



INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

**OUTLINE TO BE FOLLOWED FOR RESEARCH PROTOCOLS SUBMITTED TO THE IRB**

Applications for IRB review must include elements **A through F** to be considered complete. Send one copy of your completed application to the Office of Sponsored Research, Room 107, Service Building. **Allow a minimum of 15 working days for processing, review, and final approval of your protocol.** Reviewers appreciate complete applications that follow the outline order below.

**A. Request for IRB Review** (two-page form)

**B. Description of Project**, as outlined below. The narrative (items 1-6 below) should be succinct (**no more than two pages**) but provide sufficient detail for the IRB to conduct its review.

1. **INTRODUCTION** - Summarize the background, nature, rationale and significance of the proposed study.
2. **SPECIFIC AIMS** - In outline form, state clearly the objectives of the research.
3. **RESEARCH PROTOCOL** -
  - a. **Setting**: Describe the setting in which the study will be conducted. Indicate the source of subjects, how they will be recruited, and whether they will be compensated. (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.) **Attach recruitment materials (e.g., fliers, emails, posters, advertisements).**
  - b. **Protocols**: Describe the activities in which subjects will engage. **Attach sample instruments.**
  - c. **Consent**: Explain procedures for obtaining consent from adults. If applicable, explain how **assent** will be secured from children. **Attach copies of informed consent and assent documents/information.**
  - d. **Investigator Experience**: For all persons participating in the study, including the investigator and individuals working for that investigator, indicate the number of years of experience with the proposed research paradigm. **For student protocols/research conducted by students, the IRB requires a letter from the faculty/project advisor indicating the student's experience as well as the level of supervision the advisor will provide.**
4. **DATA** - Explain how data will be analyzed or studied (using quantitative or qualitative methodologies). Describe how the interpretation will address the research questions. Explain how data will be reported (e.g., aggregated, anonymity of participants, pseudonyms for participants). Describe where data will be stored and who will have access to it. If applicable, describe what will happen to video and/or audio recordings at the end of the study.
5. **RISKS** - List possible risks to subjects including physical, psychological, and economic (loss of employability). Also address issues of confidentiality and risks associated with a breach of confidence. **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.**
6. **BENEFITS** - Discuss benefits of participating in the study **for participants**. If none, discuss benefits of the study at the community level, and in general. In studies involving risk, discuss the relationship between risks and benefits.

**C. References** - Attach appropriate bibliographic information.

**D. Copies of recruitment materials (e.g., fliers, emails, posters, advertisements), and consent and assent documents/information.**

**E. Copies of questionnaires, guiding questions, survey instruments, tests, etc.**

**F. Other pertinent documentation as required (e.g., faculty/project advisor letter for student research) or as researcher deems necessary**



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REQUEST FOR IRB REVIEW

General Information:

Name \_\_\_\_\_ Title: \_\_\_\_\_ Today's Date \_\_\_\_\_

Department & Campus Address \_\_\_\_\_

Home Address (if applicable) \_\_\_\_\_

Day Phone \_\_\_\_\_ Home Phone \_\_\_\_\_ Fax \_\_\_\_\_

Email Address \_\_\_\_\_

Research Project Title \_\_\_\_\_

Anticipated Project Start Date\*\* \_\_\_\_\_ Anticipated End Date \_\_\_\_\_

\*\* UNH Policy on the Use of Human Subjects in Research prohibits the start of any research activity (including canvassing and recruiting of subjects) that has not been reviewed by, and received written approval without contingency from, the IRB.

Project Status Information (please check one):

New Project \_\_\_\_\_ Modification to Previously Approved Project \_\_\_\_\_ Continuation of Previously Approved Project \_\_\_\_\_

Project Funding Information (for sponsored projects only):

Sponsor \_\_\_\_\_

Is human subjects certification required by the sponsor? Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, notification deadline \_\_\_\_\_

By initialing this statement, the project director certifies that (s)he has read and understands UNH's Policy on Financial Conflict of Interest in Research http://usnholpm.unh.edu/UNH/VIII.Res/E.htm; has made all required financial disclosures; as project director, has made every effort to ensure that all individuals responsible for the design, conduct, or reporting of the research have submitted the required disclosures; and prior to the expenditure of award funds will have reached an agreement with UNH that provides for conditions or restrictions necessary to manage, reduce, or eliminate any conflicts of interest under UNH policy. \_\_\_\_\_ (initials)

Review by Non-UNH IRB(s) (if applicable):

If this project has been submitted to a review board at another institution, provide the review date, and that board's recommendations. Please attach relevant correspondence.

Name of Institution \_\_\_\_\_ Date of Review \_\_\_\_\_

FOR IRB USE ONLY
PROTOCOL # \_\_\_\_\_ DATE RECEIVED \_\_\_\_\_

**Subject Information:**

Research Site(s) \_\_\_\_\_

Number of anticipated subjects by category (complete for all that apply to this study)

- |  |  |
|--|--|
| # _____ Newborns/Infants                                 | # _____ Adults (persons 18 and over)   |
| # _____ Children Aged 2 - 12 Years                       | # _____ Institutionalized Individuals  |
| # _____ Adolescents Aged 13 - 17 Years                   | # _____ Prisoners  |
| # _____ Emancipated Minors (minors living independently) | # _____ Diagnosis of Mental Illness, Cognitive Impairment, or Learning/Language Difficulty |
| # _____ Other Special Populations (please specify below) |  |

Time commitment for each subject \_\_\_\_\_

Compensation - Indicate the amount and form of compensation, if any (i.e., cash, course requirement, mileage, etc.)

**Project Attributes (check all that apply):**

- |   |  |
|---|--|
| <input type="checkbox"/> Use of recruitment materials (i.e., flyers, emails, letters, advertisements) | <input type="checkbox"/> Audio or video recording  |
| <input type="checkbox"/> Surveys/<br>questionnaires   | <input type="checkbox"/> Administration of tests, inventories, self reports, measuring instruments, etc. |
| <input type="checkbox"/> In-person  | <input type="checkbox"/> Phone   |
| <input type="checkbox"/> Phone  | <input type="checkbox"/> Mail  |
| <input type="checkbox"/> Mail   | <input type="checkbox"/> Email   |
| <input type="checkbox"/> Email  | <input type="checkbox"/> Web   |
| <input type="checkbox"/> Web  | <input type="checkbox"/> Use of existing data  |
| <input type="checkbox"/> Interviews   | <input type="checkbox"/> In-person   |
| <input type="checkbox"/> In-person  | <input type="checkbox"/> Phone   |
| <input type="checkbox"/> Phone  | <input type="checkbox"/> Medical procedures  |
| <input type="checkbox"/> Focus groups   |  |

**Signatures:**

The undersigned accept(s) responsibility for the study, including adherence to DHHS and FDA regulations, New Hampshire law, and UNH policies relative to the protection of the rights and welfare of subjects/patients participating in this study. In the case of student protocols, the Faculty Advisor and the student share responsibility for adherence.

Signature(s) of Project Director(s) \_\_\_\_\_

\_\_\_\_\_ Faculty      \_\_\_\_\_ Undergraduate Student      \_\_\_\_\_ Graduate Student      \_\_\_\_\_ Staff

By signing this form, the Faculty Advisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the Advisee listed as *Project Director*, above, or as *other individual*, below.

Faculty Advisor Signature (required for student projects) \_\_\_\_\_ PRINT Faculty Advisor's Name \_\_\_\_\_

Faculty Advisor's Department, Phone Number, and Email Address \_\_\_\_\_

If an individual in addition to the *Project Director* will conduct the study, provide the individual's name, position, and contact information, as well as the individual's experience with the paradigm, as indicated in the Outline to be Followed for Research Protocols Submitted to the IRB, item 3-b.

Name \_\_\_\_\_ Position \_\_\_\_\_

Address, Phone Number, and Email Address \_\_\_\_\_

Return this 2-page form along with the research protocol and all pertinent information to the UNH Office of Sponsored Research (OSR), Room 107, Service Building. Direct questions to Julie Simpson at 603-862-2003 or [Julie.simpson@unh.edu](mailto:Julie.simpson@unh.edu), or visit the IRB webpage at <http://www.unh.edu/osr/compliance/irb.html>