The IRB Application

Research involving the use of human subjects must be approved by the IRB prior to implementation. In addition to protocols requiring full board approval, certain categories of research may qualify for expedited or exempt review. Expedited or exempt review only requires review and approval by the IRB Chair.

All incomplete or inadequate IRB application packets will be returned to the principal investigator without review. As a result, the applications which are returned will experience an additional delay of one month over and above the current schedule.

The IRB application consists of: the face page, the project abstract and description, data collection, funding information, risks to participants, informed consent, data use, and investigator assurances. This application is designed to increase the speed and accuracy of protocol reviewed. Please complete all sections of the application in order to reduce delays due to incomplete protocols.

For questions regarding the completion of the application, please contact Dr. Roberto Refinetti at 280-7481 or by e-mail (rrefinet@uno.edu or unoirb@uno.edu).

A. Application Form: Face Page

All sections of the form must be completed prior to submission to the IRB Office. Instructions for completing each section follow.

1. Protocol title

The protocol title is the official title of the project. This is the title used on grant proposals or theses or dissertation projects.

2. Alternate title

At times the title used to communicate to participants or participating organizations is different from the official title. This title reflects the title used in communications with participants or participating agencies. If you do not have an alternative title, leave this section blank.

3. Principal Investigator

The name, campus address, department, phone number, preferred e-mail address, and university affiliation of the Principal Investigator must be complete. For PI's who primarily use an off campus address, please put the off campus address in the campus address box.

Note: Graduate students are not eligible to serve as PI. The PI of a thesis or dissertation must be the student's faculty advisor.

4. Co-Investigator(s)

Please complete the all contact information regarding each co-investigator on the project. All identified co-investigators must complete the NIH certification course and submit a copy of that certification.

If a project has more than two co-investigators, please submit an additional copy of the face page and include only the protocol title on the second copy of the face page

B. Project Description

1. Abstract. The purpose of the abstract is to provide the IRB with a brief description of your study. All elements of the study should be contained within this paragraph. Include the purpose of and reason for the study, the sample included, the methodology included, and the expected results

2. Description. Provide a brief description of the background, purpose, and design of your research. Avoid using technical terms and jargon. Be sure to list all of the means you will use to collect data (e.g., instruments measures, tests, questionnaires, surveys, interview schedules, focus group questions, or observational procedures). Provide a short description of the tests, instruments, or measures and attach copies of all instruments, questionnaires, and procedures for review.

This section has no page limit. In general the background and purpose sections should not exceed 2 single spaced pages. The length of the study design and measurement sections will vary based on the complexity of the study.

Note: Federal regulations require that the IRB chair have complete, accurate, and up-to-date copies of all measures and procedures for each active research study.

C. Data Collection

1. Sample size

Provide the total number of participants that you plan to include/enroll in your study.

2. Age range of participants

Please include the range of expected ages of all participants in your study. If your study involves parents and children, then include the expected age of the youngest child and the oldest parent.

3. Recruiting from special populations

Check the box of each category of participants you plan to recruit. The list is not exhaustive and your participants may not fall into any of the listed categories.

If you check any of the boxes, federal regulations require that you must describe how you will provide special protections to these identified participants. See a description of special considerations in Subparts B, C, and D of the 2018 Common Rule. If no special protections are necessary for your particular study, you must explain why that is the case.

4. Type of data collected

Check the boxes for the types of data you will collect. If no box is checked go on to question 5. If you check at least one box, please describe how the media will be used and destroyed.

For instance, if you audiotape conversations with participants, you must describe what you will do with those audiotapes (e.g., hire a transcriptionist to transcribe the audiotapes, protect the participant's identity with a pseudonym, destroy the audiotapes, and analyze the data).

5. Deception

If your study involves no deception, mark no and go to question 6. If your study involves deception of any kind, please check the yes box and describe the type of deception you will use, why the deception is necessary, and provide a copy of the debriefing script.

6. Recruitment procedures

Describe how you will recruit participants and inform them about their role in the study. Please attach copies of advertisements, flyers, website postings, recruitment letters, oral or written scripts, or other materials used for this purpose.

7. Project start and end dates.

Be advised that approval is only for 1 year. Requests for continuation must be submitted before the approval expires. Do not put a start date that is early than your request for IRB approval. Approval cannot be granted for research that has already been conducted.

D. Funding Source

1. Receipt of funding

Please indicate whether you have received any source of **funding** for the proposed research (e.g., federal, state, private, corporate, or religious organization support).

2. Review status

Indicate whether or not the protocol is currently under review or under consideration for funding

3. Explanation of funding

If you have received funding or your project is currently under review, please indicate any source(s) of funding for the proposed research (e.g., NIH, NSF, departmental funds, private foundations or corporations).

4. Potential conflicts of interests

Indicate whether the funding source(s) have any potential for financial or professional benefit from the outcome of this study and explain those benefits.

E. Risks to participants

1. Actual and potential risk

Review each statement and decide whether or not the statement reflects either an actual or potential risk. If the statement does reflect an actual or potential risk, check the box. If the statement does not reflect an actual or potential risk, leave the box blank. Checking box does not mean a study will not be approved, it simply means that you must describe the risk and how you will minimize the risk to the participant. Failure to reveal real risks may result in disciplinary action.

F. Informed consent

1. Definition of Informed Consent

Informed consent is an individual's voluntary agreement to become a subject of research after having been informed of the purpose of the study, the procedures that are used, and potential risks or benefits to reasonably be expected. Additional information which must be given to the subject includes: expected duration of subject's participation, selection of subjects, alternative treatment procedures available, extent of record confidentiality, and all financial issues.

The investigator should offer any questions and, further, be satisfied that the subject, or his legally authorized representative, understands the procedure or treatment the subject is to undergo. To this end, the explanation must be in the language the subject best understands. While complete understanding is neither practical nor possible, an extra burden placed on the investigator is to serve the best interests of the subject. A legally effective consent form is to be read to or by the subject and must be signed by the subject or his/her legally authorized representative. Consent Forms in languages other than English are sometimes required. These must be submitted for IRB review and must be accompanied by certification (e.g. legal notary) that the form is an accurate translation of the English version.

Consent procedures for research involving children must be carried out in accordance with applicable federal regulations, and special provisions should be followed in obtaining parental permission and the child's assent. The investigator is responsible for following these regulations.

In giving consent, the subject should show the ability to exercise free power of choice without intervention of any element of constraint or coercion. The agreement should include no exculpatory language through which the subject is made to waive, or appear to waive, any legal rights, or to release the investigator and institution from liability for negligence. The investigator must honor a request by any subject to withdraw consent and to discontinue participation in the investigation and do so without prejudice. If significant findings develop during the course of the research which may relate to the subject's willingness to continue participation, that information must be provided to the subject.

Investigators are responsible for retaining signed consent forms in their personal research files. In addition, the principal investigator should permanently keep copies of the signed consent forms in the subject's hospital/clinic chart as a matter of record. Because consent form documents are an agreement between two parties, the subject must be

given a copy to keep. Instructions for completion of consent forms are attached to the IRB application form. The principal investigator must tailor each point individually to the specific study.

2. Procedural Consent Requirements

In Section V, item 11 describe the procedures you will use to obtain and document informed consent and/or assent. Attach copies of the consent forms that you will use. The UNO Human Subjects website has additional information on sample forms and letters for obtaining informed consent. In the case of secondary data, please attach original informed consent or describe below why it has not been included.

Consent forms must include the following items:

☐ The name, campus address, and campus phone number of the principal investigator and alternative contact persons if applicable (e.g., graduate research assistants). In order to protect the privacy of investigators, investigators are not allowed to give participants their home addresses or home telephone numbers.

☐ An explanation of the purpose(s) of the research

☐ The expected duration of the subject's participation

☐ A description of the procedures to be followed

☐ Identification of any procedures which are experimental

☐ A description of any reasonably foreseeable risks or discomforts to the subject

☐ A description of any benefits to the subject or to others which may reasonably be expected from the research

☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

☐ For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

☐ The statement: "**Please contact Dr. Roberto Refinetti (504-280-6291) at the University of New Orleans for answers to questions about this research, your rights as a human subject, and your concerns regarding a research-related injury.**"

☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise

entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

- ☐ A statement regarding the amount of financial compensation to be given for the time spent participating in the research project, if applicable.
- ☐ All consent forms must be on University of New Orleans letterhead. Electronic forms submitted for IRB approval do not have to be on letterhead, but it should be noted on the forms that they will be distributed on letterhead.

Sample consent forms can be found on the Human Subjects website. Assent forms should contain as many of these items as possible, written in a language suitable for the subject population.

3. Requests for Consent Waivers

In rare instances, investigators may request a consent waiver. See Informed Consent FAQs for a summary of the federal code documenting criteria under which written consent may be waived.

G. Data Use

1. Data use

For item 12, check the boxes corresponding to each way in which the data collected will be used.

2. Data protection

Describe all steps you will take to ensure the confidentiality of participants and the data. Be thorough! Describe how you will safeguard the data, including how you will protect identifying information. Indicate where and how you will store the data, how long you will retain it, when and how you will destroy the data. Describe procedures for each type of data collected (e.g., questionnaires, audiotaped transcripts, videotape).

H. Signature Page/ Principal Investigator's Assurance

All principal investigators must read and type their name in the assurance document. Submission via e-mail serves as an electronic signature of the PI's assurance.

I. Application checklist

A checklist is provided on the last page of the application form.