CSUB HSIRB Limited IRB Guidance and Procedures

I. Introduction

In reviewing research, the HSIRB uses the following criteria to determine exempt status:

i. the risks to the subjects,
ii. the protection of the subjects' privacy interests,
iii. the confidentiality of private identifiable information,
iv. the anticipated benefits to the subjects and others,
v. the importance of the knowledge reasonably expected to result,
vi. the process to recruit and select subjects, and
vii. the process of informed consent

The above considerations are to ensure that the research complies with ethical principles delineated in the Belmont Report. Limited IRB review is a special case of Exempt review. The revised Common Rule allows certain research in which the primary risks relate to privacy and confidentiality to be considered Exempt from IRB review even when the identifiable information might be sensitive or potentially harmful if disclosed. To qualify for the exemption, the study must meet the standards of Limited IRB review.

For Exempt categories 2 and 3, the requirement for Limited IRB Review is triggered when:

1) The information obtained is recorded by the investigator in such a manner that the identify of the participants can be readily ascertained, directly or through identifiers linked to the subjects, AND

2) Any disclosure of the participants' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.

Limited IRB Review under Exempt categories 2 and 3 requires that the HSIRB determines that the criteria for approval under the revised Common Rule at 45 CFR 46.111(a)(7) is satisfied: 45 CFR 46.111(a)(7): When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

3) The exemption at § 46.104(d)(7) calls for a limited IRB review to make the determinations required at § 46.111(a)(8) regarding broad consent and protection of privacy and confidentiality.

- Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

- An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Example: if an investigator wants to store or maintain for secondary research purposes identifiable information in a databank or identifiable biospecimens in a pathology laboratory, this exemption could apply assuming all the relevant conditions described in 45 CFR 46.104(d)(7) are met.

II. Submission & Review Procedures—

Submission of the protocol is made through Cayuse IRB, the online application system, including all required documents. The required documents may include consent forms, completion report of CITI Human Subjects Protection training, interview guides, survey questionnaires, flyers, or other instruments to be used in the gathering of information.

As per 45 CFR 46.110(b)(1)(iii), the University Research Ethics Review Coordinator (RERC) will assign the protocol to two (2) reviewers for review via Expedited review procedures and provides an authorization letter to the Principal Investigator (PI). The reviewer may require revisions to the protocol prior to approval. The Limited IRB Review does not require consideration by a convened board; however, disapprovals must be made by the convened board.

III. Continuing Review and Review of Modifications

a. Approval of exempt status is valid for one year at which time the PI shall submit a request for renewal if there are plans to continue to collect data. In the request for renewal, the PI will provide an update of their project and communicate if there have been any adverse reactions.

b. When changes to research are proposed that fall within the scope of the Limited IRB Review requirement (e.g., storage or maintenance, privacy and confidentiality), the changes must undergo Limited IRB Review and be approved before implementation (except when necessary to eliminate apparent immediate hazard to participants). If the changes do not fall into the scope of Limited IRB review, the Modification will go through Exempt review.