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Single IRB Exception Determinations

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- Exception determinations. Please note that the exceptions to the single IRB review requirement are not intended to be mutually exclusive, and a study might be eligible for more than one of the exceptions.
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Background

The revised Common Rule (i.e., the 2018 Requirements) requires at 45 CFR 46.114(b) that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Federal department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States.

The regulations at 45 CFR 46.114 regarding cooperative research appear below. [Note that 45 CFR 46.114(b)(2)(ii) allows Federal departments and agencies supporting or conducting the research to determine and document that the use of a single IRB is not appropriate for the particular context.]

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

The compliance date of 45 CFR 46.114(b) of the 2018 Requirements was January 20, 2020. For studies subject to the 2018 Requirements:

- Reliance on a single IRB of record in cooperative research was optional before January 20, 2020, even for research subject to the 2018 Requirements.
- Reliance on a single IRB of record in cooperative research was required beginning January 20, 2020, unless the study meets the criteria for an exception described in §46.114(b)(2) of the 2018 Requirements.

The requirement for the use of a single IRB in cooperative research only applies to U.S. institutions and the portion of the collaborative research conducted within the United States.

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