Pre-Submission Checklist

This list covers the most common issues that cause submissions to be returned for clarification and delay approval. Please review all of the information here and online to ensure you are submitting the most complete submission as possible.

Where to go for help:

- Instructions, information, and details specific to the School of Dental Medicine may be found on the SODM IRB Submission website.
- CWRU IRB institutional information may be found on the CWRU IRB website.
- Within the SODM, Dr. Catherine Demko (cad3@case.edu, 368-8804) and Tricia Mehosky Ribeiro (pam17@case.edu, 368-7573) are available to assist with any questions.
- You may also contact the CWRU IRB Office directly with questions (cwru-irb@case.edu)

Is the correct protocol template attached in SpartaIRB?

- Are you using a CWRU template?
    - **CWRU Biomedical Protocol (HRP-503BIOC)**: Use if your project involves **any** physical contact or medical interventions with participants.
    - **CWRU Chart Review Specimens Protocol (HRP-503CRS)**: Use this template if your project **only** includes collection of clinical data through a chart review or samples received through a repository or outside source and does not involve interventions with participants. This is the proper template for Dental Clinic data.
    - **CWRU Data Protocol (HRP-503ACQUIREDATA)**: Use this template if your project only includes collection of data and does not involve interactions with participants. This is the template for data from an external source (e.g. Medicaid data from another state).
    - **CWRU SBER IRB Protocol (HRP-503SBER)**: Use this template if your project includes survey, interviews, focus groups or educational research activities with no biomedical/clinical components
    - **CWRU Exemption Protocol (HRP-503EXEMPTC)**: Use this exemption request protocol template as a guide for protocols anticipated to meet the criteria for exemption.
        - See the Office of Human Research Protection Decision Chart #2 to determine whether or not an exemption may apply.
        - Only the IRB Office can make a determination as to whether or not the project is exempt. If the project is determined not to qualify for an exemption, additional documentation will be required.

Has the protocol template been filled out completely?

- Is there a response to every question (using “n/a” when appropriate?)
- If protocol involves clinical procedures, is there sufficient detail to determine which are standard of care (i.e. procedures that would happen even if the patient was not part of the study) and which are being performed solely for the research project?
- Are there specific details about locations where the study will take place with regards to privacy, security (locking doors/cabinets/etc.), and access, to ensure confidentiality?
- Have the details been explained so that someone with general scientific knowledge (not necessarily dental training) will understand the project?
- Have all acronyms, procedures, instruments, etc. been explained in lay terms?
- If collecting or receiving data, does the data security plan address the measures used to receive, store, destroy and if applicable share data.

Has the funding source been detailed on the SmartForm? Either external or internal funding.

- If your study is not funded, please select the following answer: "Internal/Departmental/Not External."

Have you identified all study personnel and indicated who will have access to any PHI?

- Have all personnel completed required trainings/disclosures?
    - Human Subjects Research via the CREC program
    - Conflict of Interest disclosure form

Have you attached the appropriate consent forms? Informed consent form or completed the justification for a waiver of consent in the protocol template, as appropriate.

- For **prospective** studies: All new submissions, with the exception of requests for "Not Human Research" determinations, require an Informed Consent Form to be uploaded in SpartaIRB and also the HIPAA section of the protocol template must be completely filled out.
- For **retrospective** studies and chart reviews: All submissions must include a completed Informed Consent Section (in the protocol template) which details the request and justification to grant a "waiver of informed consent". Additionally, the HIPAA Waiver Document (HIPAA Waiver Form (HRP-600)) must be uploaded in SpartaIRB. **Language on clinic intake forms is not a substitute for this form and does not constitute consent (as defined by Federal regulations governing human subjects research) to use data for research.**

Are any public-facing documents (informed consent forms, advertisements, flyers, etc.) written in lay terms that are easily understandable by the general public?