The Responsible Conduct of Research and CITI Program Training
What is the responsible conduct of research, how do I learn about it, and why do I care?
Which of the following have occurred as part of a research study?

a. entire communities intentionally exposed to radiation
b. elderly, frail patients were injected with cancer cells without their consent
c. secret injections of plutonium into unknowing patients
d. subjects’ breathing was temporarily stopped pharmacologically
e. jury deliberations were tape-recorded without the jurors’ knowledge or consent
f. institutionalized children were fed a solution of feces in order to infect them with hepatitis
g. researcher offered to serve as a lookout in order to study sexual encounters in public bathrooms
Coastal Carolina University is committed to the ethical principles for the protection of human subjects in research as set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979).

The ethical principles are:

- **Respect for persons** - which includes the requirement of a voluntary informed consent process
- **Beneficence** – which entails an obligation to protect persons from harm by minimizing risks and maximizing benefits
- **Justice** – which requires that selection of subjects be fair and equitable and that particular care be taken when working with populations (i.e. children, decisionally impaired) whose status puts them in a vulnerable position.
An institutional review board (IRB) is an administrative body which protects the rights and welfare of human research subjects participating in research activities conducted under the auspices of a university or research institution. An IRB ensures research conducted at the institution follows the ethical principles established by the Belmont Report, the Office of Human Research Protection, and various federal agencies and regulations.

It is important to protect the rights and privacy of participants and minimize risk to those participants, while creating and maintaining ethical standards with which to perform research.
1. Safety and privacy risks are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose participants to risks.

2. Risks are reasonable in relation to anticipated benefits.

3. Participants are selected equitably so that burdens and benefits of research are fairly distributed.

4. Informed consent will be obtained and documented (full disclosure usually through conservation and documented by a signature).

5. Perceived coercion to participate is minimized especially among potentially vulnerable participants.

6. Research is monitored.
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.
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.

Some examples of human subjects research:

- Interviewing cancer survivors about coping techniques
- Questionnaires about dating behaviors among college students
- Surveys about shopping preferences in rural communities
- Moderate exercise activities and venipuncture of individuals to determine certain depletions
- Music therapy intervention to determine whether it affects pain levels in a hospital environment.
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 research does not include, as examples:**

- Surveys for evaluating the performance of faculty, staff, and students, or other studies for internal institutional use only (not a "research" activity).
- Oral history of New Orleans jazz artists and memories of post-WWII era (information is not gathered for "generalizable knowledge").
- Secondary analysis of publically available data, such as reviewing US Census data (not "human subjects" – de-identified data).
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.
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 \textit{utero} cannot be exempt.

Experiments, interviews, and surveys with children are not exempt.

\textbf{Examples of research that qualify as exempt are:}

- anonymous surveys
- research involving normal educational practices
- analyses of discarded pathological specimens without personal identifiers
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.
The Responsible Conduct of Research training is **required** certification for all CCU faculty, students and staff participating in research and sponsored programs/projects which require submission of a protocol to the IRB or IACUC.

These trainings are provided by the Collaborative Institutional Training Initiative (CITI). These modules need only be completed once and the system will record your certification in a database accessible to the CITI Administrator on campus. You may print the certification, and it is good for 5 years.

Please note that it is not necessary to complete all of the modules in one session. The CITI system retains your information and you can access it at any time. Just be sure to remember your USERNAME and PASSWORD.

For step-by-step instructions to register for the CITI Program please go to: [http://www.coastal.edu/research/ors/citi.html](http://www.coastal.edu/research/ors/citi.html)
For more information and frequently asked questions on the IRB, Compliance, and the CITI Training Program please visit:

http://www.coastal.edu/research/ors/citi.html

Bruxanne Hein, Director
IRB Administrator
Office of Research Services
SNGL 201C  843-349-2918
bruxanne@coastal.edu