April 2015

Human Subjects Protection Update

IRB (Institutional Review Board) *Boston Children's Hospital*

Inside this issue:

AAHRPP Reaccreditation

As we begin 2015, we also begin the process for reaccreditation with the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This is an accreditation process for Boston Children's Hospital human subject protection program and this will be our 4th accreditation process since 2004. The first step in the reaccreditation process is to conduct a self-assessment and submit this assessment to demonstrate that we meet the standards set by the accreditation agency. The self-assessment is due in June, 2015 . Many of the standards are established to assure compliance with the federal and state regulations and compliance with our own institutional policies. The accreditation process will consider our IRB operations, the knowledge of our IRB members, the training and knowledge of investigators/ research coordinators and all of the ancillary committees and functions that review clinical research protocols for human subject protections. The self-assessment demonstrates our commitment to an integrated program at our institution. Once this self-assessment is submitted, it will be reviewed. We will receive feedback on questions, issues and any deficiencies noted. After we adequately respond to any concerns, we will be scheduled for a 3-4 day on site visit by peer reviewers. At the site visit they will request meetings with IRB members, investigators, research coordinators, institutional officials and others who play key roles in our human research protection program. This site visit will likely be in early 2016.

January begins an intensive and long process that we will undergo this upcoming year. Susan Kornetsky is responsible for this effort and she has asked Susie Corl from the Education and Quality Improvement Office to be designated as the lead in the self-assessment and organization of the entire reaccreditation efforts. Susie will also continue her responsibilities in the EQuIP office. In the upcoming months many individuals will be contacted to acquire and review updated materials for the submission. We will also perform an intensive review of our policies/procedures and forms to make sure they meet the accreditation standards. Our plan is to keep the clinical research community apprised of this effort throughout the year. We thank everyone for their assistance in any continued and upcoming efforts in this accreditation process and for your commitment to the protection of human subjects.

Memo-to-File: from the EQuIP Office

QUESTION:

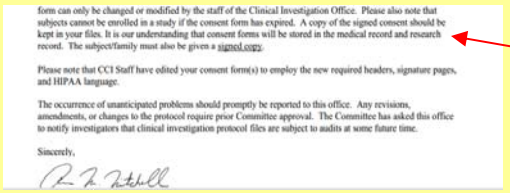
How do you know when to file a copy of a subject's signed consent form(s)* in their BCH medical record (PowerChart)?

* This includes assent forms, short forms and parental permission forms as applicable.

ANSWER:

Look in the 1) study's IRB Final Approval Letter, 2) approved consent form(s), and 3) CHERP protocol smart form:

1) **IRB Final Approval Letter**: the IRB will make a study-specific determination whether or not copies of signed consent forms should be filed in the subject's medical record. This determination will be clearly stated in the Final Approval Letter:


form can only be changed or modified by the staff of the Clinical Investigation Office. Please also note that subjects cannot be enrolled in a study if the consent form has expired. A copy of the signed consent should be kept in your files. It is our understanding that consent forms will be stored in the medical record and research record. The subject/family must also be given a signed copy.

Please note that CCI Staff have edited your consent form(s) to employ the new required headers, signature pages, and HIPAA language.

The occurrence of unanticipated problems should promptly be reported to this office. Any revisions, amendments, or changes to the protocol require prior Committee approval. The Committee has asked this office to notify investigators that clinical investigation protocol files are subject to audits at some future time.

Sincerely,

2) **IRB Approved Consent Forms**: if the approval letter specifies a signed copy should be filed in the medical records, there will be a **barcode** in the top left hand corner of the approved consent form. Otherwise, there will be a stamp "*DO NOT PLACE IN MEDICAL RECORD*".


consent form 20 of

Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:


Boston Children's Hospital

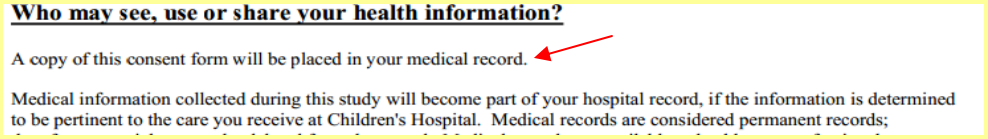
DO NOT PLACE IN MEDICAL RECORD

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

In the consent form section "*Who May See, Use or Share Your Health Information?*" there will be a statement specifying whether the consent "WILL or WILL NOT be placed in the subjects clinical medical record."


Who may see, use or share your health information?

A copy of this consent form will be placed in your medical record.

Medical information collected during this study will become part of your hospital record, if the information is determined to be pertinent to the care you receive at Children's Hospital. Medical records are considered permanent records;

3) **CHeRP Protocol SmartForm:** in the section *"Research Data, Documents, Subject Reports & Consent/Assent Forms Storage: Where will the signed informed consent and assent be stored? Check all that apply."*

It is important to make sure the determination is consistent in all of the above documents. If there is any discrepancy or question, contact the IRB immediately for clarification.

For ALL studies, don't forget:

The original, signed consent form should always be maintained securely in the PI's study records.

A copy of the signed consent forms should always be given to the subject/parent or guardian for their own records.

For more information:

IRB Policy: **Storage of Research Data and Informed Consent Documents**

Medical Records Department procedures: **December 2012 Special Communication Newsletter**

Visit the EQuIP website for more information or call Eunice Newbert or Susie Corl at the EQuIP office – 5-5308

Case Studies/Series Guidance

The IRB recently developed guidance for researchers for determining if a case study report constitutes human subjects research and requires prospective IRB review and approval. It includes definitions (case study vs. a case series) and provides specific considerations and procedures for developing and publishing case studies/series.

Please see the link to our Guidelines and Policies #2.4 Case Studies/Series.

A Fix for Consent form Header Errors

It has come to the IRB Office's attention that there is a potential consent form printing error where consent forms are printing with DO NOT PLACE IN MEDICAL RECORD when the medical records bar code should be included instead (when the consent from, actually *should* be placed in the medical records). The IRB Office and CHeRP Support are working on a solution to this problem. In the meantime please contact our office if you are running into this issue so that we are aware of the issue with your particular protocol. Study teams can apply their own barcode labels using the template available at http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/information-for-researchers/forms. This form uses the Avery 5155 address label. The IRB office has blank 5155 labels available for those who need them. Call 617-355-7052 to arrange to pick them up.

New Comic Book: Educating Children about Medical Research

We are pleased to offer all investigators access to a new comic book, "Sophie's Science Project: What is Medical Research". This comic book was developed with the goal of educating children about medical research. We also hope this comic book will be distributed to children as part of the assent process. The comic book can be accessed and downloaded from the link below. Paper copies may be obtained by: 1) Contacting your IRB administrator to arrange pick from the IRB office at Simmons College, Le Favour Building, 2 Avenue Louis Pasteur Suite L 430. We can also send you up to 50 copies through interoffice mail 2) Sending an email to IRB@childrens.harvard.edu. Be sure to indicate who is requesting copies and where they should be sent 3) Link to comic book http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/information-for-participants. There is no limit as to the number of comic books we will distribute, however, the amount will depend on whether the request is for an individual investigator or for a waiting room area within a department. When making a request please specify who is making the request and for what purpose (i.e. individual study recruitment, waiting room area). We would like to thank Athos Bousvaros, MD for his expertise in helping lead us through the development of the comic book and providing funding. We also want to thank our colleagues and advisory committee from Children's Hospital in Philadelphia, Cincinnati Children's Hospital Medical Center Hospital for their collaborative efforts and Hilarie and Joe Stanton, the writer and artist team, for their wonderful work.

Welcome Scott Meyers

Scott Meyers has recently joined us as an IRB Administrator. Scott received his bachelor's degree in political science from Virginia Tech and has spent the last couple years working as an IRB administrator at the Dana-Farber Cancer Institute. He enjoys long road trips, fishing, and other various outdoor activities. He plays numerous instruments including the guitar and the bagpipes. His email address is scott.meyers@childrens.harvard.edu and his phone number is (857) 218-4022. Scott will be handling IRB submission from the following departments:

Emergency Medicine • Nursing • Psychiatry • Endocrinology

Orthopaedic Surgery • Hematology/Oncology • Urology

Please join us in welcoming Scott to Boston Children's!

Harvard Catalyst Research Subject Advocacy Materials

Did you know that the Harvard Catalyst Research Subject Advocacy Program has developed information pamphlets to help support communication between researchers and research subjects? These resources are intended to provide research participants (or prospective participants) with clear information and helpful questions to think about and to ask before deciding to participate in a research study. Topics include the following list and some are translated into several languages. Please visit the following website for more information and access to these materials

http://catalyst.harvard.edu/services/rsa/

Should I be a research subject? (available in 15 languages)

What is genetic research?

What is social and behavioral research?

Magnetic Resonance Imaging (MRI) for research

Computed Tomography (CT) for research

Positron Emission Tomography (PET) for research

Blood draws for research

Surrogate Decision-Making

Incidental Findings

Boston Children's Hospital

Boston Children's Hospital
Institutional Review Board (IRB)

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The Institutional Review Board (IRB) has been established to oversee the protection of human research subjects at Boston Children's Hospital. Children's is committed to safeguard the rights and welfare of all children, adolescents, adults and family members who volunteer to participate in research. To this end, the Office of Clinical Investigation upholds the principles of the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, as the cornerstone of our mission, organization and daily activities.

- Have questions or comments about any of the articles in this newsletter?
- Need advice about your research?
- Want to know more about human subjects protection at BCH?

Please don't hesitate to contact the CCI and one of our staff will be happy to assist you.