September, 2012

Human Subjects Protection Update

Committee on Clinical Investigation *Boston Children's Hospital*

Inside this issue:

New Policy on Research Involving Decisionally-Impaired Adults

The Committee on Clinical Investigation (CCI) has recently developed a new policy addressing the involvement of adults with decisional impairment in research.

This policy was prompted after the CCI conducted an internal review and noted that adults with decisional impairment were recruited into research protocols. In addition, children with decisional impairment were becoming adults during the course of research. Both situations present ethical and regulatory challenges for obtaining informed consent.

Adults with decisional impairment include individuals whose decision-making capability has been restricted, in whole or in part, by disease, mental illness, or other circumstances, and who may not be legally competent to give informed consent. This makes these subjects vulnerable to coercion, undue influence, and exploitation. The ***Federal Regulations*** require that IRBs take extra procedural safeguards for these individuals. The regulations also require that consent be obtained from a legally authorized representative. In some cases, a legally authorized representative is appointed through the legal system. However, in many other situations, there is a need to determine a subject's capacity to provide consent and whether there is a need for surrogate consent. In addition, once a child turns 18, they are required to consent on their own behalf in order to remain in the research study. This raises some complex issues if the individual is decisionally impaired.

New questions have been added to the protocol application that ask investigators to think about and address these issues as pertinent to their research.

Here are the highlights of the policy:
Adults with decisional impairment may only be enrolled in: (1) research that does not involve more than minimal risk; or (2) research that involves greater than minimal risk but presents the prospect of direct benefit to the individual.

It is the general position of Children's Hospital that individuals with decisional impairment will not be enrolled in research that:

1) Involves greater than minimal risk and no prospect of direct benefit to individual subjects. It is always possible seek an exception with appropriate justification.
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New Consent Form Template

The IRB has recently adopted new template language for the confidentiality, HIPAA, and signature sections of the research informed consent document. This was a collaborative effort with the HIPAA Office, General Counsel, and Education and Quality Improvement Program (EQuIP). We have revised and combined the confidentiality and HIPAA sections to be more concise and less repetitive.

We noted that when these sections were separate, they often contradicted each other and repeated the same information. There is no longer a separate confidentiality section. If you are working with a corporate sponsor and they have provided you with suggested confidentiality language, please make sure it does not repeat what we already have included in our template language, as this will only lengthen the document unnecessarily.

We ask that protocol-specific confidentiality information be included in this new section. Please also include the template language provided. The revised confidentiality section reflects our rapidly-changing environment; it has become
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Memo-to-File: *from the EQuIP Office*

Take a few seconds to review the consent/assent form after obtaining each signature. Checking in real time can help prevent seemingly small errors which can have large consequences at the end of a study.

Verify 'Relationship to Child': ensuring legal guardianship.

Ensure the parent/guardian specifies their relationship next to their signature. Never assume the relationship or write in the relationship for them. If the person is not a parent, there should be documentation demonstrating guardianship.

Documenting Assent: signature or reason

If required, ensure child/adolescent signs the subject line on the consent form or on a separate assent form if IRB-approved. If assent is not obtained for a valid reason (e.g. too young), document reason on the consent form.

Signatures & Dates: in the right place at the right time

Ensure all signees sign the correct line and date their own signatures using the correct date. If someone signed the wrong line or misdated their signature, have them correct the error before they leave. Never date another person's signature.

Correcting Errors the right way!

As with all documentation errors, there should be a clear audit trail; cross out with single line, date, and initial and explain if correction is not obvious. Never black out an error or use white-out. Advice: throw your white-out away!

Remember, a quick check of the consent when first obtained may save you a lot of questions and time at the end of the study.

If you have any questions, please call Susie or Eunice at the EQuIP office – 5-5308.

Pre-Review Helpful Hints

The IRB staff has noted that, on occasion, the pre-review process has been prolonged due to a need for continuous feedback from our office. In an effort to help facilitate the process and improve turnaround times, we would like to offer a few helpful hints:

When a comment pertains to a specific question on the SmartForm page, the response to that question must be revised to reflect the new information in addition to the sticky note response.

Always be sure to revise documentation e.g. recruitment materials, protocol outline, consent forms, etc. as required, in addition to responding to the sticky note comment(s).

Review each sticky note thoroughly. If multiple comments are included in the note, please ensure that each issue is addressed fully.

Read questions carefully and provide complete responses. The protocol will be sent back if the responses do not address the questions.

When in doubt, or if there is any question as to what is being requested by the reviewer, please contact the administrator for clarification before responding.

New Policy on Research Involving Decisionally-Impaired Adults, continued.

(continued from page 1)

2) Investigators will be asked to provide information as to how capacity to consent will be assessed. General competency measures, such as the Clinical Dementia Rating, the Mini Mental Status Exam, or the Activities of Daily Living Scale may be helpful to establish baseline understanding of an individual's competency.

In protocols that contain significant risk, a formal psychiatric or medical assessment may be warranted by an individual who is not involved with the research. In other situations, it may be possible for investigators to consider a two-part consent process: (1) an assessment of comprehension and recall (understanding in a strictly factual sense of the parameters of the study); and (2) a test of personalized understanding (how the specific benefits, harms, alternatives, and consequences of this study apply to the individual subject's situation). Protocols will be evaluated on a protocol-by-protocol basis depending on the research, associated risk, and the population being studied.

If an adult research subject cannot give consent and has not expressed dissent, then a surrogate decision maker must be found to consent in the subject's place. Federal law allows a legally authorized representative to consent for research on behalf of decisionally-impaired persons. Currently, "legally authorized representative" is not defined in federal or Massachusetts state law.

Based on guidance, Children's Hospital Boston has decided to allow consent from the following persons, in order of preference: a court-appointed guardian who has clear authority to make health care decisions; a person designated as a health care agent under a valid health care proxy, with express authority to consent to research or make health care decisions inclusive of the proposed; a durable power of attorney with express authority to consent to research or make health care decisions inclusive of the proposed research; family members: competent spouse, competent parent, or adult child.

Any other family members involved in the care of a patient wishing to consent to research will be evaluated on a case-by-case basis. Questions regarding the use of family members may be directed to the Office of General Counsel or the Director of Clinical Research Compliance. Guardians, health care proxies, and durable power of attorneys should attach the appropriate documentation when signing consent forms for research.

When a decisionally-impaired adult is unable to consent, it may still be possible to obtain the individual's assent, and particularly dissent should be considered.

If a child turns 18 during the course of a study and the study involves continuing diagnostic/therapeutic procedures or any form of research intervention, informed consent must be obtained from the now adult in order to remain in the research. Parents do not automatically maintain the ability to consent for the now-adult study subject if they are decisionally-impaired unless parents have been appointed by the court as the subject's legal guardian. If there is no court appointed guardian, the same policies as listed above will apply for legally authorized representatives. A new consent document needs to be signed with the appropriate legal guardian or the individual providing surrogate consent.

If an investigator wants to enroll a decisionally-impaired adult subject in a protocol when it was not anticipated that decisionally-impaired subjects would be enrolled, the investigator should contact the Office of Clinical Investigation or the Office of General counsel to discuss the situation and consider any special necessary arrangements in order to include the subject in the trial.

For the full policy please review the following link:
http://childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_081_027_final_decisional_impairment.doc

Update on CCI Jurisdiction

This past July, the Medical Staff Executive Committee approved an updated policy for the jurisdiction of the Boston Children's Hospital (BCH) IRB, commonly known as the Committee on Clinical Investigation. This policy defines the scope of research that must be reviewed by the BCH IRB.

While it is clear that research involving patients of the hospital requires review by the BCH IRB, it may be less obvious that, if hospital staff perform research at other institutions—internationally, in the community, or in their private practices—but use the credentials of Children's Hospital for publication, they must also receive IRB approval by the CHB IRB. In some cases, arrangements can be made to rely on another IRB; however, the research must be disclosed to the IRB administrative office, who will help determine whether the extent of the Children's staff members involvement constitutes engagement in human subject research and whether reliance agreements can be utilized. If a reliance agreement is used, it must be in writing.

The following criteria are the categories of research that must be reviewed by the BCH IRB. The research:

1) is performed as part of an individual's academic responsibilities or an individual's employment responsibilities or is conducted during hospital time or with any hospital resources/money/space or

2) is being performed as part of a hospital training program or

3) uses the name of Boston Children's Hospital (BCH) as part of an individual's credentials for any type of publication, presentation, or abstract.

Work Force is defined as medical staff that have appointments as "active staff," research staff, or employees of Boston Children's Hospital or one of (continued on page 5)

What Human Subject Training Satisfies the IRB's Education Requirement?

Federal and hospital policies require that all persons conducting human subject research receive education in human subject protections. At Boston Children's we comply with these requirements by having every investigator and member of the research team complete a basic training in human subject protections, and require refresher training every three years. Initial training requires completion of the human subject training course offered through the Collaborative Institutional Training Initiative, or CITI: https://www.citiprogram.org. Continuing education requirements can be satisfied by taking CITI courses that have been designated for this purpose. There are also other options for satisfying the continuing education requirement. Below is a list of the trainings that we offer and/or accept for satisfying educational requirements as well as descriptions of them.

Basic Training:

Every person who is PI of a an IRB protocol, or anyone who is listed on the research team and will either interact with subjects, obtain their consent, or handle their identifiable data or specimens must complete one of the following basic training requirements.

CITI Biomedical – This a basic course catered to investigators working in biomedical sciences.

CITI Behavioral – This is a basic course catered to investigators working in social and behavioral sciences.

CITI Non-Interventional – This is a shortened course which only satisfies the training requirement for individuals whose only involvement is limited to handling of data or specimens. Anyone who interacts with subjects or obtains consent, or who is PI of a study requiring consent or interaction, needs to have completed one of the other Basic Training courses in this list.

Training from Another Institution – We accept basic human subject training completed through other **Harvard** affiliated institutions as well as **CITI** (human subjects) courses completed through other hospitals or universities that use CITI to satisfy their own training requirements. On a case by case basis and in *limited situations*, the IRB may accept other training courses completed through other institutions. Completion certificates from these courses should be submitted to the IRB Administrator to determine if they can be accepted.

CITI "Original" – This was our first CITI offering, discontinued in 2004 but still credited toward the basic training requirement.

University of Rochester Course – This was a book-based written course which preceded our first CITI course offering. It is no longer being used but we still credit it for the basic training requirement.

Continuing Education (CE):

Our policy requires that everyone undergo some form of continuing education ***every three years***. Below is a list of the trainings that we offer and/or accept for satisfying the continuing education requirement. These courses only satisfy the education requirement for persons who already have completed one of the basic Training items listed above.

CITI Refresher Course – This is a short course will only count as con*tinuing education if the person has previously completed a basic CITI course* and their basic training is on file with our office. The content of this curriculum is changed every three years so that investigators do not take the same course more than once.

CITI Good Clinical Practices (GCP) – This is a short course on GCP offered through the CITI site. Although we do accept the GCP course for continuing education, please note that *the Responsible Conduct of Research (RCR) or Conflict of Interest (COI) courses offered through CITI do not satisfy the IRB's basic training or the continuing education requirements*. These courses may be necessary to complete for other training requirements at the hospital but do not count toward any IRB requirement.

Introduction to Clinical Research Course - This is a two-day intensive course periodically offered by the Clinical Research Center/CRC which exposes new investigators to the concepts and practices of clinical research, including study design, clinical trials, biostatistics, research ethics, data management, and grant writing. The target audience includes junior faculty, fellows, nurse investigators, and any others who may develop and write their own research protocols. The Director of Clinical Research Compliance serves as faculty for this course.

Introduction to IRB Lecture – This is a lecture given periodically to new residents which covers the basics of human subjects research and CHB CCI requirements. Attendance is taken at this lecture and CE credit is given to attendees.

Education and Quality Improvement (EQUIP) Review - An EQuIP study review provides a research team with a confidential evaluation of their understanding and application of applicable regulations and policies, and offers recommendations to help them meet these requirements. EQUIP reviews are periodically conducted on randomly selected protocols and can also be conducted at the request of an investigator. Individuals listed on the protocol who are present at both the initial and closeout meetings receive continuing education credit.

EQuIP: New/Transfer PI Orientation – Investigators who are new to BCH or have never before been PI of a BCH study involving intervention with subjects are required to meet briefly with the EQuIP team to review responsibilities of the PI role as well as BCH resources available to them. CE credit is given to investigators who complete the requirement.

EQuIP: PI-Sponsor Meeting – Investigators (continued on page 5)

Update on CCI Jurisdiction, continued

(continued from page 3) the Children's Foundations. Although staff members may have appointments at multiple institutions, staff are usually considered "an employee" or a "Work Force member" of one institution. Staff who are paid by Boston Children's Hospital foundations are considered part of the Boston Children's Hospital Work Force. Human subject research conducted by an "employee" or "Boston Children's Hospital Work Force member" usually falls under the jurisdiction of the Boston Children's Hospital. The BCH IRB will review all covered research, regardless of the location of the research or its source of financial support.

For research that is conducted off Boston Children's Hospital premises, the IRB may wish to enter into a reliance agreement with another institution's IRB. When there is a question as to whether review by BCH IRB may be necessary, or whether a reliance agreement may be possible, consultation with the other organizations may also be required to help make this determination.

The following are some less obvious examples of when Boston Children's Hospital IRB approval is required:

1) A Work Force member conducts research at a school, day care center, company, community center or another healthcare facility.

2) A Work Force member receives a grant/subcontract through BCH, but proposes to conduct the research at another location.

3) A Work Force member with a joint appointment receives a grant through another institution to conduct research at an international site.

4) Use of BCH data or samples will be used at an offsite location.

5) A Work Force member obtains an appointment at another site in order to conduct research at that location and is listed as a co-investigator on the protocol submitted at the other institution.

6) A Work Force member proposes to conduct research in their private practice that is not affiliated with Children's Hospital, but will include their Boston Children's Hospital credentials in a publication.

7) A Work Force member consults on the design of a research protocol to be conducted elsewhere and also participates in data analysis.

In accordance with the Harvard Cancer Center grant, Boston Children's Hospital has relinquished review of cancer-related human subject research to the Dana Farber Cancer Institute through a reliance agreement. A chart which summarizes this arrangement may be found in a policy titled "Determining Whether a Protocol Requires Boston Children's Hospital or Dana Farber Review"

(http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_051_015_DFCI_CH.doc).

The institutional review boards (IRBs) of several Harvard schools and affiliated health care centers have entered into a Common Reciprocal Reliance Agreement under the CTSA awarded to Harvard University Medical School. This agreement creates a framework whereby investigators who wish to conduct a multi-center clinical study can request that the IRBs of the participating centers rely on the review of one center's IRB. In order to request ceded review, investigators must complete and submit a Cede Review Form prior to submitting their IRB application. Each participating IRB makes the decision on a protocol-by-protocol basis whether to rely on the review of another IRB (to cede the review) on a study or to conduct its own full review.

There are many other situations that may arise where it may be unclear whether the IRB review of Boston Children's Hospital is required or whether a reliance agreement is acceptable. Please contact the Committee on Clinical Investigation administrative office when these questions arise. To view the actual jurisdiction policy, you may go to: http://childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_031_001_cci_jurisdiction1.pdf

What Human Subject Training Satisfies the IRB's Education Requirement?, continued

(continued from page 4) who will be responsible for an investigational drug or device (sponsor of an IND, IDE, NSR) are required to meet briefly with the EQuIP team to review responsibilities of the sponsor role as well as BCH resources available to them. CE credit is given to investigators who complete the requirement.

Department Meeting – Periodically members of our office are asked to address department meetings on topics related to human subjects issues. Generally, the presentations focus on issues of particular interest or importance to the specific group. Attendance is taken at these meetings and CE credit is given to attendees.

Research Protocol Case Discussions – These are human subjects cases presented (continued on page 6)

What Human Subject Training Satisfies the IRB's Education Requirement?, continued

(continued from page 5) by CCI to faculty/ staff groups offered to departments for an opportunity to have research protocol case-based discussions with their faculty at a group meeting. CCI staff attend the departmental meeting and lead discussion on research protocol cases that are specifically selected and developed for the particular discipline giving investigators and their staffs the opportunity to consider human subject protection issues as they apply to an example protocol. Attendance is taken at this lecture and CE credit is given to attendees.

Roundtable Discussions with Research Nurses and Coordinators – These are Research Coordinators Rounds at which human subject protection issues are presented by CCI staff. Attendance is taken at these meetings and CE credit is given to attendees.

Related:

How Do I View Training Information for Myself or Research Team Members?

How Do I Print Training Certificates?

Welcome, Siena Napoleon!

In April, a new IRB Administrator, Siena Napoleon, joined our team. Siena brings with her several years of experience working in clinical research in the Neurology and Psychiatry departments at MGH, as well as in the Genetics Lab at McLean. She majored in psychology and cognitive and linguistic sciences at Wellesley and is currently pursuing a master's degree in public health at Boston University with a dual concentration in health policy and management and pharmaceuticals. Her experience and her interests will prove valuable assets to our team. Please join us in welcoming Siena to Boston Children's Hospital.

With the addition of Siena to the team, our office has reorganized the department assignments. Please also note that we have changes the administration for Psychiatry (Siena Napoleon) and Radiology (Ashley Pysczynski) so that Matt Stafford, CCI Office Manager, can devote more time to other necessary office assignments.

Please see below for the IRB administrator assigned to assist your department with IRB protocols and human subjects issues.

Robleinscky Dominguez ext. 5-5935	Anna Mitchell ext. 5-3296	Ashley Pysczynski ext. 5-3297	Matt Stafford ext. 5-4965	Siena Napoleon ext. 8-4022
Adolescent Medicine	Dentistry	Cardiac Surgery	Laboratory Medicine	Emergency Medicine
Anesthesia	GI/Nutrition	Cardiology	Molecular Medicine	Endocrinology
Immunology	General Pediatrics	Developmental Medicine	Pathology	Hematology Oncology
Medical Critical Care Program (MICU/ICP)	Genetics	Infectious Diseases	Physical Therapy & Occupational Therapy	Nursing
Nephrology	Neurosurgery	Neurology	Radiation Therapy	Orthopedic Surgery
Newborn Medicine	Otolaryngology	Pharmacy		Urology
Ophthalmology	Research Administration	Plastic Surgery		Psychiatry
Surgery	Respiratory Diseases	Radiology		

Boston Children's Hospital

Boston Children's Hospital
Committee for Clinical Investigation

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Boston, MA 02115

Phone: 617-355-7052
Fax: 617-730-0226
E-mail: cci@childrens.harvard.edu
Web: http://childrenshospital.org/cfapps/research/data_admin/Site3020/mainpageS3020P1.html

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.

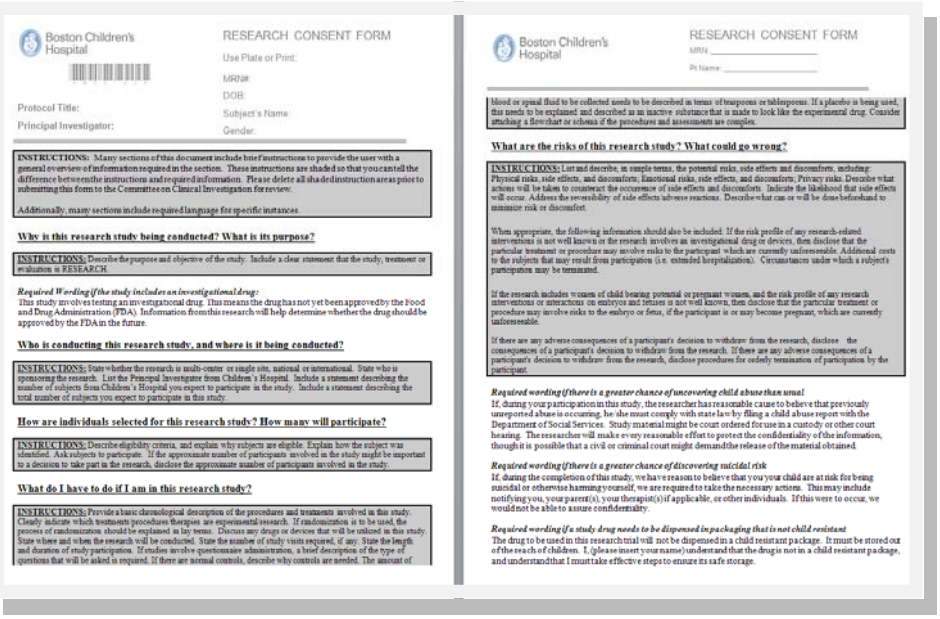
- Have questions or comments about any of the articles in this newsletter?
- Need advice about your research?
- Want to know more about human subjects protection at BCH?

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

New Consent Form Template, continued.

(continued from page 1) increasingly more difficult to guarantee that only the research team members will know that a subject is participating in research. With the increased use and integration of electronic records, it is possible that others within Children's will know that a child has participated in research. However, we all need to respect the same confidentiality provisions that exist for any other hospital record. The revised template explains to families the limits of confidentiality.

Other changes include revisions in the contact information chart and the signature templates. Our office will revise the signature section for approved studies at the time of continuing review. Please use the new template for all new submissions. The new template can be found on our website at: http://childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/Consent_Template.doc


Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Protocol Title:

Subject's Name:

Principal Investigator:

Gender:

INSTRUCTIONS: Many sections of this document include brief instructions to provide the user with a general overview of information required in the section. These instructions are shaded so that you can tell the difference between the instructions and required information. Please delete all shaded instruction areas prior to submitting this form to the Committee on Clinical Investigation for review.

Additionally, many sections include required language for specific instances.

Why is this research study being conducted? What is its purpose?

INSTRUCTIONS: Describe the purpose and objective of the study. Include a clear statement that the study, treatment or evaluation is RESEARCH.

Required Wording if the study includes an investigational drug:
This study involves testing an investigational drug. This means the drug has not yet been approved by the Food and Drug Administration (FDA). Information from this research will help determine whether the drug should be approved by the FDA in the future.

Who is conducting this research study, and where is it being conducted?

INSTRUCTIONS: State whether the research is multi-center or single site, national or international. State who is sponsoring the research. List the Principal Investigator from Children's Hospital. Include a statement describing the number of subjects from Children's Hospital you expect to participate in the study. Include a statement describing the total number of subjects you expect to participate in this study.

How are individuals selected for this research study? How many will participate?

INSTRUCTIONS: Describe eligibility criteria, and explain why subjects are eligible. Explain how the subject was identified. Ask subjects to participate. If the approximate number of participants involved in the study might be important to a decision to take part in the research, disclose the approximate number of participants involved in the study.

What do I have to do if I am in this research study?

INSTRUCTIONS: Provide a basic chronological description of the procedures and treatments involved in this study. Clearly indicate which treatments procedures therapies are experimental research. If randomization is to be used, the process of randomization should be explained in lay terms. Discuss any drugs or devices that will be utilized in this study. State where and when the research will be conducted. State the number of study visits required, if any. State the length and duration of study participation. If studies involve questionnaire administration, a brief description of the type of questions that will be asked is required. If there are normal controls, describe why controls are needed. The amount of

Boston Children's Hospital

RESEARCH CONSENT FORM

MRN: _____

Pt Name: _____

blood or spinal fluid to be collected needs to be described in terms of teaspoons or tablespoons. If a placebo is being used, this needs to be explained and described as an inactive substance that is made to look like the experimental drug. Consider attaching a flowchart or schema if the procedures and assessments are complex.

What are the risks of this research study? What could go wrong?

INSTRUCTIONS: List and describe, in simple terms, the potential risks, side effects and discomforts, including: Physical risks, side effects, and discomforts; Emotional risks, side effects, and discomforts; Privacy risks. Describe what actions will be taken to counteract the occurrence of side effects and discomforts. Indicate the likelihood that side effects will occur. Address the reversibility of side effects/adverse reactions. Describe what can or will be done beforehand to minimize risk or discomfort.

When appropriate, the following information should also be included: If the risk profile of any research-related interventions is not well known or the research involves an investigational drug or devices, then disclose that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable. Additional costs to the subjects that may result from participation (i.e. extended hospitalization). Circumstances under which a subject's participation may be terminated.

If the research includes women of child bearing potential or pregnant women, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known, then disclose that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.

If there are any adverse consequences of a participant's decision to withdraw from the research, disclose the consequences of a participant's decision to withdraw from the research. If there are any adverse consequences of a participant's decision to withdraw from the research, disclose procedures for orderly termination of participation by the participant.

Required wording if there is a greater chance of uncovering child abuse than usual
If, during your participation in this study, the researcher has reasonable cause to believe that previously unreported abuse is occurring, he/she must comply with state law by filing a child abuse report with the Department of Social Services. Study material might be court ordered for use in a custody or other court hearing. The researcher will make every reasonable effort to protect the confidentiality of the information, though it is possible that a civil or criminal court might demand the release of the material obtained.

Required wording if there is a greater chance of discovering suicidal risk
If, during the completion of this study, we have reason to believe that you/your child are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying you, your parent(s), your therapist(s) if applicable, or other individuals. If this were to occur, we would not be able to assure confidentiality.

Required wording if a study drug needs to be dispensed in packaging that is not child resistant
The drug to be used in this research trial will not be dispensed in a child resistant package. It must be stored out of the reach of children. I, (please insert your name) understand that the drug is not in a child resistant package, and understand that I must take effective steps to ensure its safe storage.

Pages 1 and 2 of the new consent template, available for download from the CCI website under the "forms" tab