

Human Subjects Protection Update

Committee on Clinical Investigation Boston Children's Hospital

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Implementation of Bar Code Headers to Facilitate Storage of Research Consent Forms in the Medical Record

In collaboration with the Medical Records department, the Office of Clinical Investigation has devised a means to allow signed research consent forms to be easily included into the appropriate section of a research subject/patient's medical record. Research consent forms will be required to include the updated headers which include a barcode for studies where consent forms should be included in the subject's medical records. The

consent template has been modified to include this header. Newly approved protocols will include this new header. In addition existing forms will be converted to the new header at the next continuing review.

Important note: You must print out a new consent form for each subject in order for the bar codes to be read by the scanner. Photocopies of consents with a bar code will produce images that cannot be easily scanned and the consent will not be placed in Power-Chart.

Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:
DOB:
Subject's Name:
Gender:

Protocol Title:
Principal Investigator:

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To help investigators and study teams understand this new procedure and how it affects their studies, we have put together this FAQ.

Q1: Why are you doing this?

A: Children's policy and good research ethics dictate that, particularly for studies that implicate present or contemplated clinical care, or that produce clinically relevant and reliable results, it is important that a subject's participation in the research, as well as certain results, be reflected in the medical record. In addition there may be safety reasons why it is important for other health care providers to know that a subject is a participant in a re-

search study. There are some limited situations when the fact that a subject is a participant research should not be disclosed in the medical record; however these situations are usually the exception not the rule.

Q2: When does this change go into effect?

A: The change to the new required format is effective immediately. Consent forms for all new protocols must adopt the new consent format (which in addition to the barcode headers includes new required HIPAA/privacy and confidentiality template language, signature sections, and the new BCH logo) before IRB approval will be released. CCI Staff will make the changes for studies that have already been submitted but which have not yet been approved. For existing/

Implementation of Bar Code Headers, continued.

approved studies, CCI Staff will update consent forms for the study team at the time of continuing review.

Q3: What protocols need to have their consent forms placed in the medical record and have the associated bar codes on their consent forms?

A: It is important to note that with a change to electronic medical records and electronic scheduling and ordering systems, it is difficult to keep the fact that a subject is in research confidential and only known by the research team. For example you may need to schedule a visit as a research visit or order a test to be billed to a research fund. This now creates a record of research participation in the electronic records of the hospital. The newly developed confidentiality template for research consents has been revised to be much more transparent about who at BCH may know that a subject is participating in research. Therefore, the inclusion of the consent form in the medical record will become the more common approach at the hospital.

All active consent forms need to be updated with the new headers but only those which need to be included in the medical record will include the bar code. When the IRB finalizes an informed consent they will include either the bar code or a notation "Do not place in medical record." The IRB will make a protocol-by-protocol determination, but generally the following criteria apply.

- For research undertaken at Children's Hospital for the intervention, treatment, or diagnosis of a disease, disorder, or condition (e.g., drug and device trials; comparison of psychological interventions; testing new diagnostic techniques), the consent form **should be placed into the patient's medical record.**
- In general for research where the hospital clinical electronic systems are used to schedule visits, order tests or analyze results the consent should be included in the medical record.
- However, for research that does not involve procedures, interventions, treatments that are part of a subject's care, diagnosis, or treatment, and the hospital electronic systems are not used; the investigator may consider storing the informed consent document and associated research data in his or her research files only. Examples of such research include: studies that involve genetic screening or testing where a diagnosis has not been confirmed; or psychiatric/behavioral assessments not intended for clinical use; and completion of questionnaires on sensitive issues that have not already been documented in the medical record.

For more information please see "Storage of Research Data and Informed Consent Documents" on the [Guidelines and Policies page of the CCI Website](#), or you may call the IRB analyst assigned to your department.

Q4: If a consent form is not to be placed in the medical record, will there be any special header?

A: Yes. We have formatted the header of our consent form so that if one simply selects the barcode and then deletes it, the following text is revealed: ***DO NOT PLACE IN MEDICAL RECORD.***

versus

Q5: What if I have submitted a protocol that is in the process of review that has not included the bar code on the consent form?

A: CCI Staff will not release approval for the study unless the consent forms are all in the new format (barcode headers, the new required HIPAA language, signature sections, and new BCH logo). CCI Staff will update the consent forms for you. If the Protocol SmartForm and the consent form state that consent forms will be included in the medical record, and if the IRB agrees, then CCI staff will include the barcode in your updated consent forms.

Q6: Do I need to change my currently approved consent form(s)?

A: No. Out of concern for the administrative burden this change would bring we are not requiring that everyone update their consent forms all at once. Our office will update each study's consent forms when processing the approvals for their continuing reviews. However, if you submit an amendment that involves revising current consent forms or creating new consent forms, or if you request that the new consent forms employ the new required barcode headers (as well as the new HIPAA language and signature sections).

Implementation of Bar Code Headers, continued.

Q7: What if I want to change the consent forms, before the next continuing review? How can I do it?

A: Any investigator can submit an amendment to update their consent forms at any time. You do not have to wait until the next continuing review of your protocol. The new template can be found on the [Info for Researchers >> Informed Consent page of the CCI website](#). However, please note that if you update your headers you will also be required to update the HIPAA language and signature sections.

Q8: Does the new requirement apply also to Assent Forms and Short Forms?

A: Yes. If the informed consent for parental permission includes the bar code any associated assent forms and short forms also need to be included into PowerChart. The assent form and short form templates have also been updated with new headers and barcodes and are available at the link given above.

Q9: What if my protocol has a consent form for subjects who are not patients and there is no medical record. Where should their consent forms be stored?

A: If the study does not fit the criteria for requiring a consent form being stored in the medical record, then their consent forms should be stored in your own research records. Note however that performing some research procedures, such as performing an MRI on subjects who are not patients of the hospital will cause a BCH medical record to be created for your subjects even if they are not current “patients” at BCH. In such cases it is important to remember this and to inform the subject that they will have a medical record created. Please see guidance on imaging studies that are performed for research for further information: http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_081_030_draft_imaging.doc

Q10: What about studies that are closed to enrollment?

A: Consent forms for studies that are now closed to enrollment only need to have their headers updated if there is a need for re-consenting any subjects, for example, if the study has changed significantly or if subjects have turned 18 since providing assent. If you have any active consent forms they will be updated for you by CCI staff at the time of continuing review.

Q11: I have some old signed consent forms that need to be included in the medical records. They do not have barcodes on them. How do I get them into the right place? Also, what about consent forms from other hospitals (Partners, DFCL, etc.)?

A: The CCI website has a barcode labels template (Avery style 5155). The template and instructions for using it can be found on the [Info for Researchers >> Forms](#) page of the CCI Website. The barcode labels can be affixed to the top of the first page of the consent form so that it can be scanned.

Please note that the only non BCH consent forms that should be included in the BCH medical records are those which are from studies in which Boston Children’s Hospital is a participating site (for example, if the BCH

IRB has ceded review to a Harvard IRB or other hospital). If the study does not involve clinical care at BCH and does not involve billing or scheduling systems at BCH it should not be scanned into the medical record using this process. Call the CCI Office if you have questions about a given consent form.

Q12 How do I send my consent forms to be scanned into the PowerChart?

A: All research consents that need to be sent from the following campuses should be in an interoffice envelope labeled Medical Records Boston.

Drop off locations at the satellites/campuses are as follows:

- Lexington: 2nd floor Pediatric clinic
- Peabody: Front registration desks on the first floor or second floor
- Waltham: Front desk in the 2 East work room

If you have any questions regarding drop off locations, please ask the department administrators in the location in question. Most clinical areas have a drop-off location for Medical Records. Persons on the main campus can deliver their consent forms to Health Information Services (Medical Records) in the Fegan sub-basement.

In the event that Medical Records cannot scan your documents for any reason they will need to have a contact name and number. Please make sure that the research consents are sent with a post-it note attached that indicates where the documents are from and a call-back number where Medical Records can reach you in case they have questions for you about the documents.

Q13: Can I send a photocopy of the signed consent form does it have to be an original?

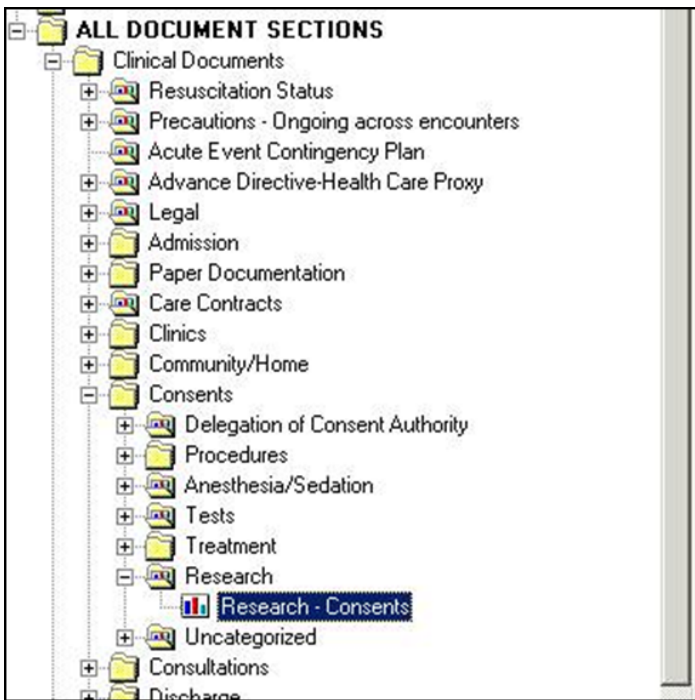
A: No. You cannot send a photocopy of the consent. You must only send a copy that has been printed. . A photocopy of the barcode—even a good one—will not work. Each consent form that you send for scanning into PowerChart must be an original first-generation print-out of the consent form and not a photocopy. You must print a fresh one for each subject that you enroll and make sure that the signed original is used for scanning. In cases where you need to retain the original signed consent form for your own study records, you should make a photocopy of the signed consent form and print a fresh first page with the barcode on it and use the copy with fresh first page for sending to Medical Records. Alternately you can use a barcode label

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(see page 2) affixed to the header of a photocopy.

Q14: Once it gets scanned, where will a research consent form be placed in the medical record?



A: The consent form will be stored in Clinical Documents\Consents\Research section of PowerChart (see below).

Q15. What happens to the paper copy of the consent after it is scanned into the medical record?

A. Consent forms sent to medical records cannot be retrieved once they are sent for scanning. Investigators are advised to retain copies of all consent documents that they send to Medical Records.

Clarification of Continuing Education for Human Subjects Protection Training

Our previous newsletter included information about how researchers can meet their continuing education requirements for human subjects protection training. There seems to be confusion in the research community about the Research Coordinator Rounds serving as continuing education. Not all of these discussions can serve as continuing education. The CCI evaluates each discussion on a case-by-case basis to determine if attendance at that specific discussion will serve as continuing education. If the rounds is to count as continuing education credit for IRB training, this will be stated in the notification of the event and at the start of rounds. Additionally, CRC Staff will forward the attendance sheet to our office, so that we can enter your training into CHERP.

Registries, Repositories, and Research Records

Recently, the IRB has noticed some confusion regarding the terms “registry,” “repository,” and “research record” with respects to data collection and storage. Although these terms are sometimes used interchangeably, they have very different meanings and policy implications. The IRB would like to dispel any confusion regarding registries versus repositories versus research records in order to help investigators to more accurately describe their research plans in protocol submissions.

Registries, repositories, and research records are all collections of data stored by research staff. These collections may or may not be shared with others within a single lab, clinical, facility, network, or geographical area. **The data contained within registries and repositories are collected for unspecified future use, while the data stored in a research record may be used for the current study, future studies, or just to keep track of certain data over time.**

A registry typically contains data (like lab values or BMI), while a repository typically contains specimens (like blood, sputum, tissue, etc.). However, repositories can contain *both* data and specimens.

When answering questions in the CHERP SmartForm about your data, writing research protocols, or composing consent forms, please be sure to think about whether the data you’re collecting will be used for or kept in a registry, repository, or record—this will help the IRB and IRB staff to better understand the purpose of your project and provide efficient review.

Did you know...

That answers to the most common CHERP issues can be found in the “How Do I?” library? In this library are help documents that will walk you through amendment submissions, printing reports, tracking submissions, responding to sticky notes, and more!

You can access these documents by logging into CHERP and clicking on the “How Do I” tab in the blue bar at the top of the page. Help documents are categorized by their intended audience—so, for example, information about submitting and viewing items in CHERP can be found under the “IRB Research Team Member Training Materials” tab.

If you can’t find what you’re looking for, you can always contact your department’s IRB Analyst or CHERP support (ext. 43267).

Memo-to-File: from the EQUIP Office

What is EQUIP?

The Educational and Quality Improvement Program's mission is to improve policies and practices in clinical research as to ensure on-going protection of human subjects, and to promote good clinical practices regarding research conduct and documentation. On way EQUIP provides support and education to the Boston Children's Hospital research community is by offering the services described below.

How can EQUIP can help you?

Study Pre-Review and Prep


At any time prior to initiating a study, upon request the EQUIP office will review any study start-up materials and will work with the PI/staff to identify the regulations and policies applicable to the study. When possible, the EQUIP office will provide educational materials/references, support and study tools.


Talks and Presentations

Upon request, the EQUIP staff is available to present various topics about research compliance and good clinical practices (e.g. informed consent, study documentation, source documents).

Study Reviews

A confidential, full or partial review of on-going studies to ensure compliance with applicable regulations and policies and to evaluate study conduct, organization, record-keeping and documentation. EQUIP office aims to help investigators implement tools and strategies to improve identified problem areas. Reviews may be voluntarily requested by PI/staff (e.g. to ensure compliance, during staff changes, to prepare for an external audit).

 Visit the [EQUIP website](http://www.childrenshospital.org/research/equip) for more information and resources. www.childrenshospital.org/research/equip

 If you have any questions or would like to request any services, please call Susie Corl or Eunice Newbert at EQUIP office at **ext. 5-5308** or **617-355-5308**

Reporting Results on Clinicaltrials.gov

We have recently learned through the DFCI that a major Comprehensive Cancer Center received a letter from the US Department of Health and Human Services (HHS) that it was out of compliance with the Food and Drug Administration's results reporting requirement for ClinicalTrials.gov. The letter stated that the FDA would take action, including possibly levying fines, if overdue results were not posted promptly. The Center was given a 10-day deadline. While this problem was raised about a Cancer Center, it is important to remember that there are requirements for individual investigators to report results for trials that are registered to be in accordance with FDA regulations. This includes;

- **Trials of drugs and biologics.** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation

- **Trials of devices.** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post-market surveillance required by FDA.

We realize for some studies sponsors are responsible for regis-

tering the trial and then become responsible for reporting the results. However if you have registered a trial which meets this criteria, you need to report the results. As mentioned in our last newsletter we also are aware of investigators who have not been able to publish results in journals because they did not register their trials. Please familiarize yourself with the registering and reporting requirements by going to the following resources. These responsibilities are obligations of the PI and cannot be handled by Clinical Investigation or Research Administration .

Why should you register and submit results: <http://clinicaltrials.gov/ct2/manage-recs/background>

How to register studies: <http://clinicaltrials.gov/ct2/manage-recs/how-register>

How to submit your results <http://clinicaltrials.gov/ct2/manage-recs/how-report>

Boston Children's Guidance document:

http://childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_014_003_ClinicalTrialsGov.pdf



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The [Office of Clinical Investigation](#) 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.

**Season's Greetings
and Best Wishes in 2013!**

from the CCI & EQuIP