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(ii) Any disclosure of the human subject would not reasonably place the subjects at risk of criminal or civil liability

educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §\_\_\_

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- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purpo
- (iv) The research is conducted by, or on behalf of, a federal department or

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may be determined by the IRB to pose ethical or other concerns and may be referred to the Chair and or Vice-Chair for guidance.

- 3.6. Upon submission of new IRB application by the investigator, IRB staff will enter the submission into the database system. IRB staff will conduct a review of the research proposal using the IRB checklist. When one or more of the exemption categories are applicable to the research, the IRB staff documents the applicable category(ies) using the checklist.
- 3.7. The PI may be required to make revisions, clarifications, or other requests before an exemption determination is final.
- 3.8. All exemption determinations are communicated to the investigator and includes the applicable category(ies) justifying the exemption determination.
- 3.9. Once an exempt determination is granted, proposed changes to a research protocol