Guidance and Procedures for Investigators

Topic: Re-Contacting Subjects from Existing Research Studies

Including a "Re-Contacting Provision" in the Informed Consent Document

Many investigators may want to "re-contact" research subjects who participated in existing studies to recruit for future studies, or to obtain additional information or clarification related to their participation in the existing study. These existing studies may be currently active or they may be closed (i.e. enrollment and all study study/follow up completed). Since it is important to protect the confidentiality and privacy of research subjects, in most situations, it will not be appropriate to re-contact research subjects unless they had previously agreed to such a re-contacting while consenting to participate in the existing study. For this reason, we recommend that all investigators include a "re-contacting" provision in the informed consent document. This provision will allow subjects to "opt in" or "opt out" of future contact about participating in future research studies. Below is some IRB recommended language for re-contacting subjects that could be incorporated into the consent form when appropriate:

> ***Participating in Future Research Studies***
>
> *We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted about any future research studies.*
>
> _____ *Yes, I agree to be contacted about future research studies.*
>
> _____ *No, I do not want to be contacted about future research studies.*

A list or database of subjects who agree to be re-contacted can be created from those who respond "yes" to future contact. Subjects who opt out of future contact should not be included in the list or database, and should not be contacted about participating in future research studies as a result of being in the present study.

Examples of Re-Contacting Subjects

The process for obtaining IRB approval to re-contact subjects will vary depending upon the re-contacting provisions that are included (or not included) in the existing study, the status of the existing study (active or closed), and the purpose behind re-contacting the subjects. Here are some examples of situations that involve "re-contacting" subjects from an existing study.

Example 1: Re-contacting subjects from an existing study that is currently active to recruit for a future study.

Example 2: Re-contacting subjects from an existing but closed.

Example 3: Re-contacting subjects from an existing study that is active to get additional information or samples or to obtain new information for a whole new (separate) study.

Review the IRB Approved Consent of the Existing Study

Before proceeding any further in preparing the IRB application (and prior to contacting the IRB), the investigator should review the IRB approved consent form being used/previously used for the existing study to determine if there is a re-contacting provision in the consent form. The procedures to follow will depend upon the presence or absence of the re-contacting provision as described below.

Existing studies with a Re-Contacting Provision

If this clause is in the informed consent of the existing study, the investigator may re-contact subjects. The investigator should include/describe the following (in addition to the other required forms and documents) with their IRB application:

1. Signed memorandum or letter of agreement from the Principal Investigator of the existing study giving permission to re-contact their subjects, and use their existing data (if applicable) for the future study.
2. Copy of the most recent IRB approved informed consent that contains the re-contacting provision for the existing study.
3. In the protocol synopsis, list the project title (s) and Principal Investigator(s) of the existing study(s) in the "Recruitment of Subjects" section, and state if the existing studies are active or closed.
4. In the protocol synopsis, describe the methods and procedures that will be used to re-contact subjects.
5. Recruitment materials (such as letters, emails, and phone scripts) that will be used to re-contact subjects.

Investigators should remember to include a re-contacting provision in the proposed (new) consent form for the new study if appropriate.

Existing studies without a "re-contacting" provision

As to you will see below, re-contacting subjects without their prior approval requires a keen respect for privacy and adherence to sound ethical principles. Often this process can seem complicated or confusing, but is still "do-able" if proper procedures are followed.

If the consent form from the existing study does not contain a re-contacting provision, the investigator does not automatically have the subject's permission to re-contact them about participating in the future study, or for additional information/clarification about the existing study.

Below are some options for an IRB submission to address this situation.

Re-contacting Subjects for Additional Information/Clarification within an Existing Study

Option #1-Modify the Existing Study: The investigator should consult with the Principal Investigator (PI) of the existing study (as long as it is still active), and determine if it is appropriate to modify the existing protocol to include the new research activities. If this is appropriate, the PI of the existing study should submit a request to amend the protocol to the North Texas Regional IRB before the re-contacting occurs. Please submit the following information with this request:

1. Signed cover memo describing the request for modification to the protocol to include the re-contacting and/or additional research activities.
2. Tracked changes and clean version of the modified protocol (and consent form if necessary) incorporating the additional research activities.
3. Addition of study personnel who will be conducting the re-contacting.
4. All letters, emails, phone scripts and other communications that will be used with subjects related to the re-contacting.

Option #2-New Protocol Submission: In some cases, it may not be appropriate to modify an existing study, there may be a need for a separate study, or the existing study may already be completed/closed. Therefore, the subjects will be "re-contacted" to see if they want to participate in a future study. Please note that in this situation, any contact with subjects from the existing study is not authorized under that protocol, and all contact (and data collected) is a part of the future study. It is important to avoid "cold calling" the subject about the new study without prior IRB review and approval. Therefore, every effort should be made to ensure that the person conducting the phone calls is someone with whom the subject is familiar. If the investigator is using a written communication, such as a letter or email, the name (and signature when appropriate) of the PI of the existing project should be included so the subject can understand the connection to his or her participation in the existing study. The following should be included with the IRB application for the new study:

1. "Waiver of Documentation of Informed Consent" requesting to "re-contact" the subjects who participated the existing study.
2. Signed letter or memo from the PI of the existing study giving permission to re-contact their subjects, and permission to use their currently existing data (if appropriate).
3. Copy of the most recent IRB approved consent form from the existing study.
4. In the protocol, under "Recruitment of Subjects," list the study title (s) and Principal Investigator(s) of the existing study(s). Also indicate if the study is currently active or is completed/closed.
5. In the protocol, under "Methods and Procedures,"
    a. Describe the process for "re-contacting" subjects.
    b. Describe the informed consent process that will be used with subjects if they are interested in participating. This may involve a signed (written) informed consent, or a study cover letter/research statement, or an oral consent script depending… upon the project.
    c. Describe the process for collecting information/data from the subjects.
6. Submit any letters, emails, or phone scripts that will be used to recruit and/or follow up with study subjects.
7. Submit an informed consent document, study cover letter/research statement, or oral consent scripts as appropriate.

Re-Contacting to Recruit Subjects for a New Study

Option 1: Existing study is active: If the existing study from which you plan to recruit is active, the PI of the existing study will need to modify his or her protocol to include your recruitment activities. The North Texas Regional IRB will need a cover memo from the PI of the existing study describing the request for modification with "tracked changes" and "clean" versions of the revised protocol, informed

consent (if applicable), and supporting documentation (if applicable). When preparing your IRB application, include the following additional information/detail with your submission:

1. Copy of the most recent IRB approved consent form from the existing study.
2. In the protocol, under "Recruitment of Subjects" list the study title (s) and Principal Investigator(s) of the existing study(s).
3. In the protocol, under "Methods and Procedures," describe the process for contacting/re-contacting subjects for recruitment purposes. This may be done in person at a study visit, via phone, mail, email, etc.
4. In the protocol, describe if subjects will be currently enrolled in the existing study at the time of recruitment or if they will have completed the existing study (or both).
5. Submit any letters, emails, or phone scripts that will be used to recruit subjects from the existing study for IRB review and approval.

Option 2: Existing study is closed/completed: If the existing study from which you plan to recruit is closed or completed, the PI of the existing study will not be able to modify his or her study to include your recruitment activities. Therefore, you will need to submit the following with your IRB application.

1. "Waiver of Documentation of Informed Consent" requesting to "re-contact" the subjects from this previous ("existing") study to see if these subjects would be interested in participating.
2. Signed letter or memo from the PI of the existing study giving you permission to re-contact their subjects for recruitment purposes.
3. Copy of the most recent IRB approved consent form from the existing study.
4. In the protocol, under "Recruitment of Subjects" list the study title (s) and Principal Investigator(s) of the existing study(s), and indicate that it is currently closed.
5. In the protocol, under "Methods and Procedures," describe the process for "re-contacting" subjects to see if they are interested in the new study. This may be done via phone, mail, email. In an effort to avoid "cold calling", phone recruitment should be conducted by someone with whom the subject is familiar such as a study coordinator or research assistant, wherever possible. Include the name and signature of the existing study's PI or include their contact information in the email so the subjects can make the connection with their participation in the previous study.
6. Submit all letters, emails, and phone scripts that will be used to recontact subjects for recruitment purposes.