



Limited IRB Review
Approved November 10, 2017, Amended July 2, 2018

Applications qualified for limited IRB review will use an exempt streamlined application and will be granted all the benefits of exempt applications (fewer amendments required, no expiration date, etc.). The limited IRB review is used to satisfy exemptions 2, 3, 7, and 8. More information about the conditions needed for a limited review can be found in the exemption procedures (we will link).

Applicant Procedures:

1. In IRBManager, complete the Exemption Worksheet located on the Review Type Determination page to ascertain if your study qualifies for an exemption
2. If you determine from the worksheet that the study qualifies for an exemption and requires a limited review, you will select the Exempt box (as directed in IRBManager), which will open the streamlined exempt application.

La Verne IRB Procedures:

1. The IRB Analyst will verify the application must receive and is qualified for a limited review.
2. The application will go through the pre-review process by the IRB Analyst to identify any areas of revision (e.g., missing documents, unanswered questions, etc.) needed prior to a limited review and request such revisions.
3. The IRB Analyst will assign the Lead and Second IRB reviewers from the pertinent Area (college) for exemptions 7 and 8. The Chair is empowered to individually review exemptions 2 and 3 as a limited review.
4. The Lead and Second IRB reviewers (or Chair) will review the application to ensure: 1) the study meets the criteria for the exemption to which the applicant applied, 2) proper privacy and confidentiality procedures are in place for the study (applicable to exemptions 2, 3, and 8; (§ __.111(a)(7)), 3) appropriate broad consent was obtained that is consistent with the proposed research (exemption 8), and 4) for exemption 7 only, storage and maintenance procedures are adequate to protect the confidentiality of the human subjects and for an appropriately prepared broad consent as stated in § __.111(a)(8) (listed below):
 - a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § __.116(a)(1)-(4), (a)(6), and (d) (will link broad consent policy)
 - b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § __.117 (we will link to broad consent policy); and
 - c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

5. The Chair will review the application after the Area reviewers for the same 2 items as the reviewers, and based on the reviewer and Chair findings, will either return the application to strengthen the confidentiality procedures, make an exempt determination, or request the applicant apply as an expedited application.
6. The IRB Analyst will issue an exempt determination letter that reads a limited review was conducted.