Tufts | Health Sciences

Health Sciences Campus Institutional Review Board

Welcome to the Winter 2019 Edition of Tufts MC / TUHS IRB News

Providing updates and useful information from the IRB office for Investigators, Coordinators, and other members of your Research Team

Final Revisions to the Common Rule

The set of revised federal regulations for the ethical conduct of human subjects research took effect on **January 21, 2019**.

These regulations implement new steps to better protect human subjects involved in research while helping to facilitate valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

As part of this new update to the federal regulations, some of our forms and review procedures have changed. Below you can find information about major updates that impact your submission. Please contact the IRB Office with any questions.

Update: Common Rule Changes Affecting Minimal Risk Research Review

Changes to the exempt categories include:

- Changes to the definitions
- Revisions to all but one of the exempt categories
- The addition of new categories
- The introduction of two new processes:
    - *Limited IRB review*
    - *Broad consent (not being implemented at our institution at this time)*

Refer to the following Tufts Health Sciences IRB resources:

- Overview of the Common Rule Change
- Changes affecting Minimal Risk Research
- Recorded Presentation

Other resources:

- CITI Program Final Rule Resources

Update Common Rule Changes Affecting Continuing Review

Find the updated Form 5 here [*Version Date: 01/01/2019*]!

Continuing Review is no longer required for some minimal risk research. Rather, an Administrative Annual Review is conducted for the following studies :

- Studies that are not subject to FDA regulations
- Studies that are not federally funded and have never received federal funding
- Studies that are federally funded, which were initially approved after 21 January 2019
- Studies reviewed under OHRP expedited review categories 1 to 7 at the study's most recent IRB review (initial or continuing)
- Research that has advanced to involve only one or both:
    - Data analysis, including analysis of identifiable privacy information

Important Update: New Request for Exemption Form

Form 7 and the Request for Exemption form have been consolidated. The updated Form 7 (Request for Exemption) can be submitted for all studies that qualify for exemption under the new rule, which includes chart/data/specimen review studies.

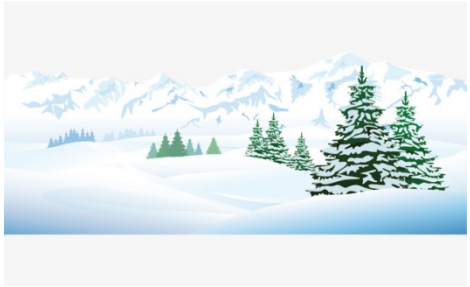
Tufts University / Tufts Medical Center	**FORM 7: Request for Exemption**

What this means for your study:

- Prospective data/specimen analysis is permitted for exempt studies.
- Auditory and visual recording is permitted for exempt studies.
- Adequate provisions must be put in place to protect the privacy of subjects and to maintain data confidentiality for categories that allow for use of sensitive or identifiable health information.
- A new term "*Benign Behavioral Intervention*" has been introduced: brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, unlikely that subjects will find interventions offensive or embarrassing.
- Categories 7 and 8 involve the use of "*Broad Consent*". These categories relate to the broad or blanket consent for storage and future use of identifiable private information or biospecimens. ***Broad consent will not be implemented at Tufts Medical Center or Tufts University at this time.***

Updated Form 7 (Request for Exemption Form) will be required for all exempt submissions starting 1 February 2019.

Studies submitted prior to 1 February 2019 may be reviewed on the old forms but must comply with the new rule as of 21 January 2019.



  - or identifiable biospecimens, and/or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care; not specifically for research

***NOTE:* Eliminating continuing review does NOT apply to federally funded research initially approved before 21 January 2019.**

***What this means for your study*:**

- If your study meets the above criteria, you will need to complete an Administrative Annual Review (AAR) using the revised Form 5.
- If your study does **NOT** meet the above criteria, you still need to submit a Continuing Review (complete the entire Form 5 and submit supplemental documents).
- Reportable New Information (RNI) and Amendments / modifications to the approved research must be submitted to the IRB for review and approval regardless of whether Continuing Review or Administrative Annual Review applies to your study.
- **Reminder: Make sure to submit by the deadline in order to avoid a lapse in IRB approval! Conducting research after IRB approval has expired for the study will constitute non-compliance.**

New: Common Rule Changes related to IRB review of grants

1. The IRB no longer requires a copy of the grant or grant progress reports
2. The IRB will no longer make a finding that the proposed research is within the scope of the grant (grant congruency)
3. If there is an overarching grant* or "general certification", a separate IRB approval will no longer be required for the overarching grant.

The Form 1 and Form 5 have been updated to reflect these changes. Feel free to take a look!

**A general certification refers to IRB review and approval of a grant that has no human subjects research itself, but covers multiple studies under different IRB #s, such as an overarching cooperative group grant.*

Update: Common Rule Changes Affecting Vulnerable Populations

The changes in regards to vulnerable populations are as follows:

- Pregnant women are no longer considered to be a vulnerable subject population.
- The term “mentally disabled persons” has been replaced with “individuals with impaired decision-making capacity”.
- There is now more of a focus on vulnerability to coercion or undue influence in reference to subjects’ ability to make informed decisions about participating in research (so less of a focus on physical vulnerability).

As a researcher, consider factors such as societal marginalization or discrimination that can lead to the following in your subject populations:

- Being targeted to take on the burdens of research, potentially without the promise of proportionate benefits.
- Vulnerability to being exploited or disrespected during the research process, due to inequalities of power or other resources.
- Vulnerability to taking on excessive risks such as environmental or social factors that make research participation particularly risky for some populations
- Vulnerability to being excluded from the opportunity to participate in research for reasons of convenience.

Update Common Rule Changes Affecting Informed Consent

The informed consent form (ICF) templates have been revised to include changes required by the Common Rule. The goal of the changes is to help prospective subjects understand the reasons why they might or might not want to participate in the research:

- The ICF must begin with a concise and focused presentation of key study information that a “reasonable person” would want to have
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

The template has also been revised to combine the Adult ICF and Parent/Guardian Permission Form into one template. Click here for the revised template.

This template is required for all new studies that use an ICF.

New: Looking to Request a Reliance Agreement? Check Out New Versions of the IRB Forms!

Form 10 has been split into three separate forms! Reliance agreement forms are now designed for each specific situation:

- Form 10A (Request to Assume Oversight; IAA) To request Tufts Health Sciences IRB ***assume (take on)*** IRB oversight for research at another institution
- Form 10B (Request to Cede Review; IAA) To request Tufts Health Sciences IRB ***cede (give up)*** oversight for research to

New: New Modules for CITI IRB Training

In September of 2014, Tufts Medical Center and Tufts University posted updated Human Subject Research Educational Requirements. Updated requirements included new modules and a requirement for certification every 4 years.

Researchers who completed their CITI in 2014 should keep their eyes open for expiration notices sent from CITI and complete a “Refresher Course,” which will be valid for

another IRB

- Form 10C (Request for Independent/ Institutional Agreement; IIA) To request Tufts Health Sciences IRB ***assume (take on)*** IRB oversight for research for an independent investigator or ***institution that does not have an FWA***.

another 4 years. You will find this Refresher Course when you log onto the CITI website.

New optional modules are available for investigators who are interested in learning more. These modules include:

- ✓ Revised Common Rule
- ✓ Responsible Conduct of Research for Administrators
- ✓ Clinicians - Information Privacy Security
- ✓ Clinical Research Coordinator Training
- ✓ Clinical Research Coordinator (CRC) – Foundations or Advance
- ✓ Privacy and Security Course

New: Recruitment Phone Scripts

As a reminder, plans for using recruitment scripts should be detailed in the Protocol or Site-Specific Appendix. Please be sure to describe:

- Information that will be provided to participants about the study
- Information that will be collected from subjects (e.g. name, telephone number, etc.)
- Submit the proposed e-mail text and/or telephone script (including both the telephone conversation if the person answers and a voicemail message script if the person doesn't answer) for IRB review and approval
- A plan describing how many times you will attempt to call, and how many times you will leave a voicemail message
- Remember to limit the amount of information disclosed in a voicemail / e-mail / text message. Avoid describing the study details, diagnosis / health condition, and other eligibility criteria to protect the potential subject's privacy.

New: IRB Electronic Submission System is coming!

We are excited to announce that Tufts University and Tufts Medical Center are working with Huron Consulting Group on implementation of a new electronic submission system that can be used for Tufts Health Sciences IRB and Social, Behavioral & Educational Research Institutional Review Board (SBER IRB) submissions.

Over the next year, we will be reaching out to investigators, research teams, and committee members to get feedback on how to seamlessly implement the electronic system. As new information becomes available, we will share it with our research community.

Tip: Best Practices for Submitting Revisions for Study Documents

1. Some Amendment Cover Letter items are expandable, so when you click "Yes" on a specific question (i.e. #19), it may expand to ask additional questions. To activate this, click "Enable Content" at the top of the document when you open the cover letter

Tip: How to Determine if Your Study is Subject to FDA Regulations

The FDA oversees the conduct of clinical studies involving FDA-regulated products. FDA requires IRB review of all:

- Clinical investigations using test articles regulated by the FDA, as well as
- Clinical investigations conducted in support

2. Please make an effort to not submit multiple, separate amendments at the same time, and instead put them together into one amendment whenever possible. Study modifications will be reviewed in the order they are received in the office.
3. You can submit an amendment with your continuing review if needed. When you do so, make sure to also include the Amendment Cover Letter with the submission.
4. Revisions to study documents should be made and tracked off of the most recent IRB-approved version of that document.
5. Always update the version date of the revised document.
6. When updating your header and footer (including the version date), make sure the update happens on every page of the document.

If you have any questions please contact the IRB Office!

of applications for research or marketing permits for other articles regulated by the FDA, including:

- Foods,
- Dietary supplements, that bear a nutrient content claim or a health claim,
- Infant formulas,
- Food and color additives,
- Drugs for human use,
- Medical devices for human use,
- Biological products for human use, and
- Electronic products.

Refer to this link for additional information about what the FDA regulates: https://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm

You may also refer to the decision tree on page 2 of the Form 2 (Drug) or Form 3 (Device) for more information.

If you are still uncertain if your study is regulated by the FDA, reach out to the study sponsor to provide this information.

If you have any questions, always feel free to contact the IRB office at ext. 6-7512.

Attention! Louis Lasagna Award 2018

Featured Andreas Klein, MD and Britta Magnuson, DMD

Congratulations to **Britta Magnuson, DMD** Assistant Professor for the Department of Diagnostic Sciences and Assistant Director of Biostatistics and Experimental Design at Tufts University School of Dental Medicine (TUSDM) for being the 2018 recipient of the Louis Lasagna, MD Outstanding Institutional Review Board (IRB) Member Award. This award is given to an IRB member who exemplifies Dr. Lasagna's extraordinary care, concern, and compassion for research subjects and his

Attention! Plain Language for Health Workshop, March 28-29

Want to improve your writing skills and communicate health research information and results in ways people can understand? Join Tufts University School of Medicine (TUSM) and Tufts CTSI at Plain Language for Health: Writing and Design for Health Research and Practice on **Thursday, March 28 and Friday, March 29** at the Jaharis Family Center for Biomedical and Nutrition Sciences (150 Harrison Avenue, Boston).

In this exciting two-day workshop, speakers from TUSM, Tufts Medical Center, and the University of Arkansas for Medical Sciences will lead interactive discussions and exercises to apply the principles of health literacy and plain language in health research and practice. The workshop will teach actionable skills and techniques to improve community engagement and connections with patients, research participants, and the community.

advocacy for candor, honesty, and integrity in the design and execution of clinical research.

Britta has served as a member on the IRB since 2014. She was commended for her expertise in dental research, her keen and thorough reviews, and her ability to help investigators interpret complicated human subjects regulations and apply them to their research.

[Sign up here](#) today!

Ask the IRB…

Question: Are requests for Tufts Medical Center / Tufts University to give up or take on IRB oversight for a study always automatically approved?

Answer: The institutions have a process for carefully considering each request on a case-by-case basis in order to decide whether or not to give up oversight or take on oversight. There are many factors that are considered, such as the type of study, the proposed research procedures, the participating sites, etc.

Note: For NIH applications, NIH expects that all sites participating in multi-site research, will use a [single Institutional Review Board (sIRB)](#) to conduct the ethical review required for the protection of human subjects.

Ask the IRB…

Question: I am the PI at Tufts but we have relied on another external institution for IRB review. What consent form should I use for enrolling participants at Tufts?

Answer: The external IRB should provide you a consent form that they have reviewed and approved for use. Take this consent form then and insert Tufts-specific information (i.e. headers, HIPAA language, research related injury language, contact information, etc.). Then submit to both Tufts IRB and the external IRB for review and approval.

Typically, informed consent forms approved by the IRB of record are distributed to all relying sites for them to insert their local information. The site-specific consents are then submitted to the external IRB of record for final approval and validation.

Ask the IRB…

Question: I am completing the Form 5 for my chart review study. If I have completed reviewing records, would Section B: questions #1-4 apply for my study?

Answer: No. Questions #1-4 under Form 5: Section B are **only** intended for studies that enrolled subjects with an informed consent form and are now permanently closed to subject enrollment. If your study is a retrospective chart review, complete question #7 instead.

Ask the IRB…

Question: An IRB Authorization Agreement (IAA) has been executed for my study, where Tufts is the IRB of record. How do I complete Form 5s for these external sites?

Answer: Refer to the guidance webpage on this that we just posted to our website!: [How to Complete Form 5 for External Sites under an IAA](#).

This page provides guidance on what information is needed section-by-section from the Site PI.

Attention! New Coordinators & PIs

Please add new PIs and Coordinators to the IRB email distribution list to receive IRB newsletters and other important IRB information. Email IRBOffice@tuftsmedicalcenter.org to request for someone to be added.

If you know someone who is new to the IRB process, please let them know they can schedule an orientation meeting with the IRB office staff to review our website, types of IRB review, discuss meeting deadlines, IRB tips, and more! You can also schedule an appointment to review a study submission you are working on. We are always happy to meet with you in person to answer questions!

IRB Office Staff Updates:

Jen Arcuri has joined the IRB staff as our IRB Administrative Assistant II. **Welcome, Jen!**

Rebecca Elias, MPH, has been promoted to IRB Administrator I and works on new minimal risk submissions. **Congratulations, Rebecca!**

Contact us!

Bookmark our IRB Staff page for guidance to contact the staff member who can best provide assistance with specific questions.

Follow us on Twitter

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Tufts MC / TUHS IRB website: http://viceprovost.tufts.edu/HSCIRB/

Do you know someone who would like to receive IRB News?
Send us their name and e-mail address so we can add them to our IRB distribution list: irboffice@tuftsmedicalcenter.org

Contact our office at **617-636-7512 Monday to Friday, 8:30 am to 5 pm** or stop by during IRB Drop-In Hours **Tuesday 2 to 4 pm.** We are located in the **Tupper Building at 15 Kneeland Street, 1st floor.**

Tufts University

Tufts Medical Center