**Saint Mary-of-the-Woods College**

**Institutional Review Board**

**FORM D: REQUEST FOR LIMITED STATUS**

Investigator: Enter investigator name here. Date: Enter date here.

Title of Research: Enter title of research here.

Please indicate research activities (show number and sub-number)Click or tap here to enter text.

Limited IRB review is review by an IRB Chair or designated IRB member as a condition of exemption for categories 46.104:

1. (d)(2)(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 § \_\_.111(a)(7) (HHS 2017)”.
2. (d)(3)(i)(C) “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 § \_\_.111(a)(7) (HHS 2017)”.
3. (d)(7) “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 § \_\_.111(a)(8) (HHS 2017)”.
4. and (d)(8) “Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   * 1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § \_\_.116(a)(1) through (4), (a)(6), and (d);
     2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § \_\_.117;
     3. An IRB conducts a limited IRB review and makes the determination required by § \_\_.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
     4. 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 (HHS 2017).

The new limited IRB review process is intended to “ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens” (HHS 2017).

In addition to other criteria, limited IRB review is also needed to ensure respect for subject’s autonomy and that the research conducted is within the scope of broad consent (HHS 2017) for both:

* Category 7 (the category that requires broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens)
* Category 8 (the category that requires broad consent for secondary research use of identifiable private information or identifiable biospecimens)

Limited IRB review involves making and documenting these determinations. It is a conditional review for exemption.