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Conducting your study

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CONDUCTING YOUR STUDY

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Today's Topics

- Policies and guidance that surround study conduct
- Study closure
- Tips for Study Conduct

HRPO Guidance that helps with study conduct

- Investigator's Assurance of Commitment to Responsible Research
- Notification guideline
- Consent Guidance

Approvals & Change of PI

- Approval by IRB
  - No changes in the conduct without prior IRB approval
- Change in PI
  - If you are leaving WU and still need access to individually identifiable information, change the PI

Education Requirements

- Anyone that helps you with individually identifiable information or consenting participants needs to be added via a modification and must take CITI.

- If PHI is being used, these individuals need HIPAA training as well.
  - PHI = private health information that comes out of or is put into a medical record

Exempt Status

- Only the IRB can grant this.
- If there is a change or unanticipated problem, send in the modification or notification.

Exempt Studies

- You may only look at information that was put in the medical chart before the date of IRB approval.
- You may not extract any individually identifiable information.
- There is no follow-up.

Final Report

- Closes the study
  - No more access to individually identifiable information
- What is kept?
  - All source documents in their original form – where information was first recorded including consent documents
  - Must be kept for at least 6 years after study closure

BEFORE YOU CLOSE YOUR STUDY:

- All data cleaning and auditing must be completed, including queries from the sponsor.

- Be sure that all currently planned data analyses being conducted by WU investigators have been completed
  OR
  If data will continue to be used for research purposes at this time, it has been anonymized (All identifiers and links to identifiers have been removed/destroyed – EXCEPT consent documentation must be kept in accordance with HRPO record retention policy. You should remove information in the data that would link the data to the consent document.)

  - NOTE: *If you don't currently have plans to use/analyze the data but wish to keep identifiers, you should close the current study and submit a NEW IRB project for review and approval when you are ready to conduct further analyses.*

BEFORE YOU CLOSE YOUR STUDY:

- Review the research record to confirm that all reporting requirements were met as defined by HRPO Policies and Procedures and Reporting Guidelines.

- Consider plans for record retention. Records must be kept in their original format for at least 6 years from the completion of the study. There may be additional retention requirements from applicable federal or state laws or at the request of the study sponsor.

- Review your IRB approval to determine if you need to destroy identifiers associated with PHI.

HIPAA Minimum Necessary

- Only extract data you are approved to extract for the study.
- Only access records you are approved to access based on the IRB submission.
- Only share with those you are approved to share with, e.g. research team.
- Only share in the manner approved based on your IRB submission.

Informed Consent

- Consent all participants using the method approved in the IRB submission.
  - Written consent means a signature on a consent form.
    - If a non-English speaking participant presents and you want to enroll that person into a study that uses written consent, you need a written consent document in the native language.
  - Waiver of consent means no one is consented.
    - Therefore, there is no follow-up.

No Grace Period

- Studies may only stay open for a period of exactly 12 months.
  - Send in renewals at least 6 weeks prior to expiration to ensure timely renewal of your study.

- Once the study expires, all activity with including data analysis must cease until the study is renewed again.

Non-Compliance

- Not abiding by Federal regulations, institutional policies or guidance
  - This can include State Statues if they apply to your study.

Record Retention

- All information generated as part of a research study is the property of WU
  - If you leave and you want to take copies with you, you must get permission from your department.
- All PHI must be kept behind two locked doors
  - Get any electronic devices used for research verified by your HIPAA security liaison to ensure it meets WU standards

Recruitment of Participants

- Use warm contacts to recruit participants
- If you do not have a clinical need to be in someone's medical record, apply for a partial waiver of authorization.
  - This is separate from the Waiver of Consent, consent document or other form of consent.
- If you want to recruit from your department, you must do so in a general way such as a IRB approved departmental e-mail.

Recruitment

- Have all recruitment materials and modes of recruitment approved by the IRB.
  - Provides information about the study or changes in study procedures

- HRPO does not need to see:
  - Reminder cards
  - Birthday cards

Reporting of Events

- Report events listed on the front page of the Notification Guideline found at: http://hrpohome.wustl.edu/study_team/guidelines.aspx

1. Changes in the status of the study due to safety concerns (such as a suspension or closure of enrollment)

2. Adverse Events:

A. *Internal Adverse Events and External Adverse Events occurring in the same study if they are:*

- Serious (regardless of expectedness or relatedness) or;
- Unexpected and reasonably related (regardless of seriousness)

B. *External Adverse Events occurring in a different study if:*

- the adverse event places the participant(s) at a greater risk of harm than was previously known or recognized

3. Unanticipated Adverse Device Experiences (UADEs)

4. Protocol Deviations (formerly Violations/Errors and Exceptions)

5. Complex Complaints

6. Breaches of Confidentiality

7. Audit/Inspection/Inquiry

8. Participant Incarceration

9. New Information (Safety Monitoring, Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) reports, interim analysis reports, progress reports or any event or new information that suggests the research places participants or others at a greater risk of harm than was previously known or recognized)

Consent Guidance

- Gives information on who may obtain consent
  - Qualified and trained members of the research team
- Who may give consent
  - Adults (18 years and older in MO)
  - Legally Authorized Individuals
    - Not Foster Parents but Case Managers
  - Emancipated Minors

http://hrpohome.wustl.edu/study_team/guidelines.aspx

TIPS for Study Conduct

- Develop Source Documents to be used for data collection
  - Examples can be found at

http://hsrqa.wustl.edu/default_files/Page514.htm

- Keep delegation logs

http://hsrqa.wustl.edu/default_files/Page982.htm

TIPS for Study Conduct

- Keep copies of all engaged members CITI and HIPAA training
  - If needed for the study, keep copies of licensure
- Follow your protocol
  - If you want to make a change, get IRB approval

TIPS for Study Conduct

- Limit the number of individuals who have access to individually identifiable information
- Only collect what you are approved to collect
- Chart reviews are human subjects research

TIPS for Study Conduct

- Do not transmit PHI via e-mail without written authorization to do so

- Do not recruit populations or use recruitment methods that have not been IRB approved

What comes with your IRB approval?

- Permission to publish de-identified information
- Permission to analyze data for research purposes

Questions

- Contact HRPO at any point with any questions you may have

314-633-7400

http://hrpohome.wustl.edu