# Informed Consent Guidelines

## for

## Research Studies

Harris Health System

Research and Sponsored Programs

# Objectives

- Review the Informed Consent Process for research
- Define the Harris Health Injury Disclaimer and use in consent document
- Explain Harris Health requirements for consent documents
- Detail the process of registering research subjects
- Describe the process for placement of the research consent document in participants' electronic medical record (EMR)

# Informed Consent Process

Informed consent is:

- The process of telling potential research participants about the key elements of a research study and what their participation involves
- One of the central components of the ethical conduct of research with human subjects
- A dialogue, i.e. an exchange of information between two parties, which begins at initial contact and continues until the study is complete
- A process that typically includes providing a written consent document containing the required information (i.e., elements of informed consent) and the presentation of that information to prospective participants, unless the IRB has waived the consent requirement or documentation requirement

# Injury Disclaimer

**"In the event of injury resulting from this research, *(insert affiliate IRB)* and Harris Health System are not able to offer you financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community."**

- Required for any study that includes an intervention as part of research procedures (e.g. blood draw, research medication administration, etc.)
- Used in addition to medical affiliate injury disclaimer
- Usually placed on the last page of consent document above signature line

# Requirements for Consent Documents

- Research consent documents must be approved by IRB of record and Harris Health prior to use

- As Harris County area is a diverse region of many cultures and languages, investigators who enroll research subjects at Harris Health must consider the likelihood of encountering eligible subjects with limited English proficiency.

- Language and communication barriers such as those from limited English proficiency can contribute to misunderstandings between participants and investigators, obstacles to high quality of care and negative clinical outcomes.

# Requirements for Consent Documents (cont.)

- For primary Spanish speaking subjects, a fully Spanish translated long consent is required.
- The alternative “short form” method for obtaining informed consent can be used for all other languages except for English and Spanish speaking subjects.
- Written HIPAA authorization is combined with the research informed consent as one document with one signature page.
- Harris Health does not provide written translation services for consent documents.

# Enroll, Register & File

1. Enroll subject into research study
2. Register patient as a research subject
    - Required to flag patient as research subject in Epic, as detailed in the Epic Research Personnel training.
3. Place research consent document in participants' medical record
    - IRB and Harris Health approved
    - Signed by subject/Legally authorized representative
    - Confirm consent has valid dates, signatures, versions, and a current Harris Health approval stamp

# Consent Placement - Electronic Medical Record

## In-person submission:

- For identification purposes, all consent documents must include the IRB protocol number on the forms (e.g., add a post-it note or highlight the protocol number)
- Each consent must include the patients name, MRN, and DOB
- Health Information Management (HIM) will upload the research consents to Epic
- If a protocol number is not found on the submitted documents, the study team will be contacted by the HIM Manager to retrieve the number

## Electronic submission:

- Send consent via email to HCHDIntradepartmentalProcs@harrishealth.org
  - Email must be secured
- IRB protocol number must be included in the subject line
- Each consent must include the patient name (printed), MRN, and DOB (if available)
- HIM will upload the research consents to Epic
- If the protocol number is not listed in the subject line, the study team will be contacted by the HIM Manager to retrieve the number