Appendix D

Procedures for Reviewing Human Subjects Research:
To be utilized by members of the Internal Review Board of the
Western Institute for Endangered Language Documentation

Updated April 30, 2023

Name of reviewer: _____

Part I Introduction

The Institutional Review Board (IRB) may approve a study, may exempt it from review, or may indicate that a study does not follow federal guidelines (a 'rejection'). The IRB will review a study with regard to the requirements of the *Common Rule*:

- The Common Rule is a federal policy that covers the protection of human subjects in research.
- The Common Rule requires that researchers obtain informed consent from each human subject for their participation in the research at the time data is recorded, OR
- If certain conditions are met, the IRB may waive the Common Rule requirement to obtain informed consent. The waiver is also implied if the IRB exempts the study from review (or exempts the study from the Common Rule).

Part II Background

Institutional Review Boards must comply with HHS and FDA regulations 45 CFR part 46 and 21 CFR parts 50 and 56, respectively, when reviewing research subject to those regulations. Both the HHS regulations at 45 CFR 46.103(b)(4) and (5) and the FDA regulations at 21 CFR 56.108(a) and (b) state that an IRB must follow written procedures for the following functions and operations.

- Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution;
- Determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
- Ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i.e., OHRP) for research conducted or supported by HHS, and FDA for FDA-regulated research of any:
    - Unanticipated problems involving risks to human subjects or others;
    - Instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;

- Suspension or termination of IRB approval.

Part III: Initial or renewing review (to be completed by the chair)
___Study is being reviewed for the first time.
___Study is being renewed (skip to Part VI unless there is a specific request for exemption).

Part IV: Determining appropriateness of IRB approval (to be completed by the chair)
_____If the study intends to present and publish its findings and if the subject involves (involved) human subjects, it needs to be reviewed by the IRB. For studies that do not meet these criteria, the IRB may choose to review them on a case-by-case basis.

Part V: Applying the common rule to exempt studies (to be completed by the chair)
Human subject: A living individual about whom an investigator conducts research to 1) obtain information or biospecimens through intervention or interaction with the individual or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

____ Does the research involve prisoners, children, fetuses, or the mentally disabled/compromised? If so, the study is to be rejected outright. At this time, WIELD cannot approve proposals that work with such human subjects.

____ Are the human subjects exempt?
Is the research conducted in educational settings and does it involve normal educational practices unlikely to adversely impact a student's opportunity to learn? Does the research involve the assessment of educators who provide instruction in the same setting?[1]
Answers of 'yes' indicate an exempt study.

____ Does the research involve interactions involving tests, survey procedures, interview procedures, or observation of public behavior (including recording)? If one or more of the following applies, it may be exempt of full review and instead subject to limited IRB review.[2]

1) Information is recorded in a way such that the identity of the human subjects cannot be easily ascertained. 2) Any disclosure of human subjects' response outside research would not put the subjects at risk of criminal or civil liability or be damaging to the subject's reputation, finances, employability, or education. 3) Secondary research with

[1] This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
[2] In linguistics, some anonymized phonetics studies qualify for exemption.

private information that is identifiable but can be adequately secured. There should be broad consent in such cases. The IRB will need to conduct a limited review to determine if the study fits one or more of the types of research in 1-3.[3]

____ If not exempt, the chair of the IRB may refer the proposal to full IRB review.

Part VI: Applying the common rule to non-exempt studies (to be completed by all IRB members)[4]

To approve a study, the following criteria must be met by the study. Please answer 'yes' or 'no' to the following questions after reviewing the study. If uncertain, answer 'no.' For answers of 'no,' please specific why in a separate document to the chair.

___ Risks[5] to subjects are minimized.

___Is the research hypothesis clear?

___Is the study design appropriate to prove the hypothesis?

___Does the research design minimize risks to subjects?

___Is there appropriate use of the exclusion criteria? Do the criteria serve to minimize risks? Can the study be better conducted another way?

___Risks should be estimated in magnitude and severity, particularly with regard to how similar the study would be to routine procedures or daily life.

___ Risks to subjects are reasonable in relation to anticipated benefits.

___Benefits are typically for others, and a better study has benefits to the participants themselves.

___If consultants are shouldering the burden of time, travel, cost, etc., the PI should state what will be done to lessen those burdens.

___If compensation is offered in the form of money, resources, or a combination of the two, such compensation should be adequate to local expectations and needs.

___ Selection of subjects is as egalitarian as the research situation allows.

___The target population is stated.

___There are additional safeguards for subjects likely to be vulnerable to coercion or undue influence.

___The target population is appropriate for answering the research question.

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[3] *Identifiable private information* refers to information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

[4] Studies already completed should be treated with regard to their past adherence to stipulations set out here.

[5] The possibility that something unwelcome or unpleasant will occur.

___The inclusion criteria are adequate for the needs of the study.

___ Informed consent will be obtained to ensure safety of subjects. Note that consent may be recorded by audio or given in written form.

___PI has stated how consent will be obtained.

___Informed consent must provide information 1) needed for an informed decision about participation, 2) in a language understandable to the potential participant, and 3) be presented under circumstances that promote voluntariness.

___Those who may be unable to volunteer truly (such as those with impaired decision-making) are excluded from the study.

___Those who are vulnerable for economical or educational reasons have safeguards in place.

___Information needed is defined as information a reasonable person would want to have in order to make an informed decision, and the information should be of sufficient detail and should be organized and presented in a way that facilitates understanding of why one might or might not want to participate.[6]

(___Consent forms in a language other than English are translated for the IRB.)

___ Adequate provisions for data monitoring ensure safety of subjects.

___There is a Data Safety Monitoring Plan (DSMP).

___The DSMP prevents personally-identifiable data from unauthorized access or use.

___Any special privacy and confidentiality issues are properly addressed. There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data.

___ Vulnerable populations (prisoners, children, and the mentally disabled) are excluded from the study.

Attach any questions or considerations to this questionnaire in a separate document. These concerns should be addressed to the chair of the IRB.

Chair of the Institutional Review Board
Timothy Henry-Rodriguez, Ph.D.

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[6] Scholars are encouraged to use common, everyday words. They are encouraged to avoid jargon and acronyms, and they are encouraged to use the active voice. Sentences and paragraphs should be short. Complex concepts should be broken into sections. Consent does not need to be written.

E-mail:
timothy.j.p.henry@gmail.com

Phone number:
+1 (951) 543-7299