

# Valparaiso University

## IRB Application Review Checklist

Date Submitted: \_\_\_\_\_ Date Reviewed: \_\_\_\_\_

Project Title: \_\_\_\_\_

PI Name: \_\_\_\_\_ Email: \_\_\_\_\_

Faculty Advisor (if PI is a student): \_\_\_\_\_ Email: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_ Email: \_\_\_\_\_

### Protocol Documents

Protocol documents include but are not limited to consent/assent forms (see below), recruitment materials, certificates of ethics training completion for all members of the research team, and written descriptions of the protocol.

- 1) ☐ **Yes** ☐ **No** Are certificates of completion of ethics training provided for every member of the research team?
  - a) ☐ **Yes** ☐ **No** ☐ **N/A** If the project is funded by the NSF, are certificates for RCR training provided for every member of the research team?
- 2) ☐ **Yes** ☐ **No** Description of all documents to be used in the study?
- 3) ☐ **Yes** ☐ **No** Are they all submitted?
- 4) ☐ **Yes** ☐ **No** Do the documents adequately describe the purpose of the study?
- 5) ☐ **Yes** ☐ **No** Do the documents adequately describe appropriate and relevant research design/methodology to answer the research question?

### Risk to Participants

**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- 6) ☐ **Yes** ☐ **No** The study poses minimal risk. If not, select type of risk: ☐ Physical ☐ Psychological ☐ Legal
- 7) ☐ **Yes** ☐ **No** Protocol does not involve sensitive topics.
- 8) ☐ **Yes** ☐ **No** Participation does not pose a risk to participants through loss of insurance or entitled services, social or self-stigma, or screening or diagnosis of diseases.
- 9) ☐ **Yes** ☐ **No** Protocol does not involve deception. If no, answer the following:
  - a) ☐ **Yes** ☐ **No** ☐ **N/A** Is the deception justified?
  - b) ☐ **Yes** ☐ **No** ☐ **N/A** Is the deception adequately addressed in the debriefing?
- 10) ☐ **Yes** ☐ **No** ☐ **N/A** Are there adequate protections for those who have diminished autonomy or are otherwise protected?

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- 11) ☐ **Yes**   ☐ **No**   Does the protocol adequately provide for monitoring the data collected to ensure participant safety?
- a) ☐ **Yes**   ☐ **No**   Are procedures adequate to maintain the subjects' confidentiality, anonymity, security, and privacy?
- b) ☐ **Yes**   ☐ **No**   ☐ **N/A**   Will the non-computer data be held in a secure manner?
- c) ☐ **Yes**   ☐ **No**   ☐ **N/A**   Will computer data be held in a secure manner?
- 12) ☐ **Yes**   ☐ **No**   Are participants protected from risk?
- 13) ☐ **Yes**   ☐ **No**   Are the risks to the subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably expected to result?

### Subject Selection and Recruitment

- 14) ☐ **Yes**   ☐ **No**   Are subjects targeted for recruitment done so for ease of access/convenience?
- 15) ☐ **Yes**   ☐ **No**   Is the selection of subjects equitable?
- 16) ☐ **Yes**   ☐ **No**   ☐ **N/A**   If any group is excluded, is there adequate justification for the exclusion?
- 17) ☐ **Yes**   ☐ **No**   Is there adequate consideration of cultural norms or other special circumstances?
- 18) ☐ **Yes**   ☐ **No**   The recruitment process does not include influence or coercion that unduly entices participation.
- a) ☐ **Yes**   ☐ **No**   If faculty or staff are recruiting students, have the potential human subjects been adequately protected from coercion or undue influence?
- b) ☐ **Yes**   ☐ **No**   ☐ **N/A**   If used, are participation incentives appropriate? Are tax/other ramifications explained?

### Consent/Assent Form and Process

**Consent/Assent Form** - Does the consent/assent form include:

- 19) ☐ **Yes**   ☐ **No**   Explanation of the purpose of the study?
- 20) ☐ **Yes**   ☐ **No**   Reason for participant's selection?
- 21) ☐ **Yes**   ☐ **No**   Description of expected benefits to participants?
- 22) ☐ **Yes**   ☐ **No**   Description of procedures?
- 23) ☐ **Yes**   ☐ **No**   Identification of any experimental procedure?
- 24) ☐ **Yes**   ☐ **No**   Expected length of time of participant's participation?
- 25) ☐ **Yes**   ☐ **No**   Description of foreseeable risks/discomforts?
- 26) ☐ **Yes**   ☐ **No**   Description of confidentiality of records, and identification of individuals with access to records?
- 27) ☐ **Yes**   ☐ **No**   Anticipated circumstances under which participant's participation might be terminated?
- 28) ☐ **Yes**   ☐ **No**   Statement that participation is voluntary and refusal or withdrawal results in no penalty?

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- 29) ☐ **Yes**   ☐ **No**   Offer to answer any questions?
- 30) ☐ **Yes**   ☐ **No**   Identification of contact person(s) with phone number and email (including faculty supervisors of students)?
- 31) ☐ **Yes**   ☐ **No**   IRB contact information?
- 32) ☐ **Yes**   ☐ **No**   Statement that copy of consent form will be given?
- 33) ☐ **Yes**   ☐ **No**   Assurance that the participant is at least 18 years of age, if necessary?
- 34) ☐ **Yes**   ☐ **No**   Is the form written in a manner that the participants can understand (reading level, fluency)?

**Consent/Assent Process**

- 35) ☐ **Yes**   ☐ **No**   Are the procedures adequate to obtain informed consent/assent?
- 36) ☐ **Yes**   ☐ **No**   The consent/assent process does not include influence or coercion that unduly entices participation.
- 37) ☐ **Yes**   ☐ **No**   ☐ **N/A**   If requested, is waiver of documentation or alteration of consent process provided and justified?

**IRB Decision and Comments**

**IRB Vote:**      ☐ Approved              ☐ Not approved              ☐ Return to PI for further information/clarification

**Comments:** \_\_\_\_\_

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