research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs;
7) explanation of whom to contact if questions arise about the research, the subject's rights or whom to contact if research related injury occurs; and
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Investigators are responsible for protecting the rights of research subjects by safeguarding the confidentiality of all individual data and all data that could be used to identify subjects. Should any investigator be called upon to reveal research data to an outside entity which would in any way endanger confidentiality, it is his or her obligation to refuse to divulge such information as

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and approval or verification of exemption by one of the Institutional Review Boards (IRBs) listed on the CWRU FWA.¶
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d. Investigator Non-compliance

All CWRU investigators working with human subjects have a responsibility to comply with federal regulations and university policy. Human research non-compliance is defined as conducting research involving human subjects in a manner that disregards or violates federal, state or local requirements, or policies established by the applicable IRB. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects; inadequate or non-existent procedures for informed consent; failure to follow the current approved protocol; failure to follow recommendations made by the IRB to safeguard the rights and welfare of subjects; failure to report adverse events or request permission for proposed protocol changes to the IRB; and failure to provide required ongoing progress reports.

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Exempt Determination. All research involving human subjects that is exempt from federal regulation, must be registered with the appropriate IRB. Research may be exempt from IRB review if it meets the criteria described in 45 CFR 46. Determination of exemption must be made in accordance with the policy of the applicable IRB. If a determination of exemption is made, investigators are still responsible for ethical conduct of human research in accordance with The Belmont Report.

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Expedited Review. Expedited review is a procedure through which human research posing no more than minimal risk may be reviewed and approved without convening a meeting of the full IRB. DHHS regulations[3] specifically define when minimal-risk research can receive expedited review by an IRB.

Full Review. All research that has not received an exemption determination or an expedited review must be reviewed at a convened meeting of the IRB where a quorum of voting members is present.

Amendments. Changes to a study, including, but not limited to, the enrollment criteria or sample size, recruitment methods, consent form language, procedures for data collection, or study interventions require prior approval by the IRB*. Investigators wanting to change a procedure in a study that has already been approved by an IRB must prepare a written description of the proposed change and the reason for the change. Upon review of the proposed amendment, the IRB will then reassess the balance of risks to benefits.

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[3] (45§46.110)

[4] http://www.hhs.gov/ohrp/policy/advevntguid.html

3. Studies Eligible for CWRU IRB Review

The CWRU IRB reviews social/behavioral/educational studies and biomedical research not conducted in a hospital setting. The CWRU IRB does not review biomedical research protocols that involve patients, employees, data, and/or equipment at one of the below affiliated hospitals:

- University Hospitals Cleveland Medical Center
- MetroHealth System
- The Cleveland Clinic

Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be the IRB of record for CWRU research. When research conducted at the LSCVAMC is funded through CWRU, a CWRU IRB must be the IRB of record, and that approval must be supplemented by LSCVAMC IRB approval. Investigators planning research to take place at LSCVAMC that will be funded through CWRU, should consult with the CWRU Research Compliance Officer in order to determine which IRB will be the IRB of record.

Any questions about whether a research activity can be submitted to the CWRU IRB should be referred to the CWRU IRB Office (see https://case.edu/research/faculty-staff/compliance/irb/).

4. International Research

All human research, regardless of funding, performed outside the United States must obtain appropriate institutional IRB approval according to federal regulations and the FWA. Typically, this means IRB approval from CWRU or one of its affiliate IRBs plus local approval at the study site. The university recognizes that the procedures normally followed in the foreign countries may differ from those set forth in U.S. federal regulation.

All applicable ethical standards and regulations are applied consistently to all human research, regardless of whether it is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring; quality assurance
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process (when applicable)
- Ensuring all necessary approvals are met

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<#>The CWRU IRB reviews only social/behavioral/educational and other non-biomedical human research.¶
<#>¶
<#>When CWRU investigators wish to engage in biomedical human research, including all human research subject to FDA regulations (tests of drugs, devices, and biologics, and other biomedical interventions), they must seek review and approval from the IRB at the affiliated clinical site where the study will take place. The CWRU-affiliated hospital IRBs that have agreements with CWRU to review biomedical research are:¶
<#>University Hospitals of Cleveland¶
<#>MetroHealth Hospital¶

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<#>*The Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC)¶
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<#>Any questions about whether a research activity is considered biomedical or otherwise subject to FDA regulations should be referred to a representative from the CWRU IRB who will provide assistance.¶
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- Coordination and communication with local IRBs

5. CWRU HRPP Components

Institutional Official

CWRU's Vice President for Research is designated as the Institutional Official (IO) for the CWRU HRPP. In addition to oversight of the HRPP, the Institutional Official ensures that CWRU evaluates Conflicts of Interests in research and conducts education on the responsible conduct of research.

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The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Allocate university resources within the HRPP budget.
- Appoint and remove CWRU IRB members and IRB chairs.
- Approve and rescind authorization agreements for CWRU IRBs.
- Suspend or terminate research approved by the CWRU IRB.
- Disapprove research approved by the CWRU IRB.

Organizational Official

The Associate Vice President for Research is designated as the Organizational Official. The Organizational Official is responsible for oversight of, among other things, policies, procedures, and business decisions related to how research and sponsored project administration are overseen and monitored.

The Organizational Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP budget.
- Make IRB staff personnel decisions.
- Determine upon which IRBs the university will rely[5].
- Place limitations or conditions on an investigator's or research staff's privileges to conduct human research.
- Develop policies and procedures related to the HRPP that are binding on the university.

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The Organizational Official has the responsibility to:

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- Oversee the review and conduct of human research under the jurisdiction of the HRPP
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that human research will be conducted in accordance with all applicable ethical and legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the HRPP.
- Ensure that the research review process is independent and free of undue influence, and ensure that officials of the organization cannot approve research that has not been approved by one of the IRBs designated by the organization.

[5] The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to rely on another IRB for review and approval of research.

- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in the HRPP.
- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Fulfill federally-mandated educational requirements.

CWRU Investigators and Study Staff

Investigators and research staff have the responsibility to:

- Understand the definition of Human Research.
- Consult the relevant IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by an IRB designated in the CWRU FWA.
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.
- Follow HRPP requirements.
- Follow IRB policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB.

Institutional Review Boards (IRB)

Reliance on an IRB that is not at a cooperating institution requires an Institutional Authorization Agreement for IRB review (IAA) executed by the Institutional or Organizational Official.

The CWRU IRB, as well as any IRBs relied upon by CWRU, has the authority to, for the studies they are monitoring:

- Approve, require modifications to secure approval, and disapprove human research.
- Suspend or terminate approval of human research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process.
- Determine whether an activity is human research.
- Determine whether additional protections are warranted for studies involving vulnerable subject populations.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved. (http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.htm)

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[5] The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to relay on another IRB for review and approval of research.¶
The IRBs relied upon by CWRU are listed in CWRU's FWA and on the CWRU IRB website (https://research.case.edu/Compliance/).¶

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IRB members and IRB staff have the responsibility to follow HRPP policies and procedures, including disclosure of outside financial interests and recusal from review of protocols with which the member or staff may have a conflict.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide legal advice upon request to the Institutional Official, Organizational Official, IRB, and other individuals involved with the HRPP.
- Help resolve conflicts among applicable laws.

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

- Assure scientific review and oversee the conduct of human research in their department or school.
- Forward complaints and allegations regarding the HRPP to the Organizational Official.
- Affirm that each human research study proposed to be conducted in their department or school can be done responsibly by the study team using the resources described in the proposal.

Office of Research Administration

The Office of Research Administration (and similar offices with delegated authority, such as the School of Medicine Office of Grants and Contracts) has the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

6. Education and Training

IRB members, IRB staff, and others involved in the review of human research must complete initial and continuing training on the protection of human subjects.

Investigators and research staff must complete the initial and continuing training on the protection of human subjects.

7. Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Office, the IRB Chair, the Organizational Official, Office of General Counsel, Integrity Hotline, Internal Audit Department, Deans, or Department Chairs.

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The relevant IRB has the responsibility to investigate allegations and findings of non-compliance related to conduct of research for studies under its jurisdiction and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed. In some instances, the IRB and the Organizational Official may, for different purposes, both be required to investigate the same matter, or may collaborate or share resources as necessary.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Organizational Official or designee.

To make such reports, contact:

The Office of the Associate Vice President of Research
Sears Library Building, 6th Floor.
2083 Martin Luther King, Jr. Drive
Cleveland, Ohio 44106-7230
216-368-0143

8. Monitoring and Auditing

In order to monitor and assure compliance, auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic not-for-cause audits.

9. Disciplinary Actions

The IRB and the Institutional Official may terminate or suspend IRB approval. In addition, the IRB and/or the Institutional Official and/or Organizational Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the IRB and/or the Institutional Official and/or Organizational Official, such actions are required to maintain the integrity of the HRPP.

Proposed Policy

Assignment of the incomplete grade

The Incomplete grade (I) can only be assigned for letter-graded courses and Pass/No Pass courses by and at the discretion of the instructor when:

1. There are extenuating circumstances, explained to the instructor before the assignment of the grade, which clearly justify an extension of time beyond the requirements established for and met by other students in the class, and
2. The student has been passing the course and only a small segment of the course, such as a term paper, final exam or project, etc. remains to be completed.

It is the student's responsibility to notify the instructor of the circumstances preventing completion of all assigned work. In the absence of notification or adequate justification, the instructor has the authority to assign the student a final grade that assumes a failing grade for the missing work.

An Incomplete grade should not be assigned when:

1. A student has been absent for much of the semester and/or has done little of the work required for a course, or
2. A student is absent from a final examination, unless the School of Graduate Studies has authorized the grade.

The amount of additional time allowed for the student to make up incomplete work should serve to accommodate the student while being fair to other students in the course. It should be proportional to the duration of a student's illness or absence and might be no more than a few days or weeks. At the extreme, it should not extend past the 11th week of class of the semester following the one in which the incomplete grade was received.

Students may not sit in the same course in a later semester to complete the work required for the original course.

In certain cases, (such as students on probation or many incompletes in the same semester) the School of Graduate Studies may establish an earlier date for completion of courses with incomplete grades.

In exceptional circumstances a student may petition for an extension of the incomplete deadline of no more than one additional semester. The petition should be submitted by the original deadline date, and must contain the reasons for the extension, a proposed new completion date and a letter from the faculty supporting the extension.

Changing an Incomplete Grade

When the student has completed the required work, the instructor shall enter in the Student Information System a final evaluative grade to replace the Incomplete. When a student fails to submit the work required for removing the Incomplete by the date established, the instructor shall enter a final grade that assumes a failing performance for the missing work. In the absence of the assignment of a grade by the instructor, the Registrar will convert the I to F when the deadline for making up Incomplete grades from a previous semester has passed.

Proposed Guidelines to Create a University Certificate and Professional Certification

Background

Case Western Reserve University has official governance processes for academic degree programs. These formal processes, which define and detail objective criteria and standards for awarding degrees, ensure that CWRU's degree programs maintain high quality and are consistent with the university's mission and strategic goals.

CWRU currently does not have an established university-level process for defining and approving criteria and standards for awarding certificates. Since there is no officially recognized university definition of what constitutes a certificate program, over the years, departments and other units of the university have established a variety of certificate programs on their own. These programs range from a single-day workshop to completion of 9-12 credit hours; some require a minimum gpa for completion and others merely require attendance at a one-day class. In these cases, the offering units individually verify completion of program requirements Consequently, participation in or completion of certificate programs are typically not recognized on the official university transcript. If the courses that make up the certificate are regular courses that appear in the General Bulletin, the courses appear on a student's official transcript, but in most cases there is no notation on the transcript that the student is enrolled in a certificate program or that they have completed and been awarded a certificate. In some instances, the transcript will notate that the student is in a certificate program, but when they complete the program (or leave the program before completion), the transcript permanently shows that the student has been "discontinued" from the program.

There is now a growing desire to notate both participation in and completion of certificate programs on the university transcript. If this university-level recognition is to occur, CWRU must establish a formal process for approving certificate programs as well as defining and approving criteria and standards for such programs. This document intends to define the different types of certificates that may be offered at CWRU and establishes the minimum requirements for each type of certificate to be officially recognized by CWRU.

Please note, academic units can continue offering established certificate programs or develop new programs that do not meet University Certificate criteria, however, these will not be recognized on official university transcripts and the academic unit will continue to be responsible for conferring and validating its credential.

Definitions and Standards

Case Western Reserve University awards University Certificates as a credential for completing a set of courses (possibly in combination with other learning experiences)

that focus on a specific topic or theme. Courses taken as part of a Certificate program are to be regular courses that appear in the General Bulletin. Certificates are recorded at the university level in the Student Information System and will appear as awarded on the student's official university transcript upon final confirmation from the units that certify degree requirements (i.e., Undergraduate Studies, Graduate Studies, school registrars).

The scope of Certificate programs is generally narrower than that expected for full degrees, and thus can normally be completed in a shorter period of time. Certificate programs may be embedded within degree programs and offered as an option for degree-seeking students, or can be stand-alone programs to which students apply and are granted admission. Courses taken as part of a certificate program may be double counted for degree programs.

Graduate Certificate

1. A graduate certificate program contains courses taught at the graduate or professional level.
2. The program must include a minimum of 15 credit hours.
3. The student must earn a minimum GPA of 3.00 in order for the graduate certificate to be awarded.
4. A stand-alone graduate certificate may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for graduate certificates are reviewed by the Graduate Studies Committee of the Faculty Senate, following review and approval through the offering academic unit. Graduate certificates are to be approved by the Faculty Senate before implementation. The objectives, admission requirements and learning outcomes for the certificate program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certificate requires 21 or more credit hours.
7. Certificates must be reported to (and if financial aid eligible must also be reviewed by) the Higher Learning Commission.
8. The certificate program may be subject to Gainful Employment reporting requirements to the federal government.
9. A description of the certificate program, including requirements for successful completion, must appear in the General Bulletin.

Post-Baccalaureate Certificate

1. A post-baccalaureate certificate program contains courses taught at the undergraduate and/or graduate/professional level.
2. The program must include a minimum of 15 credit hours.
3. The student must earn a minimum GPA of 3.00 in order for the post-baccalaureate certificate to be awarded.

4. A stand-alone post-baccalaureate certificate may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for post-baccalaureate certificates are reviewed by the Graduate Studies Committee of the Faculty Senate, and/or the Faculty Senate Committee on Undergraduate Education, as determined by the Faculty Senate Executive Committee, following review and approval through the offering academic unit. Post Baccalaureate certificates are to be approved by the Faculty Senate before implementation. The objectives, admissions requirements and learning outcomes for the certificate program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certificate requires 21 or more credit hours.
7. Certificates must be reported to (and if financial aid eligible must also be reviewed by) the Higher Learning Commission.
8. The certificate program may be subject to Gainful Employment reporting requirements to the federal government.
9. A description of the post-baccalaureate certificate program, including requirements for successful completion, must appear in the General Bulletin.

<u>Professional Certification</u>

1. Professional certification programs are intended for students who need to meet requirements and/or eligibility for licensure, exams, or board approval for certification in a particular professional area or skill.
2. A professional certification program is an approved sequence of courses that leads to a certification of completion in a specialty recognized by the school's, or discipline's, accrediting body or licensing agency.
3. The professional certification must meet the criteria set forth by the school's, or discipline's, accrediting body.
4. A stand-alone professional certification may be designated as Title IV eligible if students will be eligible for federal financial aid. Additional approval through the Provost's Office is required.
5. Proposals for professional certification are reviewed through the standard curriculum review process through the offering academic unit. Professional certifications are to be approved by the Faculty Senate before implementation. The objectives, admissions requirements and learning outcomes for the certification program must be articulated and will be considered during the review process.
6. Review by the Chancellor's Committee on Graduate Study (State of Ohio) will be required if the certification requires 21 or more credit hours.
7. The certification program may be subject to Gainful Employment reporting requirements to the federal government.
8. A description of the professional certification program, including any specific requirements for successful completion, must appear in the General Bulletin.

Additional Information

University Undergraduate Certificate

At this time there are no plans to offer university undergraduate certificates. Instead, "minors" play an analogous role, and these are notated on the transcripts of undergraduate students who complete them.

Certificates of Completion

Various units of the university offer courses and other learning experiences aimed at continuing education or professional development. Such programs generally include courses that do not carry CWRU academic credit and which do not appear in the General Bulletin. These programs are not tracked at the university level, and are not eligible to be recorded on official transcripts. If regular credit-bearing courses are included as part of such programs, these courses will appear on an academic transcript but the transcript will not make reference to the continuing education or professional development program.

The academic or administrative units offering these not-for-credit programs may wish to issue certificates of completion to students who satisfy program requirements. In these cases, the offering units may issue such certificates, but these are not considered official university documents, and no records of the student's participation in the program are entered into the Student Information System.

Guidelines to Create a University Certificate

Current Status of Certificate Programs at CWRU:

- no officially recognized university definition of what constitutes a certificate program
- no established university-level process for defining/approving criteria and standards for certificates
- current certificates vary widely across university – credits, time, GPA, Bulletin vs. non-Bulletin courses
- completion is verified by individual departments
- typically not recognized on the transcript, but when it is…

Student ID:
SSN:
Student Name: [redacted]

Case Western Reserve University
Cumulative Grade Report

Academic Program History

Program: Design, Innov & IP Mgmt (Cert)
Discontinued
Design, Innov & IP Mgmt (Cert) Certification

Appears as “Discontinued” whether the certificate is completed or not

Transfer Credits

Transfer Credit from Case Western Reserve University
Applied Toward Design, Innov & IP Mgmt (Cert) Record

Fall 2011

Course	Description	Attempted	Earned	Grade	Points
MIDS 420A	*Design in Mgmt: Concept & Prac*		3.00	A	
LAWS 367-1	*Commercialization & IP Mangmnt*		3.00	B	
Course Trans GPA: 3.500	Transfer totals:	6.00	6.00		21.000

Transfer Credit from Case Western Reserve University
Applied Toward Design, Innov & IP Mgmt (Cert) Record

Spring 2012

Course	Description	Attempted	Earned	Grade	Points
MIDS 420B	*Design in Mgmt: Concept & Prac*		3.00	A	
LAWS 367-1	*Commercialization & IP Mangmnt*		3.00	B	
Course Trans GPA: 3.500	Transfer totals:	6.00	6.00		21.000

Beginning of Nondegree Record

			Attempted	Earned	Averaged	Points
Career Totals Cum GPA:	3.500	Cum Totals	12.00	12.00	12.00	42.000
Total Credits Earned:	12.00					

End of Nondegree Record

Guidelines to Create a University Certificate

Rationale: There is growing desire to notate both participation in and completion of certificate programs on the university transcript

For university-level recognition to occur:

- formal process for approving certificate programs
- defining and approving criteria and standards for such programs

Committee (formed 03/2016): Lynmarie Hamel (lead), Don Feke, Amy Hammett, Jeremy Naab, Nancy Issa , Paul MacDonald

This document:

- defines the different types of University certificates that may be offered at CWRU
- establishes the minimum requirements for each type of University certificate to be officially recognized by CWRU
- it DOES NOT eliminate existing certificates or prevent the development of new certificates that do not meet these new criteria (non-University certificates)

Guidelines to Create a University Certificate

Types of University Certificates

- Graduate
- Post-Baccalaureate
- Professional Certification

General Minimal Requirements

- minimum of 15 credit hours
- minimum GPA of 3.0
- reviewed by School, FSCGS (post-bac exception), FS Exec Comm, and FS
- must appear in General Bulletin

FACULTY SENATE STANDING COMMITTEE CHAIRS

COMMITTEE	2017-2018 Chairs	2018-2019 Chairs	Schools
BYLAWS	Kenneth Ledford	Kenneth Ledford	CAS
COMPENSATION	Jerry Mahoney	David Matthiesen	CSE
FACULTY PERSONNEL	Christine Cano- replaced Jeremy Bendik-Keymer	Christine Cano	CAS
FINANCE	Glenn Starkman	Glenn Starkman	CAS
GRADUATE STUDIES	Paul MacDonald	Janet McGrath	CAS
INFORMATION/COMMUNICATION TECHNOLOGY	Steven Hauck	Steven Hauck	CAS
MINORITY AFFAIRS	Joachim Voss- replaced Ronald Hickman	Joachim Voss	SON
NOMINATING	Maureen McEnery	Leena Palomo	SODM
RESEARCH	Harihara Baskaran	Harihara Baskaran	CSE
FSCUE	Gary Chottiner, chair	Steven Eppell, chair	CSE
	Steven Eppell, vice chair	Peter Shulman, vice chair	CAS
LIBRARIES	Paul Iversen	Paul Iversen	CAS
WOMEN FACULTY	Leena Palomo	Kathryn Mercer	LAW

DRAFT FOR COMMENT

Dear Deans and Department Chairs:

Last year, the Faculty Senate approved a new policy that requires that the library conduct a review and assessment of the university's libraries content and services to support all new graduate and undergraduate degrees and programs that require Faculty Senate approval, including undergraduate majors and minors, and certificate programs. Attached is a copy of the policy document, and a ***sample*** template that the library might use as its report format.

Through this process the library is asked to identify the ***minimum*** (not the ideal) level of resources to support the proposed degree or program), both at the time of the launching of the program and as the program develops. Please know that the objectives of this process are aimed at ensuring student and faculty satisfaction. Through this review, the library can attempt to identify any current inadequacies, and do so prior to the new degree or program being undertaken. If there are some expectations that the library cannot meet with existing resources, this is valuable information for the Faculty Senate to consider in its deliberations. Through early identification of issues, it may also be possible for the proposers to work with their schools and the libraries to identify potential alternative solutions.

Although the minimum lead-time for the library to prepare and deliver its findings is three weeks, we strongly urge proposers to start engaging with the library as early in the planning process as possible. *By involving the library early in the process, this will give the library greater time to conduct the formal review, and to clarify and discuss with proposers questions that may arise during the process and make modifications that might be incorporated into the final report.*

Please use the table at the end of this message to determine to which library director the program or degree proposal should be sent. Should the proposal be interdisciplinary, or if you are otherwise unsure of to whom it should be sent, forward it to any one of the library directors and that person will ensure it is forwarded properly.

Using the table at the end of this message, we ask that you share this information and the attachments with anyone who is now or who plans to develop a new degree or program. We would be happy to answer any questions you may have about the process. Thank you for your cooperation as we work to make this process as effective as possible.

Sincerely,

Kathleen Blazar, Interim Director, CHSL

Joseph Custer, Law Library Director

Arnold Hirshon, Associate Provost & University Librarian

Samantha Skutnik, MSASS Library Director

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School/College	Library	Send Proposal to:
Case School of Engineering College of Arts and Sciences Weatherhead School of Management	Kelvin Smith Library	Arnold Hirshon Associate Provost & University Librarian arnold.hirshon@case.edu 368-2992
School of Law	Ben C. Green Law Library	Joseph Custer Library Director joseph.custer@case.edu 368-2794
School of Dental Medicine School of Medicine School of Nursing	Cleveland Health Sciences Library	Kathleen Blazar Interim Director Kathleen.blazar@case.edu 368-1361
Jack, Joseph and Morton Mandel School of Applied Social Sciences	Lillian and Milford Harris Library	Samantha Skutnik Library Director samantha.skutnik@case.edu 368-2283

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Library Content and Resource Review Process for New Programs and Degrees

9 March 2017 (rev. 31 January 2018)

When a school or the College plans to submit to the Faculty Senate for final approval a proposal for a new CWRU degree or program (including new undergraduate majors or minors), the sponsor (e.g., the school or one of its departments) must include in its submission materials a "library resource assessment report" regarding the adequacy of library content and services to accommodate the academic requirements of the program or degree. This report must be prepared and certified by the appropriate library of the university, independent of any review conducted by the sponsoring school or one of its departments.

For interdisciplinary programs or degrees that span the scope of more than one of CWRU's libraries, the school or College should submit its proposal to the library primarily responsible for the program or degree. When in doubt, the school or College should submit the form to the Kelvin Smith Library. In all cases where there is a potential for interdisciplinary content (regardless of whether the program or degree is designed to be an interdisciplinary program or degree among two or more schools), the libraries of the university will coordinate their efforts so that the final report comprehensively addresses all library resources. The report will specify which library or libraries are affected, and to what extent.

To initiate this process, when the school or College is considering a program or degree proposal, it should submit thatproposal as early as possible in the process to the appropriate library. Under most circumstances, it is likely that the library will need no additional information.

A library review is required for any new degree or program that requires Faculty Senate approval, such as:

- any new undergraduate or graduate degree;
- any new programs, including new undergraduate majors and minors, regardless of whether or not they were previously a track in another registered program;
- new dual or multi-degree programs combining two or more University programs;
- new joint-degree programs with other universities and colleges, regardless of their location;
- new certificate programs;
- the addition of a significant on-line component to an existing degree or certificate program; and
- changes in the degree of a registered program.

Unless the proposal will require approval by the Faculty Senate, it is ***not*** necessary to submit for review any proposed new courses, tracks or pathways that are within an existing program.

The responsible library will usually complete its review and return it to the school or College within three (3) weeks.

The library assessment will provide a statement concerning of the quality of the existing and required staffing and content resources to provide a minimum quality program. The content assessment will include printed media, e-books and e-journals, audio and/or video recordings, and other associated technologies that are available on campus or that are readily available through OhioLINK.

If additional resources are found to be necessary, the library will specify a plan (with dollar amounts) necessary to acquire these resources within a specified time frame. The library will indicate whether there are or are not current funds to purchase the needed resources.

The final report must include a letter from the director of the appropriate library of the University to certify the findings of the report.

At the conclusion of the library assessment, the library director will provide a letter with a five-year estimate of expenses for essential new content, services, and technology. The letter will be accompanied by the library assessment report. (See Appendix for a sample template for a library report.)

Appendix - Sample Template CWRU Libraries Resource and Service Assessment Report Regarding New or Revised Programs and Degrees

Assessment for:

Program level ☐ **graduate** ☐ **undergraduate**

Degree ☐ **Major** ☐ **Minor** ☐ **Certificate**

Title of proposed program or degree: _____

Sponsor (School/College or Department): _____
[For interdisciplinary proposals, list all schools/College affiliated with the proposal, and the libraries covered under this report.]

Report prepared by: [Librarian]:_____ Date of Report: _____

ADEQUACY OF SERVICES

- **Current library staff expertise (depth and availability) in the area of the new program or degree**:

- **Ability of the library to accommodate funder data management requirements (e.g., access to essential technology or media) to support the program or degree**:

ADEQUACY OF CURRENT CONTENT AND ABILITY TO SUPPORT FUTURE NEEDS

- **General strength of the current collection to accommodate new program needs, including major available content resources currently available**:

- **Minimum additional required resources required to accommodate the new program needs**:

Content Category	Adequacy of Current Content Resources *	Additional Resources Required (list specific titles whenever possible)	One-time Cost to Fill Content Gaps	Recurring Cost to Fill Gaps for the next 5 years (including inflation)
Books: ***Essential***				
Books: ***Supplemental***				
Journals: ***Essential***				
Journals: ***Supplemental***				
Databases: ***Essential***				
Databases: ***Supplemental***				
Media: ***Essential***				
Media: ***Supplemental***				

* "Current content" includes content available through OhioLINK.

Library Content and Resource Review Process for New Programs and Degrees

9 March 2017 (rev. 31 January 2018)

When a school or the College plans to submit to the Faculty Senate for final approval a proposal for a new CWRU degree or program (including new undergraduate majors or minors), the sponsor (e.g., the school or one of its departments) must include in its submission materials a "library resource assessment report" regarding the adequacy of library content and services to accommodate the academic requirements of the program or degree. This report must be prepared and certified by the appropriate library of the university, independent of any review conducted by the sponsoring school or one of its departments.

For interdisciplinary programs or degrees that span the scope of more than one of CWRU's libraries, the school or College should submit its proposal to the library primarily responsible for the program or degree. When in doubt, the school or College should submit the form to the Kelvin Smith Library. In all cases where there is a potential for interdisciplinary content (regardless of whether the program or degree is designed to be an interdisciplinary program or degree among two or more schools), the libraries of the university will coordinate their efforts so that the final report comprehensively addresses all library resources. The report will specify which library or libraries are affected, and to what extent.

To initiate this process, when the school or College is considering a program or degree proposal, it should submit that proposal as early as possible in the process to the appropriate library. Under most circumstances, it is likely that the library will need no additional information.

A library review is required for any new degree or program that requires Faculty Senate approval, such as:

- any new undergraduate or graduate degree;
- any new programs, including new undergraduate majors and minors, regardless of whether or not they were previously a track in another registered program;
- new dual or multi-degree programs combining two or more University programs;
- new joint-degree programs with other universities and colleges, regardless of their location;
- new certificate programs;
- the addition of a significant on-line component to an existing degree or certificate program; and
- changes in the degree of a registered program.

Unless the proposal will require approval by the Faculty Senate, it is ***not*** necessary to submit for review any proposed new courses, tracks or pathways that are within an existing program.

The responsible library will usually complete its review and return it to the school or College within three (3) weeks.

The library assessment will provide a statement concerning of the quality of the existing and required staffing and content resources to provide a minimum quality program. The content assessment will include printed media, e-books and e-journals, audio and/or video recordings, and other associated technologies that are available on campus or that are readily available through OhioLINK.

If additional resources are found to be necessary, the library will specify a plan (with dollar amounts) necessary to acquire these resources within a specified time frame. The library will indicate whether there are or are not current funds to purchase the needed resources.

The final report must include a letter from the director of the appropriate library of the University to certify the findings of the report.

At the conclusion of the library assessment, the library director will provide a letter with a five-year estimate of expenses for essential new content, services, and technology. The letter will be accompanied by the library assessment report. (See Appendix for a sample template for a library report.)

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Appendix - Sample Template CWRU Libraries Resource and Service Assessment Report Regarding New or Revised Programs and Degrees

Assessment for:

Program level ☐ **graduate** ☐ **undergraduate**

Degree ☐ **Major** ☐ **Minor** ☐ **Certificate**

Title of proposed program or degree: _____

Sponsor (School/College or Department): _____

[For interdisciplinary proposals, list all schools/College affiliated with the proposal, and the libraries covered under this report.]

Report prepared by: [Librarian]:_____ **Date of Report:** _____

ADEQUACY OF SERVICES

- **Current library staff expertise (depth and availability) in the area of the new program or degree**:

- **Ability of the library to accommodate funder data management requirements (e.g., access to essential technology or media) to support the program or degree**:

ADEQUACY OF CURRENT CONTENT AND ABILITY TO SUPPORT FUTURE NEEDS

- **General strength of the current collection to accommodate new program needs, including major available content resources currently available**:

- **Minimum additional required resources required to accommodate the new program needs**:

Content Category	Adequacy of Current Content Resources *	Additional Resources Required (list specific titles whenever possible)	One-time Cost to Fill Content Gaps	Recurring Cost to Fill Gaps for the next 5 years (including inflation)
Books: ***Essential***				
Books: ***Supplemental***				
Journals: ***Essential***				
Journals: ***Supplemental***				
Databases: ***Essential***				
Databases: ***Supplemental***				
Media: ***Essential***				
Media: ***Supplemental***				

* "Current content" includes content available through OhioLINK.

Email from Ron Occhionero to Rebecca Weiss dated February 5, 2018

Yes, to answer your question both programs have the backing of the Dean and the faculty.
The EFDA (Expanded Function Dental Auxilary program- current program) is a non-baccalaureate continuing education program which is part time.

This new program, dental assisting is a full time certificate program which essentially trains individuals to perform dental assisting responsibilities. It will be a 10 month tuition based program to train 15-20 students post high school or community college in these skills.
We have developed a total format that includes all syllabii and didactic, preclinical and clinical evaluation tools.
The first phase of the training program will be a pilot study project to test the market. We have clinical space, both here in the School of Dental Medicine and in the new facility. This initial training program may result in dental assistants we utilize in the new facilities at the Health Education Center.
The second phase of the study if successful will be to submit our documentation to the American Dental Association Council on Dental Accreditation for provisional approval. It is usually granted after a site visit of the facilities. The second phase of the program may include as many as twenty students. Again, tuition based, non-baccalaureate certificate program.
I would like to know if both of these phases need to be approved by the faculty senate or only the one that needs to be ADA accredited. If you have any other questions I would be happy to answer then.

Standard 1 – Institutional Effectiveness

Planning and Assessment

1. The program must demonstrate its effectiveness through a format and ongoing planning and outcomes assessment process that is systematically documented and annually evaluated. This process must include the following:

The dental assistant program of the School of Dental Medicine is in compliance with this standard.

The mission statement of the School of Dental Medicine ("The School") reflects the School's commitment to teaching, patient care, service, research and institutional effectiveness.

1-1a. The dental assisting program goals that include, but are not limited to student learning outcomes are congruent the School of Dental Medicines goals.

Education

- Prepare students to become highly knowledgeable, clinically competent and critically thinking dental assistants of general dentistry and dental specialties through the provision of curricula that integrates clinical, biomedical, and behavioral sciences. In the process, these auxiliary personnel shall develop the foundations of caring, ethics, and professionalism.
- Develop the environment and opportunity for life-long learning.

Patient Care

- Provide a broad range of high quality supportive patient services as a principal means of furnishing clinical education opportunities for students.

Research and Scholarship

- Support the educational, patient care, and service components of the mission through a focused research program integrated with student development, and education and placement.
- Promote the role of the School of Dental Medicine as a scholarly and productive member of the university, health science, and dental communities.

Service

- Extend institutional citizenship by providing school-based outreach service and health education in the local community.
- Support the profession through service to and leadership in the dental professional community, including a strong and relevant continuing education program.

Institutional Effectiveness

- Maintain the resources and institutional climate necessary to support the achievement of the school's education, patient care, research and scholarship, and service goals.

1-1 b These goals are consistent with the goals of the sponsoring institution and are in concert with the dental assistant educational program; namely, Education, Patient Care, Research and Scholarship, Service and Institutional Effectiveness. Education is represented in didactic presentation of the listed syllabi of the ten courses. It is also present in the pre-clinical exercises.

Patient assisted care will be delivered in our undergraduate and graduate programs with in-training dental assisting students and performance will be monitored.

Research will be accomplished through training methodologies implemented, quality of laboratory projects and the amount and quality of redoes. Scholarship will be addressed in the quality and quantity of laboratory procedures, and the methods of evaluation and feedback in publishable materials.

Service will be accomplished, monitored and evaluated in the School of Dental Medicine undergraduate and graduate clinics along with remote site activity in the greater Cleveland area.

Institution effectiveness will be measured through the performance of the trainees in the classroom, laboratories and all affiliated clinics. We will assess this new activity in our local and remote site partners, and facilities.

Financial Support

1-2 **The institution must demonstrate stable financial resources to ensure support of the dental assisting program's stated mission, goals and objectives on a continuing basis. Resources must be sufficient to ensure adequate and qualified faculty and staff, clinical and laboratory facilities, equipment, supplies, reference materials and teaching aids that reflect technological advances and current professional standards.**

The Dental Assisting Program of the Case Western Reserve University, School of Dental Medicine is in compliance with this standard.

SEE EXHIBIT 1-2-1

Narrative Response and Documentation:

1. **Describe/explain the process utilized to develop the program's budget. Include the timeframe, individuals involved, and final decision making body/individual(s).**

1-2-1 The program's budget was developed over the past year after a study of the certified programs in the northeast region of Ohio as well as the proprietary programs in this area. The issue of tuition in the area was discussed with the Advisory Board. The primary individuals involved were the Associate Dean for Administration, the Assistant Dean for Finance and CFO, the Director of Allied Dental Health programs and the Director of the Dental Assisting program.
The final decision rests in the Dean's office with input from the subgroups mentioned.

EXHIBIT 1-2-1 (In progress)

Using the following sample format, list the program's goals and/or objectives and describe the assessment methods utilized.

	Program Goal EDUCATION	Program Goal PATIENT CARE	Program Goal SCHOLARSHIP	Program Goal SERVICE	Institution EFFECTIVENESS
Time-table for process implementation	Didactic & Preclinical Education throughout the year.	Provide information that comports with patient centered case throughout the year.	Student's performance to demonstrate scholarship in their projects.	Demonstration of service to the patients provided care with students and doctors in the community.	Goals are consistent with the SODM CODA accreditation completed in 2016.
Participant(s)	The entire Class of dental assisting student.	Demonstrations of Patient Centered Care by each student member of the class.	Demonstration of scholarship in the quality of their projects.	Demonstration of quality service to the patients of the SODM and patient in outreach experiences.	Goals are consonant with those of the SODM.
Participant(s) roles and responsibilities	Defined in each of the 10 syllabi.	Defined in each of the syllabi and the Patient Bill of Rights.	Student option to select a project or activity that demonstrates their skill developed.	Defined patient service role and _____ in the student's clinical manual. (on line)	Roles and Respond carried out sati____ support the Goals of the programs and SODM.
Method of goal assessment					
Appropriate benchmark?					
Analysis timeframe for obtained data					
Related findings and conclusions					
Program changes made as a result of findings					
Changes made within outcomes planning and assessment process					
Follow-up					

Narrative Response and Documentation:

1. **Using the Exhibit 2 format, identify the sources of fiscal support for the dental assisting program and the percentage of the total budget that each source constitutes.**

SEE EXHIBIT 1-2-2

EXHIBIT 2

Using the following format, identify the sources of fiscal support for the program and the percentage of the program's total budget that each source constitutes:

Current fiscal year: 2018

A. State support	$ 0	0%
B. Local support SODM	$ 20,000	11.1%
C. Grant		
federal	$ 0	
State - ODA F	$ 10,000	5.5%
Local - GCDS F	$ 5,000	2.7%

Private -	$ 0	0%
D. Student tuition (15 students)	$150,000	80.4%
E. Outside Entities Women's Foundation (TBD) (specify)	$?	? %
F. Other (specify)	$ 0	0%
TOTAL	$ 185,000	99.7%

Narrative Response and Documentation:

3. If financial resources include grant monies, specify the type, amount and termination date of the grant. What is the primary use of these funds? Upon termination of the grant(s), how will these funds be replaced?

1-2-3 The primary sources of the grant funds are the Ohio Dental Association Foundation ($10,000) and the Greater Cleveland Dental Society Foundation ($5,000). These funds are primarily dedicated to educational programs and not to capital improvements. The grants are usually allocated for one year although it can be for multiple years with a phase out process.
The funds will be replaced and raised by programmatic increases in overall revenue from the Allied Dental Health Programs.
We have some requests in Woman Foundations but as yet have had no commitments. We will continually investigate other financial resources; such as, foundation, community health grants, and corporate funding not in conflict with Case Western Reserve University's funding resources.

Narrative Response and Documentation:

4. **Using the Example Exhibit 3 format, provide information on the program's budget for the previous, current and ensuing fiscal years.**

SEE EXHIBIT 1-2-3

EXHIBIT 3

Using the following form, provide information on the dental assisting program's budget for the previous, current and ensuing fiscal years.

	Previous Year 2017 to 2018	Current Year 2018 to 2019	Ensuing Year 2019 to 2020
I. Capital Expenditures	N/A		
A. Construction	$ 0	$ 0	$ 0
B. Equipment			
1. Clinic (dental unit, chair, etc.)	0	0	0
2. Radiography (including darkroom)	0	0	0
3. Laboratory	0	0	0
4. Locker Room	0	0	0
5. Reception Room	0	0	0
6. Faculty & Staff offices	0	0	0
7. Instructional equipment	0	0	0
8. Other (specify) _____	0	0	0
	0	0	0
TOTAL	**$ 0**	**0**	**$ 0**
II. Non-capital expenditures			
A. Instructional materials, e.g., slides, films	$ 0	$ 567	$500
B. Clinic supplies	0	460	500
C. Laboratory supplies	0		1,567
D. Office supplies	0	0	0
E. Program library collection			
1. Institutional	0	0 TBD	0
2. Departmental	0	0 TBD	0
F. Equipment maintenance and replacement	0	0	0
G. Other	0	0	0
(specify)_____	0	0	0
	0	0	0
TOTAL	**$ 0**	**$967**	**$2,567**
III. Faculty			
A. Salaries	$ 1,000	$ 75,000 ?	$ 88,000
B. Benefits	0	22,000	24,000
C. Professional Development	0	1,000	1,000
D. Travel for Student Supervision	0	500	500
E. Other (specify)	0	0	0
	0	0	0
TOTAL	**$ 1,000**	**$98,500**	**$122,500**
IV. Staff			
A. Secretarial Support	$ 4,000	$ 10,000	$ 15,000
B. Other (specify)	0	0	0
TOTAL	**$ 5,000**	**$10,000**	**$ 15,000**
V. Other Categories, if any	$ 15,600 *	$ 0	$ 0
(specify)_____ * CODA			
		$ 0	$ 0
TOTAL			
GRAND TOTAL	**$ 20,600**	**$ 109,467**	**$ 140,067**

added*Books

Narrative Response and Documentation:

5. Using the Example Exhibit 4 format, provide the actual expenditures for the previous academic year.

EXHIBIT 1-2-4

Provide the actual dental assisting expenditures for the previous year using the following form.

	Previous Year 2017 to 2018
I. Capital Expenditures N/A	
A. Construction	$ 0
B. Equipment	0
1. Clinic (dental unit, chair, etc.)	0
2. Radiography (including darkroom)	0
3. Laboratory	0
4. Locker Room	0
5. Reception Room	0
6. Faculty & staff offices	0
7. Instructional equipment	0
8. Other (specify) _____	0
_____	$ 0
TOTAL	
II. Non-capital Expenditures	
A. Instructional materials, e.g., slides, films	$ 0
B. Clinic Supplies	0
C. Laboratory supplies	0
D. Office supplies	0
E. Program library collection	0
1. Institutional	0
2. Departmental	0
F. Equipment maintenance and replacement	0
G. Other (specify) _____	0
_____	$ 0
TOTAL	
III. Faculty	
A. Salaries	$1,000
B. Benefits	0
C. Professional Development	0
D. Travel for Student Supervision	0
E. Other (specify) _____	0
_____	**$ 1,000**
TOTAL	
IV. Staff	
A. Secretarial Support	$ 4,000
B. Other (specify) _____	0
_____	**$5,000**
TOTAL	
V. Other Categories, if any (specify) * CODA	**$ 15,600***
_____	$
TOTAL	$15,600
GRAND TOTAL	**$ 21,600**

Narrative Response and Documentation:

6. **Using the format shown in Example Exhibit 5, provide information on the salary schedules for full- and part-time faculty for the current academic year, include the program administrator.**

SEE EXHIBIT 1-2-5

EXHIBIT 1-2-5

Provide information in the salary schedule for full-time and part-time faculty for the current year. If appropriate, use the following format.

FULL-TIME FACULTY

	Categories of Faculty Rank	INSTITUTION			DENTAL ASSISTING PROGRAM		
		Minimum	Average	Maximum	Minimum	Average	Maximum
Professor	Ronald Occhionero, D.D.S.						
Instructor	Shelly Feiwell						
Instructor	DA Director						

PART-TIME FACULTY

Categories of Faculty Rank	INSTITUTION			DENTAL ASSISTING PROGRAM		
	Minimum	Average	Maximum	Minimum	Average	Maximum
Staff Lecturer					→	
Pre-Clinical Trainer					→	
Clinical Trainer					→	
					→	
					→	

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 1-2 in the Accreditation Standards for Dental Assisting Education Programs.

Institutional Accreditation

1-5 Programs must be sponsored by institutions of post-secondary education which are accredited by an agency recognized by the United States Department of Education.

The dental assistant program of Case Western Reserve University, School of Dental Medicine is in compliance with this standard.

1-5-1 Case Western Reserve University, School of Dental Medicine has successfully completed the accreditation process with the Commission on Dental Accreditation (CODA) associated with the American Dental Association. Case Western Reserve University is a four year University that has oversight of the School of Dental Medicine, a four year private (not for profit) institution.

1-5-2 The United States Department of Education recognizes the Commission on Dental Accreditation (CODA) as the accrediting body for dental schools both public and private in the United States.

Accreditation occurs every seven years for Case Western Reserve University, School of Dental Medicine for which we have received full accreditation since its inception.
The most recent accreditation site visit was November 1-3, of 2016. We were verbally advised at the conclusion of the visit that we were fully accredited; however, we will not receive the full written report for a period of time until it is competed and approved, approximately one month.

1-5-3 As stated we will be sent the final report in approximately one month which will be available as in Exhibit #1-5-3. Examples of Evidence to Demonstrate Compliance in the Accreditation Standards for Dental Assisting Educational Programs.

See Exhibit 1-5 Example of Evidence to Demonstrate Compliance

Insert report of CODA for the SODM

1-6 All arrangements with co-sponsoring as affiliated institution must be formalized by means of written agreements which clearly define the roles and responsibilities of each institution involved.

<u>Special note</u>: This standard is not applicable because the School of Dental Medicine and its Allied Dental Health Programs is a designated extended campus facility. The dental assisting program students utilize all resources available to include libraries, health fitness, center fitness facility, bookstore, and parking.

1-7 There must be an active advisory committee to serve as a liaison between the program, local dental and allied dental professionals and the community. Dentists and dental assistants must be equally represented.

The dental assist program of Case Western Reserve University is in compliance with this standard.

Case Western Reserve University, School of Dental Medicine is in compliance with the Community Resources Standard 1-7. The Dental Assistant Advisory Committee provides mutual exchange of ideas, direction and information for program enhancement which is developed to meeting both programmatic community needs. Standards of patient care and the scope of practice are consistent with the Rules and Regulation of the Ohio State Dental Board.

1-7-1 • The Structure of the Dental Assistant Advisory Committee (DAAC) is the following:

- There is an equal number of dental assistants and dentists on the Dental Assistant Advisory Committee (DAAC).
- Overall Director of the Dental Assistant Programs who is both a dental assistant and expanded dental function auxiliary.
- An assistant director of dental assisting who is a certified dental assistant.
- A faculty oversite dentist member from the School of Dental Medicine.
- A two active dentist member from the Greater Cleveland Dental Society (GCDS).
- The director of Tri-C Dental Hygiene Program.
- Two expanded function dental auxiliaries from the community.
- Two employed dental assistants from the community.
- Two representatives from dental industry.

• The functions of the Advisory Committee are the following:

- Appropriateness of the dental assisting curriculum.
- Nominations for members of the Advisory Board.
- Issues dealing with new delegable duties, programmatic financial condition.
- Consider evidence based procedure consistent with the Ohio State Dental Board.

• The responsibilities of the Advisory Committee:

- General Meeting of all members twice a year.
- Special meetings as needed.
- Attendance at General Meetings. (Quorum 70%)
- Nomination and election of new members.
- Familiarity with the School of Dental Medicine (SODM), dental assistant curriculum in concert with the Ohio State Dental Board (OSDB) Rules and Regulations.

1-7-2 • The Membership Process is as follows:

- Nomination of potential members of the Dental Assistant Advisory Committee (DAAC) by the leadership group of the dental assistant program of the School of Dental Medicine.
- Submission of an application.
- Request for involvement from possible candidates.
- Name brought before the Dental Assistant Advisory Committee (DAAC) for approval.

• Terms and Length of Service:

- A staggered format beginning with a two year responsibility, thereafter staggered and followed by 1 year sabbatical, then a staggered or full succession.
  term of two years.
- In the event that suitable replacement cannot be met, the position holder can be extended one year at a time.

• Membership recruitment process:

- Request presented at Greater Cleveland Dental Society (GCDS), Dental Assistant Society (DA), Dental Hygiene Society (DH), local meeting for possible submission of a letter of intent to potential members of the Dental Assistant Advisory Committee (DAAC).
- Review the submissions and select candidates with an approval vote of the Dental Assistant Advisory Board Committee.

1-7-3 Describe the recent advisory action:

- Reviewed various aspects of the Dental Assistant Training Program such as curriculum, numbers of hours and CODA Standards.
- Discussed recommendations regarding the standards, curriculum and evaluation methodology, tuition, numbers of students, number of courses and possible financial grants.

1-7-4 List Names, affiliation, role/title, committee team, disciplines, appointment dates.

	Names	Affiliation	Role/Title	Committee Term	Discipline	Appointment Dates
1	Shelly Feiwell	CWRU SODM	Director, EFDA / DA	2 Years	EFDA/DA Education	12/2016 – 12/2018
2	Margaret Bertin	CWRU SODM	Assistant Director / DA	2 Years	DA Education	12/2016 – 12/2018
3	Dr. Ronald Occhionero	CWRU SODM	Faculty Oversight Dentist	2 Years	Dental Education	12/2016 – 12/2018
4	Dr. Fady Faddoul	CWRU SODM	Dentist	2 Years	Dental Education	12/20/16 12/20/18
5	Monica Jackson	CWRU SODM	Coordinator of Clinical Data	2 Years	Dental Education	12/20/16 12/20/18
4	Dr. Roderick Adams	Local Dentist (GCDS)	Dentist	2 Years	General Dentistry	12/2016 – 12/2018
6	Dr. L. Don Shumaker	Local Dentist (GCDS)	Dentist	2 Years	General Dentistry	12/2016 – 12/2018
7	Mary Lou Gerosky	Dental Hygiene Education (CCC)	Director, Dental Hygiene	2 Years	Dental Hygiene	12/2016 – 12/2018
8	Karin Hein	Local EFDA	Expanded Function Dental Auxiliary	2 Years	EFDA Educator	12/20/16 12/20/18
9	April Lonsbury	Local EFDA	Expanded Function Dental Auxiliary	2 Years	EFDA	12/2016 – 12/2018
10		Local Dental Assistant	Dental Assistant	2 Years	DA	12/2016 – 12/2018
11	Carolyn Calhoun	Local Dental Assistant	Dental Assistant	2 Years	DA	12/2016 – 12/2018
12	Bradley Kilbane	Designs For Vision	Sales Representative	2 Years	Dental Sales	12/2016 – 12/2018
13	Raul Payes	Henry Schein	Sales Representative	2 Years	Dental Sales	12/2016 – 12/2018
14	Gladys Ina	CWRU, SODM	Department Assistant	2 Years	School of Dental Medicine	12/20/16 12/20/18

1-7-5 Description of the duties and responsibilities of the individuals involved in the advisory committee

	Duties	Responsibilities
1	**Shelly Feiwell**	**Director, ADHP**
2	**Margaret Bertin**	**Assistant Director, ADHP**
3	**Dr. Ronald Occhionero**	**Faculty Dentist ADHP**
4	**Dr. Fady Faddoul**	**Faculty Dentist CWRU**
5	**Monica Jackson**	**Clinic Data Coordinator CWRU**
6	**Dr. Roderick Adams**	**Community Dentist**
7	**Dr. L. Don Shumaker**	**Community Dentist**
8	**Mary Lou Gerosky**	**Dental Hygiene Director, CCC**
9	**Karin Hein**	**Community EFDA, Dental Assistant**
10	**April Lonsbury**	**Community EFDA, Dental Assistant**
11	**Roz Lader**	**Community Dental Assistant**
12	**Carolyn Calhoun**	**Community Dental Assstant**
13	**Bradley Kilbane**	**Dental Sales Representative**
14	**Raul Payes**	**Dental Sales Representative**
15	**Gladys Ina**	**Department Assistant**

1-7-6 Minutes for the last two meetings:

1-7-7 Describe the mechanism used to ensure participation when the committee meets in a technology based forum.

Use GO TO Meeting as the primary vehicle after meeting minutes an gendas are sent to each participant. Voting can be either by e-mail or voice vote roll call.

The vote will be taken in the following manner:
Yes _____
No _____
Abstain _____
Recuse _____
Need a face to face meeting _____

A simple majority carries the motion in a "face to face meeting", votes can either be tallied by voice or secret ballet.

STANDARD 2 – EDUCATIONAL PROGRAMS
Admissions

2-1	**Admission of students must be based on specific published criteria, procedures and policies that include a high-school diploma or its equivalent, or post- secondary degree.**

The Dental Assistant Program is in compliance with this Standard.
Intent:
The dental assisting program is based on a science-oriented program of study and skill development offered at the post-secondary level that requires critical thinking, psychomotor skills, and ethical reasoning.

The program administrator and faculty, in cooperation with appropriate institutional personnel establish admissions criteria and procedures which are non-discriminatory, contribute to the quality of the program, and allow selection of adult students with the potential to successfully complete the program. Published promotional materials and website information related to student recruitment and admissions comply with the Commission's "Policy on Principles of Ethics in Programmatic Advertising and Student Recruitment".

Narrative Response and Documentation:

2-1-1 Describe the admission criteria for the dental assisting program. What are the prerequisites? Are the criteria weighted? If so, explain.

- Completed application.
- Available GED
- The applicant will take the Worderlic Test to measure basic reading, writing, numerical skills and have an interview with the program director.
- The student must score at least 75%.
- Case Western Reserve University, School of Dental Medicine is seeking a high quality of students that will be committed to the demands of the dental assisting program.

2-1-2 As an Exhibit, please provide examples of any entrance examinations.

See Exhibit 2-1-2

2-1-3 Describe the process for student selection. List names and titles of individuals participating in the process.

The students will take the Wonderlic test, and have an interview with a member of the Admissions Committee. The Allied Dental Health Director, Dental Assistant Director and a Clinical Faculty will be the primary person involved in this process.

- Application
- Testing
- Interview (Selective Students)
- Selection
- Admission Vote
- Acceptance

2-1-4 How are applicants informed of the program's criteria and procedures for admission, program goals, functions performed by dental assistants and employment opportunities?

- Students are informed by the school's web site or local and state dental journals, social media, school visitation and Dental Assistant training brochure.
- The program's goal is to train quality dental assistants to provide the community with high high caliber dental assistant.
- Dental assistant graduates will be prepared to seek employment utilizing routine dental assisting functions listed in this document. Dental assistants will seek employment in dental practice settings in the region and other institutions.

2-1-5 If students who do not meet the program's admission criteria are admitted, what academic strengthening is suggested in the area(s) of deficiency(s)?

Students will be granted provisional status depending on their grades. Tutorial assistance will be provided by designated faculty and students in good standing.
The students will complete extra laboratory and written work depending on the area of deficiency.

2-1-6 How are applicants informed of the programs policies on infectious diseases?

The applicants are informed of infectious diseases through a 12 module on-line course that has a concentration on infectious diseases. Then the students will be tested on this material to measure the level of competency of infectious disease concepts and must pass at 70% level, and offered remediation to receive passing grade.

2-1-7 As Exhibits please provide the following: Admissions packet information; promotional materials, website information (screen shots).

See Exhibit 2-1-7

2-2 Admission of students with advanced standing must be based on the same criteria required of all applicants admitted to the program. The program must ensure that advanced standing credit awarded is based on equivalent didactic, laboratory and preclinical content and student achievement.

The dental assistant program of the School of Dental Medicine is in compliance with this Standard.

Intent:

Policies ensure that advanced standing credit is awarded based on equivalent coursework, knowledge, and/ or experience that meets or exceeds content required in the curriculum and results in equivalent student competence. The curriculum may be structured to allow individual students to meet performance standards specified for graduation in less that the required length as well as to provide the opportunity for students who require more time to extend the length of their instructional program. The curriculum design may provide maximum opportunity for students to continue their formal education with minimum duplication of learning experiences.

Advanced standing refers to applicants that may be considered for admission to a training program whose curriculum has been modified after taking into account the applicant's past experience. Examples include transfer from a similar program at another institution, completion of training at a non-CODA accredited program, or documented practice experience in the given discipline. Acceptance of advanced standing students/residents will not result in an increase of the program's approved number of enrollees. Applicants for advanced standing are expected to fulfill all of the admission requirements mandated for students/residents in the conventional program and be held to the same academic standards. Advanced standing students/residents, to be certified for completion, are expected to demonstrate the same standards of competence as those in the conventional program.

Narrative Response and Documentation:

2-2-1 Does the dental assisting program admit students with advanced standing? If yes, describe the policies and methods for awarding advanced standing credit.

The dental assisting program does not have an advanced standing program as yet but we are in the process of considering giving credit for courses attended and satisfactorily completed at other institutions. This would be done on a case by case basis.

2-2-2 Indicate the type of courses for which advanced standing is granted and the maximum number of credits that can be awarded.

Initially, the courses will be anatomy, dental materials, radiography credit hours would be awarded pending satisfactory performance based on a bench test in each of the aforementioned .

2-2-3 Who reviews transcripts and determines course equivalency? Describe the process for evaluating courses taken at another institution and used as a basis of credit award?

- This would be conducted by Dental Assistant Director, Director of Allied Dental Program and the Associate Dental for Administration.
- The advance standing candidate will be evaluated on a case to case basis. This
- includes courses
  and experiences taken at other institution.
- Application
- Wonderlic Test
- Bench Test
- Transcript
- Interview

If a formal policy has been developed, please provide. Addressed om 2-2-1

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-2 in the Accreditation Standards for Dental Assisting Education Programs.

2-3	**The program must demonstrate that student enrollment numbers are proportionate to the number of faculty, availability of appropriate classroom, laboratory, and clinical facilities, equipment, instruments, and supplies.**

The Dental Assistant Program of the School of Dental Medicine is in compliance with this Standard.

One class per year
One main classroom
One laboratory
Student clinic and faculty clinic, graduate clinics
Supplies will be ordered according to the amount of students in the program

Intent:
In determining the maximum number of dental assisting students enrolled in a program, including off-campus sites, hybrid, or on-line courses, careful consideration is given to ensure that the number of students does not exceed the program resources including, as appropriate, financial support, scheduling options, facilities, equipment, and faculty.

Narrative Response and Documentation:

1. **How many classes does the dental assisting program admit each year? In what month(s) of the year do students begin their course of study?**

    - The program accepts students once a year.
    - The program begins in August.

Curriculum Management

2-4	**The curriculum must be structured on the basis of, a minimum of, 900 instructional hours at the postsecondary level that includes 300 clinical practice hours.**

The Dental Assistant Program of the School of Dental Medicine is in compliance with this standard.

Intent:
Instructional hours should include didactic, laboratory, preclinical, and clinical content required in the standards. Curriculum content not required by the standards accordingly increases the length of the program. Clinical practice hours assisting a dentist are obtained in a facility that provides comprehensive dental treatment.

Narrative Response and Documentation: see Exhibit 2-4

- Catalog – Instructional Hours
- Information Sheet

1. Describe the structure and sequence of the dental assisting curriculum for each term and all enrollment cycles.

See Exhibits 2-4,
1) 2-4-1
2) 2-4-2
3) 2-4-3
4) 2-4-4

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-4 in the Accreditation Standards for Dental Assisting Education Programs.

2-5 **The curriculum must be designed to reflect the interrelationship of its biomedical sciences, dental sciences, clinical and behavioral sciences, preclinical and clinical practice. Curriculum must be sequenced to allow assimilation of foundational content in oral anatomy; basic chairside skills, medical emergencies, confidentiality and privacy regulations, infection control, sterilization, and occupational safety precautions, procedures and protocols prior to any patient contact or clinical experiences. Content must be integrated and of sufficient depth, scope, sequence of instruction, quality and emphasis to ensure achievement of the curriculum's defined competencies and program's goals and objectives.**

The Dental Assistant Program of the School of Dental Medicine is in compliance.

Intent:
Curriculum content must be sequenced to allow assimilation of foundational knowledge and critical thinking skills necessary to ensure patient safety, and opportunity for students to develop the knowledge and skills necessary to ensure patient, student, faculty, and staff safety when performing or assisting in clinical procedures involving patients, including student partners.

Programs that admit students in phases, including modular or open-entry shall provide content in tooth anatomy, tooth numbering, general program guidelines, basic chairside skills, emergency and safety precautions, infection control and sterilization protocols associated with, and required for patient treatment, prior to any other program content and/ or performances of activities involving preclinical/clinical activities.

Documentation:

1. **For each term of the current year's dental assisting curriculum, provide a class schedule as illustrated in Example Exhibit 9. Include course number and name; faculty, setting (clinic, lab, classroom number); and number of students. Modify the exhibit as needed to account for multiple sections. Note: Programs with multiple enrollment starts must modify the exhibit to provide the requested information.**

2. **Outline the sequence of the dental assisting curriculum as illustrated in Example Exhibit 8.**
   See Exhibits: 2-5-1, 2-5-2

Instruction

2-6 Written documentation of each course in the curriculum must be provided to students at the start of each course and include:

a. **The course title, number, description, faculty presenting course and contact information**
b. **Course content outline including topics to be presented**
c. **Specific instructional objectives for each topic presented**
d. **Learning experiences with associated assessment mechanisms**
e. **Course schedule including time allocated for didactic, laboratory, and clinical learning experiences**
f. **Specific evaluation procedures for course grade calculation**

See Exhibits for 2-6

Narrative Response and Documentation:

1. **Describe how and when course documentation is provided to students.**

   The syllabus is given the first day of class and consists of the schedule, rules, quizzes, tests, and competencies.
   The first day of class is an orientation/class.

2. **Explain the grading process for each course. How is the final course grade determined? What factors are included? (e.g., exams, homework, skill evaluations, projects, participation?) Include the specifics for each category (number or type, weight, etc.) and explain how points are awarded, a grade is determined, and then combined to arrive at final course grade.**

   a Final course is determined by tests, quizzes, skill evaluations, daily grade, final exam, and homework.

   b The grades are weighted:

Tests	30%
Quizzes	20%
Homework	10%

Skill Evaluations	15%
Daily grade	5%
Final Exam	20%
Total grade	100%

3-c Tests percentage (30%) is awarded at the end of each textbook..

- Quizzes percentage to determine understanding while working on the chapter.
- Homework is assigned utilizing a workbook supplemental to the textbook.
- Skill evaluations are done to evaluate the student's hands on skills.
- Daily grade is derived from student participation and they are in proper attire.
- Final Exam is administered at the end of the course.
- The above grading measurements are calculated to develop the students' final grade.

3. **In a separate curriculum document, provide documentation/syllabus provided to students, for each course in the dental assisting curriculum. Materials for each course should be grouped together, in sequence, and include the following:**

   a. course title and number;
   b. course description;
   c. faculty and contact information;
   d. course content outline including topics to be presented;
   e. specific instructional objectives for each topic presented;
   f. learning experiences with associated assessment mechanism;
   g. Course schedule including time allocated for didactic/laboratory/clinical learning experiences;
   h. Specific evaluation procedures for course grade calculation;
   i. date of syllabus preparation/update

Please refer to the curriculum document check-list at the end of the Site Visitor Evaluation Form (SVER).

For applicable courses, include all skill/competency evaluation forms for skills listed in the standards. For each course, submit the final exam and an example of a quiz or other evaluative tool. Submit appropriate rubrics used to evaluate assignments and projects.

The curriculum document must include a table of contents with corresponding and continuous page numbers. The document should begin with page 1 and is sequentially and continuously paginated to the end of the document. Present course documentation in sequence of presentation. On hard copy, include tabbed dividers between courses with labels.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-6 in the Accreditation Standards for Dental Assisting Education Programs.

2-7 **Objective student evaluation methods must be utilized to measure all defined course objectives to include:**

a. Didactic, laboratory, preclinical and clinical content
b. Specific criteria for measuring levels of competence for each component of a given procedure
c. Expectation of student performance elevates as students progress through the curriculum

Narrative Response and Documentation:

1. **Describe how the students' laboratory, preclinical skills and clinical performance/competence are evaluated. Include the mechanisms utilized to evaluate students' skills in the separate curriculum document within the appropriate course.**

See Exhibits for 2-7-1

2-7-1-a The students are evaluated in the laboratory, preclinical, and clinical performance by skill evaluations. Each course that has a laboratory has skill evaluations.
2-7-1-b The students will take skill evaluations for each laboratory, preclinical and Clinical course. Criteria for each course listed in Exhibits.
2-7-1-c Student performance is monitored in gradebook to ensure that performance elevates as student progress through the curriculum.

3. **What standards of achievement/competence level are required for dental assisting students to continue in the curriculum? What is considered a minimum passing grade/score? How and when are these standards assessed and explained to the students?**

2-7-2-a Students must maintain a 70% average to stay in the program.
2-7-2-b Students must maintain a minimum of a 70 % average to have a passing score.
2-7-2-c Students are assessed by written exams, quizzes, and skill evaluations. This is explained to the students the first day of class through the course syllabi and the review of all associated skill evaluation grade sheets.

3. **Describe the mechanism for reviewing academic performance academic performance and the action(s) taken when a student's performance is below minimum standards? How frequently is the student made aware of her/his performance?**

2-7-3-a The students are informed of their academic performance through the Canvas Learning Management System gradebook evaluation application. Then the program director will advise them
about their performance.
2-7-3-b The students continuously keep appraised of their performance by utilizing gradebook function of Canvas Learning Management System

4. Describe procedures for assisting students who are having academic difficulties.

The students will be informed that they must attend tutoring sessions, which include the date, time, course, and material to be covered in the tutoring session.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-7 in the Accreditation Standards for Dental Assisting Education Programs.

Preclinical Instruction

Essential Dental Assisting Skills

2-8 **Curriculum content must include didactic and laboratory/preclinical objectives in the following dental assisting skills and functions. Prior to performing these skills/functions in a clinical setting, students must demonstrate knowledge of, and laboratory/preclinical competence in the program facility.**

a. **Take/review and record medical and dental histories DAS 103**
b. **Take and record vital signs DAS 103**
c. **Assist with and/or perform soft tissue extra/intra oral examinations DAS 103**
d. **Assist with and/or perform dental charting DAS 103**
e. **Manage infection and hazard control protocol consistent with published professional guidelines DAS 105**
f. **Prepare tray set-ups for a variety of procedures and specialty areas. DAS 108**
g. **Seat and dismiss patients DAS, 103, 110, 108, 114**
h. **Operate oral evacuation devices and air/water syringe DAS, 103, 110, 108, 114**
i. **Maintain clear field of vision including isolation techniques DAS, 103, 110, 108, 114**
j. **Perform a variety of instrument transfers DAS, 103, 110, 108, 114**
k. **Utilize appropriate chairside assistant ergonomics DAS 101**
l. **Provide patient preventive education and oral hygiene instruction DAS, 103, 110, 108, 114**
m. **Provide pre-and post-operative instructions prescribed by a dentist**
n. **Maintain accurate patient treatment records DAS, 103, 110, 108, 114**
o. **Identify and respond to medical and dental emergencies DAS, 103, 110, 108, 114**

Chairside Dental Assisting Functions

2-9 **Curriculum content must include didactic and laboratory/preclinical objectives in the following dental assisting skills and functions. Prior to performing these skills/functions in a clinical setting, students must demonstrate knowledge of, and laboratory/preclinical competence in the program facility.**

a. **Assist with and/or apply topical anesthetic and desensitizing agents DAS, 103, 110, 108, 114**
b. **Assist with and/or place and remove rubber dam DAS 103, 104**
c. **Assist with and/or apply fluoride agents DAS 101**
d. **Assist with and/or apply bases, liners, and bonding agents DAS 103, 104, 110, 114**
e. **Assist with and/or place, fabricate, and remove provisional restorations DAS 108**
f. **Assist with and/or place and remove matrix retainers, matrix bands, and wedges DAS 104**
g. **Assist with and/or remove excess cement or bonding agents DAS 108**
h. **Assist with a direct permanent restoration DAS 103**
i. **Fabricate trays, e.g., bleaching, mouthguard, custom DAS 107**
j. **Preliminary impressions DAS 107**
k. **Clean and polish removable dental appliances DAS 108**

Narrative Response and Documentation (for Standards 2-8 and 2-9):

1. **Using the format illustrated in Example Exhibit 10, list the courses that provide major instruction (didactic, preclinical and clinical) in each category of functions specified in Standards 2-8 and 2-9.**

   Please see Exhibit 2-9-1
2. **If any function(s) specified in Standards 2-8 and 2-9 is not included in the curriculum, what is the rationale for its omission?**

Advanced/Expanded Dental Assisting Functions

2-10 **Where graduates of a CODA-accredited program are authorized to perform additional functions defined by the program's state-specific dental board or regulatory agency, program curriculum must include content at the level, depth, and scope required by the state. Further, curriculum content must include didactic and laboratory/preclinical objectives for the additional dental assisting skills and functions. Students must demonstrate laboratory/preclinical competence in performing these skills in the program facility prior to clinical practice.**

Intent:
Functions allowed by the state dental board or regulatory agency for dental assistants are taught and evaluated at the depth and scope required by the state. The inclusion of additional functions does not compromise the length and scope of the educational program or content required in the Accreditation Standards.

Narrative Response and Documentation:

1. **Describe each additional state-allowed skill not listed in the Standards and the instructional level required. Include number of patient experiences and/or number of didactic, preclinical/laboratory, and clinical experience hours required by the state.**

2. **Provide as an exhibit the appropriate pages of the state dental practice act or regulatory code and corresponding administrative code related to dental assisting.**

3. **Using the format illustrated in Example Exhibit 11, list ANY additional functions included in the curriculum and presented within the program, not specified in Standards 2-8 and 2-9.**

4. **Using the format illustrated in Example Exhibit 12, indicate which extra oral and intra oral functions are allowed within the State Dental Practice Act for Dental Assistants. (Do not include additional hours in advanced training (EF) taught outside the program curriculum)**

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-10 in the Accreditation Standards for Dental Assisting Education Programs.

2-11 **Students must demonstrate competence in the knowledge at the familiarity level in dental practice management:**

a. **Computer and dental software DAS 103**
b. **Business ethics and jurisprudence DAS 106**
c. **Business oral and written communications DAS 106**
d. **Inventory systems and supply ordering DAS 106**
e. **Maintenance and retention of business records DAS 106**
f. **Management of patient information DAS 103, 106**
g. **Recall systems DAS 106**

Biomedical Sciences

2-12 **The biomedical science aspect of the curriculum must include content at the in-depth level in bloodborne pathogens and hazard communications standards and content must be integrated throughout the didactic, preclinical, laboratory and clinical components of the curriculum.**

Intent:
The biomedical sciences provide a basic understanding of body structure and function; disease concepts; and dietary considerations of the dental patient.

Narrative Response:

1. **The program's curriculum is to be provided in a separate curriculum document. List the relevant exhibits or pages within the curriculum document that identify instructional content in, and student evaluation of activities related to, bloodborne and infectious diseases.**

Refer to DAS 105 Syllabus which refers to page 9-18.

Dental Sciences

Intent:
Dental science content provides the student with an understanding of materials used in intra-oral and laboratory procedures, including experience in their manipulation; an *understanding of the development, form and function of the structures of the oral cavity and of oral disease; pharmacology as they relate to dental assisting procedures; and scientific principles of dental radiography.*

2-13 **The dental science aspect of the curriculum must include content at the familiarity level in:**

a. **Oral pathology DAS 108**
b. **General anatomy and physiology DAS 102**
c. **Microbiology DAS 105**
d. **Nutrition DAS 101**
e. **Pharmacology to include: DAS 103**
    i. **Drug requirements, agencies, and regulations**
    ii. **Drug prescriptions**
    iii. **Drug actions, side effects, indications and contraindications**
    iv. **Common drugs used in dentistry**
    v. **Properties of anesthetics**
    vi. **Drugs and agents used to treat dental-related infection**

2-14 **The dental science aspect of the curriculum must include content at the in-depth level in oral anatomy.**

Intent:
Content in oral anatomy should include oral histology and oral embryology

2-15 **The curriculum must include content at the in-depth level in dental materials. Students must demonstrate knowledge of the properties, and competence in the uses and manipulation of, dental materials to include:**

a. **Gypsum DAS 107**
b. **Restorative materials DAS 104**
c. **Dental cements DAS 104**
d. **Impression materials DAS 107**
e. **Acrylics and or thermoplastics DAS 107**
f. **Waxes DAS 107**
g. **Fabrication of casts, temporary crown and/or bridge DAS 108**
h. **Abrasive agents used to polish coronal surfaces and appliance DAS 107**
i. **Study casts/occlusal registrations DAS 107**

2-16 **The curriculum must include content at the in-depth level in dental radiology. Students must demonstrate knowledge and skills to produce diagnostic dental image surveys on manikins. Prior to exposing dental images on patients, students must demonstrate competence in:**

a. **Radiation health protection techniques DAS 109**
b. **Processing procedures DAS 109**
c. **Anatomical landmarks and pathologies DAS 109**
d. **Mounting survey of dental images, and DAS 109**
e. **Placing and exposing dental images on manikins DAS 109**

2-17 **Prior to exposing dental images during extramural clinical assignments, students must demonstrate competence, under faculty supervision, in exposing diagnostically acceptable full-mouth dental image surveys on a minimum of two patients in the program, or contracted facility.**

Intent:
Full-mouth dental image surveys are comprised of periapical and bitewing images.

Clinical and Behavioral Sciences

2-18 **The curriculum must include didactic content at the in-depth level to include:**

a. **General dentistry DAS 103**
b. **Dental specialties DAS 108**
c. **Chairside assisting DAS 103**
d. **Dental-related environmental hazards DAS 105**
e. **Preventive dentistry DAS 101**
f. **Management of dental and medical emergencies DAS 103**

Intent:
Content provides background for preclinical and clinical experiences.

Narrative Response and Documentation (for Standards 2-11, 2-13, 2-14, 2-15, 2-16 and 2-18):

1. **Using the format illustrated in Example Exhibit 13, list the courses that provide the major instruction in each content area specified in Standards 2-11, 2-13, 2-14, 2-15, 2-16 and 2-18.**

2. **If any content area(s) specified in Standards 2-11, 2-13, 2-14, 2-15, 2-16 and 2-18are not included in the curriculum, what is the rationale for its omission? However, all standards are included.**

Narrative Response and Documentation (for Standards 2-16 and 2-17):

1. **Describe how students acquire an understanding of radiation safety prior to exposing radiographs on patients.**

   DAS 109 Radiography the instructor will explain the concepts of radiation safety to the students during lecture. The instructor will explain the x-ray unit to the students regarding radiation safety.

2. **Using the format illustrated in Example Exhibit 13, summarize the type and minimum number of acceptable radiographic surveys that each student is required to expose, process and mount during the dental assisting program.**
3. **Describe how faculty instruction and evaluation are provided to students throughout all of their radiographic experiences.**

   The instructor will provide the didactic instruction during lecture time.
   The students are graded through written examinations and
   Skill evaluations on radiography unit, full mouth series, and bite wing films on both manikins and patients.

2-19 **The program must demonstrate effectiveness in creating an academic environment that supports ethical and professional responsibility to include:**

a. **Psychology of patient management and interpersonal communication DAS 106**
b. **Legal and ethical aspects of dentistry DAS 101**

Intent:
Faculty, staff and students should know how to draw on a range of resources such as professional codes, regulatory law and ethical theories to guide judgment and action for issues that are complex, novel, ethically arguable, divisive or of public concern.

Narrative Response and Documentation:

1. **Describe how the program supports ethics and professionalism.**

   The Faculty are members of the American Dental Assistants Association.
   The Faculty are members of the American Dental Education Association.
   Students are members of the American Dental Assistants Association.
   Professional Code of Conduct.
   State Dental Practice Act.
   Professionalism and ethical expectations to the faculty, students, and staff.
   The students' handbook is available to reinforce professional expectations.

2. **Assess the degree to which students assume responsibility for professional judgment and ethical conduct.**

The faculty will review the student handbook and the State Dental Practice Act. The faculty will also reinforce the professional and ethical expectations of the department and the school.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-19 in the Accreditation Standards for Dental Assisting Education Programs.

2-20 **The dental assisting program must provide opportunities and encourage students to engage in service and/or community-based learning experiences.**

Intent:
Community-based experiences are essential to develop dental assistants who are responsive to the needs of a culturally diverse population.

Narrative Response and Documentation:

1. **What opportunities are students provided for service and/or community-based learning experiences?**

   The dental assisting students participate in Give Kids A Smile, Professionals Day. and the Sealant Program.

2. **Describe the ways in which students are encouraged to engage in service and/or community-based learning experiences.**

   The students are given extra points towards their grades for participating in the above community service activities.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-20 in the Accreditation Standards for Dental Assisting Education Programs.

Clinical Externship Experience

2-21 **Clinical experience assisting a dentist must be an integral part of the educational program designed to perfect students' competence in performing chairside assisting functions, rather than to provide basic instruction. Students must have a minimum of 300 hours of clinical experience.**

2-22 **Each student must be assigned to two or more offices or clinics for clinical experience and assisting in general dentistry situations is emphasized.**

2-23 **The major portion of the students' time in clinical assignments must be spent assisting with, or participating in, patient care.**

2-24 **The dental assisting faculty must plan, approve, supervise, and evaluate the student's clinical experience, and the following conditions must be met:**

a. **A formal agreement exists between the educational institution and the facility providing the experience**
b. **The program administrator retains authority and responsibility for the student**
c. **Policies and procedures for operation of the facility are consistent with the philosophy and objectives of the dental assisting program.**
d. **The facility accommodates the scheduling needs of the program**
e. **Notification for termination of the agreement ensures that instruction will not be interrupted for currently assigned students**
f. **Expectations and orientation are provided to all parties prior to student assignment**

2-25 **Students must maintain a record of their activities in each clinical assignment.**

2-26 **During the clinical phase of the program, program faculty must conduct seminars periodically with students for discussion of clinical experiences.**

Intent:
Seminar discussions provide students with opportunities to share clinical experiences with other students and faculty.

2-27 **When clinical experience is provided in extramural facilities, dental assisting faculty must visit each facility to assess student progress. Budgetary provisions must be made to support faculty travel.**

2-28 **Objective evaluation criteria must be utilized by faculty and office or clinical personnel to evaluate students' competence in performing specified procedures during clinical experience.**

Narrative Response and Documentation (for Standards 2-21 through 2-28):

1. **Provide a typical clinical rotation schedule for a dental assisting student as an Exhibit. Indicate the type of practice and approximate length of each rotational assignment.**

   Exhibit 28-1 This provides the clinical rotation for the students for the 8 weeks of the Externship portion of the program

2. **Describe the manner in which the students' clinical experiences are planned, supervised and evaluated by dental assisting faculty in conjunction with personnel in the facilities. Identify the individuals who participate in supervision and evaluation of dental assisting students. How often are the facilities visited by dental assisting faculty?**

   1-a The student will receive a syllabus for the externship course. The students will provide mostly patient care that was previously discussed between the office and the

dental assisting program. There are evaluation forms with the syllabi for the office to complete and return on weekly basis for a weekly grade.
1-b The dentist and the leading assistant will complete the evaluation of the student on a weekly basis.
1-c The dental assisting faculty will visit the site twice during the clinical portion of the program.

3. **Specify students' expected levels of performance in the specified skills at the beginning and the end of the clinical practice phase of the program.**

   The students are expected to have 85% performance on chairside assisting skills at the beginning of the clinical practice, and 95% performance at the end of the clinical experience.

4. **How do students share clinical experiences? As an Exhibit, provide example seminar schedules or agendas.**

   Exhibit 2-28-4
   DAS 201 Seminar course will provide weekly experiences for the students to Practice and sharpen up their assisting skills.

5. **Please provide to the visiting committee, examples of student-maintained records of activities.**

   The course syllabus DAS 201 Seminar Course

6. **As an exhibit, provide a listing of externship/clinical facilities for which a current formal agreement exists. For each facility, indicate the number of students it will accommodate and the type of practice.**

   Exhibit 2-28-7 Please see the Exhibit attachment.

7. **Describe the program's communications with personnel in the clinical facility for familiarization with the program's goals, curricular content, policies, methods of instruction and evaluation and roles and responsibilities of all parties. If students' clinical practice experiences are scheduled in off-campus facilities, specify the criteria used for facility selection.**

   The program provides the clinic site with a syllabus that has the requirements and the evaluations, program goals, curricular content, policies, methods of instruction. The program evaluates sites that will give the student a good experience and a possible place of employment. The site needs to be clean, organized, up-to-date equipment, and the staff needs to have their radiography certification.

8. **As an exhibit, please provide an example completed clinical facility agreement.**

   Exhibit 2-28-8 is the exhibit for the clinical facility agreement.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 2-21 in the Accreditation Standards for Dental Assisting Education Programs.

STANDARD 3 – ADMINISTRATION, FACULTY AND STAFF

3-1 **The program must be a recognized entity within the institution's administrative structure which supports the attainment of program goals.**

Intent:
The position of the program in the institutions administrative structure should permit direct communication between the program administrator and institutional administrators who are responsible for decisions that directly affect the program The administration of the program should include formal provisions for program planning, staffing, management, coordination and evaluation.

The Dental Assisting Program of the Allied Dental Health Programs is in compliance with this Standard. Please see the School of Dental Medicine's flow chart in the Appendix titled 3-1A Administration Faculty and Staff on page_____

Narrative Response and Documentation:

1. **As an exhibit, provide the most recent organizational chart for the institution indicating the position of the dental assisting program in the administrative structure.**

3-1-1 Please see the most recent organization chart for Case Western Reserve University which indicates the position of the dental assisting program of the Allied Dental Health Programs in the administrative structure. See 3-1-Appendix Administrative Faculty and Staff organization chart on page ____

See Exhibit 3-1-A Organization Chart of the School of Dental Medicine.

2. **Describe the opportunities for direct communication between the dental assisting program director and the institutional administrators who are responsible for decisions that directly affect the program.**

3-1-2 The primary opportunity for direct communication between the dental assisting program director of the Allied Dental Health Department and the institutional administrator who are responsible for decisions that directly affect the program is through the monthly administrator's and chairman's meetings where each administrator and departments and program have opportunity for discussion. If there is urgency, other meetings can be and are scheduled with this group.

3. **Are there opportunities for the dental assisting program administrator and faculty to participate in decisions which directly affect the program? Please give examples.**

3-1-3 There are opportunities for the dental assisting administrator and faculty to participate in decisions which directly affect the program.

- The dental assisting faculty is part of the Allied Dental Health program which includes the EFDA faculty. At a minimum there two faculty groups meet monthly to review activities, progress and recommendations.

- The dental assisting administrator meets with the Dean, the associated Deans and the chairs of departments and programs monthly to review activities, progress and recommendatiosn.

4. If an institution-wide committee which has significant impact on the dental assisting program does not include a member of the program faculty, explain the procedure whereby faculty provide consultation when matters directly related to the dental assisting program are considered.

3-1-4 An institution side committee that could have impact on the dental assisting program could be the university Faculty Senate. However, we have four dental faculty representatives that serve on the committee who can provide input from the School of Dental Medicine about the program and impact of decision and/or faculty or administrators of the Allied Dental Health Programs specifically dental assisting can attend and provide testimony as needed.
This did occur when the Dental Assistant program was approved by the University Faculty Senate.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 3-1 in the Accreditation Standards for Dental Assisting Education Programs.

Program Administrator

3-2 The program administrator must have a full-time commitment to the institution and an appointment which provides time for program operation, evaluation and revision. The program administrator must have the authority and responsibilities to perform the following for:

a. Budget preparation
b. Fiscal administration
c. Curriculum development and coordination
d. Selection
e.
f.
g.

See Exhibit 3-2 A Program Director Office Hours
3-2 B Program Directors Job Description

3-3 The program administrator must be a Dental Assisting National Board "Certified Dental Assistant"

The Dental Assistant Program of the Allied Dental Health Program is in compliance with this standard.

The Program Director is a graduate of _____ and has a baccalaureate degree and has had several courses related to education to include but not limited to educational methodology, development, psychology, test construction, measurement and evaluation.

See Exhibit 3-___ - A Copy of the Baccalaureate degree.
3- ___ - A Substantiation of educational courses.

3-3 The Dental Assistant Program of the Allied Dental Health Programs is in compliance with this standard. The program administrator is a Dental Assisting National Board "Certified Dental Assistant" with occupational chairside experience in four _____ dentistry both in private practice and the School of Dental Medicine at Case Western Reserve University.

See Exhibit 3-3 Program Administrator Certification Document

3-4 The program administrator must have a minimum of a baccalaureate degree or be currently enrolled.

3-1-4 The Dental Assisting Program of the Allied Dental Health Programs is in compliance with this standard. Please see the Job Description of the Program Administrator of the Dental Assisting Program.

STANDARD 4 – EDUCATIONAL SUPPORT SERVICES

4-1 The program must provide adequate and appropriately maintained facilities to support the purpose/mission of the program and which are in conformance with applicable regulations.

Intent:
The physical facilities and equipment effectively accommodate the schedule, the number of students, faculty and staff, and include appropriate provisions to ensure health and safety for patients, students, faculty and staff. The facilities permit attainment of program goals. This Standard applies to all sites where students receive instruction.

1. **In what year was the program facility constructed and/or last remodeled?**

   The facility was constructed in November 2002.

2. **What procedures have been established for assessing program facilities and equipment in relation to current concepts of dental assistant utilization?**

   The School of Dental Medicine has been involved with instructional methods of dental students and four-handed dentistry since 1968 when they received their first grant for dental assistant utilization. The dental students are assigned dental assistants in the dental clinics. The dental clinics are equipped to permit the practice four-handed dentistry and expanded function dental auxiliary utilization.

   Who is responsible for the assessment and how frequently is it made?

   The persons responsible for the assessment are the Dean of the School of Dental Medicine, Associate Dean for Administration and the Director of Finance and Operations. This is done on an annual basis or as the program funds permit.

   What is the program's long-range plan for maintaining, replacing and adding equipment?

   The equipment will be replaced or changed as technology improves. Annually, programs are required to submit a budget for maintaining, replacing and adding new equipment. The School of Dental Medicine is affiliating with the Cleveland Clinic system of Greater Cleveland. A facility is in the building stage and will be available in 2019. There is a dedicated area in the new facility for dental auxiliary programs including Dental Assisting and Expanded Function Dental Auxiliary training.

4-2 A clinical facility must be available for students to obtain required experience with faculty supervision.

Pre-doctoral and clinical facilities and faculty are available to the students 5 days a week.

4-3 Each treatment area must contain functional equipment including:

a. Power-operated chair(s) for treating patients in a supine position
b. Dental units and mobile stools for the operator and the assistant which are designed for the application of current principles of dental assistant utilization.
c. Air and water syringe
d. Adjustable dental light
e. High and low speed handpieces
f. Oral evacuating equipment
g. Work surface for the chairside assistant

All items listed are available in the pre-doctoral clinics and are being planned for in the new facility.

4-4 Each treatment area must accommodate an operator and a patient as well as the student and faculty.

Operatory size is 10 feet deep by 7 feet across. The clinics all are designed to accommodate the dental health team. In the planning for the new school, the operatory size will be approximately 10 feet by 10 feet.

4-5 The sterilizing area must include sufficient space for preparing, sterilizing and storing instruments.

The sterilization area provides services for 140 students and was renovated in 2002 to provide a smooth - flowing process from instrument check-in to sterilization to instrument check-out. The facility is divided into two sections; one side for "dirty" and the other for "clean".

4-6 Instruments and appropriate models and armamentaria must be provided to accommodate students' needs in learning to identify, exchange, prepare procedural trays and assist in procedures including:

a. Diagnostic
b. Operative
c. Surgical
d. Periodontal
e. Orthodontic
f. Removable and fixed prosthodontics
g. Endodontic

Instruments are available for general restorative and specialty procedures. Students will be provided a rotation through all specialty departments so that they become acquainted with the instrumentation in order to prepare for procedural trays.

Narrative Response and Documentation (for Standards 4-2 through 4-6):

1. **How many complete, functional treatment areas are used for preclinical and clinical instruction and practice?**

   There are 20 preclinical areas located on the second floor. There are 140 clinical practice areas located in the A and B dental clinics on the ground floor of the present facility. The new facility with the Cleveland Clinic Foundation is in the planning stages.

2. **If the capacity of the facility does not allow all students to be in laboratory, pre-clinical and/or clinic courses at the same time, please provide documentation of how students spend laboratory, pre-clinical and/or clinical sessions.**

   There is adequate space in the dental auxiliary pre-clinical facility and the 140 chair pre-doctoral clinic is more than adequate.

3. **List the type and quantity of major equipment provided in each treatment area.**

   There are 140 dental operatory units with Adec dental units, patient chairs, and assisting stools– REF Back to 4-3. All cubicles are also equipped with computer hardware and software

4. **If the clinic is shared with other program(s), how many hours per week is it used by each program? How many treatment areas are used each session?**

   The A & B clinics which have 140 cubicles are primarily used by pre-doctorial dental students 5 days per week approximately 7 hours a day. Dental assisting students will be assigned during the time available depending on their rotation.

   What procedures have been established for scheduling utilization of the clinic?

   Director of Dental Assisting Program schedules the rotations in concert with the Associate Dean for Administration, Clinical Directors of Specialties and Assistant Dean for Clinical Education

5. **Describe the size and design of the space provided as the sterilizing area. Identify the type, quantity and capacity of equipment utilized to sterilize and disinfect instruments, small equipment and supplies.**

   There is 425 square feet of area with the following designations:
   - Lab coat room / dispensary

   There is 710 square feet of area with the following designations:
   - Contaminated instrument check-in area
   - Area for ultrasonic cleaning and sterilization of instruments
   - Room for dispensing clean/ sterilized instruments

6. **As an Exhibit, list the types and quantity of instruments and small equipment provided by the program and purchased by students.**

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-3 and 4-6 in the Accreditation Standards for Dental Assisting Education Programs.

Radiography Facilities

4-7 A radiography facility must accommodate initial instruction and practice required for students to develop competence in exposing and processing dental images with faculty supervision.

4-8 Each radiography area must provide equipment for faculty supervision and effective instruction to accommodate several students simultaneously that include:

a. **Dental radiography units which meet applicable regulations**
b. **Radiographic teaching manikins**
c. **Radiographic view boxes and/or monitors**
d. **Processing units with darkroom capacity or digital equipment**
e. **Multiple sets of image receptor holding devices**
f. **Radiation-monitoring devices are provided for students and faculty (according to state regulations)**
g. **Lead aprons and cervical collars for each unit**
h. **Counter with sink**
i. **Dental chair or unit**

Intent:
The radiography facilities should allow the attainment of program goals and objectives. Radiography facilities and equipment should effectively accommodate the clinic and/or laboratory schedules, the number of students, faculty and staff, and comply with applicable regulations to ensure effective instruction in a safe environment.

Narrative Response and Documentation (for Standards 4-7 and 4-8):

1. **Describe the radiographic facility, e.g. rooms, location of sinks, view-boxes and/or monitors and darkroom, if applicable.**

   There are 7 operatories each equipped with a sink, viewbox, monitor and radiographic unit and patient chair. There is a separate darkroom and panoramic unit.

2. **How many radiography units are there for taking intraoral radiographic surveys? Of this number, how many are separate from the general treatment area(s)?**

   In the Oral Diagnosis clinic there are 7 radiographic units in separate rooms. There are also 2 located in the A clinic ;2 are located in the B clinic; 3 located in AEGD / Faculty Practice and 2 located in the preclinical lab.

3. **With respect to equipment used for radiography instruction and practice:**
   a. **Identify the type(s) and date of manufacture of the radiography units.**

Oral Diagnosis Clinic
- Bay 1 Planmeca – manufactured 4/2001
- Bay 2 Planmeca – manufactured 4/2001
- Bay 3 Planmeca – manufactured 4/2001
- Bay 4 Planmeca – manufactured 4/2001
- Bay 5 Planmeca – manufactured 6/2005
- Bay 6 GE Focus – manufactured 7/2009
- Bay 7 Planmeca – manufactured 5/2001

A Clinic
- Room 1 Planmeca – manufactured 7/2007
- Room 2 Planmeca – manufactured 10/2010

B Clinic
- Room 1 Planmeca – manufactured 7/2007
- Room 2 Planmeca – manufactured 7/2007

AEGD / Faculty Practice
- GE Focus – manufactured 7/2014
- Airbex Nomad – manufactured 11/2011
- Airbex Nomad – manufactured 8/2011

Pre-clinical Lab
- Gendex – manufactured 5/2011
- Planmeca – manufactured 11/2015

   b. **Describe the applicable inspection/certification schedule for radiographic exposure equipment.**

The equipment is checked by the University department of Environmental Health and Safety annually. Additionally, they are checked by the Ohio Department of Radiation and Safety every 2 years. Any new equipment is always checked and approved before use.

   c. **Identify the type(s) and quantity of radiographic teaching manikins provided.**

There are two dexter manikins and 6 skulls mounted on poles that insert into headrest of the patient chairs in the Oral Diagnosis clinic

   d. **Identify the type(s) and quantity of mechanical devices utilized as aids in exposing acceptable radiographs.**

Rinn kit sensor holders, Snap-A-Ray devices and disposable sensor tabs are available in the Oral Diagnosis clinic

e. Specify the type(s) and quantity of devices which provide protection from ionizing radiation.

In the Oral Diagnosis clinic there are 7 lead aprons with thyroid collars; 1 lead apron with no thyroid collar (for panoramic films) and 1 pedo lead apron with thyroid collar. In the A and B clinics there are 4 lead aprons with thyrpid collars.

f. Identify the type(s) and quantity of devices utilized to monitor the emission of ionizing radiation.

In the Oral Diagnosis clinic, 2 dental assistants wear a monitoring badge. In addition, there are 5 monitoring badges affixed to the wall of 5 operatories and one affixed to a wall in an office that is in close proximity to the panoramic unit.

4. Identify the type(s) and quantity of processing equipment provided.

There are 2 processors (Air Techniques 2000) in the Oral Diagnosis Clinic and 4 in the Pre-clinical Lab (Perio - Pro)

5. What area is designated for mounting and viewing radiographs?

7 operatories and a viewing table (has built in viewboxes)

How many students can be accommodated simultaneously?

All 20 students can be accommodated simultaneously.

How many viewboxes/monitors are provided and where are they located in proximity to exposure units?

There are 7 monitors (one in each operatory) and 11 viewboxes in Oral Diagnosis. 7 are located within each operatory and 4 located approximately 10 feet away from one unit. Additionally, there are 140 cubicles the A and B clinics and each cubical has a view box and monitor. The two radiography rooms in the A and B clinic also each have a monitor.

Laboratory Facilities

4-9 A sufficient multipurpose laboratory facility must be provided for effective instruction which allows for required laboratory activities and can accommodate all scheduled students simultaneously. There must be an appropriate number of student stations, equipment, supplies, instruments and space for individual student performance of laboratory procedures with faculty supervision.

Intent:
The location and number of general use equipment such as lathes, model trimmers, dremmels, handpieces, vibrators, and other devices as well as dental materials, instruments, trays, mixing bowls, spatulas, etc. allows each student the access needed to develop proficiency in performing procedures.

Narrative Response and Documentation:

1. **Describe the laboratory facility. Please refer to Examples of evidence listed under DA Standard 4-9.**

   The EFDA Lab will be utilized as a multipurpose facility for the dental assisting program. There are 20 stations to allow for each student to have their own workstation and all students can be accommodated simultaneously. The room is adjacent to a "wet lab" that contains models trimmers, vibrators, Vacuum forming machines and Triad units.

2. **How many work areas (student stations) are there in the laboratory(s) used for instruction in dental science courses such as dental materials?**

   There are 20 workstations in the EFDA Lab.

3. **List the type(s) and quantity of equipment provided for each work area.**

   There is a Kavo Manikin for each student, student stool, light, work area, chair, drawers for storage, 1 highspeed and 1 low speed handpiece, rheostat, instruments and supplies.

4. **List the type(s), number and location of general use equipment and instruments such as lathes, model trimmers and vibrators.**

   There are 16 lathes, 8 model trimmers, 5 vibrators, 6 Triad units and 2 vacuum forming machines. This equipment is in the Wet Lab adjacent to the EFDA lab.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-9 in the Accreditation Standards for Dental Assisting Education Programs.

Extended Campus Laboratory/Clinical Facilities

4-10 **It is preferable and, therefore recommended, that the educational institution provide physical facilities and equipment which are adequate to permit achievement of the program's objectives. If the institution finds it necessary to contract for use of an existing facility for laboratory, preclinical and/or clinical education, then the following conditions must be met in addition to all existing standards.**

All lab and instructional facilities are owned and operated by CWRU. Not applicable.

a. **There is a formal agreement between the educational institution and agency or institution providing the facility.**
b. **The program administrator retains authority and responsibility for instruction.**
c. **All students receive instruction and practice experience in the facility.**
d. **Policies and procedures for operation of the facility are consistent with the philosophy and objectives of the educational program.**
e. **Availability of the facility accommodates the scheduling needs of the program.**
f. **Notification for termination of the contract ensures that instruction will not be interrupted for currently enrolled students.**

Intent:
This standard applies to sites off-campus used for laboratory, preclinical and/or clinical education. All students assigned to a particular facility are expected to receive instruction and practice experience in that facility. ***This standard is not applicable to dental offices/clinic sites used for clinical/externship practice experience.***

Narrative Response and Documentation:

Note: Clinical externship dental offices/clinics are addressed in DA Standard 2-24.

1. **If the program depends on an "Extended Campus Laboratory/Clinical Facility" for the provision of laboratory, preclinical and/or clinical education:**
   a. **Identify the facility and its distance from the institution**
   b. **State the extent to which the program is dependent upon the extended campus facility.**
   c. **As an Exhibit, provide a signed copy of the formal agreement between the educational institution and the agency or institution providing the facility.**

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-10 in the Accreditation Standards for Dental Assisting Education Programs.

Classroom Space

4-11 Classroom space must be provided for, and be readily accessible to, the program.

Narrative Response and Documentation:

1. **Is there a classroom assigned exclusively to the dental assisting program? If not, what arrangements have been made to ensure the availability of a classroom for the program?**

   The EFDA lab is the main learning facility. There is another lab that the dental assisting students will use two days a week. Additionally, dental assisting students have access to a class rooms on the third floor that can accommodate 20 students. There are other classrooms that can be scheduled.

2. **Indicate the capacity of the classroom(s) utilized by the program. What equipment is available in each classroom?**

   The class room / lab can accommodate 20 students. There is a manikin for each student and each workstation has student chair, handpieces, air/water syringe, rheostat, overhead light and drawers for storage. There is AV hook up and monitors to utilize the ELMO camera and computer to supplement instruction to students. The room is well ventilated and conducive for learning.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-11 in the Accreditation Standards for Dental Assisting Education Programs.

Office Space

4-12 Office space must be provided for the program administrator and faculty.

Narrative Response and Documentation:

1. **Specify the number, capacity and location of the program administrator and faculty offices.**

   The office for the dental assisting program is approximately 10 square feet and located on the ground floor.

2. **Describe the space available for securing student and program records.**

   The student records will be kept with the coordinator for Office of Administration for the dental assisting program.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-12 in the Accreditation Standards for Dental Assisting Education Programs.

Learning Resources

4-13 The program must provide adequate and appropriately maintained learning resources to support the goals and objectives of the program.

Intent:
Instructional aids and equipment, and institutional learning resources are provided and include access to a diversified collection of current dental, dental assisting and multidisciplinary literature and references necessary to support teaching, student learning needs, services, and research. All students, including those receiving education at a distance site, are provided access to learning resources.

Narrative Response and Documentation:

1. **Where is the major collection of books and periodicals related to dental assisting retained?**

   Located in the program administrator's office and as a virtual library.

   If the major collection is housed in the central library or database, is a separate collection of books and periodicals related to dental assisting retained in the program's facilities?

   Not applicable

2. **Do students and faculty have access to additional libraries and on-line/electronic sources?**

   The students are provided with a listing of on-line resources for their review.

3. **As an Exhibit, provide a list of periodicals/periodical databases related to dental assisting, and general and specialty dentistry that are available for student and faculty reference.**

   Please see the Exhibit Standard 4-13 C-1 on library resources

4. **As an Exhibit, provide a comprehensive listing of the specialized reference texts and the collection of books related to dental assisting and general and specialty dentistry which are available for student and faculty reference.**

   Please see the Exhibit on library resources Standard 4-13 C-1

5. **Describe the procedure for updating and expanding library holdings.**

   This is done by the recommendation of the School of Dental Medicine through the departments and administration.

6. **Briefly describe the instructional aids used in the program, i.e., skeletal and anatomical models and replicas, slides and videos which depict current techniques.**

   There is software for dental charting, videos on four-handed dentistry and dental procedures, an ELMO camera for live demonstrations anatomical tooth models and typodonts.

7. **Describe the computer lab facility, if applicable.**

   Not applicable in the current facility.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-13 in the Accreditation Standards for Dental Assisting Education Programs.

Student Services

4-14 There must be specific written due process policies and procedures for adjudication of academic and disciplinary complaints, which parallel those established by the sponsoring institution.

Intent:
These policies and procedures protect the students as consumers; provide avenues for appeal and due process; ensure that student records accurately reflect work accomplished, and are maintained in a secure manner; ensure confidentiality of and access to student records is followed; ensure student participation when appropriate. The institution provides services to the allied dental students equal to those available to other students.

Narrative Response and Documentation:

1. **Provide information concerning the institution's ethical standards and policies which protect students as consumers. What avenues for appeal and due process have been established?**

   The student handbook is attached to provide this information. The Student Faculty Relations Committee is designated to deal with situations that concern the student as the consumer. Refer to Exhibit Standard 4-14 A-1.

2. **Describe the manner in which confidentiality and access to student records and work are maintained.**

The coordinator for the Office of Administration of the dental assisting program keeps these records in a secure filing cabinet in the office of the Associate Dean for Administration.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-14 in the Accreditation Standards for Dental Assisting Education Programs.

4-15 The program must provide a mechanism to facilitate student remediation when indicated.

Intent:
Students are provided with opportunities to successfully complete the program without compromising the integrity of the program.

Narrative Response

1. **Describe the process used to facilitate student remediation.**

The student handbook is attached to provide this information. The Student Faculty Relations Committee is designated to deal with situations that concern the student as the consumer. Refer to Exhibit Standard 4-14 A-1.

Academic / clinical remediation is designed by the directors of the respective programs.

Disciplinary remediation is handled by the Student Faculty Relations Committee and as described in the Student Handbook.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 4-15 in the Accreditation Standards for Dental Assisting Education Programs.

STANDARD 5– HEALTH AND SAFETY PROVISIONS

5-1 The program must document its compliance with institutional policy and applicable regulations of local, state and federal agencies including, but not limited to, radiation hygiene and protection, ionizing radiation, hazardous materials, and blood borne and infectious diseases. Policies must be provided to all students, faculty and appropriate support staff and continuously monitored for compliance. Additionally, policies on blood borne and infectious disease(s) must be made available to applicants for admission and patients.
The School of Dental Medicine is in compliance with the standards.

The students and faculty are required to have hepatitis vaccinations. The students must show written documentation of the vaccination. The School of Dental Medicine requires annual review of blood borne and infectious diseases protocol. This is accomplished via the University web based training program. The University requires that all affected personnel complete an evaluation after viewing the blood-borne infectious diseases instructional training program. The School of Dental Medicine has a clinical policy and procedures manual that guides the students, faculty, and staff in the areas of infection and biohazard control, and disposal of hazardous waste, and ionizing radiation.

Narrative Response and Documentation

1. **As an exhibit, provide policies and procedures related to radiation hygiene and protection and ionizing radiation.**
   The School of Dental Medicine is in compliance.
   Please refer to Exhibit 5-1-1.

2. **As an exhibit, provide policies and procedures related to infection and hazardous control.**

   The students are required to wash their hands, wear gloves, face mask and safety glasses. They are required to have all sterilized armamentarium that will be needed for a particular procedure in the treatment room to avoid leaving the area. The dental units must be prepared with infection control barriers before a seating the patient in the treatment area. All students participating in preclinical and clinical areas must wear barrier gowns which are provided by the school. The School of Dental Medicine Infection Control Manual lists all policies and procedures that relate to this item.

   Please refer to Exhibit 5-1-2.

3. **As an exhibit, provide policies and procedures related to blood borne and infectious disease(s). How are policies made available to applicants for admission and patients?**

Policy and procedures are in the Infection Control Manual. All students, faculty, and appropriate staff are reviewed and monitored on these policies. The information related to blood borne infectious is not available to applicants until they are accepted into the program. The patients are informed in the patient bill of rights located in the patient's brochure.

Please refer to Exhibit 5-1-2

4. **How does the program monitor policies for continuous compliance?**

The students must take the infection control portion of the program and are evaluated by didactic exams, laboratory exams, and competencies before they can proceed to the dental clinics. The dental assisting students are instructed about the infection control policies and procedures before entering the dental clinics and the dental assisting students are tested on their clinical rotations regarding proper infection control procedures. All issues related to infection control are overseen by the infection control office who is a member of the dental faculty.

5. **How are these policies provided to students, faculty and appropriate staff?**

The students, faculty and appropriate staff are given an orientation regarding infection control policies. The students will take the infection control portion of the program and they will have a presentation from the infection control officer who is a regular full-time faculty.

5-2 Students, faculty and appropriate support staff must be encouraged to be immunized against and/or tested for infectious diseases, such as mumps, measles, rubella, hepatitis B and tuberculosis prior to contact with patients and/or infectious objects or materials, in an effort to minimize the risk to patients and dental personnel.

All students, faculty, and appropriate staff must have the hepatitis vaccination or show proof of vaccination before they can participate in clinical activities in house or off campus externship. If they cannot have the vaccination for some type of medical reason they must have written documentation from a Physician. This activity is monitored by the office of Finance and Operations for the School of Dental Medicine.
Students encourage to be immunized for mumps and measles. This is available on campus in the Student Health Services Office.

Narrative Response

Note: Do not include Patient Protected Health Information (including any student, faculty, or support staff). Please refer to the EOPP for additional clarification and penalty fee information.

1. **Describe how students, faculty and appropriate support staff are encouraged to be immunized against and/or tested for infectious disease(s)?**

The students must have the hepatitis B vaccination before they can participate in the externship portion of the program. These vaccinations are available at the Health Clinic on the University campus. If the student cannot have this vaccination they must have a written letter form a physician explaining the situation. The hepatitis vaccination is a series of three injections that are given over 6 month period. The students must provide written documentation that this vaccination was completed and the documentation will be placed in the students' file. The externship doctors may ask if the hepatitis vaccination has been in process or completed. The student must have documentation of the hepatitis vaccination for the radiography licensure for the State of Ohio.

Emergency Management

5-3 The program must establish and enforce preclinical/clinical/laboratory protocols and mechanisms to ensure the management of emergencies; these protocols must be provided to all students, faculty and appropriate staff.

The students, faculty and staff required to have CPR and these classes are mandatory at the School of Dental Medicine. They are offered annually by the certified CPR instructors at the School of Dental Medicine. The CPR course is interwoven into the dental assisting program.

5-4 All students, faculty and support staff must be currently certified in basic life support procedures, including cardiopulmonary resuscitation with an Automated External Defibrillator (AED), prior to the direct provision of patient care.

The students are required to take a First Aid course in the dental assisting program. The faculty, students, and appropriate staff are required to maintain their CPR certification on a yearly or biennial basis depending on how their testing was performed.

Narrative Response and Documentation (for Standards 5-3 and 5-4):

1. **As an Exhibit, provide preclinical/clinical/laboratory protocols that have been developed related to the management of emergencies.**
   Use emergency protocol sheet. Please refer to Exhibit 5-3-1

2. **How and when are these protocols provided to all students, faculty and appropriate staff?**
   Policy and Protocol are available in the School of Dental Medicine Clinic Manual.

3. **Demonstrate how the program ensures continuous recognition/certification in CPR with AED for all students, faculty and support staff is maintained**
   Please refer to Exhibit 5-4-3

4. **For review on-site, please provide copies of all current student, faculty and staff CPR cards.**

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 5-3 and 5-4 in the Accreditation Standards for Dental Assisting Education Programs.

STANDARD 6– PATIENT CARE SERVICES

THIS STANDARD APPLIES WHEN A PROGRAM HAS AN ON-SITE CLINIC AND PROVIDES DENTAL CARE.

Intent:
These standards apply to any dental assisting program operating an on-site or distance site clinic which provides comprehensive dental care to patients (e.g., diagnosis and treatment planning, operative and/or surgical procedures).

Note: This standard does not apply to on-site clinics owned and operated by an outside entity or organization.

6-1 The program must conduct a formal system of quality assurance for the patient care program that demonstrates evidence of:

a. **Standards of care that are patient-centered, focused on comprehensive care and written in a format that facilitates assessment with measurable criteria**
b. **An ongoing review of a representative sample of patients and patient records to assess the appropriateness, necessity and quality of the care provided**

6-2 The program must develop and distribute to appropriate students, faculty, staff and each patient a written statement of patients' rights.

6-3 Patients accepted for dental care must be advised of the scope of dental care available at the dental assisting program facilities. Patients must also be advised of their treatment needs and appropriately referred for the procedures that cannot be provided by the program.

Narrative Response and Documentation (for Standards 6-1 through 6-3):

1. **Describe the program's quality assurance process and procedures for the patient care program.**

   Quality assurance program starts with patient brochure. Periodically, patient charts are audited to check for compliance, and that treatment meets diagnosis and standards of care. Random, patients are examined. There are parameters that were set by way of percentage of errors.

2. **As an Exhibit, provide a copy of the written statement of patients' rights. Describe how the statement is distributed to students, faculty, staff and patients.**

   This pamphlet is given to students on the first day of class. The pamphlet is reviewed over to make sure that all parties involved understand the information in the pamphlet.
   The patients receive this pamphlet upon the initial oral diagnosis appointment and the student doctor reviews the information with the patient to familiarize the patient with

their rights and responsibility which include appointment scheduling, financial considerations, and care.

3. **Describe how the patients are informed of the scope of dental care available at the program facilities, advised of their treatment needs and referred for further treatment.**

   The patients are informed of the types of treatments available from the patient's information brochure.
   When the patient calls and makes the initial appointment, they are informed of the dental care that is available at the dental school.
   During the first appointment, the student dentist conducts a brief examination to see if the patient is a good candidate for the student clinic. If so, a thorough examination and complete radiographs is conducted. If the case is beyond the student's scope, the patient will be referred to the specialty programs of the school, or referred to a private dental facility.
   During the second appointment, the student dentist consults with attending dentist and a comprehensive examination is conducted. Then treatment options, costs, and approximate time table for treatment (this includes number of appointments) are discussed.

   Please see Exhibit 6-2-2.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 6-2 in the Accreditation Standards for Dental Assisting Education Programs.

STANDARD 6– PATIENT CARE SERVICES

THIS STANDARD APPLIES WHEN A PROGRAM HAS AN ON-SITE CLINIC AND PROVIDES DENTAL CARE.

Intent:
These standards apply to any dental assisting program operating an on-site or distance site clinic which provides comprehensive dental care to patients (e.g., diagnosis and treatment planning, operative and/or surgical procedures).

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1. **Describe the program's quality assurance process and procedures for the patient care program.**

   Quality assurance program starts with patient brochure. Periodically, patient charts are audited to check for compliance, and that treatment meets diagnosis and standards of care. Random, patients are examined. There are parameters that were set by way of percentage of errors.

2. **As an Exhibit, provide a copy of the written statement of patients' rights. Describe how the statement is distributed to students, faculty, staff and patients.**

   This pamphlet is given to students on the first day of class. The pamphlet is reviewed over to make sure that all parties involved understand the information in the pamphlet.
   The patients receive this pamphlet upon the initial oral diagnosis appointment and the student doctor reviews the information with the patient to familiarize the patient with

their rights and responsibility which include appointment scheduling, financial considerations, and care.

3. **Describe how the patients are informed of the scope of dental care available at the program facilities, advised of their treatment needs and referred for further treatment.**

   The patients are informed of the types of treatments available from the patient's information brochure.
   When the patient calls and makes the initial appointment, they are informed of the dental care that is available at the dental school.
   During the first appointment, the student dentist conducts a brief examination to see if the patient is a good candidate for the student clinic. If so, a thorough examination and complete radiographs is conducted. If the case is beyond the student's scope, the patient will be referred to the specialty programs of the school, or referred to a private dental facility.
   During the second appointment, the student dentist consults with attending dentist and a comprehensive examination is conducted. Then treatment options, costs, and approximate time table for treatment (this includes number of appointments) are discussed.

   Please see Exhibit 6-2-2.

For additional guidance you may refer to "Examples of evidence to demonstrate compliance" following Standard 6-2 in the Accreditation Standards for Dental Assisting Education Programs.

CASE WESTERN RESERVE UNIVERSITY EST. 1826

Faculty Senate Meeting
Tuesday, February 27, 2018
3:30p.m. – 5:30p.m., Toepfer Room, Adelbert Hall,

3:30 p.m.	Approval of Minutes from the January 30, 2018, Faculty Senate Meeting, *attachment*	Juscelino Colares
3:35 p.m.	President and Provost's Announcements	Barbara Snyder Bud Baeslack
3:40 p.m.	Chair's Announcements	Juscelino Colares
3:45p.m.	Report from the Executive Committee	Cynthia Beall
3:50 p.m.	Secretary of the Corporation Report, *attachment*	Juscelino Colares
3:55 p.m.	Proposed Revisions to the Human Research Protection Policy, *attachment*	Kenneth Ledford
4:05 p.m.	Graduate Studies Committee: Incomplete Grade Policy	Paul MacDonald Lynmarie Hamel
4:15 p.m.	Graduate Studies Committee: Proposed Guidelines to Create a University Certificate and Professional Certification	Paul MacDonald Lynmarie Hamel
4:25 p.m.	Approval of CWRU 5-Year Calendar	Carlier Myers
4:30 p.m.	Update on Provost Search	Roy Ritzmann Suzanne Rivera
4:40 p.m.	CUE Status Update	Kimberly Emmons