# Human Subjects Protection Update
# Special Communication
# November 26, 2018



**Mailing Address**
Mailstop BCH 3164
300 Longwood Avenue
Boston, MA 02115

**Office Location**
Landmark Center
401 Park Drive
7th Floor
Boston, MA 02115

Phone: 617-355-7052
Fax: 617-730-0226
Email: irb@childrens.harvard.edu
Web:
http://www.childrenshospital.org/research/IRB

On January 21, 2019 the Federal Policy for the Protection of Human Subjects (a.k.a. the New "Common Rule") revisions will take effect. The regulatory changes apply to all federally-funded research. Investigators and their research teams need to understand the changes. We are revising functions in CHeRP and the associated forms in order to implement these changes. Many changes will be transparent and appear as revisions in the CHeRP forms and notices, however there are significant changes that will apply to the consent format for all (including FDA regulated) consent documents.

**As of now, FDA has not revised their regulations; however the consent revisions are permissible for FDA regulated research. FDA will likely harmonize their regulations in the near future. Boston Children's Hospital has voluntarily decided to apply some of the new regulations to research projects that ARE NOT under FDA or HHS jurisdiction in order to help reduce regulatory burden.** This includes research supported by non-profit foundations and internally-funded research.

Please read this communication and plan to attend one of the training sessions being offered. Attendance will count as continuing education credit for human subject protection training. The following training sessions will be held in the **Enders Auditorium:**

| | |
|---|---|
| December 6, 2018 | 2-3 |
| December 12, 2018 | 11-12 |
| December 20, 2018 | 3-4 |
| January 7, 2019 | 3-4 |
| January 11, 2019 | 9-10 |

In addition, IRB staff are available to attend department, divisions and program meetings during December and January if there be a minimum of 20 or more individuals present. We will do our best to accommodate smaller groups after the implementation date. Please email **Lauren Sever** (lauren.sever@childrens.harvard.edu) with requests for training. Please include the name of your group, suggested times and the expected number of individuals that will attend. You will be responsible for establishing the training location.

**All changes will apply to research that has *an approval date as of January 21, 2019***. For this reason, if you have a protocol that is under review on January 21, 2019 it is possible you will receive requests for additional changes in order to bring the protocol/consent into compliance. More information about the transition period will be forthcoming. We have tried to anticipate and plan for all the transition and new requirements with very limited guidance from the federal agencies. We are told guidance will be forthcoming. We know we may need to "course correct "and there will be "bumps" along the way. Thank you for being patient and understanding as we implement these changes.

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## Summary of Regulatory Changes: Informed Consent:

There are several required changes involving the informed consent. **As an institutional policy we are applying these changes to ALL consents approved by the IRB on or after January 21, 2019. The changes include the following:**

a. "Key information" must be presented at the beginning of the consent form. This includes a concise summary of study activities, risks, and benefits presented to research participants at the start of the consent. This new section is intended to help a subject decide why they would or would not want to participate in the research protocol. We have developed a template and some sample documents that may be found on our website.

b. There are new required elements for the consent document. Please note many investigators have already included these provisions in their consents, however we need to make sure they are included in all consents going forward. You may find template language in the revised informed consent template on the IRB website.

Theses sample documents and the new consent form template are available at http://www.childrenshospital.org/research/institutional-review-board/information-for-researchers/informed-consent.

| When your protocol involves | Must be included in the consent |
|---|---|
| collecting identifiable private information or identifiable biospecimens | <u>You must choose one:</u><br>A statement indicating whether:<br>• identifiers might be removed and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator; or<br>• the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. |
| collecting and using biospecimens | A statement indicating whether:<br>• biospecimens may be used for commercial profit, and whether the subject will share in that profit<br>• the research will or might include whole genome sequencing (sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) |
| research that could produce clinically relevant individual results | A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions. |

<u>You should begin to develop consents with key information and these statements included at this time. Any consent form that is "in process" on January 21 may be returned and require revision.</u>

c. **For federally-sponsored clinical trials**, a copy of an approved consent form must be posted to a "publicly available, federal website" after the last subject is recruited but no later than 60 days after the last study visit by any subject. ClinicalTrials.gov is an acceptable website. Investigators are responsible for posting their consents within this time frame. More information about this requirement will be provided as we receive additional regulatory guidance.

*Please note the new regulations contain a very specific provision for a method of limited IRB review and approval of "Broad Consent" for unspecified future use of identifiable data/specimens. BCH will not implement this new regulatory option at this time. This provision in the regulation is optional. Most large academic institutions are not implementing this provision because of the complex provision for institutional recording keeping track of those who "opt out".* ***Please note this does not interfere with the ability to have IRB reviewed protocols/consents that contain broad provisions for collecting, sharing and using biological samples and data.***

## Continuing Review Regulatory Changes (Cannot apply to FDA regulated research)

**Continuing review will no longer be required for:**

a. minimal risk research that falls under the regulatory categories for expedited review.

b. studies where the only remaining activity is data analysis of identifiable data/bio specimens or activities to obtain only follow-up clinical data.

**How we will implement**:

Instead of requiring a continuing review submission, we will require a brief annual administrative "check in" in order to keep the research active, but it will not undergo IRB review. These changes will be implemented in CHeRP. Investigators will receive the pertinent review reminders through CHeRP.

## Exemption Categories (Cannot apply to FDA regulated research)

The categories for exemption have expanded. The regulations provide a list of "exempt" research activities that meet the definition of human subject research, but may be conducted without applying all of the IRB review requirements. We have revised our exemption form to cover the new criteria. The biggest change at BCH will apply to research involving the secondary use of specimens and data acquired for purposes other than research. The new exemption criteria are expanded to include the use of data and documents that will be collected in the future (not just those that already exist) and in some cases, even when identifiers are maintained. This expansion will reduce the number of protocols that need to undergo expedited review and may now be considered exempt. Investigators are still required to complete a form to request an exempt determination by the IRB administrative office. There is also a new exemption category for benign behavioral interventions; however, this only will when adults are research subjects.

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**How we will implement:**

The Exemption and Limited Data and Specimen Use forms have been revised and will be posted as of January 21, 2019 to include the new categories. All uses of biological specimens and data must still be submitted through CHeRP on the Limited Specimen and Data form. We have revised some questions to help us with make the new exempt determinations. The IRB staff will determine whether the use of the specimens/data is exempt or needs to go through expedited review. HIPPA provisions for waivers of authorization will still need to apply. We will post additional information on the exemption categories on our website as of January 21, 2109.

## Single IRB review

IRB oversight for federally-funded collaborative research projects located in the U.S. will be required to use a single IRB starting January 20, 2020. The NIH currently requires the use of a single IRB. This requirement will be expanded to all federally funded research by January 20, 2020. There is still on year before this is a mandatory requirement. Investigators may consider the use of a single IRB on a voluntary basis at any time.

*Additional information about the regulatory changes and transition provisions will be provided as we receive additional guidance from the regulatory agencies and as it gets closer to the implementation date. Please feel free to call your IRB analyst with questions at any time.*