



Opus Institutional Review Board

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OPUS IRB¹ UTILIZATION OF A CENTRAL/INDEPENDENT IRB AUTHORIZATION AGREEMENT

Protocol Name	
Sponsor	
Principal Investigator Name	
Address	
Phone Number	
Email	

For a Study Site that is a Private Practice

Check all options that apply

<input type="checkbox"/>	No local non-commercial IRB exists to review research performed.
<input type="checkbox"/>	My study subjects will not receive study related therapies or key study related procedures in a facility affiliated with a local, non-commercial IRB.
<input type="checkbox"/>	Opus IRB is geographically the local board for our site.
<input type="checkbox"/>	Opus IRB is the usual and customary IRB/IEC used by our site.
<input type="checkbox"/>	Other: (Please specify)

Signature of Principle Investigator

Date

¹ IORG0005982, IRB00007215

When Study Site is an Institution (e.g. Hospital, University)

Our institution does not have an IRB and our institution agrees to accept the decisions of Opus IRB.

Institution Representative/IRB Signature

Date

We are aware that the above named protocol is being conducted at our institution and agree to defer authority to Opus IRB.

Institution Representative/IRB Signature

Date

Division of Responsibilities between the Central IRB and Local Institutions

The following Division of Responsibilities is based on the premise that Opus IRB's primary function is IRB review of research studies and that the local institution's primary function is consideration of local context and oversight of local performance of these studies.

The responsibilities of Opus IRB are to:

- 1) Perform initial full board review of new studies, discuss any issues with the sponsor, require modifications to be made by the sponsor, and make a final decision of approval or disapproval of the study;
- 2) Conduct continuing review;
- 3) Conduct review of study amendments;
- 4) Conduct review of individual adverse event reports for studies without a Data and Safety Monitoring Board (DSMB);
 - a) Individual adverse event reports distributed by the sponsor which have a DSMB do not receive Opus IRB review. Opus IRB reviews the DSMB report and the study report at the time of continuing review as recommended in the following guidances: OHRP Guidance "OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" dated January 15,

2007, FDA Guidance “Adverse Event Reporting to IRBs – Improving Human Subject Protection” dated January 2009, and NIH Guidance “Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials” dated June 11, 1999;

- 5) Conduct review of all other documents submitted by the sponsor;
- 6) Provide the CIRB application, primary reviewer reviews, outcome letters, and other relevant documents to the designated representative/IRB at the local institution;
- 7) Notify each local institution of new materials that have been reviewed for an active study and any changes in the study approval status;
- 8) Maintain an Opus IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
- 9) Make available to the local institution the roster of Opus IRB membership and the Opus IRB Standard Operating Procedures;
- 10) Ensure that Opus IRB members receive orientation and continuing education on topics relevant to human subjects protection;
- 11) Notify the local institution immediately if there is ever a suspension or restriction of Opus IRB’s authorization to review a study; and
- 12) Notify the local institution of any changes in Opus IRB SOPs that might affect the institution’s reliance on Opus IRB reviews or performance of the research at the local institution

The responsibilities of the local institution are to:

- 1) Ensure the safe and appropriate performance of the research at its institution. This includes, but is not limited to, monitoring protocol compliance, managing any major protocol violations, managing any serious adverse events occurring at the institution, ensuring qualifications of research staff and providing a mechanism by which complaints about the research can be made by local study participants or others.
- 2) Maintain records for each Opus IRB approved study opened at your institution as per your local institution policy.
- 3) Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 56; and
- 4) Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.

Further Delineation by Topic (alphabetically)

HIPAA

Compliance with HIPAA regulations are considered local context issues and remain the purview of the local institution.

Incompetent Adults

Opus IRB determines whether 'individuals with impaired decision making capacity' as a category are eligible for a study. The local institution must follow state law and institutional policy regarding the authority of legal guardians to consent to research, as well as documentation of proxy consent.

Informed Consent Document

As part of facilitated review, the local institution may:

- Add local boilerplate additions to the informed consent document to comply with state or local laws, institutional requirements, or IRB policies
- Make minor word substitutions or additions in the informed consent document to facilitate better comprehension by the local population as long as the proposed changes do not alter the meaning of the Opus IRB approved contents.

The informed consent text may not be otherwise deleted or contradicted. Revisions/changes to the informed consent document other than those described above require full Board review at the local level, and facilitated review may not be used.

The translation of the informed consent document is the responsibility of the local institution.

Serious Adverse Events

Serious adverse events that occur at the local institution must be reported to the local IRB as per local institutional policy and should not be reported to the Opus IRB. The investigator should continue to report SAEs to the sponsor per the study protocol.

Reporting Unanticipated Problems

Local unanticipated problems occur at and are limited to a specific institution. The local institution is responsible for managing these according to its FWA and local institutional procedures. If the local institution determines that an unexpected incident, event or outcome meets the regulatory definition of unanticipated problem, it is the local institution's responsibility to report it to OHRP/FDA.

Unanticipated problems within the purview of the Opus IRB are those unexpected incidents, events or outcomes which the sponsor identifies and which impact the trial nationally. These are reviewed by Opus IRB and Opus IRB accepts the responsibility to ensure reporting to the appropriate agency, i.e. OHRP and/or FDA.