HRP-841 | 3/29/2024

CHECKLIST: Criteria for Relying on an External IRB

The purpose of this checklist is to provide support for HRPP staff to determine eligibility when reviewing requests to rely on an External IRB. This checklist must be used. All determinations for reliance on an external IRB are made on a case-by-case basis. The HRPP staff saves the completed checklist in the ETHOS record.[[1]](#endnote-2) IRB leadership may determine (in consultation with other institutional stakeholders as appropriate) that the use of an external IRB is appropriate for the research even if the considerations below do not apply.

Submission Information

|  |  |
| --- | --- |
| **Basic Information** | **Submission Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text.  |
| Person Completing Checklist (Name): | Click or tap here to enter text. |
| Date Checklist Completed: | Click or tap here to enter text. |

1. exclusion Criteria

If any of the following are checked, the institution will not rely on an external IRB.

[ ]  The institution does not maintain an OHRP-approved Federalwide Assurance (FWA).

[ ]  The institution is not engaged in the research activities.

[ ]  The study is determined to not involve Human Research.

[ ]  The study is determined to be Exempt.[[2]](#endnote-3)

[ ]  The institution resides outside of the United States (e.g. foreign, non-domestic institution).

[ ]  The study is a single-site study where no institutional conflict of interest exists.

[ ]  The study involves human embryos or embryonic stem cells or fetal tissue.

[ ]  The study was disapproved or terminated by the UMN IRB or an external IRB.

[ ]  The study is already under UMN IRB review or oversight and is not required to transition to an external IRB.

[ ]  An agent of the University of Minnesota, regardless of whether that individual is a member of the study team, holds an Investigational New Drug (IND) or an Investigational Device Exemption (IDE) for a/the study test article.[[3]](#endnote-4)

[ ]  The principal investigator or co-investigator is restricted.

[ ]  The principal investigator and/or co-investigator have not completed requirements related to an IRB determination of serious or continuing non-compliance for a study that they are listed as study personnel.[[4]](#endnote-5)

[ ]  The principal investigator and/or co-investigator have had a study suspended or terminated by the IRB within the past year.[[5]](#endnote-6)

1. INCLUSION CRITERIA to RELY ON A Commercial IRB

The institution will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether to cede IRB review to a Commercial IRB (e.g., Advarra IRB, WCG, etc.). (At least one of the following considerations should be true)

[ ]  The project is commercially sponsored research.

[ ]  The institution’s IRB lacks sufficient expertise or resources to conduct the IRB review.

[ ]  The institution is the lead site of a Multi-Site Study and the institution has elected to use a commercial IRB for the review of the study.

[ ]  The University of Minnesota has an institutional conflict of interest.

[ ]  Other relevant considerations: Click or tap here to enter text.

1. INCLUSION CRITERIA FOR RELYING on AN OTHER (NON-COMMERCIAL) IRB

The following requirements that must be met in order to cede IRB Review to an institution with a valid OHRP-approved Federalwide Assurance (FWA).

[ ]  Ceding IRB review is mandatory (e.g. by a federal agency or other agency).

Comments: Click or tap here to enter text.

[ ]  The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study.

Comments: Click or tap here to enter text.

[ ]  The reviewing IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns (e.g., recruitment of socially or economically disenfranchised populations, local cultural mores, or unique clinical circumstances).

Comments: Click or tap here to enter text.

[ ]  The external IRB is AAHRPP-accredited (or is able to document comparable standards).

Comments: Click or tap here to enter text.

1. OTHER CONSIDERATIONS FOR RELYING on AN EXTERNAL IRB

The following considerations may impact the decision to allow reliance on an external IRB. HRPP leadership may be consulted to determine whether reliance is appropriate if any of the following are checked.

[ ]  The principal investigator and/or other study team members have an individual conflict of interest in relation to the study, such that a management plan has been required by the Office of Institutional Compliance (OIC).

[ ]  The objectives, focus of the protocol, or study design (gene transfer, research that requires review by the University’s Institutional Biosafety Committee (IBC), high-profile research otherwise subject to additional institutional policy, research involving natural emergencies, disasters, or pandemics, phase 1 research (See “Manual: HRPP Manual (HRP-101)”).

[ ]  HHS-supported research that will likely require the Secretary (through OHRP) to certify or review the IRB’s determinations and findings.

[ ]  Implications for the institution of the decision, including:

a) analysis of lost research opportunities (i.e., unwillingness of a sponsor or funder to allow local, non-ceded IRB review);

b) the additional administrative time and costs associated with establishing authorization agreements.

[ ]  Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB.

Additional Comments (if applicable): Click or tap here to enter text.

1. This document satisfies AAHRPP element I-9 [↑](#endnote-ref-2)
2. For a HHS funded or supported, non-exempt collaborative research study involving human subjects, any site that is engaged must rely on the sIRB for review. If the research as a whole is non-exempt and an institution is engaged in the research (even if their portion of the research is exempt), then the institution must rely on the sIRB. *(Correspondence with OHRP, September 27, 2022)*. [↑](#endnote-ref-3)
3. In most cases, reliance will not be allowed unless there is an institutional conflict of interest. [↑](#endnote-ref-4)
4. This information is collected through the HRP-829 – FORM - PI Attestation. [↑](#endnote-ref-5)
5. If a study was suspended and then re-opened during the last year, the request to rely on an external IRB for IRB review should be evaluated by HRPP leadership. [↑](#endnote-ref-6)