
Nov 6, 2020

NOT-HS-21-002 provides information regarding the Agency for Healthcare Research and Quality (AHRQ)'s 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 and 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.

AHRQ 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 Section 3.2 under G 500 - PHS Human Subjects and Clinical Trials Information in the grant application.
- Name the PDF ?SIRBexceptionrequest.pdf? and follow instructions in section 3.2 for AHRQ applicants to submit an exception request, instead of a single IRB plan.
- Proposed budget in the application or contract proposal must reflect all necessary single IRB costs without an approved exception. Applicants and offerors should not assume that an exception will be granted when considering what single IRB 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: HopeHongzhu.He@ahrq.hhs.gov