

IRB Basics

The purpose of the IRB is to protect the rights and welfare of human subjects in research. In order to do so, the IRB reviews each research project at NCSU that uses human subjects. This document is meant to help you understand and navigate IRB review.

Some Helpful Hints

- Your IRB submission is the blueprint for your research. Any research activities that deviate from the IRB submission are not approved and will be considered noncompliant. For this reason, it's important for researchers to provide full details about their research along with specific, practical information on how procedures will be carried out, confidentiality protected, etc. All study activities and components must be described in the IRB form.
- The IRB must see all study materials from recruitment materials (ads, letters, emails, etc.) through thank you letters/debriefing. Send these to the IRB along with the appropriate review form.
- When the IRB asks about confidentiality of data, it is referring to the collection, analysis and storage of data - not just the reporting of results. Information to the IRB should include descriptions of how confidentiality will be protected in all phases of the research.
- "Anonymity" means that there is absolutely no way for anyone (not even the researcher) to trace a subjects' identity from the data.
- If a project is "Approved with modifications," the required modifications must be made and submitted to the IRB office for final approval before the research may begin. A project is not approved to begin until the researcher receives an official letter from the IRB office indicating full approval.
- ANY changes made to research after IRB approval is granted must be reported to the IRB and approved prior to implementing them.
- Any problems or adverse events must be promptly reported to the IRB.

IRB Review

The following numbered points are criteria for a research proposal to be approved by the IRB.

- 1) That risks to subjects are minimized
 - ◆ By using research procedures which are sound science, but do not unnecessarily expose subjects to risk

- ◆ Risk in social and behavioral research is primarily risk of loss of confidentiality. This means that someone besides the researcher could find out, a) that a person is involved in a study, and b) the data collected about an individual in a certain study. Either scenario could have a harmful effect on a subject, depending on the study. For example, if someone is discovered to be participating in a study entitled, “Psychological Causes of Impotence,” just knowledge of participation is embarrassing. If an employer finds out a certain employee’s answers in a management study, “how satisfied are you with your job?” there could be professional repercussions for that employee.
- ◆ Other risks from social research includes psychological risk, embarrassment, discomfort, loss of social or professional standing, and legal or civil prosecution.

Risks from research fall under 5 categories:

1. Physical
2. Emotional
3. Legal
4. Social
5. Fiscal/Professional

- ◆ Primary considerations for social and behavioral research should be; what sort of information is covered in the study, how could it possibly be discovered by someone outside of the study, and how could that embarrass, harm, or cause discomfort to the subject? The IRB considers “worst case scenarios,” such as an investigator leaving behind a briefcase full of research notes, or the theft of a computer containing data. Also keep in mind that research records can be subpoenaed.
- ◆ Sometimes, the survey questions themselves could cause harm to subjects. For example, questions about experiences with sexual assault or other violence could trigger memories in a subject who had experienced assault. Some depression measures may contain potentially upsetting questions such as “I am worthless”. If research activities contain any questions that may be potentially upsetting to subjects, that must be planned for in the research procedures.

2) Risks to the subject from the research are reasonable in relation to expected benefits to subjects, and/or the importance of the knowledge that may be reasonably expected to result.

- ◆ In evaluating risks and benefits only those that result from the research are considered, not possible long-range effects of applying knowledge gained in the research (for example, effects of the research on public policy).

3) Selection of subjects is equitable

- ◆ The setting and the purpose of the research are taken into account
 - ◆ Recruitment procedures should guarantee a diverse sampling, and if the study focuses on one segment of the population, there should be justification as to why
 - ◆ Amounts of compensation should not be so great as to provide undue inducement to people who are economically disadvantaged
 - ◆ Be aware of the use of, and special considerations for, vulnerable populations (i.e. minors, students, cognitively impaired people, prisoners).
- 4) When some or all of the subjects are vulnerable to undue influence to participate (such as students in a class taught by the investigator), additional safeguard have been included in the study to protect the rights and welfare of the subjects.
- 5) Informed consent will be sought and properly documented from either the subject or his/her legally authorized representative.
- ◆ Consent must be sought under conditions that allow the subject to learn as much as possible about the research, and to make a decision for him/herself about whether or not to participate. Conditions should minimize undue influence, and either verbal or written assent should be obtained from minors, as well as parental permission.
 - ◆ Language in the consent form should be understandable to the subject or his/her representative. This means that consent forms should, in general, be written in eighth grade language, and should not use scientific terms.
 - ◆ Consent forms may not contain any exculpatory language through which a subject waives, or appears to waive, any of his/her rights, or which release the investigator or NCSU of any liability
 - ◆ Basic elements of informed consent are listed on the “Informed Consent Checklist” found on the IRB website
 - ◆ The IRB may decide that the basic elements of consent, and consent itself, can be waived if appropriate. Waiving of some or of the elements of consent may be appropriate if,
- 3 The study involves no more than minimal risk to the subjects
 - 3 A waiver or alteration of the consent process will not adversely affect the rights and welfare of the subject
 - 3 The research could not practicably be carried out without the waiver or alteration
 - 3 Whenever appropriate, subjects will be provided with pertinent information after participation

Waivers of some or all of the elements of consent are appropriate for a variety of social and behavioral studies, but must be adequately justified by the investigator. Studies that involve deception may not give subjects a complete description of study procedures in the consent form. If this occurs, the

researcher should hand out an “information sheet” about the true purpose of the study after data has been collected. Subjects would then have the option of destroying their data afterwards, if they decide they don’t wish to participate. Likewise, obtaining informed consent may not be appropriate for studies using previously collected data, if the data was collected a long time ago and contact information for the subjects is no longer available. The IRB must approve any requests for consent waivers.

- ◆ The IRB may decide that written documentation of consent (a.k.a. a signature on a consent form) can also be waived, if appropriate. Usually in these instances, verbal consent is obtained, provided the IRB approves a “script” used to obtain consent that has the same elements of a consent form. A signature on consent may be waived if;
 - 3 The only record linking the subject to the research would be the consent document, and the principal risk is a breach in confidentiality. Each subject will be asked if s/he wants documentation linking him/her with the research, and the subject’s wishes will govern.
 - 3 The study presents no more than minimal risk to subjects, and involves no procedures for which written consent is required outside of the research context.

Telephone survey studies may use verbal consent obtained over the telephone, since there will be no physical interaction between the investigator and subject. The IRB must approve all request for signature waivers.

- ◆ Studies involving subjects that do not speak or read English should have appropriate provisions for obtaining consent. Appropriate provisions are either: a witnessed translator reads the consent form for the subject, followed by a short form signed by the subject and witness, or for non-English speaking subjects, a verified, translated consent form should be used.

IRB review Procedures

Applications can be submitted electronically to carol_mickelson@ncsu.edu . In this case, the e-mail transmission containing the submission will evidence the PI’s and faculty sponsor’s signature agreeing to the relative statements of responsibilities described on the IRB Cover Form.

Research proposals, based on the procedures of the study and potential risks to subjects, undergo three types of review by the IRB:

Administrative review - performed by the IRB office and does not need review by a board member. This approval does not expire, but any changes must be reported to the IRB office.

Expedited review - requires review by one board member only. Approval expires after one year. Any changes must be reported to the IRB office.

Full board review - requires review at a convened meeting of the IRB. Approval expires after one year. Any changes must be reported to the IRB office.

Administrative Review

Certain studies, depending on their procedures and the level of risk involved, may be eligible for administrative review. This is also known as “exempt” research, meaning the research is exempt from the federal regulations. The IRB office, rather than individual investigators, determines whether or not research is exempt. If you believe that a study is exempt, and should receive administrative review, a “Request for Exemption” on the IRB’s website should be submitted. If administrative review is granted, the initial review is the only necessary review, unless the study undergoes changes. In addition, the research is subject to university policy and basic ethical principles.

Expedited Review

Only research that meets specific criteria set by the federal government may receive expedited review. If a study qualifies for expedited review, a complete application from the IRB website should be submitted, which will be reviewed by the IRB office and one board member. This review usually takes 3 to 5 weeks to complete. Both the IRB office and the board member may request changes in the proposal. The board member has the authority to approve, approve with modifications, or table the research that s/he reviews. If the board member feels that the research study should be disapproved, it must be taken to the full board. Studies undergoing expedited review must be re-reviewed every year, and any changes or adverse events must be reported to the IRB office.

Full Board Review

If a proposal must receive full board review, it is reviewed by the board at a convened meeting. The board can vote to either approve, approve with modifications, table, or disapprove the proposal. After the meeting, the IRB office will notify the investigator of the board’s decision, and handle the rest of the approval process for the proposal. The board convenes every month. A proposal must be at the IRB office a few weeks before a meeting at which it is reviewed, and study PI’s are encouraged to attend IRB meetings in order to answer questions. Studies undergoing full board review must be re-reviewed every year, and any changes must be reported to the IRB office before they are implemented.

Websites

NCSU IRB website: <http://www.ncsu.edu/sparcs/IRB/human.html>

Federal guidance (OHRP): <http://ohrp.osophs.dhhs.gov>