Child Health Research Institute





Dear Investigator,

Thank you for communicating your interest in conducting a new human research study. CHRI/PRO offers a variety of guidance and resources to help investigators carry out such endeavors safely, productively, and in full compliance with regulations and ethical standards.

Typically, setting up investigator-initiated studies does not require significant hands-on support from our staff. Standard paths are already set up by the UNMC IRB that enable you to apply for approval or exemption, which even new investigators can navigate. **As a first step, fill out the questionnaire at IRB's page titled,** "Does my project require IRB review?"

If the answer is "yes," proceed to the next tab on the same menu, titled, "Which Application Do I Use?" Explanations there are relatively straightforward, but here are some quick tips:

- If you plan to collect human tissue or specimens from volunteers or from a biorepository, without any further physical interactions with the donors, you will likely use either the **Human Biological Material (HBM) application** or the **Tissue Bank application**.
- If your plan only involves collecting information/data from medical records, you will likely use either the **Medical Records application** or the **Data Registry application**.
- If your research plan falls in a list of several miscellaneous low-risk categories, you may be prompted to fill out the **Exempt Research application**.
- Studies that seek more generalizable knowledge and/or introduce more sensitivity or risk for human participants will likely use one of the 3 other application forms. In those cases, if your study requires more hands-on support, please fill out the PRO <u>intake form</u> to set up a consultation with us, after completing a <u>CHRI membership application</u>.
- CHRI is happy to provide examples of approved IRB applications for your reference.

Once you have used the "Which Application Do I Use" page to identify the right application for your study, you can begin filling out the specified electronic application form via the Research Support System (RSS). If any questions arise, please email us at PedsResearch@unmc.edu, and we will be glad to help you move forward in IRB review.

Sincerely,

Ann Anderson Berry, MD, PhD

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Executive Director, Child Health Research Institute