

# Definition of Human Subject Research

**... is a systematic investigation designed to develop or contribute to generalizable knowledge.**

**Human Subject is any individual about whom an investigator (professional or student) conducting research obtains:**

- 1) data through an intervention or interaction with the individual  
or**
- 2) identifiable private information for which the ID of an individual can readily be ascertained by investigator or associated with the information.**

# HHS Definition of Identifiable Private Information for Research

➤ **Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place [PRIVATE]**

**and**

➤ **which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (eg. a medical record). [CONFIDENTIAL]**

# 2004 OHRP Broadened Definition of Non-Identifiable

- **PHI or specimens not identifiable when cannot be linked to specific individuals by the investigator(s), either directly or indirectly through coding systems**
- **Agreement between investigators & key holders (no IRB review required) prohibits release of key to investigators under any circumstances until individual deceased... or**
- **IRB approved written policies & procedures for a repository that prevents release of key... or**
- **legal requirement prohibiting the release of the key to investigators ... or**
- **key to decipher code destroyed before research starts**
- **If investigator unexpectedly learns identity or believes important to know... becomes research & needs ICD unless exempt**

# FWA- Federal Wide Assurance

- **Document** negotiated between Institution & HHS - OHRP has oversight (45CFR46.103)
- **Written assurance** that Institution will comply w/HHS Protection of Human Subjects regulations (45 CFR 46)- once approved, a number is assigned

# Exemption to 45 CFR 46.101

- ❖ **Research & demonstration projects which are conducted by or subject to the approval of department or agency heads, & which are designed to study, evaluate, or otherwise examine:**
  - **Public benefit or service programs;**
  - **Procedures for obtaining benefits or services under those programs;**
  - **Possible changes in or alternatives to those programs or procedures; or**
  - **Possible changes in methods or levels of payment for benefits or services under those programs**

# Waiver of authorization / IC requirements

HIPAA rule

45 CFR,  
p46

21 CFR,  
p50/56

## Waiver or alteration of authorization permitted if:

- No > min. risk to privacy
- Adequate plan to protect PHI from improper disclosure
- Identifiers destroyed at earliest opportunity unless health/research/legal requirements
- Written assurance PHI not disclosed to 3rd party except as req. by law, research oversight
- Research impractical w/out waiver or access to use of PHI

## IRB can waive some or all IC requirements (except FDA)

- No >min. risk of harm & no added procedures requiring IC
- If rights/welfare not affected
- ICD only link between research & subject & possible harm from ID
- Subject provided w/additional info later
- To preserve life/emergency research
- President's waiver

# MD ANDERSON CANCER CENTRE

- is a “covered entity” under the “Privacy Rule”
- conducts HHS supported human research under the “common rule”
- conducts FDA regulated clinical trials/studies

Therefore, any human research study approved by the MDACC IRB needs to be in compliance with all applicable.