IRB Services Agreement between MCW and CW

Children's Wisconsin and the Medical College of Wisconsin entered into a research agreement that went into effect July of 2022, which specifies that CW will rely on the IRB services of the MCW pediatric IRBs as our primary IRBs of record. CW may also rely on other organization or independent IRBs to serve as the IRB of record for some projects as deemed appropriate by Children's Wisconsin HRPP leadership, such as when required by the Common Rule or NIH single IRB mandate (e.g. NCI IRB).

Consistent with the terms of the agreement, Children's Wisconsin maintains a Human Research Protection Program (HRPP), and its own FWA, to oversee research conducted in Children's Wisconsin space or with Children's Wisconsin data.

What is an Institutional Review Board?

The Institutional Review Board is an independent reviewing body ensuring that research involving human subjects is conducted ethically and with utmost consideration for participant welfare. This committee is made up of diverse members with a variety of expertise appropriate to the types of research being reviewed. Per regulations the IRB has a minimum of 5 members, including at least 1 non-scientist and 1 member representing the perspective of participants (community member). This member can also serve as the non-scientist member. 21 CFR 56.107 and 45 CFR 46.107.

- **Ethical oversight:** the primary responsibility of an IRB is to ensure that the ethical principles and regulatory requirements governing human subject research are upheld. This includes protecting participants from potential harm and ensuring their informed consent.
- **Protocol review:** IRBs review protocols to assess the scientific validity, relevance, and safety of the proposed study. They examine study design, methodology, data collection procedures and the potential risks and benefits involved.
- **Participant protection:** The IRB evaluates the level of risk and benefit associated with a study. They ensure that measures are in place to protect the participants' privacy, confidentiality, and well-being. Protocols involving vulnerable populations such as minors, prisoners, or pregnant women receive extra scrutiny and have additional regulatory protections that must be in place.
- **Regulatory criteria for approval:** In order to approve proposed human subject research, the IRB reviews the proposed protocol and consent documents against the regulatory criteria for approval (45 CFR 46.111/21 CFR 56.111). All criteria must be met in order for the IRB to approve the proposed human subject research.

- **Ongoing monitoring:** The IRB monitors the progress of approved studies and may conduct periodic reviews or audits to ensure compliance with ethical guidelines, regulations, and enrollment. They also assess any adverse events, unanticipated problems, investigator non-compliance, protocol deviations, or any unexpected outcomes that may occur during the course of the research.

Scope of authority of an IRB:

21 CFR 56.109 and 45 CFR 46.109. An IRBs scope is limited to oversight of research involving human subjects. Research determined to be exempt, or to not involve human subjects does not require IRB review and oversight, although different institutions may handle these determinations differently. The scope is also limited to making regulatory determinations about proposed human subject research. An IRB has the authority, based on federal regulations, to:

- Approve human subject research (including renewal of human subjects research prior to the expiration date determined by the IRB)
- Require modifications to human subject research.
- Disapprove human subjects research.
- Grant waivers related to Consent/assent/parental permission.
- Grant waivers related to HIPAA authorization (if also serving as the privacy board for an institution)
- Determine if reported non-compliance is serious or continuing.
- Determine if reported problems or adverse events constitute an Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO)

Note: an IRB is serving the institution in which the research is being conducted. An institution either has its own IRB, OR it decides on what IRB to rely on for the above regulatory determinations. It is the IRB's responsibility to be aware of and take any institutional policies, requirements, practice (i.e. Children's Wisconsin local context) into consideration when reviewing research to be conducted at that institution.