Guidance
Departmental Sign-Off for Research

Purpose

The purpose of this guidance is to help investigators and study team members understand what is expected when requesting Children's Wisconsin administrator/CW department acknowledgement.

The CW HRRP has a local context requirement that research involving human subjects have departmental administrative review (department, laboratory, unit or clinic) when any procedures, tests, medications and/or space are to be provided by Children's as part of the research activities. The purpose of this review is to ensure the administrators of departments are aware of the impact that the proposed research study may have on the area for which they hold administrative responsibility.

It is important that each area involved in research understand their responsibility to protect the rights, safety, and welfare of each patient/potential research subject and individuals are cognizant of the resources that may be needed to conduct this study. In its deliberation, the HRPP and the IRB of record must take many items into consideration, including the ability of the institution to provide adequate facilities and staffing, in order for the research to receive IRB approval.

When a Children's Wisconsin administrator is approached by an investigator (or the investigator's staff) the items below require consideration when granting administrative acknowledgement (there may be additional considerations that are not addressed in this guidance). This guidance is only intended to facilitate the evaluation.

Some examples of how a research study can lead to a change in normal Children's Wisconsin ambulatory and inpatient unit processes:

- Operating suite or imaging managers, for instance, may need to adjust schedules or work with research teams if research activities may prolong a procedure beyond average timeframes.

- During surgery, a study may require recording of events or timelines which are not usually recorded. Researchers sometimes assume that operating room personnel will be able to focus on this data collection.

- Researchers may assume that unit staff will transport patients within the hospital for research procedures, which can involve repeatedly moving a patient from their home unit to Radiology or elsewhere and then back to the home unit. For a large hospital, this can involve considerable staff time spent away from the home unit, which may affect unit operations.

- An investigator may want a hospital unit to temporarily or permanently store blood or tissue samples, but the unit may not be equipped to do this in the manner required by the protocol.

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- Research teams may assume, without checking with hospital managers, that hospital staff (such as nurses, imaging technicians, respiratory therapists, phlebotomists) will perform research procedures of the kind they usually perform as standard clinical procedure.

- Researchers may assume, for example, that bedside nurses will perform frequent blood draws necessary for a pharmacokinetic sub-study. Unit managers, however, may not agree to commit nurses' time to this task, depending on the number and timing of the draws.

In order to ensure that Children's Wisconsin hospital units/clinics/departments are able to support your research, please be sure to discuss the protocol with the **Children's Wisconsin** leaders of any ambulatory or inpatient units where your research is anticipated to be conducted (this includes recruiting, consenting, sample/data collection or interventional procedures). IRB approval for your protocol does not mandate that hospital units support your research activities.

Study activities must be approved by the Children's Wisconsin leaders of the departments/areas where the research activity will take place - they must agree that the activity can be conducted in that space.

Examples include, but are not limited to:

- Nursing support (administration of study drug, additional assessments for study data capture, collection of blood/tissue samples to be performed by unit staff, etc.);

- Diagnostic procedures (Radiology, Pulmonary, etc.);

- Laboratory processing/services (phlebotomy, sample processing, specific lab tests, etc.);

- Pharmacy (study drug storage, dispensing, etc.);

- Procedure specific support (example: anesthesiology during a procedure);

- Pediatric Translational Research Unit support (Nursing support, BodPod access, etc.);

- Recruiting;

- Consenting;

- Survey/questionnaire completion;

- Blood samples and buccal swabs collected by your study's own staff.

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If in doubt about a specific research activity, please contact the Children's Wisconsin HRPP Office for guidance.

The CW HRPP, as part of the local context review, will look for sign off from affected departments using the attached attestation form, to be included in the package submitted to the IRB. Review of your protocol will be delayed if you do not have all needed approvals prior to submission to the IRB.

The individual that should be giving approval is the **Children's Wisconsin administrator** that provides leadership over the specific Children's area where the proposed activity will take place. Support from **Medical College of Wisconsin** faculty or staff, such as the provider serving as the department chair, medical director, etc. is important, but it is not sufficient for this purpose.

It is the PI and study team's responsibility to know who the appropriate Children's administrator is; the HRPP Office does not have this information readily available. If you are unsure, begin by reviewing the Department Directory search on Children's Connect.

When providing this approval, the leader is indicating the following:

- Awareness that study activities will take place in the Children's area;
- Awareness and agreement that patients in this area are being approached to participate in research;
- Confidence that the research activity won't disrupt daily operations in a negative way;
- Agreement that their area can support the research activity; that staff resources in the area are adequate and may be used for study activities as described in the protocol.

Any questions regarding this guidance can be directed to the Children's Wisconsin HRPP at CWHRPP@childrenswi.org or (414) 337-7133.

*****See next page for a sign off acknowledgment template *****

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Children's Wisconsin Administrative/Departmental Approval to Support Research

Department in which the research will be conducted, or services will be needed:

Children's Wisconsin Administrative Leadership for this department is:

Clinic/ambulatory service area manager is:

As the Children's Wisconsin Administrative leader I acknowledge and attest to the following:

- I have reviewed the protocol and details for the proposed research and have discussed the logistics with a member of the research team
- The CW department/ambulatory or inpatient service area has the resources to provide the required support for this research as described in the protocol
- I am in agreement with and support research activities, including interactions with subjects and their families, to occur in this space
- I attest that the proposed research activities as described should not disrupt daily operations in this area in a negative way

_____ _____

Administrator signature Date