

WORKSHEET: Considerations for Ceding IRB Review

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13.202 (HRP-832)	11/21/2024	1 of 1

The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite's IRB to serve as sIRB. This worksheet may be used as a working document for the Reliance Administrator or IRB staff during the process of evaluation and may be saved until a determination has been made.

1 General Exclusion Criteria. The following are circumstances in which the institution <u>will not</u> cede IRB review for a multisite study.	
<input type="checkbox"/>	The institution does not maintain an OHRP-approved Federalwide Assurance (FWA)
<input type="checkbox"/>	The institution is not engaged in the research activities.
<input type="checkbox"/>	The study is determined to not involve <u>Human Research</u> .
<input type="checkbox"/>	The study is determined to be Exempt.

2 Considerations to Cede IRB Review to Commercial IRBs. 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, WIRB, etc.). (At least one of the following considerations should be true)	
<input type="checkbox"/>	The project is commercially sponsored research
<input type="checkbox"/>	The institution's IRB lacks sufficient expertise to conduct the IRB review
<input type="checkbox"/>	The institution is the lead site of a multi-site project and the IRB lacks sufficient resources to provide oversight of the project
<input type="checkbox"/>	Other relevant considerations: Click or tap here to enter text.

3 General Considerations for Ceding IRB Review to Other (Non-Commercial) IRBs. The following are additional considerations for evaluating the institution's willingness to cede IRB Review to an institution with a valid OHRP-approved Federalwide Assurance (FWA). (At least one of the following considerations should be true)	
<input type="checkbox"/>	Ceding IRB review is mandatory or optional. Comments: Click or tap here to enter text.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	Whether ceding IRB review could create or mitigate unique institutional risks, such as conflicts of interest Comments: Click or tap here to enter text.
<input type="checkbox"/>	The financial implications of the decision—this includes: 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 Comments: Click or tap here to enter text.
<input type="checkbox"/>	Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB Comments: Click or tap here to enter text.