Georgetown-Howard Universities
Center for Clinical and Translational Science

RESEARCH INTEGRITY AND COMPLIANCE

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Conflict of Interest

- Conflict of Interest is an important part of any research program
- The IRB should not review studies without having reviewed potential conflicts or management plans for conflicts
- Potential conflicts are looked at within the context of the specific research an investigator is participating in
- Management plans vary, but are generally intended to minimize potential bias and inform subjects

Conflict of Interest

- Familiarize yourself with your institution's COI policies for research
- Ensure you have completed your disclosures accurately and in a timely manner

Scientific Misconduct

- Regulations define scientific misconduct as falsification, fabrication or plagiarism
- Scientific misconduct can occur any time during the lifecycle of the research- from grant application to final publication
- Timelines are important in research misconduct, so report any suspicion of misconduct promptly!
- Review your Scientific Misconduct Policy for examples of what can be reported as scientific misconduct and how it will be investigated

HIPAA and Privacy

- Only access protected health information you need to know for your position or task
- Privacy reports of lost or misused PHI, lost or stolen devices, accidental disclosure of PHI- should be reported to compliance
- It may be reportable to the IRB but privacy concerns will always be reportable to compliance

HIPAA: The Privacy Rule

- 45 CFR parts 160 and 164
- Establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions

HIPAA: The Privacy Rule

- Generally, the rule requires a written, signed permission (Authorization) before the covered entity can use or disclose the individual's PHI for research purposes
- One way a covered entity can use or disclose PHI without an Authorization for research is by obtaining a waiver of the Authorization requirement by an IRB or Privacy Board

Waiver of the HIPAA Authorization Requirement

- A waiver in whole occurs when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria set forth in the Privacy Rule have been met.
- A partial waiver occurs when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a specific part of a research study, such a recruitment

Alteration of the HIPAA Authorization

- The IRB may approve a request to remove some, but not all, of the required elements of an Authorization.
- Example: IRB could approve a request to remove the requirement that the authorization describe each purpose of the requested use or disclosure- *if the identification of the specific research study would affect the results of the study*

Waiver - Criteria

- PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of
  - (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
  - (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification of retraining the identifiers or if retention is otherwise required by law; and
  - (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, of (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule

Waiver – Criteria (cont.)

- The research could not practicably be conducted without the requested waiver or alteration
- The research could no practicably be conducted without access to and use of the PHI

Preparatory to Research

- The Privacy Rule permits a covered entity to provide investigators with access to PHI for purposes preparatory to research, such as for preparing a research protocol, assisting in the development of a research hypothesis or identifying potential human subjects to aid in study recruitment
- Under this provision, no PHI may be removed from the covered entity during the course of the review

Where Does Screening Fit In?

- Generally, you can obtain a list of patients who fit certain criteria without a waiver or an authorization. This would likely fall under preparatory to research.
- Once you open a medical record to verify eligibility or contact a patient, you must obtain a waiver of authorization from the IRB for this activity

Questions??