Checklist for Investigators

Necessary documents which need to submitted to the IRB committee.

1. **For Exempt Review**
   - ☐ Institutional Review Board Application form **(see criteria for acceptable exempt reviews on page 3 and 4).**
     - Supporting Documents
     - ☐ Investigator's Assurance & Confidentiality Agreement form
     - ☐ Certification of Exemption form
     - ☐ Instrument(s) (include questionnaire, interview guide, therapeutic exercise protocols, tests, etc.)
     - ☐ Document(s) indicating authorization from participating institutions (e.g., IRB approval letter(s) Institutional HIPAA forms)

2. **For Expedited or Full Review**
   - ☐ Institutional Review Board Committee Application form
     - Supporting Documents
     - ☐ Investigator's Assurance & Confidentiality Agreement form
     - ☐ Consent
       - ☐ Consent to Participate in Research form (*studies where subjects are ≥18 years of age*)
       - ☐ Parental Permission/Informed Consent form*
       - ☐ Assent to Participate form* *(*For studies where subjects are 17 years of age or younger*)
     - ☐ Instrument(s) (include questionnaire, interview guide, therapeutic exercise protocols, tests, etc.)
     - ☐ Document(s) indicating authorization from participating institutions (e.g., IRB approval letter(s), Institutional HIPAA forms)

3. **For Grant Proposals**

Health and Human Services (HHS) proposed or funded projects (Federal grants). HHS regulations require that the IRB review the actual application or proposal for HHS support to ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB. Provide the cover page and narrative section of the proposal (specific aims, background, preliminary studies, research design/methods and human subjects) unless otherwise requested by the IRB.

☐ Not applicable

REMINDERS…PLEASE CHECK THE FOLLOWING BEFORE YOU SUBMIT YOUR APPLICATION:

- The Institutional Review Board Committee Application protocol is paginated (especially if additional pages are needed for the IRB Proposal Outline section of the application). All sections are complete to the detail requested .

- The consent and/or parental permission is written in the 2nd person, targeting a 6th to 8th grade reading level and includes all content areas with headings per the template.

- All supporting documents are submitted (survey/interview, recruitment flyers, letters). These documents should be separate from the main document,

- If submitting an application to additional [local] IRB(s), please submit applications to the additional IRB(s) and NPU IRB simultaneously so that the necessary revisions from both IRBs can be made on both documents (particularly consent forms) before resubmitting for approval. A copy of the approved IRB application and a letter of the approval letter from the additional IRB(s) should be submitted as soon as they are available.

- Keep a copy of the application materials for your records.

- For all applications, submit the Institutional Review Board Committee Application form, consent form(s) as appropriate, along with all supporting documents.
    - Be sure that both you and your advisoron provide signatures when all your documents are in order. Your signature indicates that you acknowledge:
        (1) This application represents an accurate and complete description of the proposed research;
        (2) The proposed research will be conducted in compliance with the recommendations of and only after approval has been received from the Institutional Review Board (IRB).
        (3) The principal investigator is responsible for reporting any serious or unexpected adverse events or problems to the IRB, for requesting **prior IRB approval for modifications, and for requesting continuing review and approval.**

Note: Information and guidance pertaining to the use of human subjects in research can be obtained through the NPU web site https://my.northpark.edu/organizations/Provost/Committees/IRB/ , by telephone (773) 244-5591, or by email irb@northpark.edu

RESEARCH QUALIFYING FOR EXEMPTION
FROM FEDERAL REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS

(Quoted from the Code of Federal Regulations, Title 45, Part 46. 101)

1. Educational Research Conducted in Educational Settings: "Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
2. Survey/Interview/Observational Research: "Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to subjects; and (ii) any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation."
3. Survey/Interview Research not Exempted in (2) Above: "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal Statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter."
4. Secondary Use of Existing Data: Research involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or though identifiers linked to the subjects." (See below for exceptions.)

NORTH PARK UNIVERSITY HEALTH PROFESSIONS EXCEPTIONS TO EXEMPTION: UNIVERSITY-LEVEL REVIEW REQUIRED

The following clarifying notes on and exceptions explain exemption categories. Studies of subjects involving 1a through 1e as listed below are NOT exempt and require IRB committee approval.

1. Research activities involving subjects except in the case of categories 1, 2, and 4, above:
    a. Minors under the age of 18
    b. pregnant women where pregnancy is the focus of the research;
    c. prisoners;
    d. fetuses in utero;
    e. persons incompetent to provide informed consent.
2. Research involving the use of medical, academic and other personal records (including psychiatric records) without consent.
3. Research involving the use of tissue obtained at autopsy.

GENERAL PRINCIPLES OF RESEARCH WITH HUMAN SUBJECTS

A. North Park University Health professions and the individual members of its faculty, appointed master's committee members, staff and student body recognize their responsibility for protection of the rights and welfare of human subjects.
B. Appropriate professional attention and facilities shall be provided to insure the safety and well being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
C. Research involving children (persons under 18 years of age), other legal incompetents, and persons unable to give informed consent may be approved if there is no risk of suffering for the individual subject. On the other hand, research involving a child, other legal incompetent, or a person unable to give informed consent should not be approved if there would be a significant risk of suffering without the possibility of benefit to the individual subject.
D. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
E. Before a subject participates in research involving risk or substantial stress or discomfort, this shall be carefully explained; the investigator shall be satisfied that the subject has understood the explanation; and the consent of the subject shall be obtained. The elements of informed consent are established by the federal government and by the University.
F. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or loss of benefits to which the subject is otherwise entitled, within the limits of the research.