DOCUMENTATION OF CONSENT

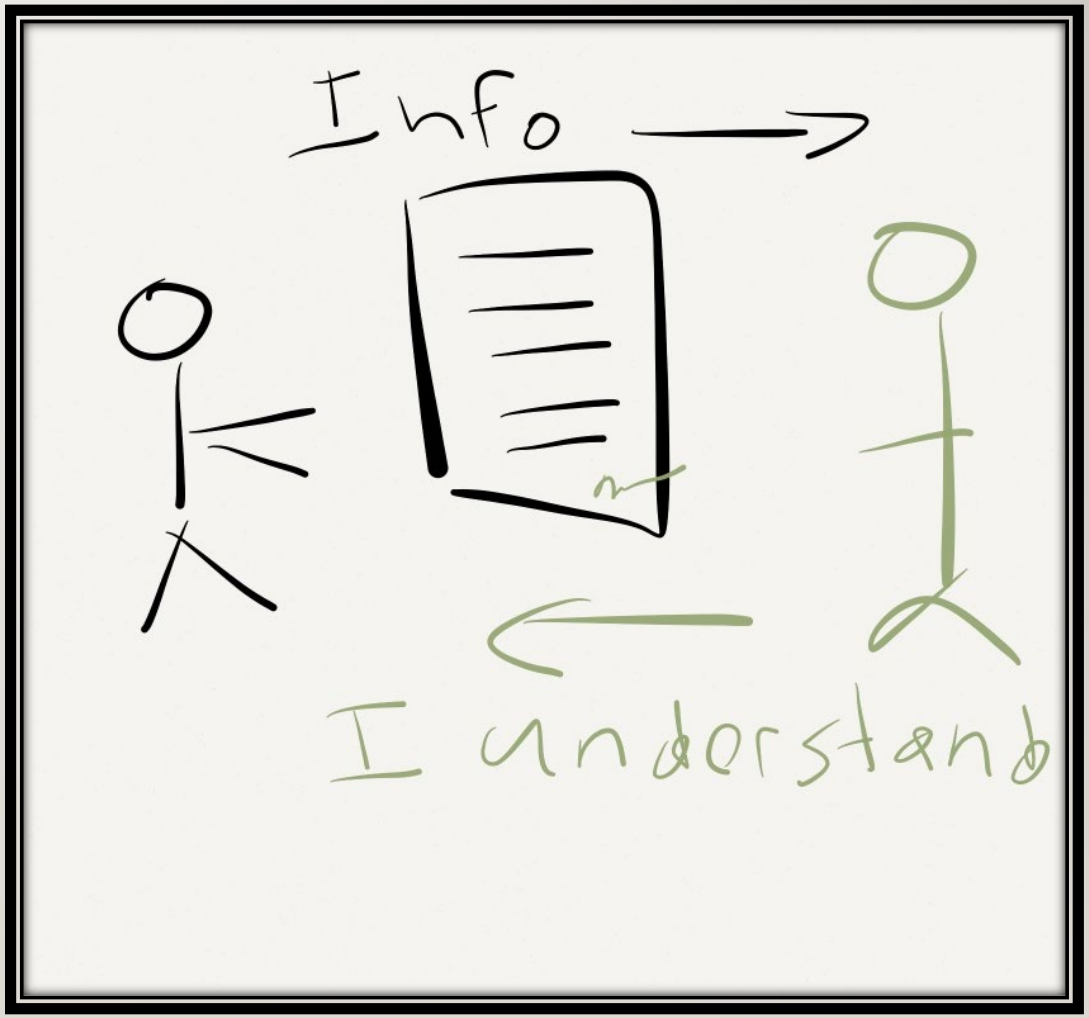
INFORMED CONSENT

IN FEBRUARY, WE BEGAN HERE

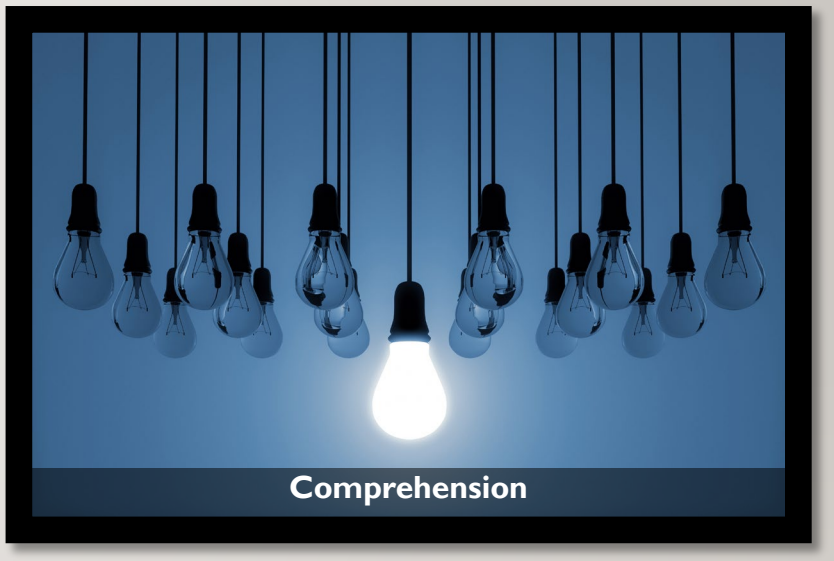
RESPECT FOR PERSONS

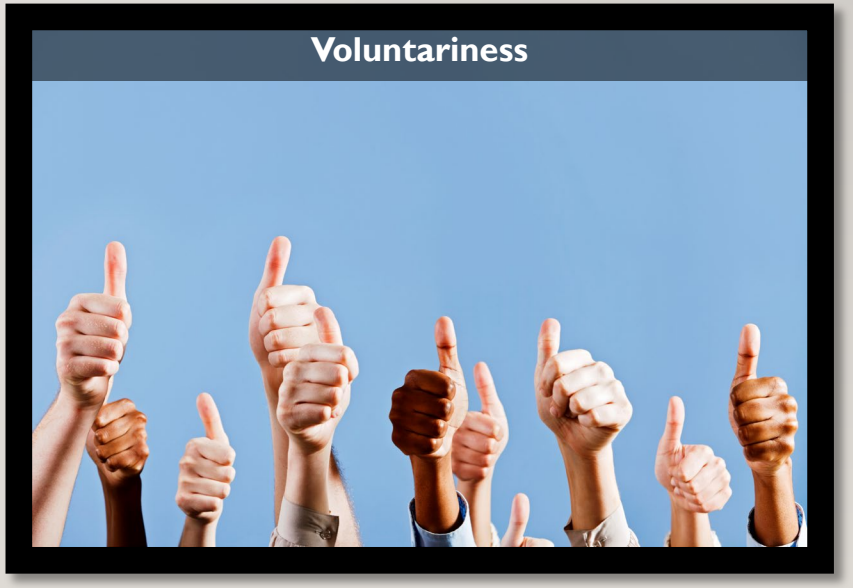
1) Individuals should be treated as autonomous agents

2) Persons with diminished autonomy are entitled to protection



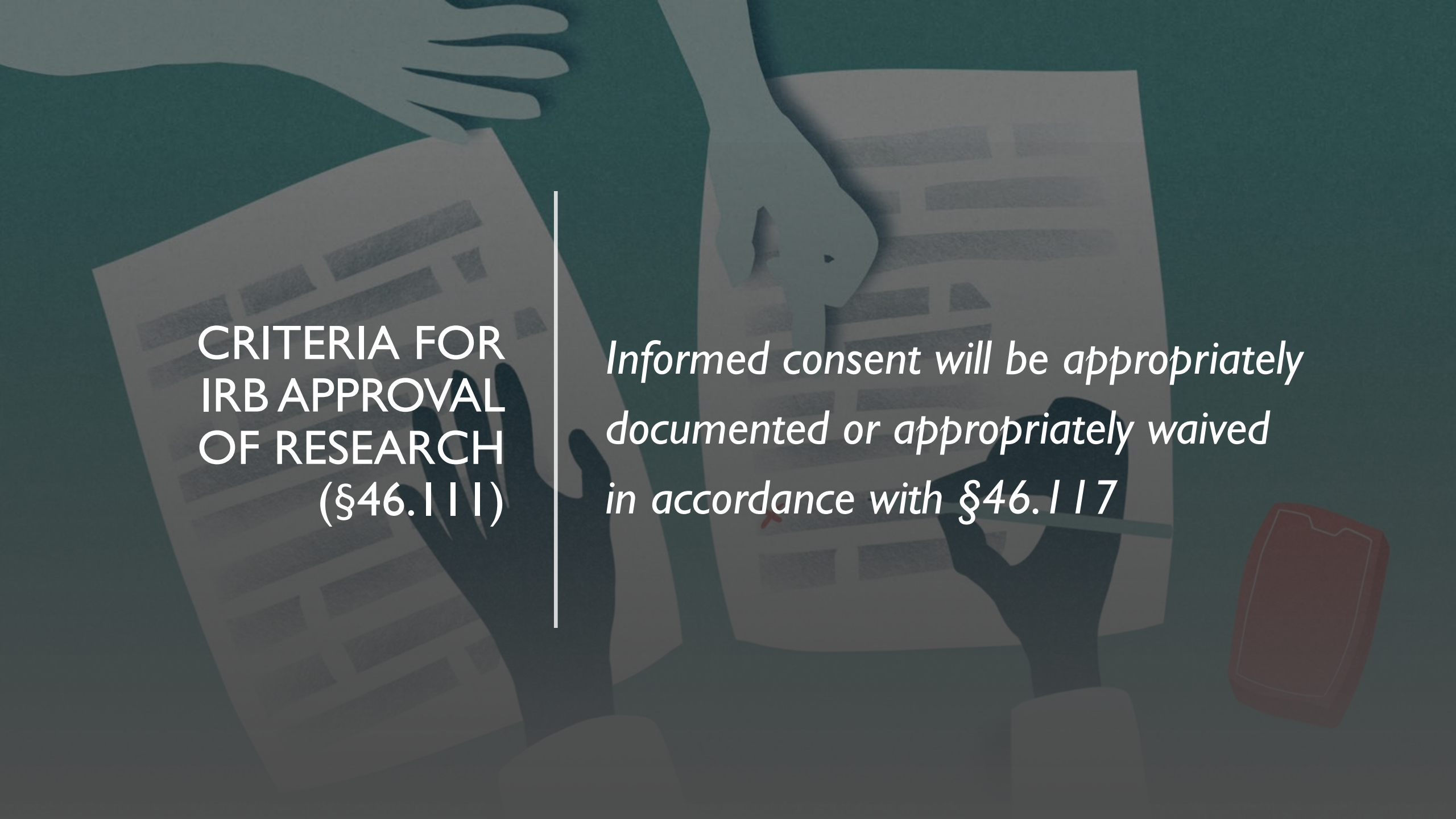
PRINCIPLES APPLIED





FROM PRINCIPLES TO (COMMON) RULE

- Apply Common Rule (45 CFR 46)
- Criteria for approval (§46.111)
- Regarding informed consent:
  - Consent is obtained (§46.116)
  - Consent is documented (§46.117)



CRITERIA FOR IRB APPROVAL OF RESEARCH (§46.111)

Informed consent will be appropriately documented or appropriately waived in accordance with §46.117

DOCUMENTATION OF INFORMED CONSENT(§46.117)

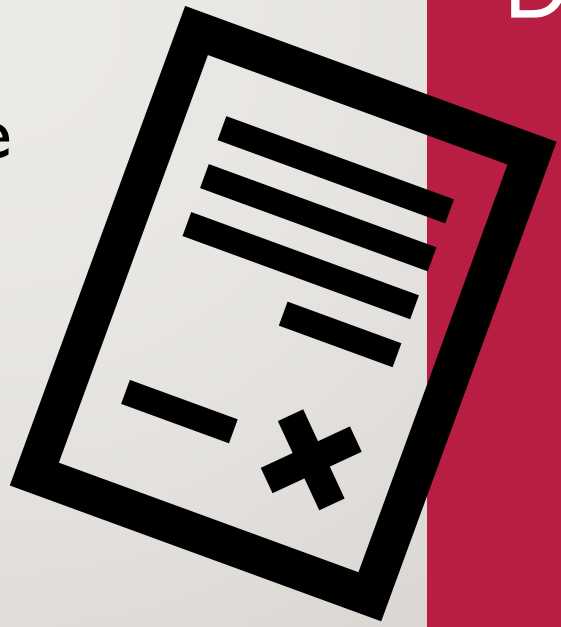
…informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

CONSENT DOCUMENTATION DEFAULT

- IRB-approved consent document with signature line is implemented
- Participant or legally authorized representative signs and dates form
- Individual obtaining consent signs and dates form
- Copy of form provided to the participant or legally authorized representative
- Signed and dated form is retained as part of the study documentation

CONSENT DOCUMENTATION DEFAULT

The Common Rule and other state, local, and institutional laws, policies, and guidance **do not directly outline what is considered acceptable documentation**; however, they do provide guidelines to ensure that the documentation is valid



CONSENT DOCUMENTATION

MARK MADE BY SUBJECT

- Wet signature
- X
- Thumbprint
- Other culturally appropriate mark
- Electronic signature

VERIFYING IDENTITY

- In-person interaction
- Virtual meeting or teleconference where the Study Team witnesses signature
- Using technology that supports an electronic signature
- Other, including IDs, documentation, personal questions

CONSENT VERIFICATION

OHRP encourages a risk-based approach to the consideration of subject identity. For example, when consent form are mailed (by postal mail, email, fax, etc.) directly to the individual, it may be sufficient verification if the signed informed consent form is sent back to the study team via the same method.

DOCUMENTATION OF INFORMED CONSENT(§46.117)—WAIVERS

RISK ASSOCIATED WITH BREACH OF CONFIDENTIALITY

MINIMAL RISK AND NOT TYPICALLY REQUIRED

GROUP OR COMMUNITY NORMS

DOCUMENTATION OF INFORMED CONSENT(§46.117)—WAIVERS

1	**Waiver of Written Documentation of Consent**[2] (Check if **"Yes"**. All must be checked)
☐	The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the WORKSHEET: Criteria for Approval (HRP-314).
☐	The research presents no more than Minimal Risk of harm to subjects.
☐	The research involves no procedures for which written consent is normally required outside of the research context.
Select one of the following: **(One must be checked)** ☐ Written information describing the research **is to be provided** to the subject or the subject's Legally Authorized Representative (LAR). ☐ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.	