GUIDELINES FOR WRITING A RESEARCH PROTOCOL

The University of New Hampshire (UNH) Institutional Review Board (IRB) for the Protection of Human Subjects in Research is a standing faculty committee responsible for protecting the rights and welfare of people who are subjects in UNH research activities. UNH's policy regarding the use of human subjects states: All UNH research activities proposing to involve human subjects must be reviewed and receive written, unconditional approval from the IRB before commencing. This applies to all research activities conducted under the auspices of UNH involving human subjects regardless of discipline or whether or not the activities are funded.

In order to review research involving human subjects, the IRB requires completion and submission of a two-page Request for IRB Review application form AND a research protocol (available at http://unh.edu/research/human-subjects). The following guidelines are to help researchers develop a comprehensive yet succinct research protocol to facilitate timely review by the IRB. (Thesis/dissertation proposals cannot be submitted as or in lieu of research protocols as they do not contain all the required information).

General
- Use the format stated in the UNH IRB Outline to be Followed for Research Protocols Submitted to the IRB (see the Application Materials for IRB Approval at http://unh.edu/research/human-subjects). These guidelines utilize this format.
- Use the topic headers provided.
- Keep the Description of Project under four pages (references, informed consent/assent documents, and copies of questionnaires, guiding questions, survey instruments, tests, letters of support, etc. do not count toward the four-page limit).
- Write your narrative in an active (versus passive) voice.

Description of Project - Recommended Topic Areas

1. **Introduction**
   - Provide limited background on the broad issue your research is addressing.
   - State the purpose of your project in the context of the broader issue.
   - Be concise and limit this information to one or two paragraphs.

2. **Specific Aims**
   - Bullet or number your specific aims to facilitate review.
   - Be concise.

3. **Research Protocol**
   a. Setting:
      - Explain who or what is the source of subjects.
      - Describe how subjects will be contacted (i.e., by whom and in what manner). Be sure to explain how privacy of individuals will be maintained (e.g., if not publicly accessible, subject information won't be released to researcher by source without subject's consent).
      - If conducting record or chart reviews, clarify if the researcher will have access to the entire record or will be provided select information from the chart, who will provide the records or information, and, if identities will be masked.
      - Explain any compensation provided to subjects for their participation (e.g., money, goods, course credit), and if so, how will it be administered. (Note: While not a requirement for IRB review, researchers should check with their Business Service Center Director to ensure that compensation methods comply with federal tax regulations.)
      - Describe the physical site/location where the research will occur (e.g., elementary school, college classroom, participant's home, Main Street in Durham).
      - Describe any procedures where the researcher will videorecord, audiorecord, or photograph subjects and explain the rationale for doing so. Subjects (and their guardians, if applicable),
should be given the opportunity to review their audiorecordings, videorecordings, or photographs before inclusion in the final data compilation. Researchers must honor requests to edit a subject from a presentation.

- Attach to the application any recruitment materials that will be used (e.g., fliers, emails, posters, advertisements).

b. Protocols:
- Describe all the activities in which the subjects will engage (e.g., completing a survey, taking a test, answering questions in an interview, completing a specific task, completing tasks on a computer, running on a treadmill).
- Describe the arrangements for protecting privacy of subjects' responses (e.g., responses will be anonymous, assigning pseudonyms, assigning codes). If seeking permission to identify participants, explain how this will be done (e.g., the researcher will ask subject's permission and have them sign in a specific place on consent form giving this permission).
- If conducting research in a classroom environment, state what alternative activities will be available for students who are not participating in the study. Describe procedures for reducing peer pressure or stigmatism for non-participants.
- Attach to the application copies of sample instruments, guiding questions, etc.

c. Consent:
- Describe procedures for obtaining informed consent from adults.
- Describe special provisions for individuals who might have trouble comprehending the consent information (e.g., the researcher will explain the consent form to a person with learning disabilities as they read it, and possibly get a third party witness). If participants do not speak English, explain how translators will be involved in the project.
- Describe any circumstances wherein confidentiality cannot be guaranteed (researchers are mandated to voluntarily disclose certain confidential information such as reporting suspected child abuse and/or neglect). (See the UNH IRB document, Information Individuals in New Hampshire are Legally Required to Report available at http://unh.edu/research/irb-application-resources.) Further, if the data will be collected in a focus group setting, other participants may repeat responses outside the focus group setting.
- Describe any situations where privacy cannot be guaranteed, such as when subjects are videorecorded, audiorecorded, or photographed, and persons other than the researcher will have access to the data recorded (e.g., videotape will be presented at a conference or used as a teaching tool). Subjects (and their guardians, if applicable), should be given the opportunity to review their audiorecordings, videorecordings, or photographs before they are included in the final data compilation. Researchers must honor requests to edit a subject from a presentation.
- Where the study has multiple components, including recording of the subject's voice or likeness, researchers should ask for consent (and assent, if applicable) for recording separately (e.g., ask parents to give permission for child to take a survey, and ask for separate permission to videotape the child at play; the child would need to assent to both activities as well).
- If applicable, explain how assent will be secured from children or people who lack the capacity to give consent. (See the UNH IRB document, Child Assent Guidelines available at http://unh.edu/research/irb-application-resources.)
- In studies involving children, seek the permission (consent) of parents BEFORE seeking the assent of their minor children. The same applies to persons lacking capacity to consent themselves in that researchers should seek permission from a guardian before obtaining assent from a person with diminished cognitive capacity or who is institutionalized.
- Attach copies of consent documents (including translations if subjects are non-English speaking). If there will be more than one group of subjects, provide a consent form tailored to each group (e.g., separate forms for teachers, parents of students). As well as the basic elements mandated by federal law (see the UNH IRB document, Informed Consent Format and Checklist available at http://unh.edu/research/irb-application-resources), be sure to include the following information in the consent document, where applicable:
  - Descriptions of situations where confidentiality cannot be guaranteed as the researcher is mandated to disclose certain confidential information, such as reporting suspected child abuse and/or neglect.
  - Descriptions of situations where privacy cannot be guaranteed, such as when subjects are videorecorded, audiorecorded, or photographed and persons other
than the researcher will have access to the data recorded (e.g., videorecordings will be presented at a conference or used as a teaching tool).

- Explanations of what will happen to audiorecordings and/or videorecordings after transcription and/or how they will be used.
- A separate signature line giving the researcher specific permission to use subjects' identify in the research.

- Attach copies of assent documents. If there will be a large age range of children participating, provide assent documents to reflect different capacities to assent relevant to age (i.e. assent documents for six year olds will be much simpler than those for sixteen year olds).

4. Study Personnel
- Identify all the individuals involved in conducting the study.
- Briefly describe their experience in conducting research similar to that proposed, if any.
- Briefly describe their experience in working with groups similar to the subjects, if any.
- For student protocols or research conducted by students, a letter from the faculty/project advisor is required indicating the student's experience as well as the level of supervision the advisor will provide.

5. Data
- Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively).
- Explain how the interpretation will address the research questions.
- Describe where the data will be stored and who will have access to it.
- Describe what will happen to video and/or audiorecordings after transcription. Will they be destroyed or used later for research purposes?
- Explain how data will be reported (e.g., aggregated, anonymity of participants, pseudonyms for participants).
- Explain how data will be used (e.g., in a thesis, reports, publications, presentations).

6. Risks
Risk is the probability of harm occurring as a result of participation in research. Any project involving risk of physical injury, civil, financial or criminal liability, risk to a subject’s employability, or instances where the research involves sensitive aspects of the subject’s own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol, has the potential of involving more than minimal risk.
- Describe any risks to subjects that are reasonably foreseeable, even if unlikely, and the safeguards in place against these risks? Risks may include:
  - Psychological: Does the study involve sensitive issues (e.g. sexuality, victimization, alcohol, or drug use) that may create emotional upset or raise questions for subjects? Is there a referral path readily available for subjects who need it (e.g. free mental health counseling)?
  - Social: Could participation or a breach in confidentiality create social stigma for the subject?
  - Economic: Could participation or a breach in confidentiality cause the subject to lose their job? Could a business be negatively impacted?
  - Physical: Does the study involve blood draws, the placement of electrodes, or maximal exercise? How likely is it that discomfort, illness, injury, or death may occur?
  - Legal: Is the information gathered subject to subpoena? Are subjects asked to report illegal behaviors? Could subjects be identified through demographics or other means?
- Address issues of confidentiality and risks associated with a breach of confidence. The researcher must clearly outline specific situations wherein they are mandated to disclose certain confidential information (i.e., cannot maintain confidentiality of responses), therefore potentially putting participants at risk for legal action, such as reporting suspected child abuse and/or neglect. (See the UNH IRB document, Information Individuals in New Hampshire are Legally Required to Report available at http://unh.edu/research/irb-application-resources.)
- Researchers cannot promise to maintain confidentiality of highly sensitive information unless they obtain a Certificate of Confidentiality for the project against forced disclosure. Even then, New Hampshire law mandates voluntary reporting of certain information (see previous bullet).

7. Benefits
Benefit is a valued or desired outcome or an advantage.
- Describe any direct benefits participants could potentially accrue or benefits the subject class/population may accrue.
• If there are no direct benefits to participants, state this.
• Describe the benefits of the knowledge gained at the community level, and in general.
• In studies involving risk, address the relationship between risks and benefits.

References
• Provide bibliographic information. References should show thoughtful consideration of the research topic, particularly if the study involves greater than minimal risk to subjects.
• References should be current and should reflect recent advances or changes in the field of inquiry.

A copy of the certificate of completion of the UNH Web-based training on the ethical use and treatment of human subjects in research.
• Applications missing this certificate will not be processed.

Copies of recruitment materials (e.g., fliers, emails, posters, advertisements).
• Attach any recruitment materials that will be used (e.g., fliers, emails, posters, advertisements).

Copies of consent and assent documents/information.
• Attach copies of proposed consent and assent documents/information delineated in the protocol.

Copies of questionnaires, guiding questions, survey instruments, tests, etc.
• Attach copies of all questionnaires, surveys, test instruments, or other documents delineated in the research protocol.
• If an interview will be open-ended or the research is ethnographic, provide information on the line of inquiry and sample questions to be asked.

Other pertinent documentation
• Students must attach a letter in support of the research from their faculty advisor.
• Attach letters of support from collaborating organizations, agencies, or individuals, where applicable.

Additional supporting materials are available on the IRB webpage at:

http://unh.edu/research/human-subjects

Send your completed Request for IRB Review application form and research protocol to:

Research Integrity Services
University of New Hampshire
Service Building, 51 College Road
Durham, NH 03824-3585

Address questions to Julie Simpson, Director, at julie.simpson@unh.edu or 862-2003.