JANUARY 2021 | VOLUME 7 | ISSUE 1

HUMAN RESEARCH NEWSLETTER

A QUARTERLY NEWSLETTER FROM
THE CHILDREN'S WISCONSIN HRPP/IRB

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WHAT'S IN STORE FOR 2021

2021 GOALS

2020 was a challenging year for research thanks to COVID-19, and this continues to alter how research is conducted. The Children's Wisconsin HRPP appreciates the cooperation and diligence of our entire research community in making sure research is conducted in the safest way possible during this pandemic.

As we welcome the arrival of 2021, we are excited to begin setting HRPP goals for the year. Here is a preview of what we will be working on:

- We continue to review and revise of all HRPP/IRB policies and SOPs.
  - Revisions do not reflect a change, but rather a clearer way to describe what we are already doing.
  - When complete and published, we will hold sessions to review the revised documents with research teams and answer questions.

Who is considered a Children's patient? A Children's patient is any person who is being seen for care at Children's Wisconsin, regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (pTRU) is available to provide these patient care services, or can direct you to appropriate personnel.

For more information on our education opportunities, visit our NEW Educational Offerings Connect Page!

- The launch of a new Research Proposal Application that will replace our current Protocol Summary.
  - We anticipate this will give our research teams more direction to be sure the submission provide the IRB with the information needed for approval, which should help improve time to final approval.
  - We have shifted and will be releasing this application in a document format that will be completed, saved, and uploaded to the submission package.
  - There will be a main application that is completed for all submissions, and a variety of additional supplements that are completed only if applicable.
  - There will be sessions held to orient research teams to this new application, answer questions, etc.

- A revision of the HRPP web pages.
  - Most of the content will be moving to the external Children's Wisconsin site for easier accessibility.
  - The information will be reorganized to improve navigation, locating specific content and tools to help with submission, especially for those new to our system.
  - This will continue to evolve and content will continually be added so keep checking back once the new pages are live.

ANNUAL CRI TOWN HALL

RESEARCH CONFERENCE

A reminder that the annual Children's Research Institute Town Hall will be held on Friday, February 12, 2021 from 12:00 PM -- 1:15 PM.

ON-GOING RESPONSE TO COVID-19

UPDATED GUIDANCE

Children's continues to revise COVID-19 Considerations for Researchers in response to the global pandemic. Whether you have institutional approval to conduct your research may have changed based on the status of the pandemic. Please review the Coronavirus (COVID-19) Considerations for Researchers Guidance closely before conducting any human subjects research activities. Effective 01/01/2021, you must work directly with your division/department and associated clinical areas to prioritize and plan for any study activities.

Reliance Questions? You can initiate the Reliance Request Process by visiting *our HRPP Connect Page*. Look under, "Reliance requests," on our homepage. You can find insight to the reliance process by viewing our flow sheet.

Questions, comments, or suggestions: Your thoughts and recommendations for future newsletter items are much appreciated. Please send your ideas and feedback to Michelle Martin, JC, CCRP, CIP at mmartin@chw.org.

DID YOU KNOW?

REMINDER

In order to maintain hospital accreditation and compliance with the Joint Commission standards it is crucial that any skill performed on a Children's patient is only performed by Children's employees or providers who have competencies on file.

Who is considered a Children's Patient? A Children's patient is any person who is being seen for care at Children's facilities regardless if it is for clinical or research care.

What does this mean for my research? The Pediatric Translational Research Unit (TRU) is available to provide these patient care services or can direct you to appropriate personnel.

***To register for education sessions*, visit our NEW** Educational Offerings Connect Page**.** Space is limited. For more information, visit us on Connect.

Join us for Open Office Hours! Open Office Hours are returning every Tue from 9:30 - 11:00 am via Zoom! Contact chwirb@chw.org to sign up.

Open Office Hours is a chance for study teams to drop-in for general questions and guidance, typically lasting no more than 15 minutes.

PEDIATRIC TRU

CELLULAR AND GENE THERAPY PROCESSING

Cellular and gene therapy studies are becoming more common, and the Pediatric Translational Research Unit has supported a few of these studies in the past few years. To do this in the safest manner, Children's has an approval process for taking on non-oncology gene and cellular therapy studies. Please send your protocol and investigator brochure to Dr. James Verbsky and Beth Gissibl before agreeing to use Children's as a site for your study.

DEPARTMENTAL SIGN-OFF FOR RESEARCH

NEW GUIDANCE

A requirement when submitting a research study to the Children's Wisconsin IRB is to obtain 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 are aware of the impact the proposed research 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 Children's IRB 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.

In order to ensure that Children's hospital units/clinics/departments are able to support your research, please be sure to discuss the protocol with the Children's 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 leaders of the departments/areas where the research activity will take place - they must agree that the activity can be conducted in that space.

Have complex questions? Consultations are available to study teams with complex questions that may take significant time to answer. To schedule a consultation, please complete our Consultation Request form on our *HRPP Connect Page*.

To ensure you're using the most current documents, always access our forms, templates, and documents directly from IRBNet.

Continues on next page.

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 Principal Investigator 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 Clinical Departments Landing Page on Children's Connect. See Departmental Sign-Off for Research Guidance for more information.

COURT-APPOINTED GUARDIANS

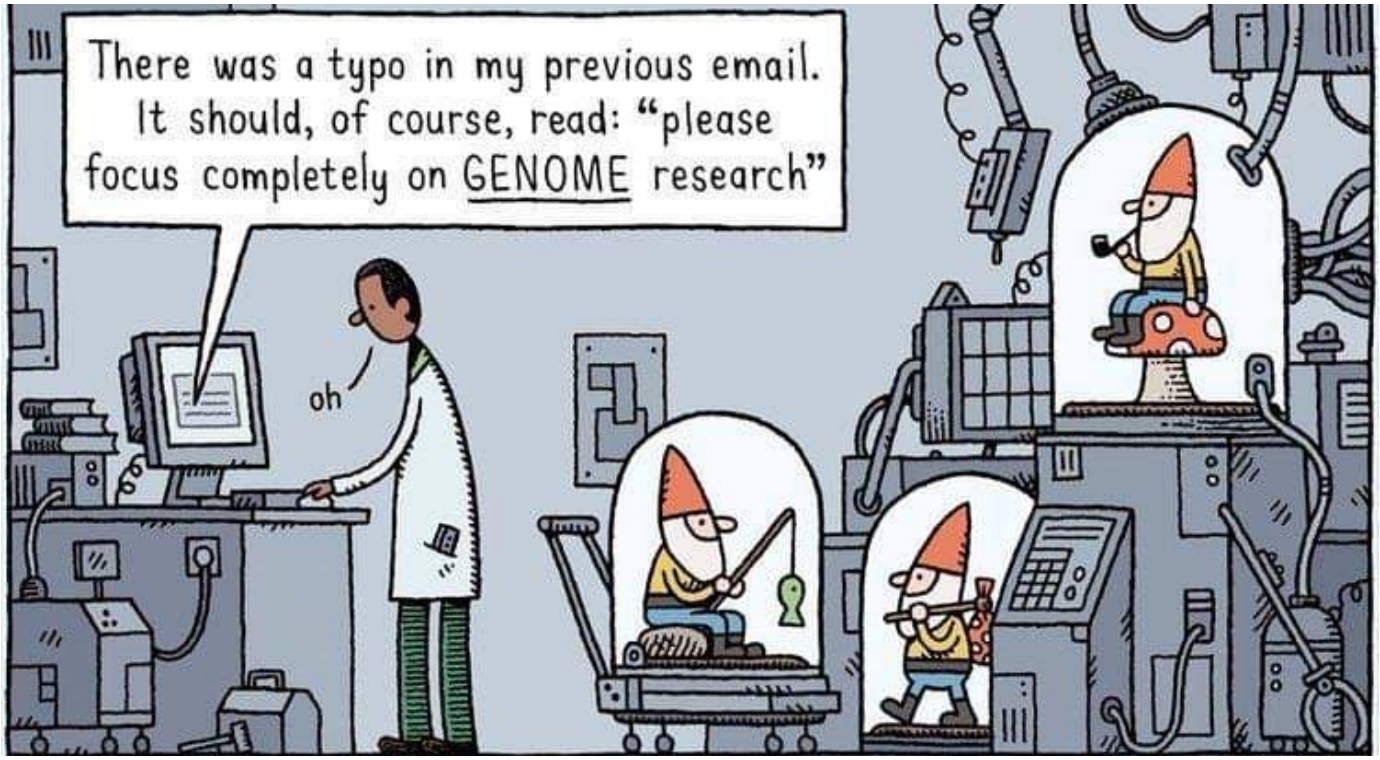
GUARDIANS AND LEGALLY AUTHORIZED REPRESENTATIVES

Typically, the guardian/legally authorized representative of a minor subject is a biological parent. However, in some cases the courts may have appointed another individual as the child's legal guardian, either on a temporary or permanent basis. When this is the case, the guardian is the individual who will provide permission for that child to participate in research instead of the biological parent.

In the case of an adult who lacks capacity, although that individual's parent may have been their guardian due to their status as a minor, as soon as they become an adult this is no longer the case. If they continue to lack capacity to consent, the court will likely have appointed a guardian – this may be the individual's biologic parent, or it may be another individual.

These situations can get tricky, and there may be limitations placed by the court regarding the scope of authority of the appointed guardian. When a situation is encountered in which there is a court appointed guardian, or a potential subject who has reached the age of majority and lacks capacity to consent for themselves, the study team should contact the IRB Office for guidance. We address these situations on a case-by-case basis, with the help of Children's Legal and Compliance, and any other Children's individuals or departments as appropriate.

If study teams encounter a situation in which an individual is claiming to be a legal guardian, this should be confirmed and the HRPP Office consulted for guidance. If available in the medical record, guardianship documentation can be found under the media tab, and there is a filter for guardianship documents. If these guardianship documents are available, Social Work always enters an "FYI flag." Study teams should always look for this "FYI flag" in the patient section of the storyboard before approaching a family. If assistance is needed in navigating Epic to locate this section, please contact Jeff Crawford at JCrawford@chw.org. If this documentation is not available in the medical record and there is reason to believe that a court appointed guardian is in place, **contact the HRPP Office for guidance**.



REQS BEFORE NEXT CONTINUING REVIEW

READ APPROVAL LETTERS CAREFULLY

On occasion, the approval letter for a Continuing Review (CR) will indicate the need to submit an additional package, such as an Amendment or a Reportable Event, BEFORE the next CR. It is the responsibility of the Principal Investigator and study teams to read all approval letters carefully and be aware of such stipulations and track the timeline for follow through with the required packages. If any required submissions are not addressed before the next CR submission deadline, this is considered noncompliance with the directions of the IRB. The study review will be held until these items are addressed and the approval could lapse.

BACK TO BASICS

INCARCERATED RESEARCH SUBJECTS

What happens if a subject becomes incarcerated during participation in research?

If a human subject involved in ongoing research becomes a prisoner during the course of the study, and the relevant research proposal was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners under Subpart C of 45 CFR Part 46, this is considered an Unanticipated Problem and the investigator must promptly notify the IRB.

This Unanticipated Problem should be submitted to the IRB using the Reportable Event form. Unless there are special circumstances warranting uninterrupted, continued participation (such as safety concerns with stopping a research medication or other intervention), all research interactions and interventions, and obtaining identifiable protected health information about the now incarcerated subject must cease immediately upon learning of the incarceration. The Principal Investigator needs to assess whether it is in the subject's best interest to continue participation in the study, and this should be explained in detail on the Reportable Event Form. If the investigator wishes to have the prisoner subject continue to participate in the research, the IRB must promptly re-review the proposal in accordance with the requirements of Subpart C of the Common Rule. Once the IRB reviews and determines that the regulatory requirements of Subpart C are met, the subject can resume participation. If the plan is to withdraw the subject from the research, this should be explained in the report to the IRB.

We're here to help! The particular circumstances will be unique to each research study and situation, so please consult with the HRPP Office for guidance should this occur.

EDUCATION OPPORTUNITIES

SMALL GROUP, INTRO SESSION, AND MORE

Small Group
Join the Children's HRPP/IRB Office and the Pediatric Translational Research Unit (pTRU) Staff for Small Group to discuss select research topics. The same topic will be discussed at both sessions each month. An open forum, you'll have the chance to get your own questions answered, and get help with Epic or IRBNet.

Small Group is held via Zoom. Topics and Zoom call-in information will be included in the Outlook meeting requests. Please feel free contact Jeff Crawford directly at (414) 266-7254 with any questions or to share any suggestions that you may have regarding discussion topics for future sessions.

Quarter 1 Dates
Thursday, February 4, 2021 @ 11:00 AM
Thursday, February 16, 2021 @ 2:00 PM

Thursday, March 4, 2021 @ 11:00 AM
Thursday, March 16, 2021 @ 2:00 PM

Quarter 2 Dates
Thursday, April 1, 2021 @ 11:00 AM
Tuesday, April 13, 2021 @ 2:00 PM

Thursday, May 6, 2021 @ 11:00 AM
Thursday, May 18, 2021 @ 2:00 PM

Thursday, June 3, 2021 @ 11:00 AM
Tuesday, June 15, 2021 @ 2:00 PM

Introduction to the Children's Wisconsin IRB
This training session provides practical advice for working with the Children's HRPP Office to help ensure successful IRB submissions and ongoing (regulatory) study management. The goal of this program is to provide research staff – both coordinators and investigators – with important information on the workings of the Children's IRB, while sharing tips and tools for the safe, efficient, ethical, and compliant conduct of research. Register for the next quarterly session!

DE NOVO REVIEW

NEW GUIDANCE

To ensure that research protocols continue to meet current regulatory requirements and institutional standards, studies may be selected to undergo a "De Novo Review." Studies that may be selected for De Novo Review are those that have been modified extensively, been open for several years, or may not be clearly written as determined by the IRB reviewer. The criterion for requiring a De Novo Review is an inability for the IRB to ensure and document that the activities continue to meet current regulatory requirements.

For additional details, please see our De Novo Review Guidance.

ADMINISTRATIVE UPDATES

NEW AND UPDATED RESOURCES

The HRPP Office is reviewing and updating forms and documents posted in IRBNet and on the HRPP web pages. To ensure you are using the most recent version, please use the documents posted in IRBNet when preparing a new submission.

Recently released and updated policies, guidance, and forms:

- New Guidance: De Novo Review
- New Guidance: Departmental Sign-Off for Research
- New Guidance: Planned Protocol Exception Requests
- Updated Guidance: Coronavirus (COVID-19) Considerations for Researchers
- Updated Guidance: Human Subject Research Determinations
- New Form: Planned Protocol Exception Request Form
- Updated Form: Amendment Form
- Updated Form: Chart/Data Review Form
- Updated Form: Continuing Review/Status Report Form
- Updated Form: Reportable Event/New Information Form
- Updated Form: Request for Human Subject Research Determination Form

Children's Wisconsin
Human Research Protection Program/Institutional Review Board
Children's Corporate Center
999 North 92nd Street, Suite #120
Milwaukee, WI 53226

Children's Wisconsin
Kids deserve the best.