HRP-833 | 12/13/2023

**FORM: Local Compliance Assessment**

**Instructions:**

Indicate the type of changes you will or have made to this study that is relying on an external IRB. Investigators may have ongoing obligations to ancillary reviewers for studies relying on an external IRB. External IRB update submissions will not be held by the IRB for completion of ancillary reviews. Investigators are responsible for working with those ancillary review groups for what may be required over the course of the study (e.g., Fairview Research Administration, Radiation Safety, CPRC, etc.).

1. **General Information**

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| --- | --- |
| **ETHOS STUDY ID Number:** | Click or Tap to Enter Text |

1. **Ancillary Reviews** Identify the ancillary reviews that must be notified of the changes that will or have been made. The IRB will not hold the review for the completion of ancillary reviews for external IRB updates submissions.

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| **Check Box if Applicable** | **Ancillary Review Applicability: Does the change or update impact any of the following ancillary reviews?** | **Additional Contact / Resource Information** |
|  | The changes/updates do not impact any ancillary reviews. | |
|  | Gillette: Gillette resources, staff or locations | *Contact:* [*research@gillettechildrens.com*](mailto:research@gillettechildrens.com) |
|  | Fairview: Epic, or Fairview patients, staff, locations, or resources | *Contact:* [*ancillaryreview@Fairview.org*](mailto:ancillaryreview@Fairview.org) |
|  | Regulatory Review of Drugs/Devices: Evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection | *Contact:* [*medreg@umn.edu*](mailto:medreg@umn.edu)  *See:* [*https://policy.umn.edu/research/indide*](https://policy.umn.edu/research/indide) |
|  | Cancer Protocol Review Committee: Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco? | *Contact:* [*ccprc@umn.edu*](mailto:ccprc@umn.edu) |
|  | Radiation Safety (AURPC): Include the use of radiation?  (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *Contact:* [*barmstro@umn.edu*](mailto:barmstro@umn.edu) |
|  | Center for Magnetic Resonance Research (CMRR) or MR at Masonic Institute for the Developing Brain (MIDB) as a study location? | *Contact:* [*ande2445@umn.edu*](mailto:ande2445@umn.edu) |
|  | Institutional Biosafety Committee: Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *Contact:* [*IBC*](https://research.umn.edu/units/obao/institutional-biosafety-committee/ibc-overview) |
|  | OBAO: Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *Contact* [*OBAO*](https://research.umn.edu/units/obao/about-us/contact-us) *for submission instructions and guidance* |
|  | Health Information Privacy and Compliance Office: Include PHI or are you requesting a HIPAA waiver? | *Contact:* [*privacy@umn.edu*](mailto:privacy@umn.edu) |
|  | Controlled Substances: Include the use of a controlled substance? | *Contact:* [*cshelp@umn.edu*](mailto:ancillaryreview@Fairview.org) |
|  | CTSI Monitoring Services: Plan to use CTSI Monitoring services, and/or have an IND, IDE, or designated NSR-IDE by the UMN IRB? | *Contact:* [*fencl003@umn.edu*](mailto:fencl003@umn.edu) |
|  | BPIC: Data from CTSI Best Practices Integrated Informatics Core (BPIC)/Formerly the AHC Information Exchange (IE)? | *Contact:* [*bpic@umn.edu*](mailto:bpic@umn.edu) |
|  | BLS: Use the Biorepository and Laboratory Services to collect tissue for research? | *Contact:* [*BLS*](https://crsc.umn.edu/services/biorepository-and-laboratory-services) |
|  | Conflicts of Interest: PI/study team member COI change? | *Contact:* [*becca002@umn.edu*](mailto:becca002@umn.edu) |
|  | REDCap: Use of REDCap for e-consent | *REDCap Ancillary Review will be assigned to confirm external IRB approval status prior to moving your eConsent to production in* [REDCap](https://ctsi.umn.edu/tools/redcap)*.* |
|  | Indigenous Research: Collaborations with Tribal partners, Tribal communities, Tribal-serving institutions, or include focused recruitment of Indigenous Peoples? | *See* [*University of Minnesota Guidelines for Indigenous Research*](https://libguides.umn.edu/ResearchWithIndigenousPartners)*.* |
|  | CUHCC: [Community- University Health Care Center](https://www.google.com/url?client=internal-element-cse&cx=002834015805923805805:c-0k--9bdkk&q=https://cuhcc.umn.edu/&sa=U&ved=2ahUKEwistMi00onuAhWVGFkFHUbnAncQFjABegQIAhAB&usg=AOvVaw2R6-oZwyd0n55FZTLJdCRi) (CUHCC) resources or include access to patients or their data? | *Contact* [*hlogren@uumn.edu*](mailto:hlogren@uumn.edu) |