

4-H Evaluation and Protection of Human Subjects

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Federal law and professional best practices require protection of youth rights as human subjects when they are involved in evaluation and research. 4-H professionals and volunteers should clearly understand these expectations before they request feedback from youth or about youth with whom they work. This fact sheet provides a summary of these expectations, general 4-H procedures, and list of resources for further learning.

Expectations for Compliance on Protection of Human Subjects

The Code of Federal Regulations (Title 45, Part 46)¹ requires that research involving humans 1) clearly explain the nature of the study, 2) indicate that participation is voluntary, and 3) gain active consent of participants (9-17 years) and/or guardians (all youth under 18 years). North Carolina State University and other organizations that gather data with children and adults maintain Institutional Review Boards² (IRB) to oversee compliance with these regulations and assist colleagues conducting evaluation and research in a way that protects the rights of human subjects. Keys to compliance are understanding the Federal definition of research and information that must be shared with participants (and guardians).

Monitoring—Evaluation--Research: What Activities Require Compliance?

- **Monitoring**, or informal feedback between mentors and learners is the lifeblood of experiential learning and positive youth development. Most often, ongoing feedback about progress on a record book, horsemanship, or leadership skills is not used as evidence of program impact and may not even be recorded. 4-H leaders do not need to request parent consent (for youth under 18 years) for these everyday conversations. Professional³ and volunteer⁴ codes consistent with the ethics of human subjects consent offer guidance on respect for dignity and privacy, confidentiality, and disclosure.
- **Evaluation**, or assessments of the worth of a program, often meet the Federal definition of research: *A systematic investigation, including research development, testing and evaluation⁵, designed to develop or contribute to generalizable knowledge*, especially when data are shared as evidence of program quality and impact or used to improve programming and evaluation efforts.
- **Research** beyond the realm of program evaluation describes scientific exploration and testing of theories (e.g., observations of child development or learning patterns) designed to contribute to generalizable knowledge, fulfilling the Federal definition.

Proposals and Procedures--What do Professionals and Volunteers Need to do?

A state 4-H program proposal⁶ gained IRB approval for evaluation activities consistent state long-range plans of work (LRFA) and state-level programs such as camps and 4-H Ambassadors. The "Informed Consent for 4-H Research—Parent and Youth"⁶ form that is included in all 4-H enrollment and event registration packets explains these programs, procedures, and conditions and provides signature lines for parents and youth. These forms should be completed and filed in each county, with one copy sent to the state office and another given to the guardian signee. Enrollment records should indicate

whether parent consent was obtained in order to help program staff determine who can complete evaluation forms and who will be directed to alternative activities. When evaluation activities involving observations or ratings of an entire group rather than assessments of individuals, consent forms are not required for all participants.

Community-based projects not related to LRFA programs and measures will require a separate proposal, submitted with a consent form and evaluation instruments, to the NCSU Institutional Review Board. Proposal and Consent Form must address Institutional Compliance Checklist items (Figure 1). The Board's mission² includes educating scholars and practitioners, and help is available online² and by phone (919-515-4514) to expedite proposal development and clarify related issues.

Figure 1
NCSU Institutional Compliance Checklist for Consent Forms

- Language must be appropriate for and understandable by intended subjects;
- The study must be described as research, with a specified purpose, expected duration, and procedures;
- Reasonably foreseeable risks and discomforts must be described; as well as
- All reasonably expected benefits (or absence of benefits) to the subject or to society;
- Specific and precise information on confidentiality measures, and protection of subjects' identities must also be included;
- Contact numbers must be included for questions about the research (investigator's telephone number) and the University Institutional Review Board chair.
- Other elements to be contained if appropriate include:
 - Consequences of a subject's decision to withdraw early from a study;
 - Any additional costs to the subject from the research study;
 - Anticipated circumstances under which the subject's involvement in the study may be ended by the investigator without the subject's consent;
 - Under a separate heading called "Compensation," it must list the compensatory provisions of the study, and
 - The total number of subjects expected to be enrolled in the study

Compromising the trust of human subjects is intolerable by the institution and compliance begins with the investigators themselves... –NCSU IRB Regulations

Citations

¹ Federal Regulations regarding www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

² NCSU Institutional Review Board. www.ncsu.edu/sparcs/IRB/

³ 4-H Professional Code of Ethics. www.nc4h.org/extension/ethics.php

⁴ 4-H Volunteer Code of Ethics. www.nc4h.org/volunteers/CODE_OF_ETHICS-adult_volunteers.pdf

⁵ Federal Regulations definition of research
www.ncsu.edu/policies/research/research_admin/REG10.10.3.php

⁶ State IRB Proposal and Consent Forms [insert url here]