Welcome!

While everyone's joining, please share your area of research interest in the chat.

Working with the UofL Human Subjects Protection Program (HSPPO) and Institutional Review Boards (IRBs)

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Disclaimers

- Information covered in this session is not to be used as a final IRB determination.
- It does not replace required IRB reviews.
- This is a general overview and may not apply to specific projects as every situation is nuanced.

Topics We'll Cover

- What the IRB is and what requires review
- Partnering with the HSPPO and the IRB
- Compliance Considerations
- Education and Resources

What is the IRB?

What the IRB is not…

Data Safety Monitoring Board

Scientific Review Committee

Facility Approval (e.g. UofL Health or Norton facility approval)

University reviews (e.g. Grants/Contracts, Privacy Office, Information Security Office, Controller's Office, UofL Legal, Institutional Biosafety Committee, Radiation Safety, Animal Safety)

What requires IRB review?

Research - a systematic investigation designed to develop or contribute to generalizable knowledge. (Involves development, testing, and evaluation) and includes

Human Subject (aka Participant)- a **living individual** about whom an investigator conducting research obtains…

(i) ***information*** *or biospecimens* ***through intervention or interaction*** *with the individual, and uses, studies, or analyzes the information or biospecimens; or*

(ii) Obtains, uses, studies, analyzes, or generates ***identifiable private information*** *or identifiable biospecimens.*

Belmont Report
Foundation of IRB Principles

Core Principle	Description	Application in Research
Respect for Persons	Individuals should be treated as autonomous agents. Those with diminished autonomy are entitled to additional protections.	- Informed consent must be obtained. - Participants must be given adequate information and allowed to decide freely.
Beneficence	Researchers must maximize possible benefits and minimize potential harms.	- Risk-benefit analysis must be conducted. - Research design should ensure participant safety.
Justice	The benefits and burdens of research should be distributed fairly.	- Selection of subjects must be equitable. - Avoid exploitation of vulnerable populations.

IRB Approval Criteria

By regulation, IRB members must ensure that the research plans make adequate provisions to:

- **Minimize risk** to participants
  - Procedures consistent with sound research design
  - Not unnecessarily exposing participants to risk
  - Utilizing procedures already done for treatment
- Have an **equitable participant selection** and fair recruitment
- **Obtain informed consent and document consent appropriately**
- Protect the privacy and **confidentiality** of participants and their data

The IRB cannot approve a protocol that does not adequately address all of these areas.

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PARTNERING WITH THE HSPPO AND THE IRB

Working with the HSPP

IRB Analysts: They can connect you with the appropriate individuals to address your questions. Department assignments are outlined on the HSPPO website.

Microsoft Teams: We work on Teams throughout the day. This is a great way to ask quick/general questions.

HUMAN SUBJECTS RESEARCH

- Is My Project Human Subjects Research?
- Submit a New Study
- Answering Stipulations
- Continue a Study
- Amend a Study
- Report a Study Event
- Closing a Study
- Templates/Resources
- Policy Manual/Guides
- External Collaborations
- International Research
- ClinicalTrials.gov Registration

Human Subjects Research and Institutional Review Board (IRB)

Information for navigating each step of the IRB process can be found in the menu links on this page. The Human Subjects Protection Program (HSPP) has created document templates, guidance materials and other tools to assist researchers in developing a study protocol, submitting to the IRB for approval, and running a compliant research study. You may also contact the IRB analyst assigned to your department for assistance with your submission.

The Research Education Program (REP) offers training opportunities covering topics relevant to the UofL research community. Individuals can RSVP to upcoming trainings, view past offerings, or submit a request for a departmental/class session.

Self guided lessons are also available for IRB submission assistance and conducting compliant human subjects research.

- Study Personnel Requirements
- Information for Student Researchers

IRIS LOGIN AND GUIDES

Use the link below to access iRIS to submit to the IRB.

IRIS

iRIS INSTRUCTIONAL RESOURCES

iRIS VIDEO TUTORIALS

IRB SUBMISSION LESSON

For additional assistance finding information on this website or accessing iRIS, you may email, call (502.852.5188), or chat with an IRB staff member.

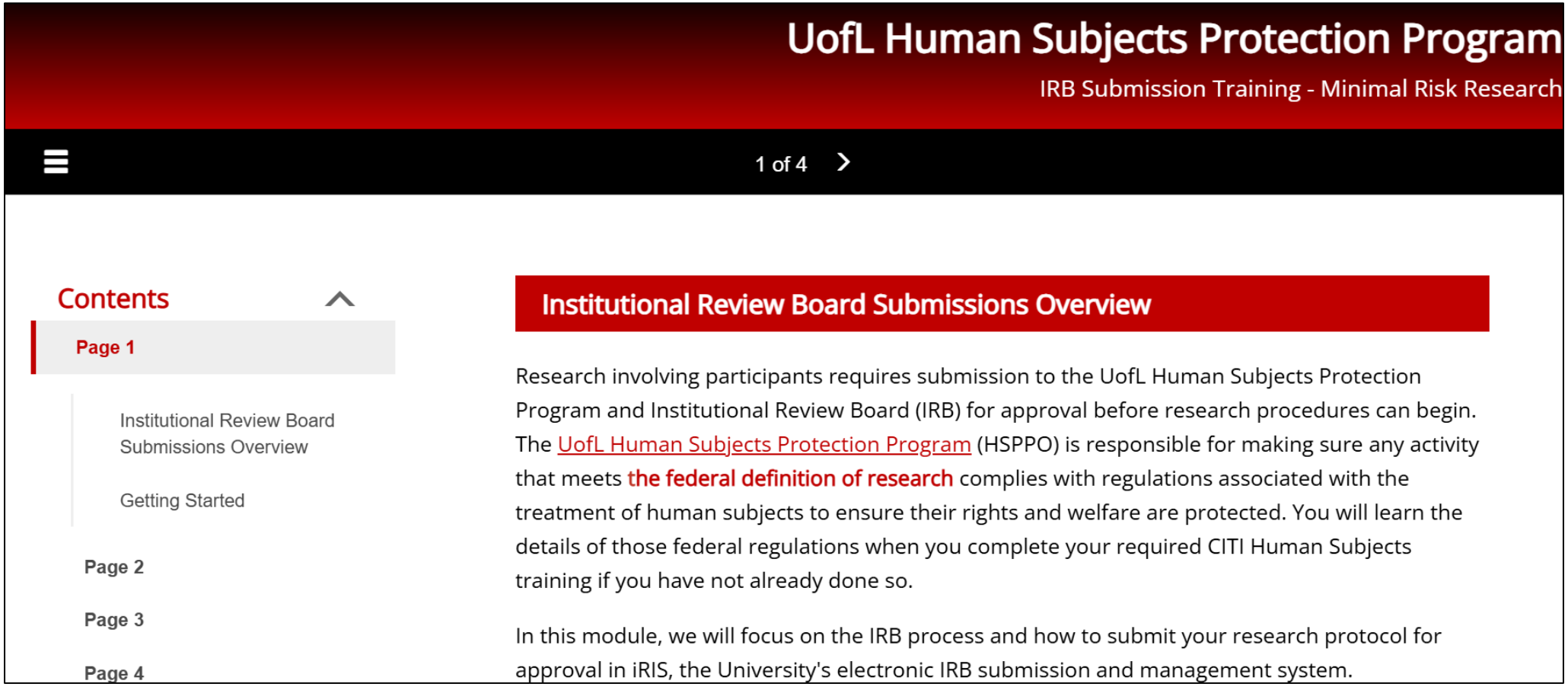
IRB COMMITTEE INFORMATION

CONTACT

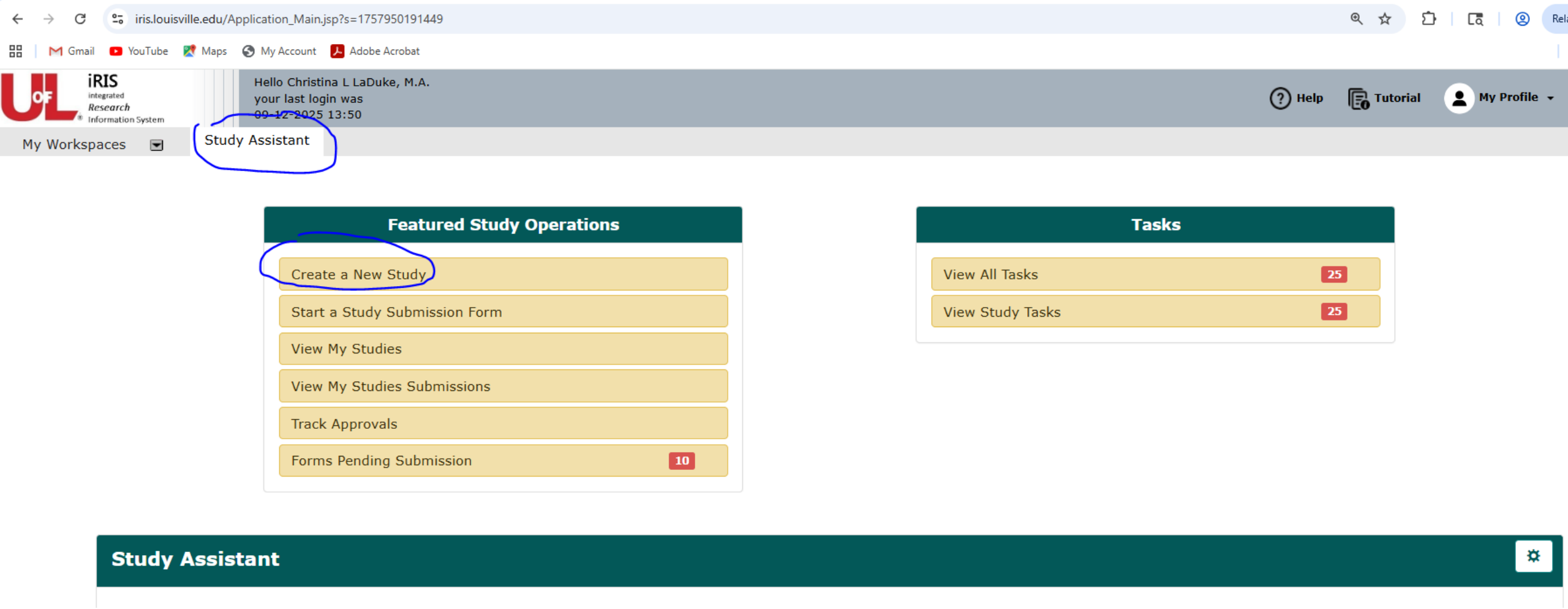
ANNOUNCEMENTS AND EVENTS

Self guided lesson available for:

Preparing an IRB Application and Protocol for IRB Submission



https://iris.louisville.edu



Key Protocol Considerations

- Use lay terms understandable to anyone outside of your field
- Outline clear criteria for the participant population you plan to study (What would qualify someone to be included? What would exclude someone from being included?)
- Outline the study design to establish what the participants will experience throughout the study
- Develop a schedule of events outlining study procedures and when they occur (detail can depend on study risk level - can allow timeframes + or -)
- Establish criteria for monitoring data for participant safety (required for greater than minimal risk research)
- Know the FDA status related to any drugs/devices being used - and include any pertinent regulatory requirements
- Ensure consistency between the protocol – consent – and iRIS IRB application

Key Informed Consent Considerations

- Think through recruitment and identification of potential participants (e.g. will you need recruitment materials?)
- Outline the logistical process of obtaining consent (and assent when applicable) from participants or their legally authorized representative.
- Consider what may be challenging based on the study specifics.
- The IRB will need to be able to follow the participants experience in the study through the consent process.
- The IRB will need to know how consent will be documented (when required) – for example wet ink signature or approved electronic consent procedures.
- Studies may need more than one consent process if different participant groups.

Responding to IRB Requested Changes

- If the IRB or IRB reviewer has changes or questions, those are referred to as “stipulations”.
- Sent back through iRIS and in an outcome letter that is received by email.
- Reach out if changes do not make sense.
- When responding, provide rational for changes not made.
- Communicate with the IRB Analyst if unsure how to respond.
- If you made additional changes beyond the requests, note those in the response.

Key Data Privacy and Security Considerations

Software, Apps & Algorithms: UofL ISCO policy requires vendor vetting for sensitive data access. Do this early in protocol development.

International Research: Researchers must be aware of the rules, laws, and regulations in the countries where they plan to conduct research. University of Louisville's legal/privacy team will review these projects to ensure the university and the research can comply with the country specific requirements.

UofL Privacy Office: https://louisville.edu/privacy
UofL Information Security Office: https://louisville.edu/security

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COMPLIANCE CONSIDERATIONS

Investigator Responsibilities

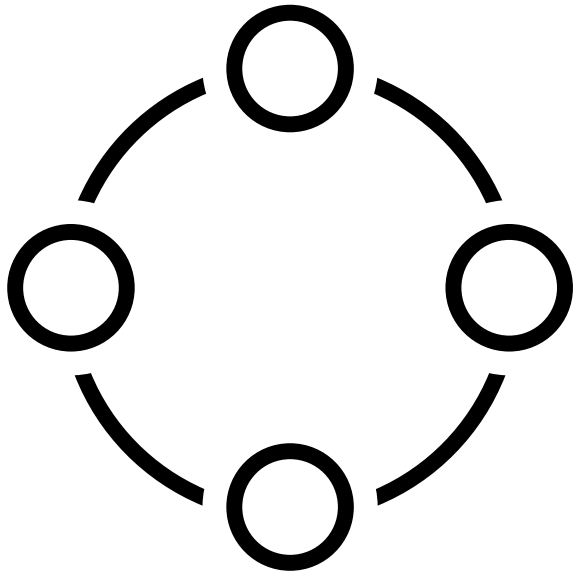
The **Principal Investigator (PI)*** is responsible for the overall conduct and compliance of the research study. PIs may delegate research responsibility; however, PIs maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility….

HSPP policy manual

*Fellows, Residents and Students research projects require a faculty/staff mentor to serve as PI.

Investigator Responsibilities

- Following the IRB approval for the study
- Training the study team on protocol and consent procedures
- Establishing research policies and procedures (could also be at the departmental level)
- Planning for data management and storage
- Ensuring communication among the study team
- Setting an environment for compliant research
- Utilizing tools available on the HSPPO website: training log, adverse event log, delegation log, screening eligibility checklists, consent documentation checklist



IRB Study Personnel Requirements

Human Subjects & HIPAA Research Training (CITI)

Annual Attestation & Disclosure Form on file in iRIS (ADF)
(also referred to as Conflict of Interest (COI) form)

CV uploaded to iRIS profile

Self guided lessons available for:

Conducting compliant human subjects research

"If it's not documented, it didn't happen"

Remember the importance of **accurate, timely, and thorough documentation** to ensure accountability, transparency, and integrity.

EDUCATION AND RESOURCES

Upcoming Education

INSPIRE Forum September 23, 2025:
Examine **real-world case studies** from clinical trials. This will be an interactive session designed for professionals involved in clinical research, compliance, finance, and regulatory affairs. We'll explore actual scenarios that challenge conventional practices and offer practical takeaways to strengthen your compliance strategies.

What to Expect:

- Analysis of billing and financial compliance issues
- Discussion of FDA warning letters and their implications
- Peer-to-peer learning and expert-led commentary
- Actionable insights to improve your trial operations

📍 **Location:** UofL Clinical & Translational Research Building, Room 101/102
🕑 **Time:** Noon to 2:00PM

To register and reserve your seat, click here

Research!Louisville 20025:

The HSPP/IRB will host the following sessions (in person and via Teams).

Save the dates, more details to come!

- Wednesday, October 15th: 9am-11:30am - Consent to Human Subjects Research with Confidence: Design, Delivery, and Documentation, Room 124
- Friday, October 17th: 9am-10:15am - Protocol Considerations from Legal and Privacy: What to know before IRB Submission, Room 124
- Friday, October 17th: 10:30am-11:30am - Fraudulent Research Participants to Return of Secondary Findings and Points in between: Learn from/with the IRB, Room 124

Tools Available for Research Support

- RedCap for building and managing research data https://library.louisville.edu/kornhauser/redcap

- Kornhauser Library research portal https://library.louisville.edu/kornhauser/researchers

- Louisville Clinical and Translational Research Center https://centers.louisville.edu/clinical-translational-research/about/lctrc-welcome

- UofL Clinical Trials Unit https://louisville.edu/research/ctu

In closing…

- Ethical conduct of research is everyone's responsibility.
- Research organizations are responsible for:
  - Providing education and training to enable the ethical conduct of research
  - Creating a culture of research compliance
- Researchers are responsible for:
  - Learning the rules for ethical conduct of research
  - Following the rules in a spirit of respect for study participants and the research process.
- Protecting research participants is our most important job.
- **The HSPPO and IRB are here to partner with you through the process.**

Important Links

iRIS Login for IRB submission: https://iris.Louisville.edu

HSPPO Website Homepage: https://UofL.me/irb

HSPPO Service Email Account: hsppofc@louisville.edu

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ADDITIONAL RESOURCES

Consent Procedures Summarized

Consent Type	Description	When It Can Be Used
Signed Consent	Participant **signs AND dates** this informed consent document.	Required for research that's greater than minimal risk.
Unsigned (preamble) Consent	Consent is obtained orally or electronically, but not documented with a signature. Typically an action triggers consent (for example, by answering survey questions, you agree to participate…)	- When IRB waives documentation requirement under **45 CFR 46.117(c)**. - Common in minimal risk studies, survey and interview research.
Waiver of Consent (or alteration of consent elements)	IRB waives the requirement to obtain informed consent – or – waives elements that are required to be included in the consent document.	- Under **45 CFR 46.116(d)** if: - Research involves no more than minimal risk. - Waiver won't adversely affect rights/welfare. - **Research couldn't practicably be carried out without the waiver.** - Subjects are provided additional information when necessary. - Research involves using identifiable information or biospecimens and could not be carried out without using that information in an identifiable format. - Comonly used in retrospective data research.

What kind of documents (including consent) *will be/could be* required? iRIS application – protocol – <u>for all</u>, *plus…*

Submission type:	Document type:
Full board: Greater than minimal risk. Even one x-ray for research purposes requires full board review. Studying investigational dental device that will require risk determination.	Scientific & Scholarly Merit Review/dept. chair sign-off SIGNED informed consent form (SIGNED assent for children 7-17) HIPAA partial (screening) waiver if accessing health information including screening clinic schedules – for treatment, for visits… Materials to be given to subject (surveys, recruitment materials, etc.)
Expedited: Not greater than minimal risk; can include sensitive information; examples include focus groups, interviews, sample collection by non-invasive means.	Informed consent form (can be signed, unsigned, or waived) HIPAA partial waiver (if screening medical records) Materials to be given to subject (surveys, recruitment materials, etc.)
Exempt: Not greater than minimal risk; no sensitive information; examples include retrospective chart reviews	UNSIGNED informed consent (preamble) HIPAA complete waiver (consent will not be obtained) Materials to be given to subject (surveys, recruitment materials, etc.)
Non-human subjects research	Often, a project description, sometimes a protocol QI often requires an information sheet (looks like a preamble)

Office of Human Research Protections (OHRP)

Applicability: Federally funded or supported research*

Subpart	Citation	Focus Area	Key Provisions
Subpart A	45 CFR 46 Subpart A	**The Common Rule**	Basic protections for all human subjects in federally funded research. Includes informed consent, IRB review, and additional safeguards. Revised in 2018.
Subpart B	45 CFR 46 Subpart B	**Pregnant Women, Human Fetuses, and Neonates**	Additional protections for research involving these populations, including risk-benefit assessments and consent requirements.
Subpart C	45 CFR 46 Subpart C	**Prisoners**	Requires special IRB composition and considerations for coercion and voluntariness in prisoner research.
Subpart D	45 CFR 46 Subpart D	**Children**	Defines criteria for IRB approval of research involving children, including assent and parental permission.
Subpart E	45 CFR 46 Subpart E	**IRB Registration**	Establishes requirements for IRBs to register with HHS, including updates and organizational information.

*Most federal agencies have adopted the common rule. There are some that have not, including Department of Justice.

Food and Drug Administration (FDA)

Applicability: FDA regulated research

Regulation	Citation	Focus Area	Key Provisions
Informed Consent	21 CFR Part 50	Protection of Human Subjects	Requires legally effective informed consent from participants, with specific exceptions (e.g., emergency research).
Institutional Review Boards (IRBs)	21 CFR Part 56	IRB Composition & Responsibilities	Establishes standards for IRB membership, review procedures, and continuing oversight of FDA-regulated research.
Investigational New Drug (IND)	21 CFR Part 312	Drug Research	Governs the use of investigational drugs in clinical trials, including sponsor and investigator responsibilities.
Investigational Device Exemption (IDE)	21 CFR Part 812	Device Research	Regulates clinical investigations of medical devices not yet approved for marketing.
Biologics License Applications (BLA)	21 CFR Part 600–680	Biologics Research	Covers safety, purity, and potency requirements for biological products.
Good Clinical Practice (GCP)	Various (e.g., 21 CFR 50, 56, 312, 812)	Clinical Trial Conduct	Ensures ethical and scientific quality standards in the design, conduct, and reporting of clinical trials.
Electronic Records and Signatures	21 CFR Part 11	Data Integrity	Sets standards for electronic systems used in FDA-regulated research, including audit trails and security.