Exceptions to the Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Nov 2, 2020

NOT-OD-21-006 provides information regarding NIH implementation of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) determination of Exception to the Single IRB Review Requirements for Certain HHS-conducted or Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak.

An exception is appropriate for cooperative research:

1. That is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency as declared by the Secretary of Health and Human Services at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx;
2. Where reliance on a single IRB would not be practical* and
3. For which the HHS division supporting or conducting the research approves of the use of this exception

*Scenarios for which OHRP anticipates it may not be practical to rely on use of a single IRB for multi-site, cooperative research trials during the ongoing COVID-19 pandemic include (but are not limited to):

1. Trials for which timely administration of an intervention for the rapidly emerging COVID-19 outbreak is paramount, but:
   1. research sites cannot be identified in advance due to the unpredictable nature of the exact location of the outbreak and patients cannot be moved to an existing trial site or to a newly established site without further increasing public health exposure risks; or
   2. institutions lacking existing reliance agreements, especially those in underserved or under-resourced areas, may face delays in starting the trial and in administration of the intervention while reliance agreements are negotiated.
2. Trials leveraging existing federally-supported trial networks to maximize access to appropriate patients, but where each network is operating under a different single IRB of record and negotiating reliance agreements between the networks and single IRBs could reduce the ability of qualified sites to access appropriate patients at the correct stage of disease.
3. Trials in which a federal research agency wishes to participate as a research site with
non-federal (but federally-supported) sites but is legally prohibited from agreeing to
certain terms in reliance agreements required by the non-federal sites.

4. A cooperative research study supporting the response to the COVID-19 outbreak in
which the lead site is engaged in administration of an intervention and in addition is
receiving study-wide identifiable samples and/or data for the purposes of determining
risk factors linked to COVID-19 disease susceptibility, severity, outcome, or for
developing potential diagnostics or therapeutics. The sites that would be engaged in the
research may include institutions that do not have standing reliance agreements within a
research network and establishing new reliance agreements would cause unacceptable
delays as well as result in a lost opportunity to collect critical COVID-19 samples and
data.

5. Trials in which the lead site or IRB is unable to provide oversight due to disruption in
operations caused by the COVID-19 public health emergency, but other sites can
continue, and selecting another site as the IRB of record would require renegotiation of
reliance agreements with a new IRB of record, and the study would otherwise be
required to halt until such agreements were in place.

Note that this exception determination is only made for purposes of section 46.114(b)(2)(ii) -
namely, for determining whether certain cooperative research may be excepted from the
single IRB mandate. This exception determination does not prevent, nor should it be viewed
as discouraging, the voluntary use of a single IRB in cooperative research subject to the 2018
Requirements that would fall into the above category. HHS fully expects use of single IRB
where possible even during the COVID-19 public health emergency. Approved use of the
flexibilities provided under this exception do not change any other obligations under the 2018
Requirements.

NIH Exception Request Content Requirements

- Justification as to why the study meets the exception criteria defined by OHRP
- Include the name of the site(s) for which an IRB other than the single IRB of record is
  proposed to review the study for the site(s).

Pre-award Exception Requests (for Federal Contracts follow instruction outlined in the RFP)

- Provide exception request and required justification in the Other Attachments section of
  the Research & Related Other Project Information form in the grant application
- Name the PDF document ?SIRBexceptionrequest.pdf and follow instruction in the
  NIH Application Guide
- Proposed budget in the application or contract proposal should reflect all necessary
  single IRB costs. Applicants and offerors should not assume that an exception will be
  granted when considering costs to include in the budget

Post-Award Exception Requests

- Submit a prior approval request in writing to the Grants Management Officer (GMO) for
  grants or to the Contracting Officer (CO) for contracts
Requests must include appropriate justification as to why the study meets the exception criteria defined by OHRP.
Requests must be submitted no later than 30 days prior to the proposed change.
Requests must be signed by the Authorized Organization Representative (AOR), please work with your assigned OSR Staff to expedite these requests.

Please direct all inquiries to: SingleIRBPolicy@mail.nih.gov