University Hospitals Clinical Research Center

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Research Data Compliance and Data Management Best Practices

Key Considerations

- **Respect the data, it belongs to a person**
- What information do you need to carry out your study?
- Who should be able to access the identifiable patient information?
- Where will the data be stored?
  - Is it secure?
  - Is it encrypted?
- Do I need to share the data with anyone outside of UH?
- How will I de-identify the data at the end of the study?

Data Access, Privacy & Confidentiality

- UH Privacy Officer approval is required to access any patient data for activities preparatory to research
- IRB Approval is required before accessing any patient data for the purpose of research
  - IRB approval is only for a specific set of data. Gathering additional data will require a modification to the IRB approved protocol
  - If answering new research questions - IRB submission, review, and approval of a new study is required
  - Ensure that the number of charts accessed does not exceed the maximum number of charts requested to be accessed in your IRB-approved protocol. If additional charts need to be accessed, a modification must be submitted to the IRB to extend the maximum prior to accessing additional charts.
- Ensure adequate provisions are in place to protect the privacy of the research participants and maintain confidentiality of data that were accessed - E.g. password protection and limited access to records by IRB-approved research staff only.

Data Collection, Documentation, Analysis & Reporting

- Only IRB-approved key study personnel are permitted to complete protocol-related study data collection, processing, analysis, and reporting.
- Have a clear and concise data collection and analysis plan in place.
  - Periodic QA/Systematic Review
  - Clear parameters for what patient data will be included
  - Succinct participant eligibility criteria (inclusion/exclusion) and appropriate sample size
- Maintain a log of the participant records or specimens that were accessed and collected.
- Maintain all screening and enrollment documents, include all screen failures, participants enrolled, and participant withdrawals (de-identified or identifiable e.g. in a Linking Sheet).
- Ensure compliant data collection and documentation by following Good Documentation Practices and the acronym ALCOA+C.
  - Attend The Basics Module 7-Good Documentation Practices & Clinical Data Management in GPS
- Ensure the accuracy, completeness, legibility, and timeliness of the data reported.
- Do not over-promise what the conclusions will bring
  - If working with big data, know the challenges - E.g. variations in data definitions or coding over time, inaccurate or inaccessible data elements, access to sufficient informatics and programming

Data Entry

- Ensure data is entered accurately and in the correct data field location.
- Double check spelling and watch for transcription errors.
- Avoid abbreviations unless these are defined within the Data Entry Guide or study protocol.
- Use the units of measurement described on the data entry tools.

Data Storage, Sharing & Transmission

- Data storage systems must be UH compliant with limited access and backups. Check with UH IT if you are unsure.
- Only UH encrypted devices can be used for study data.
- Data storage and transport precautions:
  - Digital - Devices (phone, tablet, laptop, USB device) must be approved and have encryption
  - Paper documentation - Must be in a locked location with limited access. If in your car, must be locked in the trunk out of sight.
- Only share UH study and patient data with those approved by the UH IRB
- UH study and patient data should only be sent and received by UH email addresses.
  - If data is emailed to outside organizations or non-UH staff, ensure the recipient is approved by the UH IRB with appropriate agreements and documentation in place. Include the word "SECURE" in the email subject line to ensure proper encryption.
- Work with the UH Grants & Contracts Office to ensure that appropriate contracts and agreements are in place PRIOR to sharing any study data with outside organizations or non-UH staff
  - Data Use Agreement (DUA)
  - Confidentiality Agreement (CDA)
  - Non-Disclosure Agreement (NDA)
  - Material Transfer Agreement (MTA)
  - Business Associate Agreement (BAA)
- If you anticipate sharing data with other teams for future research, develop a specific plan for this in your protocol. Do not release data without verifying that the study team has IRB approval for their project
- If study data is sent externally, verify that de-identification procedures are in place.

Informed Consent & Eligibility

- As applicable, all original informed consent and assent documents must be present and fully executed for each participant.
- If informed consent was waived, a copy of the IRB waiver should be in the regulatory binder.
- As applicable, the informed consent process must be documented via checklist or narrative note.
- Ensure that documentation or verification regarding the inclusion/exclusion criteria is present regardless of if for participants (interventions, observations) or accessing their data (chart reviews, repositories, etc.)

Specimens and Discarded Tissues

- Ensure that if specimens are utilized, including discarded tissues, that they were collected, transported, stored, and documented per protocol. This includes temperature monitoring, as applicable.
- Ensure that there are provisions in place for potential sample storage failure.

Clinical Data Management is a multi-disciplinary, cross-functional activity that includes the entire research team (Data Specialists, Investigators, Research Nurses, Research Assistants, Biostatisticians) and allows for efficient and complete data collection, processing, analysis, and reporting.

- Data management, quality control, and quality improvement is the responsibility of all key study personnel and should be proactive and ongoing.

Study Start-Up is an organized process of discussing and reviewing all of the study materials prior to when a research project is set to begin. It also serves as a forum for key study personnel protocol training.

- Study start-up should lay the groundwork for the successful execution of a research project and allows all IRB-approved study personnel on the Delegation Log the opportunity to prepare appropriately and to ask any questions prior to commencing their study-related tasks and activities.

References:

- SOP GA-102 – Use and Disclosure of Protected Health Information Preparatory to Research
- SOP SS-303 – Site Initiation Visit
- Study Start-Up/Site Initiation Visit:
  - Frequently Asked Questions (SIV FAQs), Guide and Checklist, Agenda, Slide Presentation Template

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