Instructions for COMIRB Secondary Research Application

The Secondary Research Application form is for research involving only the collection and analysis of data or biological specimens which were originally collected for another purpose and where a waiver of informed consent is requested. For example, use this application for retrospective research on data from medical records or for research involving new analysis of biological specimens collected under another study.

The Secondary Research Application does not address procedures for subject recruitment or consent. Use the regular COMIRB application for any research requiring subject contact.

The application does not require researchers to pre-select an IRB review level or category. COMIRB will review the submission to make sure risks are minimal, determine review level (e.g., expedited, exempt), and consider whether a waiver of consent is approvable. COMIRB will also make any necessary privacy board determinations if the research is subject to HIPAA, including waiver of authorization.

Submission process: Describe your research by providing a brief protocol, complete the Secondary Research application, and submit the protocol and application through InfoEd. On the routing form, select “Secondary Research.”

Exempt research: Formerly, researchers doing exempt research were asked to describe their study in the application form and did not need to provide a protocol. Now, researchers have to provide a short protocol, but do not need to describe their study methodology in the application form.

Not Human Subjects Research: You are not conducting human subjects research and do not need to submit an application to COMIRB if you:

- do not access or record identifiers for your research, or
- are only analyzing publically available data, and
- never interact (in any way) with a human subject

For more information on what qualifies as human subject research, follow this link.

Remember, identifiers include:

- Names
- Addresses (even if just counties or zip codes)
- Dates (except years) directly related to an individual
- Telephone & Fax numbers, email addresses
- Social Security Numbers
- Medical record numbers, health plan beneficiary numbers
- Account numbers, Certificate/License numbers
- Any vehicle or other device serial numbers
- Web URLs, Internet Protocol (IP) Addresses
- Biometric identifiers (such as finger or voice prints)
- Full face photographic images
- Any other characteristic that could uniquely identify the individual
- Free text fields in health records (assumed to contain PHI)

For questions and feedback, please contact us at: COMIRB@ucdenver.edu

CF-141, January 3, 2022