

Responsibilities of Extension Agents who Collaborate in Research with Human Subjects

As Cooperative Extension agents, you have a unique relationship with many communities that can be very valuable to your educational programs as well as others who wish to study those communities. Therefore, you may be approached by researchers from different institutions who would like your help in conducting research activities. Sometimes, they may not call the activities “research,” but may refer to them as “evaluations,” or “assessments,” and the projects may not involve activities that you typically associate with research, such as experimental conditions or interventions. Usually, these projects will involve human beings as research subjects. When they ask for your help, the researchers may ask you to do a variety of things; they may ask you to hand out flyers or otherwise aid in recruitment for their study, they may ask you to hand out surveys during extension programs, help arrange time and space for research activities, implement some research activities or procedures with your target populations, or they may ask you to do something else to help implement their study. Some may offer to pay you or your county for the help, others may not. **It’s important for you to understand that when you agree to help facilitate these projects, you become a human subject researcher, and as such share in the responsibilities of research compliance.**

If , as an employee of NC State University, you would like to become a partner in a research project that uses human beings as research subjects, you need to contact the NC State Institutional Review Board (IRB) office. This is true even if the institution that is conducting the full research study has already provided IRB approval for the project; because you are an NC State employee, NC State bears responsibility for the project that it must independently address. As a de facto researcher, you bear responsibility for making sure the IRB compliance needs for your role in the project are met. Prior to deciding to help out in a research project you must contact the NC State IRB office at 919-515-7515 or 919-515-4514. You cannot move forward as a partner in research activities until the NC State IRB office approves your request.

The Institutional Review Board is a committee made up of NC State faculty and community members that are charged with protecting the rights and welfare of human beings used as research subjects. IRBs exist because they are federally mandated. NC State has an agreement with the federal government such that in order to receive any federal money for research, we agree to follow their rules to protect human subjects in all our research activities. This means that we must follow the rules even for projects that are not federally funded. Federal regulations describe in detail the role of the IRB, what it has to do and how it does it. If NC State does not properly follow the federal regulations, we may be at risk for losing all federal funding.

In summary, before you agree to partner with a researcher or research project, call the IRB office to discuss your planned involvement in the research. The IRB office will make a determination about what paperwork and oversight is necessary. We will then help you navigate the IRB process in the most efficient way possible. For more information about the IRB, please pursue training online at <http://www.ncsu.edu/sparcs/tutorial/intro.php> (access the tutorials using your unity ID, and choose the “human subjects” training module) or <http://www.citiprogram.org/default.asp?language=english>.

Below is some information to help you understand the role of the IRB and how it protects the rights and welfare of human subjects. Please remember, **the question of whether or not an activity is research that requires IRB review needs to be made by the IRB office, not you, the researcher, or group that is requesting your assistance.**

WHAT IS RESEARCH WITH HUMAN SUBJECTS?

RESEARCH: “A *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*.”

- At NCSU, this definition is interpreted as any project designed to collect information in an organized manner, to examine the information to generate knowledge that will be shared with others and that others may learn from or build upon
- Can include, but is not limited to the following; dissertation and thesis research, assessments of educational techniques, research intended to produce journal articles, conference presentations or other publications, and assessments of extension or outreach programs. However, note that assessments done solely for program and operations improvements are not typically considered research that requires IRB review unless the results will be shared outside of the program. This includes but is not limited to, teaching assessments and extension program evaluation assessments.

HUMAN SUBJECT: 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 interactions with subjects and manipulations of the subject’s environment that are performed for research purposes.
- “Private information” is information that can reasonably be expected by the subject to be private.
- “Identifiable private information” means that the information can be traced in any way to a subject’s identity. Anonymous data cannot be traced by anyone (not even the PI) to the subjects’ identities.

!!! Contact the IRB office before you decide that a study does not qualify !!!!

WHAT DOES THE IRB REVIEW?

The IRB must find that the research satisfies the following criteria in order for approval:

- Risks to subjects are minimized
- Risks from the research are balanced with expected benefits
- The selection of subjects is equitable, and that no population is unfairly excluded or included for inappropriate reasons
- Informed consent will be sought and documented
- Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data
- Additional safeguards are in place for research involving vulnerable populations
 - Children
 - Prisoners
 - Pregnant women and fetuses
 - Employees/Students
 - Others