

New COMIRB Application: Secondary Research

COMIRB has published a new application form 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. This should only be used for new applications where identifiers are accessed or used.

New Approach: The questions in the application are written specifically for secondary research. 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](#).

Submission process: If your research requires review and approval, describe your study by providing a short protocol and complete the [Secondary Research application](#). Submit the 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
- are only analyzing publically available data
- never interact 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), birthdate, admission date, discharge date, date of death, and exact age if over 89
- 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

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

LINKS

- [Application](#)
- [Template protocol](#)
- [Protocol instructions](#)

WHEN TO USE SECONDARY USE OF DATA FORM

- Research involving only the analysis of data or specimens collected for purposes other than your study
- You have access to identifiers
- You are asking for a waiver of consent

WHEN TO USE THE MAIN APPLICATION FORM

- Research involving anything other than data or specimen analyses
- Research requiring informed consent

NOT HUMAN SUBJECTS RESEARCH

COMIRB does not require an application if:

- you never access an identifier for your research and you never interact with a subject
- the data used for your research are publically available