



HUA IRB News

A monthly newsletter brought to you by the Harvard University Area IRB

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Telephone Consumer Protection Act

You may remember the Telephone Consumer Protection Act (TCPA) that went into effect in the early 1990's as the regulation to stop "robocalls". This is also the same Act that created the "Do Not Call" registry. But did you know that the Act also applies to SMS/text messaging? In a nutshell, the TCPA stipulates that businesses and/or organizations must receive **express written consent** from individuals prior to sending any SMS/text messages to them.



Thinking about sending random text messages as part of your recruitment procedures? Just remember that obtaining an individual's phone number is not the same as receiving permission to contact them.

The TCPA (in all its glory) may be found [here](#).

Do You Speak IRB? Study Team Member



Did you know that not all individuals working on your study are "study team members"? While some federal agencies are only interested in knowing about the "[key personnel](#)" on a study, here at Harvard we use a different set of criteria to determine who is a study team member. Our criteria are largely based on the regulatory concept of "[engagement](#)" such that if a person working on your study: a) has contact with human subjects, b) has access to data that is identifiable; or c) is responsible for the design, conduct, or reporting of the research, they are considered a study team member and will need to be listed in your IRB submission.

Another thing to know about study team members is that study team members may be from Harvard or they may be from another institution. If you are requesting that study team members from another institution receive IRB review from Harvard and they are considered “engaged” (see above), you will need to include them in your IRB submission too.

IMPORTANT REMINDER! Once you add these study team members, there is also the responsibility to keep this study team list up to date. Instructions on how to submit a study team modification may be found [here](#).

Instructions on how to add study team members (affiliated and non-affiliated with Harvard) may be found [here](#). Just scroll down to the heading “SmartForm Section: (Local) Study Team Members”

How to send comments in ESTR

ESTR does a lot of things but one thing that many people forget is that ESTR is also a place where you can communicate with your IRB Coordinator during and after the review of your study. Using this feature in ESTR is the preferred method of communication as ESTR keeps a tidy record of the correspondence all in one place.



Go ahead and give it a try. See below for instructions on how to do so (from the [ESTR Study Submission Guide](#)).

Communicating with Staff During Review

During review (and after), you can complete the **Add Comment** activity to:

1. Post a note to the submission history that all individuals with access to the submission may view, and
2. If selected, send a notice to:
 - PI/PI Proxy and Primary Contact
 - Study Team Members and/or
 - The assigned IRB Coordinator (If the IRB Coordinator box is selected and there is no assigned IRB Coordinator, a notice is sent to all members of the IRB office.)

During review of a site (and after), you can complete the **Correspond with Site** or **Correspond with sIRB** activity, and:

1. Send a notice to any person associated with the study or site, including the other IRB office contact.
2. Include the text in the activity within the email sent to the recipient(s), and
3. While not preferred, if a person chooses to reply to this notice: you will receive replies to this notice in your email inbox, rather than posted on the submission workspace.

Important!

- The information in the comment is visible to all individuals with access to the submission even if they are not selected as notice recipients.
- Do not attach items which are part of the regulatory review.
- If a submission is in the Clarifications Requested state, use the Submit Response activity to send information back to the IRB for continued review.

Rumor – If your study is considered minimal risk, you don't need a consent form

Okay, okay, while it is true that there are minimal risk studies that do not include an informed consent process, this does not mean that this is a given. We'll try to explain the reason why without going too far down a regulatory rabbit hole –



The IRB criteria for approval found in the federal regulations take a default position on many aspects of research including that “Informed consent will be sought from each prospective subject or the subject's legally authorized representative...” If this is default position, how can a research study not have an informed consent process? This is where a waiver of informed consent comes in.

Of course, IRB's do not hand out a waivers of informed consent carte blanche; there are criteria that must be met! According to the regulations:

For an IRB to waive or alter consent, the IRB must find and document that: (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the requested waiver or alteration; (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Do these criteria sound familiar? The reason why is that the HUA IRB Protocol Template asks you about these very same criteria if your study is not planning to obtain informed consent from study subjects. If the rationale meets the threshold for a waiver, the IRB will issue one. Not carte blanche, but not a painful process either.

Tracking Staff on External IRB Submissions

Have you ever submitted an External IRB request in ESTR asking for Harvard to cede review to another institution with whom you may be collaborating? If so, have you ever wondered who should be listed on the “Study Team Members” page? While you don't need to list those who are not affiliated with Harvard, all Harvard affiliates (faculty, staff, students, volunteers, interns, and



temporary workers) who have contact with human subjects; have access to data that is identifiable; or are responsible for the design, conduct, or reporting of the research do need to be added to the “Study Team Members” page. *Sound familiar?*

All study staff, in addition to the Harvard Principal Investigator, need to be identified in External IRB submissions because when Harvard relies on another institution to provide review for a collaborative research project, the IRB of Record is trusting us to ensure that our agents are in compliance with our human subjects ethics training requirements and to evaluate any potential Financial Conflicts of Interest, among other things.

Just as with any research project, the Harvard study staff working on an External IRB project may change over the lifetime of the study. It is equally as important with these type of studies as it is with Harvard-reviewed studies to report these changes in study staff to the HUA IRB. This can be accomplished by submitting a “Site Modification” by visiting the main page in ESTR for the External IRB submission and clicking the “Create Site Modification/Modify Site” button. Detailed instructions can be found in the ESTR Study Submission Guide in the [“Updating External IRB Review”](#) section.

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