OSUCCC Prospective Data Study Tip Sheet

The purpose of this document is to provide guidance on creating a protocol for a prospective data study. It outlines the essential components of a study protocol, includes standard language that can be used, and addresses Institutional Review Board (IRB) considerations.

Following these recommendations can help facilitate a streamlined review process, minimize the need for amendments, and ensure that study activities are conducted in compliance with university policy and state and federal regulations.

Please note: In Spring 2025, the IRB moved to a new system, Huron, and issued new protocol templates. The language in this document can still be utilized towards the new protocol template.

I. Prospective Data Study Protocol

Consider the following details when developing a protocol.

Sample size and approach:

Explicitly indicate the number of participants expected for the study. This could be based on an average number of patients seen in clinics or on an aggregate count obtained through the OSUWMC honest broker process, a centralized CCC repository (e.g., Total Cancer Care, Hematology Tissue Bank), Slicer Dicer (IHIS), or Deep 6 AI.

Partial Waiver of HIPAA Research Authorization:

Prospective protocols require patient consent. State that a partial waiver of HIPAA authorization is being sought to allow for the use of protected health information (PHI) necessary to identify and recruit potential research participants. See Protected Health Information and HIPAA Policy.

Informed Consent Process:

Describe how, where and when potential participants would be approached for consent. If utilizing MyChart messaging, email, telephone, or mail, include recruitment scripts for each type of consenting method. A script for in-person consenting is optional. See Research Recruitment Tip Sheet for Investigators.

Data Collection:

List the data elements and medical information to be collected (e.g., diagnosis, stage, comorbidities, labs, images, etc.). A data collection form or list can be included in the protocol, an appendix, or as an attachment. The IRB will seek a definitive list of data elements, not data "such as," including," or "not limited to." Data collection should only be for the data elements needed to perform the research. See Minimum Necessary Requirement.

Indicate if data obtained for the study will contain protected health information (IRB-approved protocol required) or will be de-identified or coded-limited. If PHI, specify whether the study team will de-identify the patient identifiers such as name and MRN. If the data will not be de-identified, provide a justification for maintaining PHI.

Describe how where data will be stored, who will have access to the data, and how the data is protected.

Multi-site: if other sites are providing information or if Ohio State is providing information to other sites, state that data will be either de-identified or coded prior to (receipt/transmission). Provide the method of transmission (e.g., entered into a centralized database or other electronic data capture tool, sent via secure file transfer protocol (sftp), encrypted email, etc.) See Email Security and Encryption.

Biospecimen Collection:

If biospecimens are to be collected and analyzed, describe the collection process and when it would occur. State if specimens will be stored until analyzed or used immediately with remnants stored or discarded. If specimens are stored, provide details on location, duration, storage method, etc.

Participant Withdrawal:

List the contact methods a participant would use to withdraw participation in the repository. Describe the process for destroying data or specimens (if collected). Data or specimens that have already been distributed to Ohio State investigators can continue being used for analysis, however, any remaining participant information and specimens within the repository should be destroyed to prevent further use.

Risk and Benefits:

Generally, prospective studies will not provide benefit to the study participants but may provide benefit to future patients based on findings. Specify how patient privacy and clinical data will be protected. If surveys or questionnaires are administered, state whether participants can choose not to answer questions that may cause stress or discomfort.

Data Analysis Plan:

Detail the statistical analysis plans, software used (if appropriate), and whether other groups will be involved (e.g., Biostatistics Shared Resource). Indicate when data collection and analysis are expected to be completed.

II. Example Language:

Sample Size and approach:

- "(Number) patients are expected to match study criteria. This is based on an average (number) cases being seen in clinic per year and the (number)-year study period."
- "We plan to review (number) charts within the study date range. Data for the sample size request were obtained through the OSUWMC honest broker process."

Research Design

- "This is an observational, non-therapeutic clinical research protocol that involves the collection of data and patient samples in conjunction with regularly scheduled clinical visits and standard care procedures."

Partial Waiver of HIPAA Research Authorization:

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

Informed Consent Process:

- "Eligibility will be determined by one of the investigators/treating physicians. Patients will be approached for consent in a private setting during a routine clinic visit."
- "Patients will be given enough time for the study team to answer all possible questions and to consider participation."
- "Recruitment logs for those still considering participation and those who decline will be destroyed after the final participant is enrolled."

Data Collection:

- "Medical record number (MRN), demographic data (including age, sex, race and ethnicity, height, weight, body mass index), comorbidities (e.g., diabetes, heart failure, hypertension, respiratory disease), cancer primary diagnosis, stage, histology (carcinoma, adenocarcinoma, etc.), cancer treatment data (e.g., chemotherapy, surgery, radiation, immunotherapy, hormone therapy), adverse event (AE) symptoms, PET or MRI imaging, lab results."
- "All data will be de-identified, and patient identifiable information will be replaced with a unique patient identifier (series of numbers/letters), which will then become how a participant is referenced during or after data analysis. The coding key to reverse identify patients will be stored separately from the dataset."
- "The necessity of maintaining PHI stems from the complexity of the relationships between the clinical data and the trajectory of treatment. The files will be stored on a secured hard drive where only the PI and investigators directly involved in the project will have access to the raw data."

- Multi-site: "All data (received from/sent to) external institutions will be provided without identifying information."
- Indicate study duration: "Data collection should be completed within (number) months of approval by the IRB. Analysis and reporting of the data should not take longer than (number) months beyond that point."

Risks and Benefits:

- "This study will not add any further benefit to the study participants as the data analysis consists of existing clinical health information and is prospective in nature. However, the study has the potential to help future patients through the identification of factors and outcomes and aides for the prediction, early detection, and management of (condition/diagnosis)."
- "The data will be maintained in a dedicated folder within the department shared drive that will be password protected and behind the OSUWMC firewall. Only authorized study personnel reflected on the protocol will have access to the data."
- "After the data collection process is complete the data will be de-identified."
- "Data will be destroyed five years (university policy) after study completion." See Records Management Policy.
- "No personal identifiers will be used to reference participants during the study, and a unique patient identification number will be used instead."
- "The confidentiality of each patient will be rigorously maintained using existing standards at The Ohio State University Health Systems. Health Insurance Portability and Accountability Act (HIPAA) and state/federal government regulations for protecting patient privacy and security will be strictly maintained. The results of the research studies may be published but participants will not be identified in any publication." See OSU-IT Security Policy.
- "When personnel leave the project or unit, user access rights will be terminated."
- "All those listed in the protocol who can access the data have completed HIPAA and CITI Human Subjects Research training."

III. Prospective Study Tips

Note: *Two or more active prospective protocols cannot be combined to conduct research activities.*

Multi-site study:

- If multi-site, list all currently known participating **research locations** and indicate if Ohio State or another institution will be the lead site, the Institutional Review Board (IRB) of record, and/or data management and coordinating center.

Cohort Identification:

- The **study cohort** should be well-defined.
- Detail the procedures used to **identify** and **screen** patients who meet eligibility criteria.

- Are participants identified through an honest broker process, manual chart review, physician referral, departmental databases, or a combination of these sources?
- An aggregate number of participants matching the study inclusion criteria can be provided through the OSUWMC or centralized CCC repository (e.g., Total Cancer Care, Hematology Tissue Bank) honest broker processes, Slicer Dicer, or Deep 6 AI to **assess feasibility** for grants, protocol enrollment projections, and justification for participant numbers.
- If participants are identified from an existing **research database**, include the OSU study number or IRB number for the database protocol.
- **Vulnerable patient populations** that may need to be excluded from research include minors, patients with impaired decision-making ability, prisoners, and patients that are pregnant or planning to become pregnant.
- If **patient controls** are used for comparison, what are the criteria for this group, and will the same or additional data elements be collected from them?

Partial Waiver of HIPAA Research Authorization:

- Prospective protocols require a **partial waiver** of HIPAA research authorization to view and collect existing patient health information from within the electronic medical record (IHIS) to facilitate recruitment.

Informed Consent:

- Describe the informed consent process in detail.
  - See requirements Informed Consent (21 CFR 50.20)
  - Confirm the **consenting methods** (in-person, telephone, encrypted email, MyChart, advertisement, etc.), which study personnel would consent, and location(s), if relevant.
  - How will **recruitment statuses** be tracked during the recruitment phase of the study, particularly for those still considering participation or who have declined?
  - At what point will identifiable patient information that was used during recruitment (including tracked screening and declined statuses) be **destroyed**?
  - Will those who consented have the study reflected in the electronic medical record? If so, contact Research Billing to add the study and investigator contact information to the research flag in IHIS.
  - Do **recruitment scripts** reflect Medical Center policy and Privacy Office best practices?
    1. Mention the patient by **full name**,
    2. Make a connection to the **treating provider**(s) by listing their name and that they are aware the study will be approaching their patients. Notify the provider(s) that the study team wishes to approach patients,
    3. State the **voluntary nature** of the research to the patient and,
    4. Does not disclose **PHI** or **diagnosis-related** information in a voicemail or when leaving a message with another person.

- What steps are taken to ensure patient **privacy** during the consent process, that questions are answered, and that an adequate amount of time is provided for the patient to consider participation?

Data Collection:

- Provide detailed data **collection methods** (including how to avoid and minimize participant risks) so that the IRB can assess the potential study risks and benefits. See Research Data Policy.
- Will data be obtained through manual review of the electronic medical record (IHIS) by the study team or by electronic extraction by an honest broker process, or both?
    - Regardless, data provided must be within the IRB-approved **date range** reflected in the protocol and the full waiver of HIPAA authorization appendix in Huron.
    - If seeking outcomes data, consider extending the study date range to include this period.
- PHI from **non-Ohio State locations** and hospital systems cannot be included in analysis unless the necessary approvals are in place for the institution to serve as a participating research site.
    - This includes Care Everywhere, OSUWMC affiliates, and Community Connect sites (e.g., Adena Health, Community Memorial Hospital, Mercer Health, etc.)
- Is data collected from study **surveys** or **questionnaires**? Will these be administered in-person or remotely (e.g., telephone, email, website)?
    - Will participant activity be monitored or audited (e.g., participant diary, phone call)?
- Describe the methods that will be used to maximize the completeness and accuracy of data.
- Individual **PHI elements** and **dates** (DOB, diagnosis, procedures, etc.) should be listed in the protocol and under the partial waiver of HIPAA authorization appendix in Huron.
- Will data eventually be **coded** or **de-identified**? At what timepoint during the study?
- Consider whether **images** (not just reports) are needed, and if so, if they require de-identification. This process involves research imaging informatics services and may carry a fee.
- Where will data/PHI be **stored**? Include the building, room number(s), and/or specific server.
    - Examples: password-protected Excel spreadsheet, REDCap or another platform/software, physical papers in a locked cabinet within the PI's office, shared folder or department drive behind the medical center firewall, etc.
- Indicate how long participant information will be stored once the study is completed.
    - University policy states that data must be retained for a **minimum of five years**. See Records Management Policy.

Specimen Collection:

- What is the **verification process** to confirm participant enrollment prior to the collection of any specimens? How are study specimens obtained/received and transferred for storage?
- Will the specimens be **labeled** with identifiable information or coded with a unique patient identifier (numbers/letters)?
- Describe the process for **destroying** samples if a patient withdraws from the study.

Data and Specimen Transfers:

- Data that is leaving Ohio State, which is typically a coded-limited or de-identified dataset, requires a reviewed and signed **Data Use Agreement** (DUA) to be in place with the Office of Innovation and Economic Development (formerly "TCO") or the Office of Legal Affairs before information can be shared.
- Specimens that are leaving Ohio State require a reviewed and signed **Material Transfer Agreement** (MTA) to be in place with the same offices.
- Labels on specimen containers leaving OSU should be de-identified and contain no patient identifiers.
- University data and specimens must be transferred in a **secure manner.** Data would be shared via electronic data capture systems like REDCap, encrypted emails, and secure file transfer protocol (sftp). Specimens could be transferred via a package delivery service (e.g., UPS, FedEx), courier, etc.

Risks and Benefits:

- *All* prospective studies are associated with a risk of **breach of data confidentiality**. What practices or processes are in place to minimize the risk of a loss of confidentiality?
    - Examples: password protection, only approved personnel will have access to study information, replacing MRNs with unique study IDs (random or sequential numbers/letters), storing electronic records on a shared drive, encrypted email, etc.
    - The loss of confidential research data must be **reported** to the IRB as it poses a potential risk to study participants. Potential breaches of confidentiality involving PHI must also be reported to the applicable HIPAA privacy officer as soon as possible.
- Prospective studies generally do not receive direct **patient benefits**, however, what is learned may increase general knowledge and influence the treatment of future patients.
- For **surveys** and **questions**, consider if patients are able to skip over questions or sections that may cause personal stress or discomfort.

Ohio State Contact Information

Office of Responsible Research Practices (ORRP, IRB staff):

- https://research.osu.edu/contact-us?department=4
- General phone: (614)688-8457

OSU Information Technology (OSU-IT):

- https://it.osu.edu/help
- Medical Center: (614)292-6446 (HELP)
- University: (614)688-6446 (HELP)

OSU Compliance and Integrity (OUCI):

- https://compliance.osu.edu/

- General phone: (614)292-3251

Ohio State Policy and Guidance

Institutional Data Policy:
- https://policies.osu.edu/sites/default/files/documents/2025/02/institutional-data-policy.pdf

Protected Health Information and HIPAA (OSUWMC):
- https://policies.osu.edu/sites/default/files/documents/2025/04/Protected-Health-Information-HIPAA.pdf

Research Data
- https://policies.osu.edu/sites/default/files/documents/2025/03/research-data-policy.pdf

Research Health Information ("RHI," OSU-OTDI):
- https://it.osu.edu/security/research-support/research-health-information

Research Recruitment Tip Sheet for Investigators (OSU-COM):
- https://medicine.osu.edu/-/media/files/medicine/research/office-of-research/20230217-gdl-inst-113-res-recruitment-tip-sheet.pdf?rev=cbd55b39da20408b8e1e55748bad5973

Research Using Protected Health Information ("PHI," OSU-ERIK):
- https://research.osu.edu/research-responsibilities-and-compliance/human-subjects/hipaa-and-human-subjects-research/research

Secure Email (OSUSecure):
- https://it.osu.edu/security/services/secure-email

Ohio State Resources

OSUCCC Hematology Tissue Bank (HTB) Requests:
- HTB request form: https://go.osu.edu/htbrequest

OSUCCC Total Cancer Care (TCC) Data Requests:
- TCC request form: https://go.osu.edu/osutcc

OSUWMC Honest Broker Research Data Requests:
- Research Data Request form: https://go.osu.edu/researchdatarequest

US Federal Guidance

Definition for Coded-Limited Data Set:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/limited-data-set/index.html#:~:text=A%20LDS%20is%20protected% 20health,Telephone%20numbers

Health Information Privacy:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

Methods for De-Identification of PHI:

- https://www.hhs.gov/hipaa/for-professionals/special-topics/de-identification/index.html

Minimum Necessary Requirement:

- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/minimum-necessary-requirement/index.html

Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule

- https://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf