HOW TO CHOOSE THE APPROPRIATE IRB APPLICATION FORM

The Centra IRB is responsible for the oversight of all research involving human subjects.

> Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
>
> Human subjects are living individuals about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

If you are interested in pursuing a research activity involving human subjects, please review the categories below to determine which application to submit for requesting approval of your research by the IRB committee.

A. REQUEST OF WAIVER TO ANOTHER IRB

If the research has previously been approved by a non-Centra IRB, you may request a waiver to the outside IRB of record. Send a letter or email to the IRB secretary at irb@centrahealth.com with the following documents:

1. The application that was made to the IRB providing review
2. The study protocol
3. The informed consent
4. A description of the IRB providing review
   Note: A link to a website is sufficient if it provides enough information for the Centra IRB to evaluate.
5. An authorization agreement that delineates the responsibilities of each party

B. EXEMPT REVIEW

In order to qualify, the research must not be greater than minimal risk (the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons) **and** must fall into one of the exempt categories defined by federal regulations:

1. Education Research
2. Surveys, interviews, education test, public observations (that do not involve children)
3. Studies of public officials
4. Analysis of previously –collected, ANONYMOUS data
5. Public benefit or service program
6. Consumer acceptance, taste, and food quality studies

Your research is not exempt and you must apply for full board review if your research:

- Is greater than “minimal risk”
- Involves collecting identifiable information from subjects
- Involves administration of drugs or devices
- Involves minors (outside of educational settings) or prisoners as subjects

If your research meets criteria for an exempt review, please complete Form 6, Exempt Research Checklist. Forward this document and any necessary supplementary materials to irb@centrahealth.com.

C. FULL BOARD REVIEW

Any research that doesn’t meet the criteria for a waiver or exemption requires a full IRB review. Please complete Form 1, Application for IRB Approval of Human Subjects Research. Attach any necessary documentation & email to irb@centrahealth.com.