School of Dental Medicine Research News

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Contents:

DUAs, MTAs, NDAs – What are they and do I need one?

Most involved in research have heard of grants or sponsored research agreements/contracts that are used to fund and define a project. However, there are a few more types of agreements that play a key role in any researcher's toolkit. Briefly, the three agreements are:

- Material Transfer Agreement (MTA) is a contract that allows one party to perform research using the materials (data, specimens, etc.) of another party.

- Data Use Agreement (DUA) is used when transferring protected health information (PHI), including limited data sets, from one party to another.

- Non-Disclosure Agreement (NDA also known as a Confidential Disclosure Agreement CDA) is used when transferring non-PHI from one party to another for review only (no further use or dissemination), generally for the purpose of evaluating the potential for a future relationship between the parties.

All three agreements can stand alone or combined into a single agreement that defines the rights, responsibilities, and obligations of both the providing and receiving parties regarding issues such as use, ownership, and liability. This not only protects you as a researcher and Case from various claims, but it also protects your intellectual property from being used without your consent or compensation, if warranted.

If you are planning on using materials/data/info owned by another institution or you would like to allow another researcher to use Case's materials/data/info, please get in touch with SODM Research Administration at dentres@case.edu or the Technology Transfer Office at ttoadmin@case.edu.

Clinical Research Training Classes

New to clinical research? Have questions about what makes a good (and compliant!) research project? Beginning in August, UH will be presenting a series of sessions titled "The Basics" that discuss different aspects of clinical research. Sign up for all or a few. Topics include:

- Module 1 – FDA Regulations and Good Clinical Practice
- Module 2 – Required Regulatory Documentation and Essential Documents
- Module 3 – Study Feasibility through Study Activation
- Module 4 – Coverage Analysis, Research Billing Compliance, and Subject Calendar
- Module 5 – Prescreening, Eligibility, and Enrollment Process
- Module 6 – Informed Consent and RE-Consent
- Module 7 – Good Documentation Practices and Clinical Data Management
- Module 8 – Adverse Events and Protocol Deviations
- Module 9 – Avoiding Non-Compliance Findings

Training and presentations on additional topics are available as well through UH and CWRU. Please visit https://research.case.edu/researchapps/education/onlinecalendar.cfm for further details and registration.

NIH Reporting Updates

Over the past month, the NIH has made some changes that will impact reporting in the RPPR (Research Performance Progress Report) and the FRPPR (Final Research Performance Progress Report).

- In early June, the NIH introduced a new method of reporting human subjects involvement in projects. The Human Subject System is a new system to manage human subjects and clinical trials information and replaces the Inclusion Management System. In a nutshell, there will no longer be separate uploads of Inclusion and Enrollment Tables for each part of a study. Now, all will be housed in one place and can be updated at any time by the study team rather than only at the annual report.

  Within the SODM we've had one submission using the new system and as is usually the case with all new systems, there were some bumps along the way. If you have an upcoming RPPR or FRPPR and your project involved enrolling human subjects, please take some time to review the requirements.

  The official NIH notice that explains the transition in more detail can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-179.html. Training materials including videos tutorials can be found at https://era.nih.gov/hss_training.htm.

- Decimals are now allowable in the All Personnel Report. Historically, when reporting the months of effort for project personnel, the system required the use of whole numbers. While this was convenient for the system, it contributed to inaccurate reporting – a person with 2.4 calendar months of effort (20%) would be rounded down to 2 calendar months, 16.7%, on the report. With the addition of a decimal, the RPPR will now better reflect our effort on projects.

- Delegation is now allowed for FRPPRs. When the NIH instituted their policy of requiring FRPPRs instead of a final progress report upload, the ability to delegate to allow others to work on the FRPPR was not included, meaning only the PI/PD had access to the report. That has now changed in the NIH eRA Commons. If you have previously delegated authority, those delegations should now extend to FRPPRs as well.

The NIH Guide Notice for the decimals and delegations can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-202.html.

Website Updates are Coming!

Over the next month, we will be updating the information on the research website to be more user-friendly and be a one-stop-shop for all things research, including this newsletter! In the interim, if you have any ideas, comments, suggestions, etc. of what you'd like to see, please feel free to send a note to dentres@case.edu!

OMB Online Training

With the seemingly ever-changing landscape of federal regulations, at times it difficult to know what's expected of us as administrators of federal awards. Rest assured that we are not the only ones with questions! The Office of Management and Budget (OMB) developed some online tools to help its employees navigate requirements for federal awards and has now made this resource, titled "Grants 101" available to the public. There are currently 5 modules that include:

1. Laws, Regulations, and Guidance
2. Financial Assistance Mechanisms
3. Uniform Guidance Administrative Requirements
4. Cost Principles
5. Risk Management and Single Audit.

Feel free to visit https://cfo.gov/grants/training/ and take a look at some of the presentations!

Learning Opportunities

There are a number of internal opportunities to learn more about research. Please check out the following sites for available classes:

- CWRU/UH online calendar: https://research.case.edu/researchapps/education/onlinecalendar.cfm
- CAPS (CWRU Administrative Professional Series): https://case.edu/utech/caps/register/

Funding Opportunities

Have a great idea, but not sure where to look for funding? Take a look at some of the options below:

- Pivot Funding Opportunities Search Tool: https://pivot.cos.com/funding_main
  - A subscription service sponsored by the University, Pivot allows you to create an account with keywords and your interests and searches a database of funding opportunities and can identify potential collaborators.
- Office of Research Administration Funding page: http://case.edu/research/faculty-staff/funding-ops/
  - Includes links to limited submission opportunities, sponsoring agencies, and other info
- Get in touch with the SODM Office of Research Administration! See Tricia in Room 3310 or send an email with your research interests to dentres@case.edu for personalized results!