

Which application do I use?

There are eight applications to choose from depending on the type of research that is planned. Please make sure that you select the correct application type for your research. Once started, responses from one application cannot be transferred directly to a different application. Should you have any questions or are unsure as to which option to select, please contact the Office of Regulatory Affairs at 402-559-6463 or irbora@unmc.edu.

Biomedical or Social/Behavioral Research application:

Biomedical Research includes all human subject research performed with intent to develop or contribute to generalizable knowledge (i.e., test a hypothesis and draw conclusions) about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods.

Behavioral and social science research includes all research performed with intent to study behaviors, attitudes and interactions and social processes among and between individuals, groups, and cultures. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research.

Note: This research will subsequently be divided into therapeutic or non-therapeutic research. Therapeutic research is characterized as research which involves a drug, medical device, technique or other intervention or strategy (including means like diet, cognitive therapy, behavioral therapy, exercise) intended to diagnose, treat or prevent a particular condition or disease.

Human Biological Material (HBM) application:

Research involving the collection of human biological material (HBM) for use for this specific research project, or use of existing HBM (for example, from a biorepository) for a specific research project, or both, with no other type of physical interventions.

Note: HBM studies as described above which would additionally include the collection of medical information via surveys or by chart review should also be submitted using this application. If the sole purpose of this project is to obtain IRB approval for establishment of a tissue bank, complete the Tissue Banking Application.

Tissue Bank application:

Collection of human biological material (HBM) with no other type of physical or laboratory testing for the sole purpose of using the samples for FUTURE research.

Note: If the intent of the protocol is to collect HBM for use for this specific research with storage of left-over material after completion of this specific research, use the Human Biological Material (HBM) application.

Medical Records application:

Research involving the collection of information from medical records whether or not the information already exists or will be recorded in the future.

Note: Medical records research should not be submitted using the Exempt Application.

Data Registry application:

The collection of information/data (typically from medical records) for the sole purpose of using the data for FUTURE research.

Exempt Research application:

This application is only use for research which falls into specifically defined categories under the federal regulations (as outlined below). DO NOT use this application for medical record research.

1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices.
2. Research that only involves educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).
3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses.
4. Research uses of identifiable private information (either publicly available or subsequently de-identified) that has been collected for some other activity.
5. Research and demonstration projects that are conducted or supported by a Federal department and are designed to study, evaluate, improve, or otherwise examine public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

Note: The Office of Regulatory Affairs (ORA) and the IRB have sole authority to determine whether a research project satisfies requirements for exemption. Contact the IRB Office if you have any questions - irbora@unmc.edu.

Humanitarian Use Device (HUD) application:

Use of a Humanitarian Use Device (HUD) which is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 8,000 individuals in the United States per year.

Note: This application should not be used if the HUD is the subject of a clinical investigation in which safety and effectiveness data is being collected to support a pre-

marketing approval (PMA) application. The IRB Application for Biomedical Research should be used instead.

Central IRB (cIRB)/Single IRB (sIRB) application:

Multisite research where UNMC will be relying on another IRB for review. This includes commercial IRBs like Advarra and CG-WIRB, Consortium or other Network IRBs, NIH or federal agency IRBs like the NCI CIRB, or other academic institutions. Click [here](#) for more information regarding cIRB and sIRB protocols or email sirb@unmc.edu.

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