Exempt Protocols

Understanding whether a protocol may qualify for exempt status can often be confusing. "Exemption" does not mean a project is exempt from IRB evaluation: all studies involving human subjects must be submitted to the IRB for a final status determination. The section "How does the IRB decide whether a project is expedited or exempt?" offers insight into how the IRB might evaluate a study's risk level. At any point, feel free to email researchcoompliance@uca.edu for guidance in determining which application form to submit.

After reviewing the information below, if you believe your study qualifies as exempt, please complete and submit the **IRB Application for Exemption Review Form.** You do not need to submit CITI human subjects training with exemption applications. (However, if your protocol needs a higher level of review, you will be required to complete a new protocol submission and include CITI certification.) Exemption applications usually take 3-4 business days to process and issue an exemption letter (unless the study needs elevation to a higher review level).

How Does the IRB Decide if a Protocol is Expedited or Exempt?

The IRB first determines whether the study meets Federal definitions of "human subjects research" and whether any risks may exist in the data collection *process* (regardless of intention to present or publish). If the study poses no risk to participants and does not meet definitions of human subjects research, the IRB will issue a determination of "Not Human Subjects Research" and approval letter will be issued. (The researcher may still be responsible for HIPPA, local regulations, and best ethical practices.)

The IRB may determine a project to be "**exempt**" from higher IRB review if the study meets human research definitions and research activities (1) present *no more than minimal* privacy, psychological, and/or physical risk to human subjects, and (2) involve *only* procedures listed in one or more of the following categories:

Category 1

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

Category 2

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program
- [**Note:** Evaluation projects conducted as partial degree/academic requirement must be IRB reviewed unless they meet exemption criteria in another way.]

Category 3

- Interviewing public officials about a local or global issue

Category 4

- Analyzing de-identified tissue samples or data set
- Analyzing de-identified national test scores
- Analyzing census data about aging or housing

Category 5

- Research conducted in established or commonly accepted educational settings, involving normal educational practices
- Research on regular and special educational instructional strategies
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Category 6

- Taste testing whole grain food products
- Comparing taste or smell of molasses, cheese or milk
- Sampling texture of ice cream

If a project fits within a potential exemption category above, the IRB will then consider the following questions:

1. Are vulnerable subjects involved (for example: children or prisoners)?
2. Will the investigator collect or keep direct (name, address, phone number) or indirect (demographics, etc.) identifiers?
3. Is the information to be gathered of a private or sensitive nature?
4. Does the data collection process or retention of this data pose any risk to participants?

If the answer to any of these questions is YES, or if the project does not appear to fit any exempt category, it will be processed as expedited or full board.