University of South Carolina IRB

What needs IRB Review and Approval?

Any research activity involving human subjects conducted by USC faculty, staff, and students must be reviewed and approved for compliance with regulatory and ethical requirements before it may be undertaken. These activities include a wide variety of procedures such as, but not limited to, research on medical records, collection of data through surveys or observation, research using existing pathological specimens, discarded tissue or secretions, use of investigational drugs or devices and randomized trials.

Certain studies involving human subjects may be exempt from IRB review. Exempt projects fall into defined categories (see, Categories for Exempt Research). Exemptions must be approved by the IRB.

The project must be approved by the IRB if it meets the following criteria as defined under “Research” and “Human Subject”:

Research is defined as:
A systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge, or

Work that is intended to fulfill requirements for a master’s thesis, doctoral dissertation, or other research requirements of the University.

Human subject is defined as:
A living individual about whom an investigator conducting research obtains
1) data through intervention or interaction with the individual, or
2) identifiable private information.

Intervention includes both physical procedures by which data are gathered or manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communications or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

NOTE: The FDA additionally defines a human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. Because the above definition excludes non-living humans, research that uses autopsy materials or cadavers is not 'human subjects research' and therefore is exempt from review.
Non-Research Activities *(IRB review not required)*

Certain activities have the characteristics of research but do not meet the definition of research for IRB review. These activities do not require review by the IRB. Examples of data collection or observation activities that do not require review include:

- Data collection for internal departmental or other University administrative purposes (e.g. teaching evaluations, student evaluations, and “customer service” surveys), and
- Program evaluation carried out under independent contract for an external agency that is for their internal purposes only. Examples include personnel studies, human cost benefit analysis, treatment effectiveness studies, and customer satisfaction studies.

**Course related activities and/or projects** (e.g. research methods instruction) that involve the use of human participants but have no connection with research beyond the instructional function do not require IRB review. Course instructors are responsible for ensuring that students understand and abide by ethical obligations in carrying out their assignments. We suggest that, at a minimum, students complete the student training modules available through CITI (at [www.citiprogram.org](http://www.citiprogram.org)). Additionally, instructors are responsible for reviewing student class project proposals and consent procedures to ensure that the methods and procedures are ethical and appropriate, and for monitoring student activities during the conduct of the project to ensure that the rights and welfare of participants are adequately protected. Instructors who have any questions are encouraged to consult with IRB staff.