MARSHALL UNIVERSITY

Investigator's Manual
For
Human Subject Research

Prologue

This guide is based on applicable federal regulations, West Virginia state statutes, and Marshall University policy as they pertain to the conduct of human subject research at Marshall University.

Purpose

This purpose of this Investigator Manual is to help guide you through policies and procedures related to the conduct of Human Subject Research that are specific to Marshall University. In this manual, we have tried to provide answers to frequently asked questions. While this manual cannot possibly address every situation or question that may arise, it is designed to serve as a reference guide to assist you in your efforts to conduct human subject research and assist in protecting the rights and welfare of human participants in accordance with our Human Research Protection Program (HRPP).

We welcome your comments about the contents and structure of this manual. If you have suggestions on how to improve the document, please send your suggestions to the Office of Research Integrity (ORI).

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The ORI website can be located at: https://www.marshall.edu/ori

What is Human Subject Research?

Marshall University follows the regulatory definitions of "Human Subject Research," which are defined in the Standard Operating Procedures (SOP) Manual available on the ORI website. Investigators are responsible for not conducting Human Subject Research without **prior** Institutional Review Board (IRB) review and approval.

If you have questions about whether or not an activity is Human Subject Research, you can submit an abstract to the ORI (via email) and an IRB Chair or the Director of ORI will make a determination. See the section "*How to Write an Abstract"* for information about the contents of an abstract. If your abstract is deemed not to be Human Subject Research, then you will be provided a letter stating that determination. If your activity is deemed to be Human Subject Research, you will be provided assistance with an IRB submission.

What is the Human Research Protection Program?

The Marshall University Human Research Protection Program (HRPP) is a comprehensive and organized system to ensure the protection of human volunteers participating in research. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research. The SOP Manual on the ORI website describes the roles and responsibilities of the HRPP for the protection of human subjects.

How Long Does it Take to get IRB Approval?

Exempt reviews are conducted by the IRB Chair or the Exempt Designee and only take a couple of days. Expedited reviews are conducted by the IRB chair (or IRB designee) and this determination also only takes a few days. Keep in mind that if modifications are required by the IRB Chair or reviewer, approval will be dependent upon the amount of time required to make corrections.

Full board studies are reviewed at the monthly IRB meetings. IRB#1 (Medical) meets on the second Wednesday of each month and IRB#2 (Social/Behavioral/Education Research) meets on the third Wednesday. As a general rule, submissions need to be received 30 days prior to the meeting to allow proper review and process.

What is Exempt Human Subject Research?

Certain categories of Human Subject Research may be deemed as Exempt, but it still requires IRB review and approval. Investigators must obtain an IRB Exemption determination prior to conducting Exempt Human Subject Research. The Exempt categories can be found in the IRB application document located on IRBNet in the Forms and Templates Library. Investigators cannot make Exempt determinations themselves. The Exempt checklist should be used to indicate the exemption category you believe applies to your study. If you do not believe that your study is human subject research, you can submit an abstract to the Director, ORI (via email) and a determination will be made.

What Training is Required in Order to Conduct Human Subject Research?

All investigators, co-investigators and key research personnel must complete the online Collaborative Institutional Training Initiative (CITI) course. This educational training is required as part of our Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services Office of Human Research Protection (OHRP). An FWA is our contract with the federal government, stating we will abide by all federal regulations concerning human subject research and is a requirement for us to receive any federal research funding.

The course is broken up into modules that do not have to be completed in one sitting. You can log off the program and then log back on later to continue the course. CITI course registration instructions can be located on the ORI website under the Education/Training link.

There are separate courses for IRB#1 (Medical) and IRB#2 (Social/Behavioral/Education Research), so be sure to enroll in the course that relates to the IRB to which you will submit. You will find separate instructions for the two IRBs.

Please note that all key members of the research team are required to complete this training. That would be anyone handling identifiable information or consenting participants. The IRB submission will not be processed until all required personnel have completed the human research protections training.

Who can be Listed as a Principal Investigator?

Marshall University allows individuals with the proper research credentials to direct research involving human subjects by granting them Principal Investigator (PI) status. The institution has defined PIs as:

1) Full-Time or part-time faculty members who have been granted any of the following titles:
    - Probationary or tenured faculty (full, associate, assistant professors, or instructor)
    - Temporary faculty designated as visiting, research, clinical, extension, adjunct, or school of medicine that have a terminal degree and appropriate research credentials.
    - Emeritus faculty

2) Persons holding the following non-academic titles may serve as Principal Investigators on projects directly related to the mission and responsibility of their offices:
    - Director, Associate Director, Assistant Director

The Director, ORI has the authority to grant permission for an employee not meeting the above definitions to serve as a principal investigator.

Undergraduate and **Graduate students** and **students in any professional program** at Marshall University are **not** eligible to serve as PIs.

Residents (including Fellows) are also **not** eligible to serve as PIs. They are defined together under the Accreditation Council of Graduate Medical Education (ACGME).

Student Initiated Projects. For student-initiated projects, several conditions apply:

- A full-time faculty member, as identified under the policy, must serve as the Faculty Advisor.
- The Faculty Advisor will be required to manage the responsibilities as the PI under this policy.
- The student will be responsible for contributing to the project under the guidance of the Faculty Advisor.
- The student may be named as a Co-Investigator as long as the PI is still named as the responsible individual. The student should receive the appropriate acknowledgement.

The principal investigator is the person ultimately responsible for the research and protection of human subjects. It is also the principal investigator's responsibility to ensure the study is being conducted in the manner approved by the IRB.

How do I Write an Abstract?

An abstract should be written in lay terms and provide a brief summary of the study. The abstract must be 1-2 pages max and provide the reviewer with a complete and accurate description of the procedures to be performed. All of the following information should be addressed in the abstract:

- The Purpose of the Research and Scientific Rationale:
- The Procedures to be Performed (Step by Step):
- The Risks and Potential Benefits of the Research:
- Complete Inclusion/Exclusion Criteria *(this can be attached separately)*:

The bullet statements above should be paragraph headers on your abstract. Address each topic individually paying particular attention to the section titled *"The Procedures to be Performed."* In this section it is imperative you provide step-by-step instructions concerning the process of data collection.

There is an abstract template located in the IRBNet library or you can contact ORI to receive the abstract template.

How do I Submit My Study to the IRB?

All IRB studies are submitted via our online electronic submission program IRBNet. This intuitive program simplifies the IRB process and has greatly increased the efficiency of review and approval procedures. An IRBNet User Manual is available on the ORI website and will provide you with assistance with registration, study submission, amendments, continuing review, adverse event reporting and study closure. Keep in mind that the principal investigator must sign all submissions.

Once your study has been submitted it will be reviewed by the IRB coordinator. You will be contacted if any corrections are necessary or additional documentation is needed. Keep in mind that once the study is submitted, it automatically becomes locked. If needed, the IRB coordinator will unlock the package so you can correct/address any problems or additions.

What are the Components of an IRB Submission?

The research protocol application, abstract and consent form(s) are key components of all new IRB submissions. The following materials should be submitted when applicable (see the What to Submit List for IRB#1 or IRB#2 in Forms and Templates in IRBNet):

New Study – For a new study you should submit the following applicable documents:

- Application
- Protocol
- Abstract *(lay summary)*
- Copy of Survey or Interview Guide *(if these items are applicable)*
- Informed Consent(s)
- Child Assent *(if applicable)*
- Copy of CITI completion certificate for everyone involved in the study
- Copy of CV/Resume for everyone involved in the study
- Attachment C for all co-investigators and research staff
- Waiver of Informed Consent/HIPAA Waiver *(if applicable for Expedited/Full Board studies)*
- Recruitment Materials *(if applicable)*
- Expedited Protocol Assessment Form *(for Expedited Studies*)
- Initial Protocol Assessment Form *(for Full Board Initial Studies)*
- MHN Notification of Pending Research Form (*with all appropriate signatures*)
- MHN Research Data Request Form (*for all retrospective studies extracting data from medical records*)
- Data Use Agreement (*for studies sharing medical records data with other institutions*)
- Sponsor Contract Checklist (*for industry sponsored studies*)
- Investigator agreement (*for industry sponsored studies, with financials redacted*)
- Conflict of Interest Management Plan (*for any study involving a conflict*)
- ICH-GCP Checklist (*for ICH studies*)
- Site permission letters from schools or businesses

Annual Updates – For Expedited studies you will be required to submit an annual update and should submit the following applicable documents:

- The Annual Update Form *(changes to the study are to be submitted as amendments)*
- Updated CITI educational certificates for all research team members

Continuing Review – For a continuing review to a full board study you should submit the following applicable documents:

- The Continuing Review Request Form *(indicate any changes on the form)*
- Informed Consent(s) *(as a Word document without the IRB stamp)*
- Child Assent *(if applicable) (as a Word document without the IRB stamp)*
- Continuing Protocol Assessment Form
- Updated CITI educational certificates for all research team members

Amendment – For an amendment you should submit the following applicable documents:

- A memo describing the amendment in detail.
- Documents that you want to amend into the study or change.
- Modification Protocol Assessment Form *(for Expedited and Full Board Studies only and not required if the only change is in research staff)*

Closure – For a closure request you should submit the following applicable documents:

- Closure Request Form
- A summary of the study can also be uploaded in the package for future reference

When following **FDA** or **Department of Defense (DoD)** regulations refer to the HRPP Standard Operating Procedures (SOP) (Chapter 21, Recruitment and Selection of Human subjects) for guidance.

How do I Complete the IRB Application?

There are two separate applications on the ORI website--one for each IRB. The two applications are very similar, however there are significant differences. Be sure to select the application that is applicable to the IRB in which you will submit and is the most recent version in the IRBNet library. It is important you answer each question on the application. Though some of the questions may not apply to your specific research, you must either answer "No" or "N/A" at a minimum.

Here are the highlights of the different parts of the application:

Part I

This section covers the personal information of the principal investigator. Keep in mind that students cannot serve as principal investigators.

Research Staff: This is the section where you will list all the co-investigators and students involved in the study. Everyone listed in this section must complete an Attachment C. The Attachment C provides the personal information for each co-investigator/staff and is similar to the information provided by the principal investigator. Separate Attachment C forms are available under Forms and Templates in IRBNet. Each person who submits an Attachment C must also electronically sign the study. This means that you will need to share the study with research team members on IRBNet (once they have registered) so they can have access to sign. The IRBNet User Manual has instructions on how to share a study.

Remember that whenever the word "you" is used in an application question it is referring to the principal investigator. This is important because some questions ask if "you" (meaning the principal investigator) will be on the premises whenever data is collected. If data is being collected by a co-investigator or research staff, then the principal investigator may not be on the premises when data is collected. If you will not be on the premises when data is collected, you should state who will conduct that part of the research.

Be sure to list the external sites where research will be conducted (e.g., schools, business, and health care facilities). You must have written permission from each of these sites. If you are going to use all the schools in a particular county, permission from the county superintendent will suffice. There is a site permission letter template on IRBNet but you can prepare your own letter if desired. You just need the person granting permission to state they understand the purpose of the study and grant permission for you to conduct your study at their institution/business. Scan the approval letters and save them as PDFs so you can attach them to your IRBNet submission.

Part II

Title: In this section you will list the particulars of your study.

The question concerning minimal risk is very important. If your research is more than minimal risk you will need full board approval for your study. IRB#1 (Medical) meets the second Wednesday of each month and IRB#2 (Social/Behavioral/Education Research) meets the third Wednesday of each month. If your research is not more than minimal risk (Exempt/Expedited), it will be reviewed and approved by the IRB chair or designee. This process will only take a few days for initial review.

Sponsored Studies: Enter the federal department or agency sponsoring the study and, if applicable, include contact information. If not applicable, you can mark this section "No" and proceed to the next section.

Study Subjects and Procedures: It is important that you let the IRB know the number of anticipated subjects in your study. For instance, if you are conducting a survey in a Social/Behavioral environment (with detailed demographics), the number of participants is critical in the evaluation of possible identification. A large number of participants would minimize the risk; however, a small number may put the participants at risk of being identified.

In the age section you must indicate the age of participants. If the age of the participant is under 18 you will probably need a child assent. If all participants will be 18 or older, and there is no maximum age, you can simply insert "18+" in the age section and "N/A" for the maximum age. If there is a specific age range for your study, insert that information.

Recruitment: In this section you will state the location from which you will draw your subjects (i.e. a certain business, random samples, clinic patients, etc). If any advertisement is used in your study, then you will need to submit that for review and approval.

Informed Consent: You need to let the IRB know what type of consent(s) you will use (i.e. signed consent, survey consent, verbal consent, parental consent, etc). A copy of the consent/assent must be attached to your IRB submission. If you will be using a consent waiver you will find that form in the IRBNet library. Consent templates are also available in the IRBNet library. These templates contain all of the required elements for an informed consent and also include some additional elements that may be required.

If the principal investigator will not conduct the consent, you must list who will perform this procedure. The person conducting the consent must be listed on the study as part of the research staff. The consent training can be the CITI course that each principal investigator/co-investigator/staff must complete.

If you are going to use a consent form that has been translated into another language, you must submit an English version along with the translated version. The ORI will ensure that the English and translated versions of the consent form match.

Confidentiality: It is important that you list where the consent forms will be filed. This can be of great concern to the IRB Chair if the study is of a sensitive nature. There is also a question concerning copies of the consent. Generally, the consent forms are only copied in the case of a sponsored study where the sponsor requests to receive a copy. Keep in mind that a copy of the consent form is required to be provided to the participant.

List where the subject's records will be kept during the study. Again, if the study is of a sensitive nature the IRB Chair will be concerned with safe keeping. Later in this section you will also be required to state where the records will be kept after completion of the study. Once the study is complete the records should be stored with the principal investigator and must be kept for a minimum of three years after completion. For VA Medical Center studies, the principal investigator should keep the records according to Veterans Affairs policy.

If the study records are going to be coded for privacy you must complete that section. Be sure that the code used is **not** identifiable (i.e. no Social Security Numbers, 901 numbers, patient identification number, etc.). The key code should be stored separate from the study file to ensure the security of participant identities.

When following **Department of Education** regulations the following applies:

- Access to instructional material used in a research or experimentation program:
    - All instructional material--including teachers' manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
    - Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

- Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

When following **Department of Justice** regulations the following applies:

- For National Institute of Justice-funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
- For research conducted with the Bureau of Prisons:
  - At least once a year, the researcher shall provide the chief, Office of Research and Evaluation, with a report on the progress of the research.
  - At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
  - In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
  - The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
  - Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

Privacy: Describe how you will protect the privacy of the participants. Confidentiality deals with a person's data and privacy deals with the actual person. For example, if you are going to do an interview, where will you conduct the interview? Will it be in a public area where others can hear? If your study involves a sensitive survey, will the participants be completing the survey where others can see their replies?

Monetary Issues: Answer the questions concerning subject payment/charges.

Abstract: An abstract should be written in lay terms and provide a brief summary of the study. The abstract must be no more than 1-2 pages and should provide the reviewer a complete and accurate description of the procedures to be performed. All of the following information should be addressed in the abstract:

- The Purpose of the Research and Scientific Rationale:
- The Procedures to be Performed (Step by Step):
- The Risks and Potential Benefits of the Research:
- Complete Inclusion/Exclusion Criteria *(this can be attached separately)*:

The bullet statements above should be paragraph headers on your abstract. Address each topic individually, paying particular attention to the section titled *"The Procedures to be Performed."* In this section it is imperative you provide step-by-step instructions concerning the process of data collection. There is an abstract template in the IRBNet library.

Part III

Training: All investigators, co-investigators and key personnel must complete the online Collaborative Institutional Training Initiative (CITI) course. This educational training is required as part of our Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services Office of Human Research Protection (OHRP). An FWA is our contract with the federal government, stating that we will abide by all federal regulations concerning human subject research.

CITI course registration instructions can be located on the ORI website under the Education/Training link. There are separate courses for IRB#1 (Medical) and IRB#2 (Social/Behavioral/Education Research), so be sure to enroll in the course that relates to the IRB to which you will submit. You will find separate instructions for the two IRBs.

Please note that all key members of the research team are required to complete the CITI training. The IRB submission will not be processed until all required personnel have completed the human research protections training.

Part IV

Type of Review Requested: Select only one category that reflects the type of review you are requesting. For **Exempt** you must complete the exempt checklist on the following pages. For **Expedited** you must complete the checklist on the following pages and the Expedited Protocol Assessment Form. For a **Full Board** (**Convened**) study you must complete the Initial Protocol Assessment Form.

All of the assessment forms are located in the IRBNet Forms and Templates Library.

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Which Informed Consent do I Use?

It is important that you choose the Informed Consent appropriate for your study. Informed Consent templates are available in the IRBNet Forms and Templates library. These templates incorporate all the required elements of an informed consent. The following is a brief description of the different types of consents and the situations in which they apply:

Anonymous Survey Consent: This consent is used for anonymous surveys in which you would physically hand the participant a survey and consent. The consent page would be on top of the survey and the participant would read the consent, remove it and keep it for their records, complete the survey (if desired) and then return the survey as indicated in the consent.

The portions of the template that are in blue indicate the areas that must be completed. One key portion of the consent is the return instructions. It is critical that you be very explicit in providing instructions for the return of the survey. If the survey is anonymous and information in the survey is of a sensitive nature, the IRB reviewer will want to know that the survey will be returned in a manner that will ensure anonymity. In some cases, it may be necessary for you to have a box (labeled "Surveys") provided for participants to insert their completed survey. At the end of the day, you would simply have a box of anonymous surveys. Another common method of protected survey return is to provide the participants with a plain white (unmarked) envelope in which they can seal their survey prior to return. There are other ways of protecting the anonymity of the participants, but these are some commonly used methods.

Anonymous Online Survey Consent: This consent is used for anonymous surveys that are conducted online via one of the many service providers. The portions of the template that are in blue indicate the areas that must be completed. This consent is very similar to the Anonymous Survey Consent with the biggest difference being the return instructions. An online survey is not actually returned so the template contains additional information to suggest that they can delete their browsing history for added security.

Regular Signed Informed Consent: This consent is used for clinical studies, interviews, and other research studies that would require the participant to sign the consent form. The portions of the template that are in blue indicate the areas that must be completed. You will notice that some sections of the consent can be omitted if not applicable and those sections are indicated on the template. Keep in mind that you must provide the participant with a signed and dated copy of the consent form. If you do not have a copier available, you will need to provide an extra consent for the participant and investigator to sign and keep for their records.

Parental Permission/Consent: This consent is used to obtain parental permission/consent for a child (under 18 years of age) to participate in a research study. No minor can be enrolled in a research study without **prior** parental (or guardian) permission/consent. There is a difference between the words "permission" and "consent" as explained below:

- "Permission" applies when the child is of an age (7-18 years of age) and possesses the ability to understand and provide assent. This is basically the parent granting you permission to ask the child to participate in the study. The child still has the option to say no during the assent process. Children in this age group would need to sign the assent form.

- "Consent" applies when the child is not of an age (under 7 years of age) or lacks the ability to understand or comprehend the assent process. In this case, the parental consent would suffice for enrollment of their child in the study and a signed assent form would not be used. Keep in mind that verbal assent should still be obtained in these cases whenever appropriate. The absence of dissent should not be construed as assent. If a child verbally objects to taking part in a study, that child's wishes should be honored.

The signature section of the parental permission/consent form contains a place for the second parent signature if required. If the study is considered minimal risk research, the signature of one parent

would be sufficient and the second parent signature section can be omitted. If the research is more than minimal risk, then both parents should sign. If the second parent is unable to sign, the reason should be indicated on the form.

Child Assent: The basic consent/assent model when working with children is that parents (or guardians) provide permission for their children (or wards) to participate in research. Children then provide assent to become participants in the study. Assent is a child's affirmative agreement to participate. The absence of dissent should not be construed as assent. Generally, parental permission can only override a child's dissent when the health of the child is at stake. When using an assent form, the child signs the assent to indicate knowledgeable agreement (assent) to participate. Prior to the assent, the parents, guardian or legally authorized representative signs and dates the full Informed Consent/Permission Form to document legal permission. The basic guideline is that children 7-18 years of age should sign a consent form if they are mentally capable to understand. It is a requirement that the assent be witnessed by another adult (does not have to be the parent) and the witness is also required to sign the assent form. There is a template of the child assent in the IRBNet Forms and Templates library.

Verbal Consent: This consent is used in cases where a face-to-face consent process is not practical. The most common use of this consent is in phone interviews. The portions of the template that are in blue indicate the areas that must be completed. You must submit the verbal consent for approval and follow the script when consenting participants for the study. This consent form is used as a guide to ensure that each participant receives the same complete informed consent process. Keep in mind that if your study is Expedited or full board you must also submit a waiver of documentation of consent.

Short Form Consent: A short form written consent is a document stating that the elements of informed consent required by the Code of Federal Regulations (45CFR46.116) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. Also, the IRB must approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed and dated by the subject or the representative. However, the witness shall sign and date both the short form and a copy of the summary, and the person actually obtaining consent shall sign and date a copy of the summary. A copy of the summary must be given to the subject or the representative, in addition to a copy of the short form.

To use the short form consent you must:

- Obtain IRB approval prior to using the short form consent
- Provide a summary document (i.e. the full informed consent)
- Provide the short form consent document

These documents must accompany a new protocol application or be submitted as an amendment to an existing protocol and receive IRB approval prior to use.

The following are the signature requirements:

- Ensure that the short form document is signed and dated by the subject (or the subject's legally authorized representative).

- Ensure that the short summary is signed and dated by the person obtaining consent as authorized under the protocol (i.e. the oral presenter).
- Ensure that the short form document and the summary document are signed and dated by a witness.

A copy of the signed and dated short form and the summary will be given to the participant or the representative.

For VA research, consent will be documented through the use of VA forms.

When is a Consent Waiver Needed?

Under special circumstances, investigators can request one of three types of waivers of written informed consent from research subjects. **Note:** These waivers are **not** required for Exempt studies.

The first type is waiver or alteration of informed consent. With this waiver, the investigator may provide to the subject a consent which does not include, or which alters one or all of the required elements. This type of waiver is common for studies involving prospective chart/record review.

The second type is a waiver of parental permission. This waiver would be used in cases where something may be legal for a child to do (i.e. abortion, certain clinics) without parental permission and obtaining parental permission would violate that privacy. An example of this type of waiver would include wanting to survey children (which would normally require parental permission) but the survey is about their experience with an abortion or child abuse. This type of waiver is a very sensitive issue and would require close scrutiny by the IRB Chair.

The third type is a waiver of written documentation that informed consent was obtained. With this waiver, the investigator would be required to read or provide the consent form to a subject but would not need to obtain the subject's signature on the consent form. Examples of when this waiver might be applicable would be internet surveys, phone surveys or when a signature linking the participant to the study might have some negative consequence for the subject. It must be emphasized that these waivers will be given only when there are compelling reasons for doing so.

How do I add Co-Investigators/Research Staff to my Study?

To add additional co-investigators/researchers to your study you will need to submit an amendment package on IRBNet. The instructions for the submission of this package are included in the IRBNet User Manual. The items needed in the submission are:

- Memo explaining the amendment
- CITI educational certificates for each new addition
- CV/Resume for each new addition
- Attachment C for each new addition

Keep in mind that each new co-investigator/researcher will need to also sign the package on IRBNet. This will require them to be registered in order for you to share the study with them for their signature. The IRBNet User Manual has more information and instructions on the procedure for sharing a study.

How do I Close my Study?

The IRBNet system will notify you of project expiration 60, 30, and 7 days prior to expiration and will send an additional notice on the day of expiration. It is the responsibility of the principal investigator to submit a closure package prior to the expiration of the study. The closure package should include a Closure Request Form. This form is available in the IRBNet Forms and Templates library and lists the information needed for us to process your closure request.

If a study expires, it will be forced closed on IRBNet by the IRB coordinator and an email notice will be sent to the principal investigator. Once a study is forced closed it is the responsibility of the principal investigator to acknowledge receipt of the closure notice and confirm that all research activity has ceased. Failure to provide written acknowledgment of the closure notice is considered non-compliance and can result in suspension of other active studies for the principal investigator.

How do I Transfer my Study to Another Principal Investigator?

Sometimes, for whatever reason, there is a need to transfer a study to another principal investigator. This is most commonly done when one investigator leaves the university or affiliated institution, and another principal investigator has agreed to take over the study. This change is to be submitted as a study amendment. The IRBNet User Manual has a section on the procedures for submission of an amendment and will walk you through that process.

In this submission you would need to include a memo describing the amendment and stating the purpose for the change in principal investigator. The incoming principal investigator would need to include his/her CITI education certificate, a CV/Resume and an Attachment C. These four documents (memo, CITI certificate, CV/Resume and Attachment C) would make up the amendment package.

Both the outgoing and incoming principal investigator would need to sign this package as the "Principal Investigator." The outgoing principal investigator would be signing the package because he/she is still the active lead in the study until the amendment is approved. The incoming principal investigator would be signing the package to acknowledge the acceptance of the responsibilities of the study principal investigator.

How do I Address Allegations and Issues of Non-Compliance?

For issues regarding allegations and issues of non-compliance an investigator should refer to the HRPP SOP, Chapter 6 – Complaints, Non-Compliance and Regulatory Improprieties and Chapter 22 – Reporting Policy.

How do I Address Unanticipated Problems Involving Risks to Participants or Others?

For issues regarding unanticipated problems involving risks to participants or others an investigator should refer to the HRPP SOP, Chapter 12 – Ensuring Prompt Reporting of Unanticipated Problems Involving Risks to Participants or Others, and Chapter 22 – Reporting Policy.

What Happens if my Study is Suspended or Terminated?

For guidance on study suspensions or terminations an investigator should refer to the HRPP SOP, Chapter 24 – Types of Research and Types of Reviews Conducted by the IRB ("Suspension or Termination of IRB Approval of Research Section) and Chapter 22 – Reporting Policy.

What are my Responsibilities for Multi-Site Research?

For issues involving multi-site research an investigator should refer to the HRPP SOP, Chapter 12 – Ensuring Prompt Reporting of Unanticipated Problems Involving Risks to Participants or Others, and Chapter 22 – Reporting Policy.

What are the Specific Responsibilities for ICH-GCP (E6)?

When following ICH-GCP (E6) the following applies:

- The researcher reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. The researcher follows regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the IRB.
- The researcher reports adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.
- For reported deaths, the researcher supplies the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
- The researcher provides written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
- If the researcher terminates or suspends a clinical trial without prior agreement of the sponsor, the researcher informs the organization, sponsor, and the IRB.
- If the IRB terminates or suspends approval of the clinical trial, the researcher promptly notifies the sponsor.
- Upon completion of the clinical trial, the researcher informs the organization; the IRB with a summary of the trial's outcome; and the regulatory authority with any reports required.

When Following DoD Requirements:

- Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.

When Following DoJ Requirements:

- For research conducted within the Bureau of Prisons, the researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.

When Following VA Requirements:

- During the recruitment process, VA researchers are responsible for:
    - If a contractor makes the initial contact by letter, the VA researcher must sign the letter.
- For studies in which information about the participant's participation will be included in the participant's VHA medical record, information must be given to the prospective participants as part of the informed consent process that information regarding study participation will be included in the medical record.
- If the researcher contracts with a firm (e.g., a survey research firm) to obtain consent from participants, collect private individually identifiable information from human participants, or be involved in activities that would institutionally engage the firm in human participants research, the firm must have its own IRB/EC oversight of the activity.
    - In addition, the Privacy Officer (PO) must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.