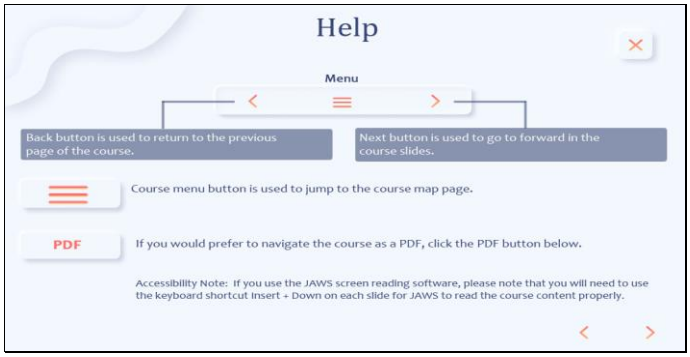
IRB803

Institutional Review Board (IRB) Training

This course is brought to you by UFHR Training & Organizational Development, in collaboration with the University of Florida Institutional Review Board.



Help

Back button is used to return to the previous page of the course.

Next button is used to go to forward in the course slides.

Menu button - Course menu button is used to jump to the course map page.

PDF - If you would prefer to navigate the course as a PDF, click the PDF button below.

Accessibility Note: If you use the JAWS screen reading software, please note that you will need to use the keyboard shortcut Insert + Down on each slide for JAWS to read the course content properly.

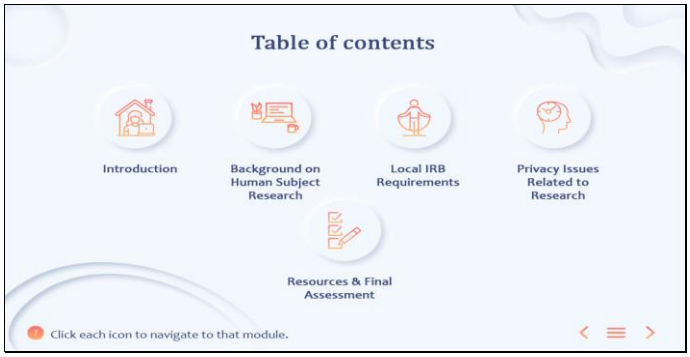


Table of contents

Introduction

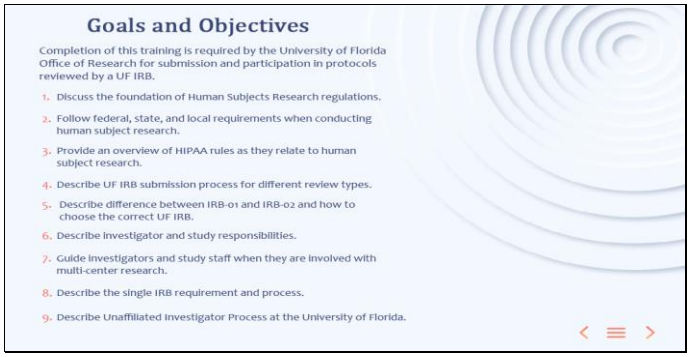
Background on Human Subject Research

Local IRB Requirements

Privacy Issues Related to Research

Resources & Final Assessment

Click each icon to navigate to that module.



Goals and Objectives

Completion of this training is required by the University of Florida Office of Research for submission and participation in protocols reviewed by a UF IRB.

1. Discuss the foundation of Human Subjects Research regulations.
2. Follow federal, state, and local requirements when conducting human subject research.
3. Provide an overview of HIPAA rules as they relate to human subject research.
4. Describe UF IRB submission process for different review types.
5. Describe difference between IRB-01 and IRB-02 and how to choose the correct UF IRB.
6. Describe investigator and study responsibilities.
7. Guide investigators and study staff when they are involved with multi-center research.
8. Describe the single IRB requirement and process.
9. Describe Unaffiliated Investigator Process at the University of Florida.

Are You an Unaffiliated Investigator?

You are considered "Unaffiliated" if:

- You are not a student at UF, or not a paid employee of UF, Shands, or the North Florida\South Georgia VA Medical Center.
- You are not affiliated with another institution covered by a Federal Wide Assurance (FWA).
    - Most universities have a FWA.
    - Any legal entity (including an international legal entity) that receives federal funds for research has an FWA.

If you are a student or employee of an institution that has a FWA, you must obtain IRB approval from your own IRB or have them cede the review to UF. This is not the correct IRB education for you.

Picture of doctor

Investigator Guidelines

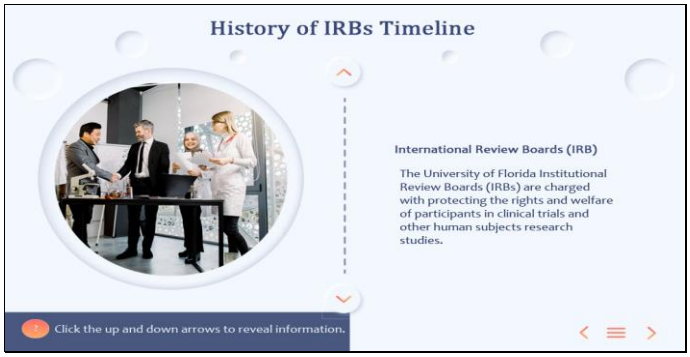
The IRB has developed numerous Investigator Guidelines on a range of topics to help investigators and study staff comply with federal, state, and local policies.

If you have a question, please refer to alphabetical index of topics.

Picture of doctor and healthcare staff

Background on Human Subject Research

Module 1



History of IRBs Timeline

Click the up and down arrows to reveal information.

International Review Boards (IRB) - The University of Florida Institutional Review Boards (IRBs) are charged with protecting the rights and welfare of participants in clinical trials and other human subjects research studies.

1945 - After World War II, numerous atrocities committed by Nazi doctors in experiments conducted in concentration camps were discovered.

1945 - The Nuremberg Military Tribunal developed 10 principles, known as The Nuremberg Code, to judge the Nazi doctors.

1964 - The Declaration of Helsinki by the World Medical Association was developed for the medical community and provides ethical principles regarding human experimentation.

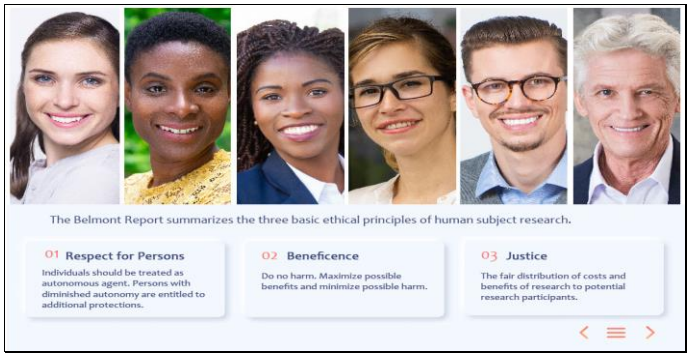
1972 - The 40-year-long U.S. Public Health Service Syphilis Study at Tuskegee — and other ethically questionable research — resulted in legislation calling for regulations to protect human subjects.

1974 - National Research Act of 1974 established a commission which recommended a set of Ethical guidelines, also known as the Belmont Report. The Belmont Report established the modern IRB system for regulating research involving human subjects.

1991 - 16 federal agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects (also known as the "Common Rule").

1996 - In response to a congressional mandate in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the U.S. Department of Health and Human Services (HHS) issued the regulations Standards for Privacy of Individually Identifiable Health Information. For most covered entities, compliance with these regulations, known as the “Privacy Rule,” was required as of April 14, 2003.

2017 - The Office for Human Research Protection issued a revision to the “Common Rule” in an attempt to streamline and harmonize these regulations.



The Belmont Report summarizes the three basic ethical principles of human subject research.

01 Respect for Persons

Individuals should be treated as autonomous agent. Persons with diminished autonomy are entitled to additional protections.

02 Beneficence

Do no harm. Maximize possible benefits and minimize possible harm.

03 Justice

The fair distribution of costs and benefits of research to potential research participants.

Pictures of people’s faces

Common Rule (45 CFR 46)

45 CFR 46 codifies the basic principles of the Belmont Report. The main elements include:

Subpart A: describes categories of exemptions from the regulations, and the required protections for all Health and Human Services (HHS) conducted or supported non-exempt human subjects research.

Subpart B: additional protections for pregnant women, human fetuses, and neonates.

Subpart C: additional protections pertaining to biomedical and behavioral research involving prisoners as subjects.

Subpart D: additional protections for children.

Picture of hands holding cutouts of people

Informed Consent

The four fundamental aspects of informed consent are:

Voluntariness - Individuals' decisions about participation in research should not be influenced by anyone involved in conducting the research: "...consent must be freely given or truly voluntary"

Comprehension - Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research

Disclosure - Of the purpose, risks and benefits, alternatives, any compensation, contact information, and the right to withdraw

Prospectively Obtained - Informed consent must be obtained prior to any research related intervention, except as allowed under an Emergent Use exemption (see Investigator Guidelines)

Picture of handing signing contract

Equipoise & Important Knowledge to be Gained

Click each card to reveal information.

Equipoise

Is ethically required for conducting clinical research that may pose risks to research participants.

Equipoise

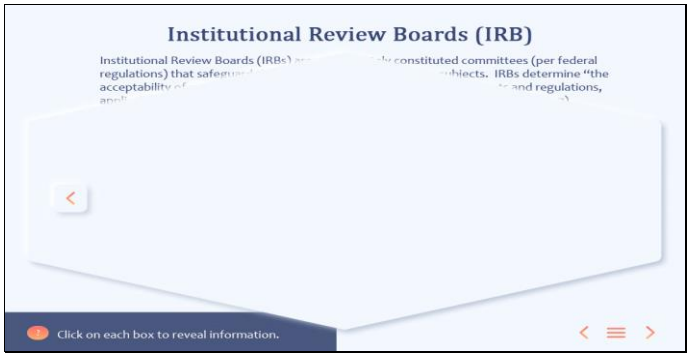
Entails that there is genuine uncertainty whether one arm of a clinical trial or treatment provides greater efficacy over another.

Knowledge

Should the investigator discover that one treatment is of superior therapeutic merit, they are ethically obliged to offer that treatment.

Local IRB Requirements

Module 2



Institutional Review Boards (IRB)

Institutional Review Boards (IRBs) are appropriately constituted committees (per federal regulations) that safeguard the rights and welfare of human subjects. IRBs determine “the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice” (45 CFR 46.107).

The major roles of IRBs in the oversight of research are:

Click on each box to reveal information.

Box 1

Topic 1

Initial review. Approval or disapproval of the proposed research activity.

Box 2

Topic 2

Ensuring that the proposed informed consent process meets all of requirements of the federal regulations (45 CFR 46.116).

Box 3

Topic 3

When applicable, providing continuing review of approved protocols.

Researcher Roles

Research roles are based on one's affiliation status or type with the University of Florida, Shands, or the VAMC.

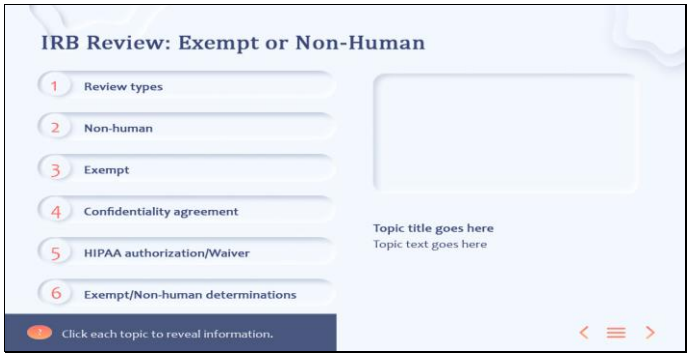
Please make sure you confirm with this guideline before you submit in myIRB or before you invite a visiting individual to be involved with your research.

UF Institutional Review Boards

IRB-01: (Biomedical) Faculty, staff students at UF, Shands, VAMC

IRB-02: (Behavioral Science) Only behavioral/social research; no biomedical or PHI.

Picture of hand holding beaker



IRB Review: Exempt or Non-Human

1 IRB Review Types

There are several types of IRB review depending on the risk level of the study. The studies that involve the least amount of risk are non-human and exempt.

2 Non-human

Non-Human is analysis of anonymous or coded data. It has minimal risk. Confidentiality of data is the main risk.

3 Exempt

Exempt studies typically include chart reviews, surveys, or benign behavioral interventions where data may or may not be identifiable. It has minimal risk. Confidentiality of data is the main risk.

4 Confidentiality agreement

For non-human review type involving coded data, a confidentiality agreement is required.

5 HIPAA authorization/Waiver

Some may require a stand-alone HIPAA waiver of authorization (prospective chart reviews).

6 Exempt/Non-human determinations

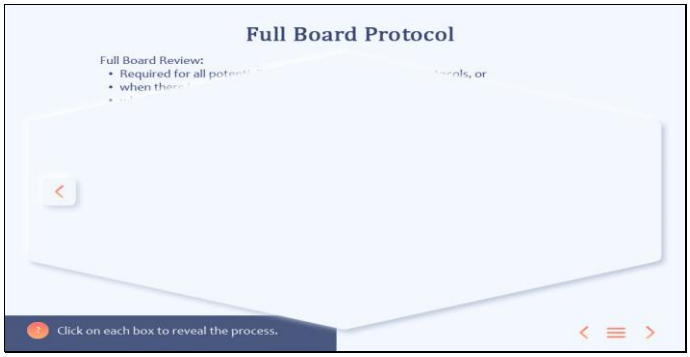
Per UF Policy, exempt and non-human determinations must be made by UF IRBs.

IRB Review: Expedited

Expedited Review Category

- Research is Minimal Risk – probability and magnitude of harm no greater than when engaging in daily life or during routine physical/psychological exams
- Must meet at least one of the nine OHRP listed expedited categories
- May or may not require documented informed consent
- Reviewed by IRB Chair or Vice Chair unless it's determined that the full committee review is needed

Picture of finger touching clock



Full Board Protocol

Full Board Review:

- Required for all potentially greater than minimal risk protocols, or
- when there is no applicable expedited category for the protocol or
- when requested by an expedited reviewer after the initial review.

Click on each box to reveal the process.

Step 1

Studies must be submitted into the myIRB software by applicable deadline for IRB-01 or IRB-02.

Step 2

Upon submission, IRB staff pre-reviews to ensure acceptability standards as specified here.

Step 3

Complete submissions scheduled for full board meeting.

IRB's Actions

1 Approved

as evidenced by the approval letter the investigator receives.

2 Approved with contingencies

minor modifications are required. The study must not start until fully approved. Approval of requested modifications may occur outside of full board.

3 Tabled

significant modifications requested, the study must come back to full board

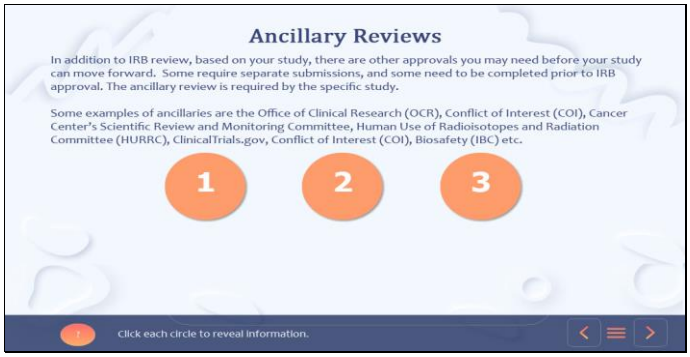
4 Disapproved

study cannot be approved without a major redesign to remove safety/regulatory concerns

5 Miscellaneous letter

might be sent as an e-mail requested action on your part which does not entail holding approval.

? Click each tab to reveal information.



Ancillary Reviews

In addition to IRB review, based on your study, there are other approvals you may need before your study can move forward. Some require separate submissions, and some need to be completed prior to IRB approval. The ancillary review is required by the specific study.

Some examples of ancillaries are the Office of Clinical Research (OCR), Conflict of Interest (COI), Cancer Center's Scientific Review and Monitoring Committee, Human Use of Radioisotopes and Radiation Committee (HURRC), ClinicalTrials.gov, Conflict of Interest (COI), Biosafety (IBC) etc.

1

myIRB software contains questions which are used to trigger applicable ancillary review.

2

IRB approval cannot be issued if there is a pending ancillary in myIRB, even if all IRB requirements are met.

3

For protocols requiring SRMC, IBC, COVID, or Institutional COI, the IRB review cannot begin its review without an approval from the appropriate ancillary.

Investigator Responsibilities

Be knowledgeable regarding the research regulations that govern your study.

- Follow your approved protocol.
    - You must conduct the protocol exactly as the IRB has approved it.
    - Changes to your protocol must be submitted and approve by the IRB before the change can be made; unless the change involves subject safety.

- Obtain consent prior to enrolling subject.
    - Each subject must at least be offered a copy of the consent form.
    - You must retain a copy of all consent forms while the study is active.

Informed Consent

Informed consent is a process, not just a piece of paper. Potential subjects must be competent and given time to review the consent form and be able to ask questions of the PI or knowledgeable study staff.

Picture of doctor talking to patients

Tips on Writing & Using the Informed Consent Form

Tip 1 Information should be written at approximately the 8th grade level reading level.

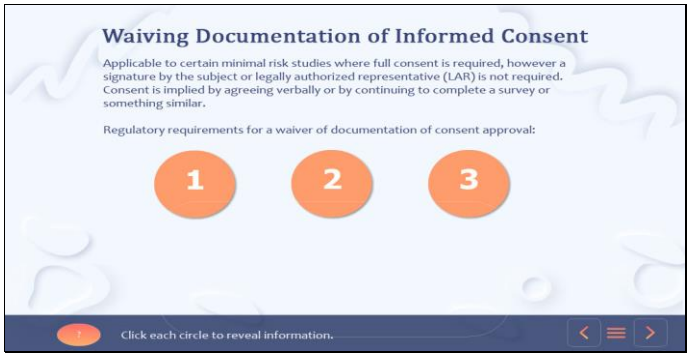
Tip 2 Always use the current IRB template from the applicable IRB website with the applicable standardized text.

Tip 3 The latest approved version of your consent form must always be used, per regulations.

Tip 4 Store original signed consents securely (consents may be scanned in their entirety).

Tip 5 When using eConsent ensure compliance with OHRP and FDA regulations.

For more information on eConsent click this link and this link.



Waiving Documentation of Informed Consent

Applicable to certain minimal risk studies where full consent is required, however a signature by the subject or legally authorized representative (LAR) is not required. Consent is implied by agreeing verbally or by continuing to complete a survey or something similar.

Regulatory requirements for a waiver of documentation of consent approval:

1

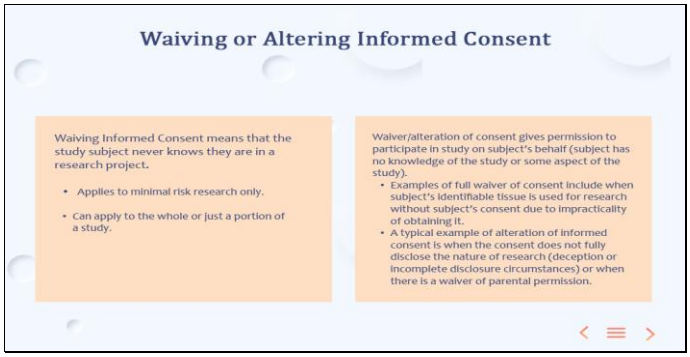
The only record linking subject to the study is the signature on the consent form where the principal risk of the study is the loss of confidentiality.

2

Minimal risk study, involves procedures that do not require consent outside of the research context.

3

Signing informed consent is at odds with the cultural norms of the group to which subject belongs, the research is minimal risk, and there is an alternative method of documenting consent.



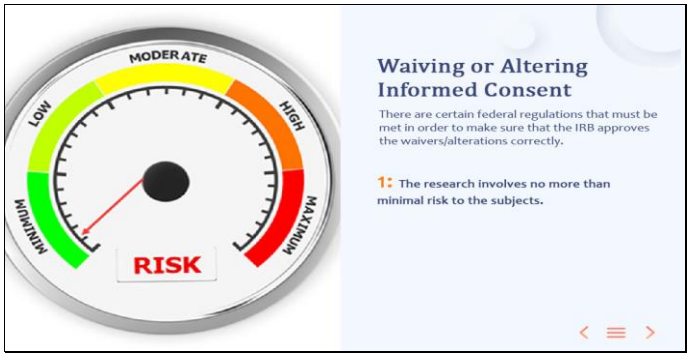
Waiving or Altering Informed Consent

Waiving Informed Consent means that the study subject never knows they are in a research project.

- Applies to minimal risk research only.
- Can apply to the whole or just a portion of a study.

Waiver/alteration of consent gives permission to participate in study on subject's behalf (subject has no knowledge of the study or some aspect of the study).

- Examples of full waiver of consent include when subject's identifiable tissue is used for research without subject's consent due to impracticality of obtaining it.
- A typical example of alteration of informed consent is when the consent does not fully disclose the nature of research (deception or incomplete disclosure circumstances) or when there is a waiver of parental permission.



Waiving or Altering Informed Consent

There are certain federal regulations that must be met in order to make sure that the IRB approves the waivers/alterations correctly.

1: The research involves no more than minimal risk to the subjects.

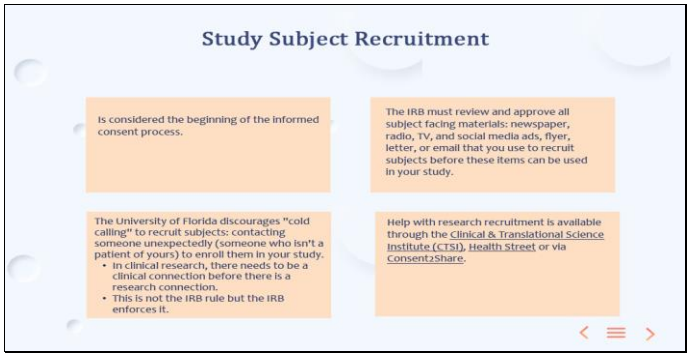
2: The waiver or alteration will not adversely affect the rights and welfare of the subjects (e.g., Delayed Consent).

3: The research could not practicably be carried out without the waiver or alteration.

4: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Remember: Even when participants are enrolled under a waiver of consent, these participants count as enrolled subjects!

Picture of risk meter



Study Subject Recruitment

Is considered the beginning of the informed consent process.

The IRB must review and approve all subject facing materials: newspaper, radio, TV, and social media ads, flyer, letter, or email that you use to recruit subjects before these items can be used in your study.

The University of Florida discourages "cold calling" to recruit subjects: contacting someone unexpectedly (someone who isn't a patient of yours) to enroll them in your study.

- In clinical research, there needs to be a clinical connection before there is a research connection.
- This is not the IRB rule but the IRB enforces it.

Help with research recruitment is available through the Clinical & Translational Science Institute (CTSI), Health Street or via Consent2Share.

Study Recruitment Telephone Scripts

Telephone Scripts

Notify potential subjects of a research project, consent subjects remotely, screen potential subjects, and to conduct follow-up on research protocols.

Script Creation

If you need to use a phone script, the script must be submitted to the IRB and approved prior to its use.

Additional Information

*For additional information, please visit the IRB's Investigator Guideline on telephone scripts.

Informed Consent Deviations

Common compliance issues that can cause problems for your study.

Topic 1

One or more enrolled subjects did not sign an approved consent form as required.

Topic 2

Wrong study consent form used.

Topic 3

Not using the currently approved version of the informed consent form.

Topic 4

Wrong person signed the consent form, did not indicate who they were.

Topic 5

Study staff obtaining consent not approved by the IRB for this study function.

Topic 6

Other miscellaneous issues (signed on the wrong line, no date, manually editing consent after approval, etc.).

Over Enrollment of Study Subjects

Over-enrollment of study subjects is another common IRB compliance issue. When your study is approved, that approval is for a specific number of subjects that you have requested in order to answer your research question. If you later need to increase or change the number of subjects, that is a change to your protocol and must be approved by the IRB. Even for minimal risk studies, the possibility of adverse events may increase as the sample size grows.

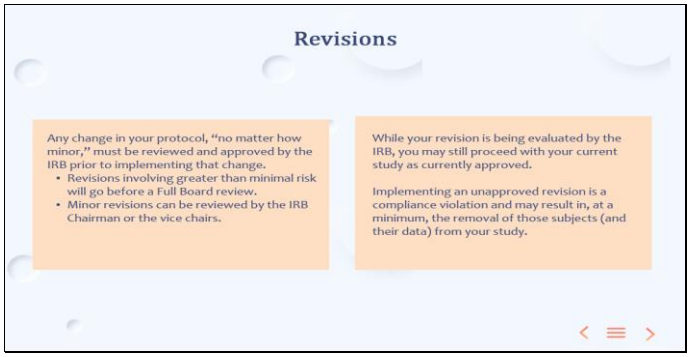
1

An enrolled subject is someone:

- Who has signed an informed consent form, or
- Whose data you have collected, or
- Whose medical record you have reviewed (in the cases where consent is not required) Every record you look at is an enrolled subject.

2

Enrolling more subjects than are approved is a compliance violation and could result in, at a minimum, the removal of the additional subjects (and their data) from your study.



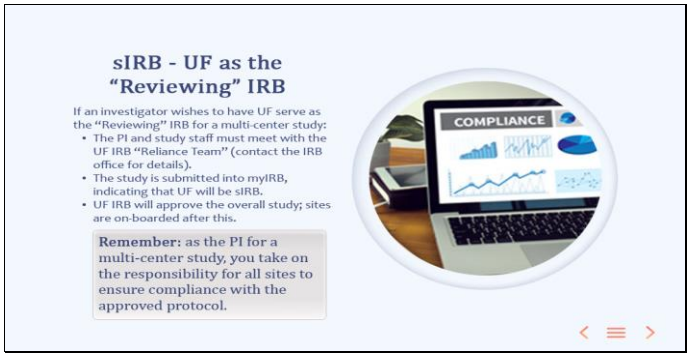
Revisions

Any change in your protocol, "no matter how minor," must be reviewed and approved by the IRB prior to implementing that change.

- Revisions involving greater than minimal risk will go before a Full Board review.
- Minor revisions can be reviewed by the IRB Chairman or the vice chairs.

While your revision is being evaluated by the IRB, you may still proceed with your current study as currently approved.

Implementing an unapproved revision is a compliance violation and may result in, at a minimum, the removal of those subjects (and their data) from your study.



sIRB - UF as the “Reviewing” IRB

If an investigator wishes to have UF serve as the “Reviewing” IRB for a multi-center study:

- The PI and study staff must meet with the UF IRB “Reliance Team” (contact the IRB office for details).
- The study is submitted into myIRB, indicating that UF will be sIRB.
- UF IRB will approve the overall study; sites are on-boarded after this.

Remember: as the PI for a multi-center study, you take on the responsibility for all sites to ensure compliance with the approved protocol.

Picture of computer showing compliance

Single IRB Requirements (sIRB)

1

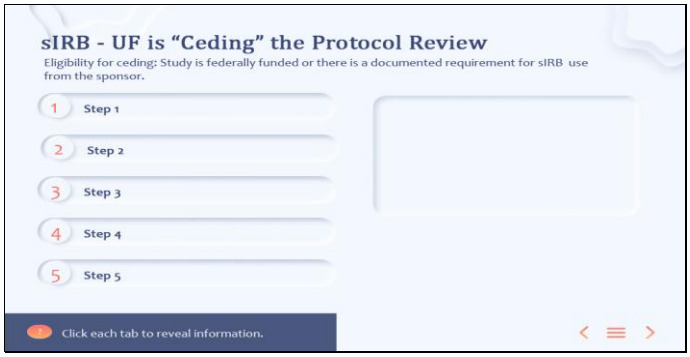
As of January of 2020, all non-exempt multi-center federally funded studies must utilize only one IRB. Thus, the UF IRB can serve as the “Reviewing” IRB for all sites or the UF IRB will “Cede” the review to another IRB.

2

For non-federally funded multi-center studies, the University will decide on a case-by-case basis if the study qualifies for sIRB review.

3

If you are submitting an NIH grant, the IRB can provide you a letter of support needed as part of your ”Just in Time” submission that requires a single IRB plan.



sIRB - UF is “Ceding” the Protocol Review

Eligibility for ceding: Study is federally funded or there is a documented requirement for sIRB use from the sponsor.

Step 1

To start ceding to a sIRB, the study must already be approved by the reviewing sIRB site.

Step 2

Then it is submitted in myIRB by using Submit a New Ceded Study workflow.

Step 3

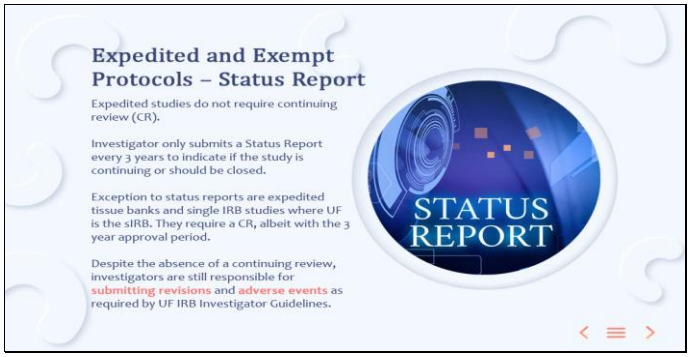
The UF IRB still must conduct a review of the study ensure all “state and local” issues are addressed.

Step 4

When ceding submission is acknowledged in myIRB, UF PI sends our “approval to cede” to the reviewing sIRB.

Step 5

Once the UF site is approved by the sIRB, study team submits correspondence in myIRB with approved study documents which results in the study being approved to begin at UF.



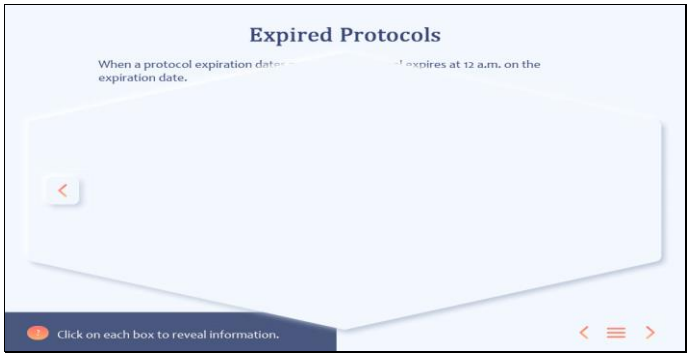
Expedited and Exempt Protocols – Status Report

Expedited studies do not require continuing review (CR).

Investigator only submits a Status Report every 3 years to indicate if the study is continuing or should be closed.

Exception to status reports are expedited tissue banks and single IRB studies where UF is the sIRB. They require a CR, albeit with the 3 year approval period.

Despite the absence of a continuing review, investigators are still responsible for submitting revisions and adverse events as required by UF IRB Investigator Guidelines.



Expired Protocols

When a protocol expiration dates passes, the protocol expires at 12 a.m. on the expiration date.

Box 1

Study Expires

Once a study expires, you may not enroll further subjects, conduct any research activities, or collect or analyze research data.

2

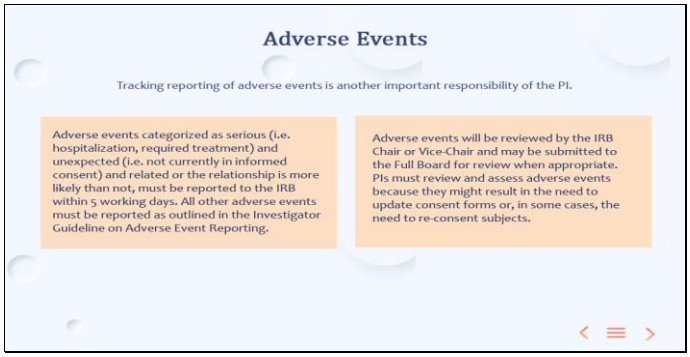
Protocol Review

If you have a protocol that involves administering a drug or any other treatment, you must ask the IRB if you can continue to treat currently enrolled subjects. To request to continue treatment of study subjects, please email the IRB Chairman.

3

Study Funds

If the study expires, access to your study funds will be limited. If the study is federally funded, this “deviation” must be reported to the Office of Human Research Protection (OHRP).



Adverse Events

Tracking reporting of adverse events is another important responsibility of the PI.

Adverse events categorized as serious (i.e. hospitalization, required treatment) and unexpected (i.e. not currently in informed consent) and related or the relationship is more likely than not, must be reported to the IRB within 5 working days. All other adverse events must be reported as outlined in the Investigator Guideline on Adverse Event Reporting.

Adverse events will be reviewed by the IRB Chair or Vice-Chair and may be submitted to the Full Board for review when appropriate. PIs must review and assess adverse events because they might result in the need to update consent forms or, in some cases, the need to re-consent subjects.

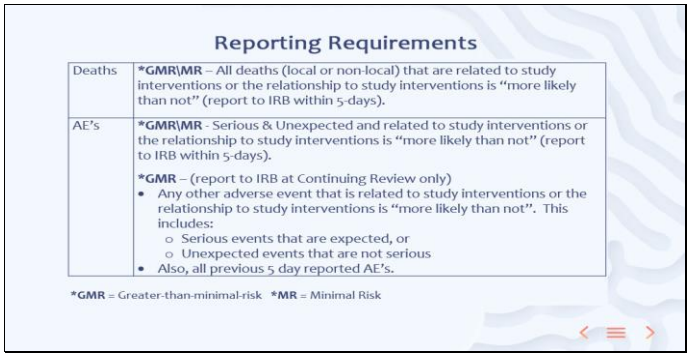
Other Reportable Events

Regulatory non-compliance: failure to adhere to regulations (federal, state, local)

Deviations = not adhering to the approved IRB protocol.

Types of Deviations:

- Major Deviations (e.g. administering incorrect dose of study medication, enrolling ineligible subjects, over-enrollment on a greater than minimal risk study, etc.)
- Minor Deviations (study visits outside of the window but no risk to participant, copy of consent not given to subject, subject did not return study diary, etc.)



Reporting Requirements

Deaths: GMR/MR – All deaths (local or non-local) that are related to study interventions or the relationship to study interventions is "more likely than not" (report to IRB within 5 days).

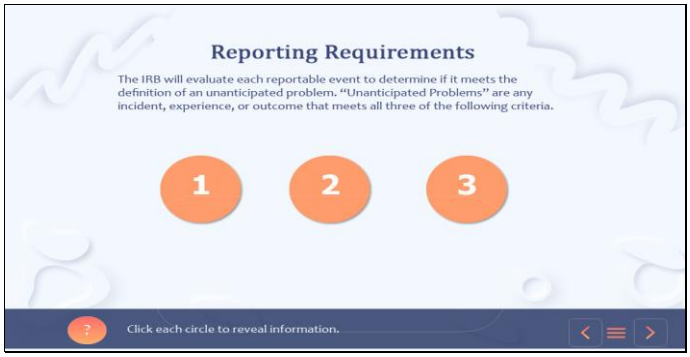
AE's: GMR/MR - Serious & Unexpected and related to study interventions or the relationship to study interventions is "more likely than not" (report to IRB within 5 days)

GMR – report to IRB at Continuing Review only)

- Any other adverse event that is related to study interventions or the relationship to study interventions is "more likely than not". This includes:
    - Serious events that are unexpected or
    - Unexpected events that are not serious
- Also, all previous 5 day reported AE's

GMR = Greater than minimal risk

MR = Minimal Risk



Reporting Requirements

The IRB will evaluate each reportable event to determine if it meets the definition of an unanticipated problem. “Unanticipated Problems” are any incident, experience, or outcome that meets all three of the following criteria.

1

Unexpected in terms of nature, severity, or frequency given (a) the research procedures and (b) the characteristics of the subjects being studied.

2

Related or the event is more likely than not related to participation in the research.

3

Suggests subjects or others are at a greater risk of harm (physical, psychological, economic, or social harm) than was previously known or recognized, even if no specific harm has yet occurred. For more information, review Guideline Events and Unanticipated Problems reports.

Research Involving Drugs, Biologics, or Chemicals

Investigational New Drug (IND)

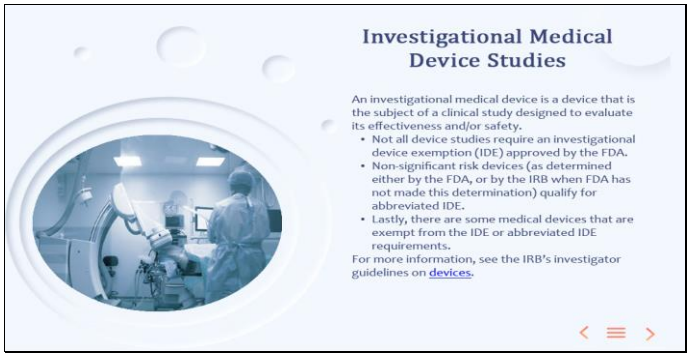
Research involving an Investigational Drugs, Biologics, or Chemicals may require an IND Application.

FDA Approval

If the FDA approval for an IND is required, it must be documented in myIRB, or a letter from the FDA waiving the need for an investigational new drug application.

More Information

Please review the Investigator Guideline on the IRB-01 web site for more information.



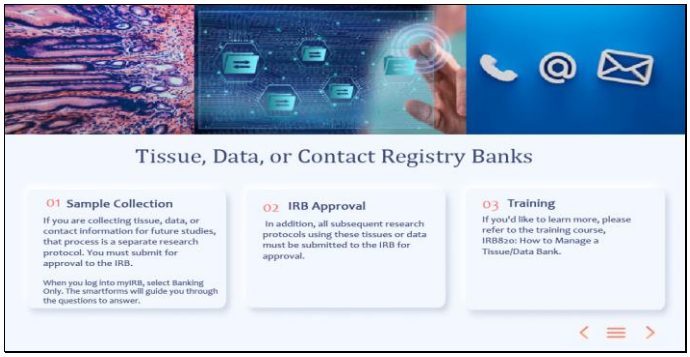
Investigational Medical Device Studies

An investigational medical device is a device that is the subject of a clinical study designed to evaluate its effectiveness and/or safety.

- Not all device studies require an investigational device exemption (IDE) approved by the FDA.
- Non-significant risk devices (as determined either by the FDA, or by the IRB when FDA has not made this determination) qualify for abbreviated IDE.
- Lastly, there are some medical devices that are exempt from the IDE or abbreviated IDE requirements.

For more information, see the IRB's investigator guidelines on devices.

Picture of science lab



Tissue, Data, or Contact Registry Banks

01 Sample Collection

If you are collecting tissue, data, or contact information for future studies, that process is a separate research protocol. You must submit for approval to the IRB.

When you log into myIRB, select Banking Only. The smartforms will guide you through the questions to answer.

02

IRB Approval

In addition, all subsequent research protocols using these tissues or data must be submitted to the IRB for approval.

03

Training

If you'd like to learn more, please refer to the training course, IRB820: How to Manage a Tissue/Data Bank.

Investigator Conflict of Interest

As part of the myIRB software submission, there will be a question regarding any conflict of interest the investigator, sub-investigators and\or the Institution (UF) may have. These potential COI's are evaluated by the Conflict of Interest Department who will then notify the IRB of any COI.

1

If you have a conflict of interest (COI), you must disclose that COI as part of the IRB submission. Such conflicts may also need to be disclosed in the Informed Consent form.

2

Examples of COI include:

- Owning a patent on the drug or device you are studying.
- Speaking for or holding a position in a drug or device company related to your research.

3

If you have any questions about conflict of interest, please contact Amber Moore, Assistant Director, Conflict of Interest and RCOI officer.

International Studies

Topic 1

International studies require extra time as approval from a research oversight body in the country that is involved in research may be required.

Topic 2

Ensure your submission in myIRB includes addendum Q (that assess local context) and International Research Involving Humans (IRIH) form that is submitted to the Office of Research.

Topic 3

Michael Scian scianmp@ufl.edu will conduct an international ancillary review before the University will allow an international research protocol to move forward.

Consenting Non-English Speaking Study Subjects

If the study targets non-English speakers, the informed consent form must be translated into the native language by a qualified third party.

If you are primarily seeking consent from subjects who do speak and read English, but unexpectedly want to enroll someone who does not speak or read English, you must:

- Use an IRB approved "short form".
- Follow the consenting process as outlined in this guideline.

Picture of computer with many flags on it

Privacy Issues Related to Research

Module 3

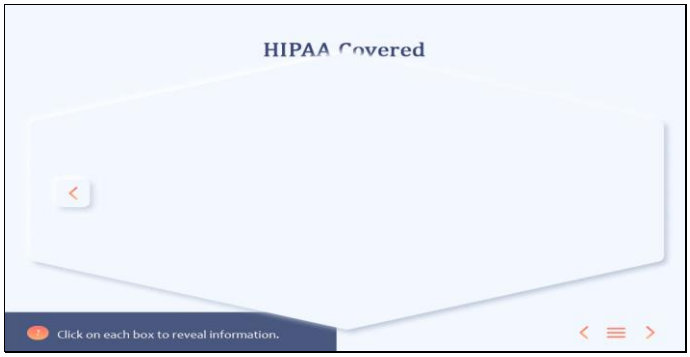
HIPAA

The HIPAA Privacy Rule establishes conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes.

Currently, most research involving human subjects operates under the Common Rule (45 CFR Part 46, Subpart A) and/or the Food and Drug Administration's (FDA) human subject protection regulations (21 CFR Parts 50 and 56), which have some provisions that are similar to, but separate from, the Privacy Rule's provisions for research.

The Privacy Rule builds upon these existing federal protections.

Picture of HIPAA



HIPAA Covered

Providers

This includes doctors, dentists, clinics, hospitals, researchers*.

*If PHI is used and research conducted as employee of UF.

Plans

Which includes insurance companies, HMOs, Government health programs.

Clearinghouse

Which converts nonstandard health information into a standard format.

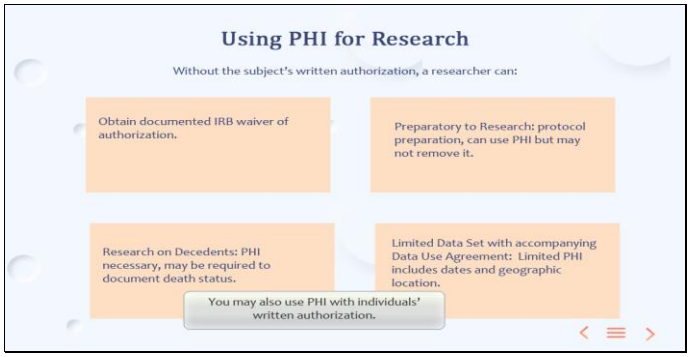
Protected Health Information

Protected health information (PHI) is individually identifiable information held by the covered entity (CE). HIPAA applies to use and disclosure of PHI by the CE.

Common Identifiers are:

- Names, Dates (except for year only), Social Security Numbers, Addresses, Identifiable Images
- Certain genetic information

Picture of nurse using ipad



Using PHI for Research

Without the subject's written authorization, a researcher can:

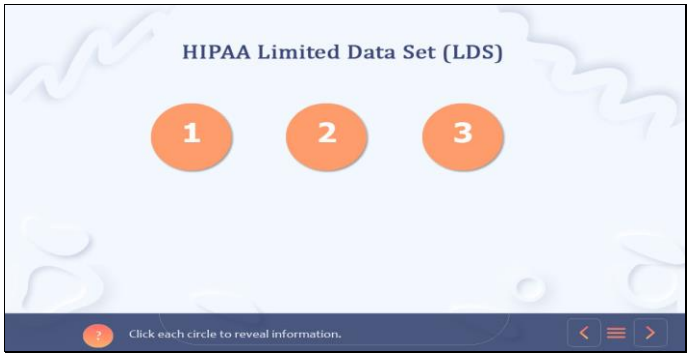
Obtain documented IRB waiver of authorization.

Preparatory to Research: protocol preparation, can use PHI but may not remove it.

Research on Decedents: PHI necessary, may be required to document death status.

Limited Data Set with accompanying Data Use Agreement: Limited PHI includes dates and geographic location.

You may also use PHI with individuals' written authorization.



HIPAA Limited Data Set (LDS)

1

HIPAA allows the use of limited PHI for research without requiring authorization when:

- the PHI is a “limited data set” of health information.
- a written HIPAA Data Use Agreement is obtained.

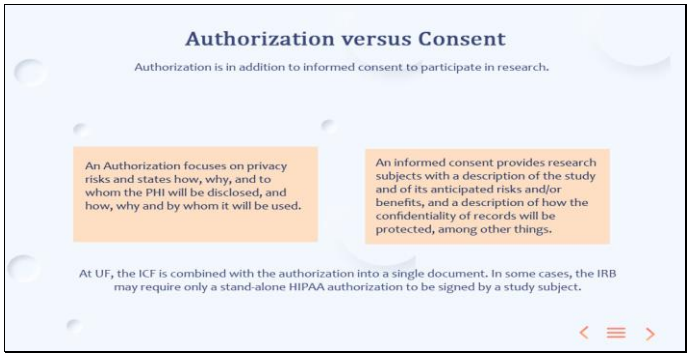
2

In a limited data set, all direct identifiers have been removed, but other PHI may remain, such as:

- City, state, 5-digit zip code
- Dates of birth, admission/treatment, discharge, service, etc.

3

Work with the Office of Clinical Research (OCR) if a HIPAA DUA is needed.



Authorization versus Consent

Authorization is in addition to informed consent to participate in research.

An Authorization focuses on privacy risks and states how, why, and to whom the PHI will be disclosed, and how, why and by whom it will be used.

An informed consent provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things.

At UF, the ICF is combined with the authorization into a single document. In some cases, the IRB may require only a stand-alone HIPAA authorization to be signed by a study subject.

Waiver or Alteration of HIPAA Authorization

In certain circumstances, the IRB (Privacy Board) may waive or alter the requirement for a signed HIPAA waiver under the following rules:

The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

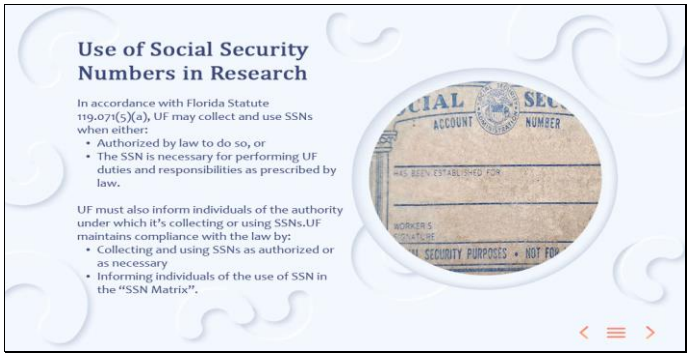
- an adequate plan to protect the identifiers.
- an adequate plan to destroy the identifiers at the earliest opportunity.
- adequate written assurances that the PHI will not be reused or disclosed to any other person or entity.

The research could not practically be conducted without a waiver or alteration; and

The research could not practicably be conducted without access to and use of the PHI.

If the IRB grants a HIPAA waiver, a subject whose PHI is shared outside of UF\Shands can request an list of those research studies under which their data was shared. It is up to the PI of the study to retain such a list.

Picture of data security on a touchpad



Use of Social Security Numbers in Research

In accordance with Florida Statute 119.071(5)(a), UF may collect and use SSNs when either:

- Authorized by law to do so, or
- The SSN is necessary for performing UF duties and responsibilities as prescribed by law.

UF must also inform individuals of the authority under which it's collecting or using SSNs.UF maintains compliance with the law by:

- Collecting and using SSNs as authorized or as necessary
- Informing individuals of the use of SSN in the "SSN Matrix".

Picture of Social Security Card

Use SS Research

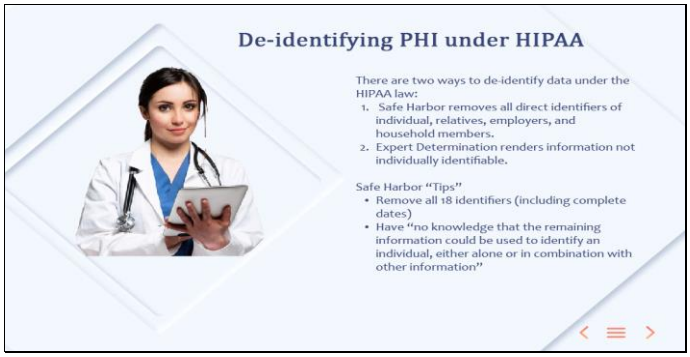
If your research is at the VAMC and you are using VINCI and need access to real SSN numbers (full 9-digit number), fill out “Request to Access Real SSN #” form and submit the signed form together with your study in myIRB.

1

Use of SSNs to pay study participants is authorized and no further action on your part is needed.

2

Use of SSNs for any other purpose requires permission from the Privacy Office.



De-identifying PHI under HIPAA

There are two ways to de-identify data under the HIPAA law:

1. Safe Harbor removes all direct identifiers of individual, relatives, employers, and household members.
2. Expert Determination renders information not individually identifiable.

Safe Harbor "Tips"

- Remove all 18 identifiers (including complete dates)
- Have "no knowledge that the remaining information could be used to identify an individual, either alone or in combination with other information"

Breaking the Rules

If conduct outside the rules is suspected, you will typically receive a letter or call from IRB letting you know the details of the alleged violation. You have 5 days to respond.

Topic 1

Upon review, the IRB Chair or IRB may determine no further action is needed or further information is required.

Topic 2

The IRB Chair or IRB may determine a ‘for cause’ audit might need be instated.

Topic 3

The IRB Chair or IRB may determine suspension of the protocol or enrollment is required.

Topic 4

The IRB Chair or IRB may determine a wrong person signed the consent form or did not indicate who they were.

Topic 5

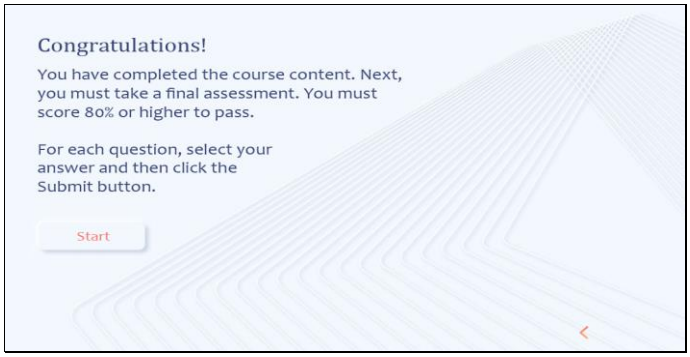
The IRB Chair or IRB may determine a study staff obtained consent not approved by the IRB for this study.

Topic 6

If the study is funded by OHRP and /or FDA, the IRB must report any serious or continuing non-compliance. In the cases of severe non-compliant, this can result in the loss of your DHHS/FDA funding. Severe noncompliance can even jeopardize all research activities at UF.

Resources and Final Assessment

Module 4



Congratulations!

You have completed the course content. Next, you must take a final assessment. You must score 80% or higher to pass.

For each question, select your answer and then click the Submit button.

Please note, you will need to navigate to the assessment in the course and pass the assessment to receive credit for attending this course.