

# **Office of Grants and Sponsored Research**

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## **What Needs IRB Review and Approval?**

**Coastal Carolina University**

# Research with Human Subjects

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- Any research activity involving human subjects conducted by CCU 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, collection of data through surveys or observation, collection of data from subjects exercising or participating in an activity, research on medical records, and research using existing pathological specimens, discarded tissue or secretions.

# Research

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- A systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge, or
- Activities portrayed (explicitly or implicitly) by faculty, students, or staff as “research”, or
- Work that is intended to fulfill requirements for a master’s thesis, doctoral dissertation, or other research requirements of the University.

# Not Research

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- Data collection for internal departmental or other University administrative purposes.
- Program evaluation carried out under independent contract for an external agency that is for their internal purposes only.
- Course-related activities (research methods instruction), unless these lead to public presentation or publication
- Faculty may certify these as Exempt (or not).

# Human Subjects

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- 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.

# Exempt Research (45 CFR 46.101b(#))

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- A project is exempt from IRB review if all of the research activities fall into one or more of the categories designated by federal regulation.
- Exemptions pertain to legal adults in non-compromised situations. Projects involving interaction with prisoners, persons incompetent to provide valid consent, pregnant women where pregnancy is the focus of the research, and fetuses in *utero* cannot be exempt.
- Experiments, interviews, and surveys with children are not exempt.

# Categories of Exempt Research

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- 5. Research and demonstration projects, which are conducted by or subject to the approval of the federal government, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the federal government.