IRB Submission Checklist

In accordance with Office for Human Subject Protection (OHSP) Policy 502 Types of RSRB Submissions, gather the following information/documents to include in your study submission to the Research Subjects Review Board (RSRB, the University of Rochester's Institutional Review Board [IRB]).

Note: To facilitate reviews, limit document uploads to Microsoft Word files, when feasible. **DO NOT upload Rich Text or Publisher Files.** When Microsoft Word files are unavailable, PDF files may be used. If you have questions about what types of files can be uploaded, contact your IRB Coordinator.

☐ ***Basic Information***

- Study protocol and any applicable site-specific supplements and/or addendums
  - ✓ A site-specific protocol supplement maybe be required if the sponsor provided protocol does not provide specific information about the conduct of the research at UR. Specifically, to address how subjects will be recruited and consented, if non-English speaking subjects will be recruited and if not, what is the rationale for excluding, etc.
- Study team members (for guidance on who should be added as research personnel see OHSP's Guideline for Listing Research Personnel on the RSRB Application):
  - ✓ For each study team member, verify whether they have a financial interest related to the research. If yes, obtain a copy of their Conflict of Interest Management Plan and/or Transparency Checklist.
  - ✓ For external study team members, obtain documentation of their current human subject protection training.
- Funding sources
- Research locations (i.e., non-UR locations [e.g., Rochester City School District] and UR-affiliated sites [e.g., Highland Hospital, FF Thompson] where research activities will be conducted by UR faculty/staff or by UR faculty/staff in collaboration with non-UR staff)
- ClinicalTrials.gov registration number, if applicable

☐ ***Study & Local Site Documents***

- All consent, permission, and assent forms, as applicable
  - ✓ All consent, permission, and assent forms should be submitted with the first page on UR letterhead.
  - ✓ For studies undergoing review by an External IRB, ensure all consent and permission forms have been edited to include local, site-specific information. Minimally this includes local site contact information and template UR language (e.g., HIPAA authorization and compensation for injury). For additional information see the OHSP Explains… Preparing Local Site Consent Documents for External IRB Submissions.
  - ✓ For multi-site research undergoing single IRB review where the RSRB is the Reviewing IRB, include all ***model*** consent forms that will be distributed for use at participating sites on the study submission under the *Study-Related Documents*. For participating site submissions,

ensure all consent and permission forms have been edited to include local, site-specific information.

- All recruitment materials (i.e., all direct advertising materials that may been seen/heard by potential subjects), as applicable
  - ✓ For studies undergoing review by an External IRB, ensure all recruitment materials have been edited to include local, site-specific information (as appropriate).
  - ✓ For multi-site research undergoing single IRB review where the RSRB is the Reviewing IRB, include all ***model*** recruitment materials that will be distributed for use at participating sites on the study submission under the *Study-Related Documents*. For participating site submissions, ensure all recruitment materials have been edited to include local, site-specific information (as appropriate).
- All study measures that will be completed by, or include questions that will be asked to, subjects (e.g., surveys/questionnaires, interview/focus group scripts, behavioral assessments, diaries)
  - ✓ If the research involves a secondary analysis, include a data collection sheet that identifies all data points that will be collected
- All supplemental educational materials that will be provided to potential or enrolled subjects, including any instructions/information sheets (e.g., concerning drug administration)
  - ✓ Educational materials developed by OHSP do not need to be uploaded (i.e., OHSP's Participating in Research: What You Need to Know and Informed Consent: What You Need to Know)
- Certificate of Confidentiality (CoC), if applicable, for research funded via a mechanism other than the National Institute of Health (NIH). For additional information see OHSP Explains… Certificates of Confidentiality.
- Translator Declaration, if applicable (for additional information see OHSP Explains… Enrolling Non-English Speaking Subjects: Considerations & Best Practices)

☐ ***Ancillary Review Documents*** (if applicable)

- Completed Data Security Assessment Form, if data will be collected, transmitted or stored electronically
- Completed Surgical Pathology Request for Human Tissues Form, if fresh, banked, or archived human tissue will be obtained from Surgical Pathology
- Completed Human Use of Radiation Committee Research Form, if radioisotopes or radiation-generating devices will be used for research purposes (i.e., non-clinical purposes)

☐ ***Drug Details*** (if applicable)

- Drug name
- Package insert or investigators brochure
- Drug management and accountability plan, if not included in the study protocol
- Randomization plan, if applicable and not included in the study protocol
- Sample of drug label
- Temperature log (for storage location)
- If the study is being conducted under an IND (Investigational New Drug):
  - ✓ IND number, IND holder
  - ✓ Verification from the FDA (or sponsor) of the IND
  - ✓ If the local PI is the IND holder, documentation of required IND training via the CTSI Office of Regulatory Support

☐ ***Device Details*** (if applicable)

- Device name
- Manufacturers brochure/device instructions
- Device management and accountability plan, if not included in the study protocol
- Randomization plan, if applicable and not included in the study protocol
- If the study is being conducted under an IDE (Investigational Device Exemption)/HDE (Humanitarian Device Exemption):
  - ✓ IDE/HDE number, IDE/HDE holder
  - ✓ Verification from the FDA (or sponsor) of the IDE/HDE
- If the local PI is the IDE holder, documentation of required IDE training via the CTSI Office of Regulatory Support