Human Research Protections Frequently Asked Questions

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1. Does my study need IRB review?

A: The IRB cannot make an official determination of whether a study requires IRB approval via email or over the phone. In order to receive a written response from the IRB confirming that no IRB approval is needed for this project, please submit a Request for a <u>Determination of Non-Human Subjects Research Form</u>. If you do not need a formal written response from the IRB, you may use the form as a guide to determine whether you need to submit to the IRB for this particular project. See <u>Definition of Human Subjects Research</u> for more information.

2. Do students' academic research projects require IRB approval?

A: Yes, if a student's research project qualifies as human subjects research; whether it is biomedical or social-behavioral in nature, IRB approval is required prior to initiation.

3. Does secondary analysis of a data set gathered for another purpose require a new research project for review?

A: Yes - IF THE DATA IS IDENTIFIABLE.

Projects that use an existing data set which includes identifiable data gathered in earlier research projects may require a new IRB protocol for review. Secondary analysis of existing data may include the review of medical records, student records, data collected from previous studies, audio/video recordings, etc. that were initially collected for another purpose. In order to be existing, the information must be "on the shelf" (i.e., it has already been collected) at the time that the current research is proposed.

4. If departmental or personal funds are used to support research, is IRB approval required?

A: Yes. UCI has assured the federal regulatory agencies that the institution will review and approve all research involving human subjects before it is initiated. This assurance covers all research regardless of funding.

5. Where can I find more information about Human Research Protections?

A: For a complete list of human research protections Frequently Asked Questions, visit the <u>webpage</u>.

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