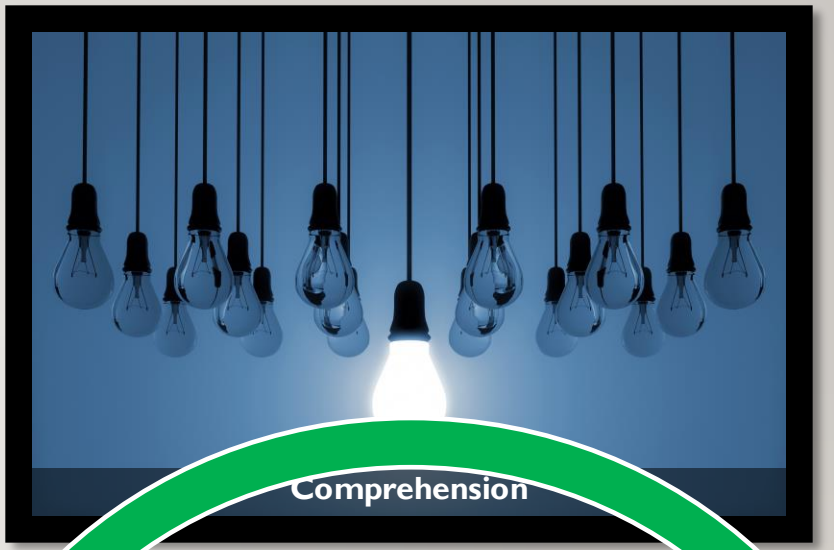
SPECIAL POPULATIONS

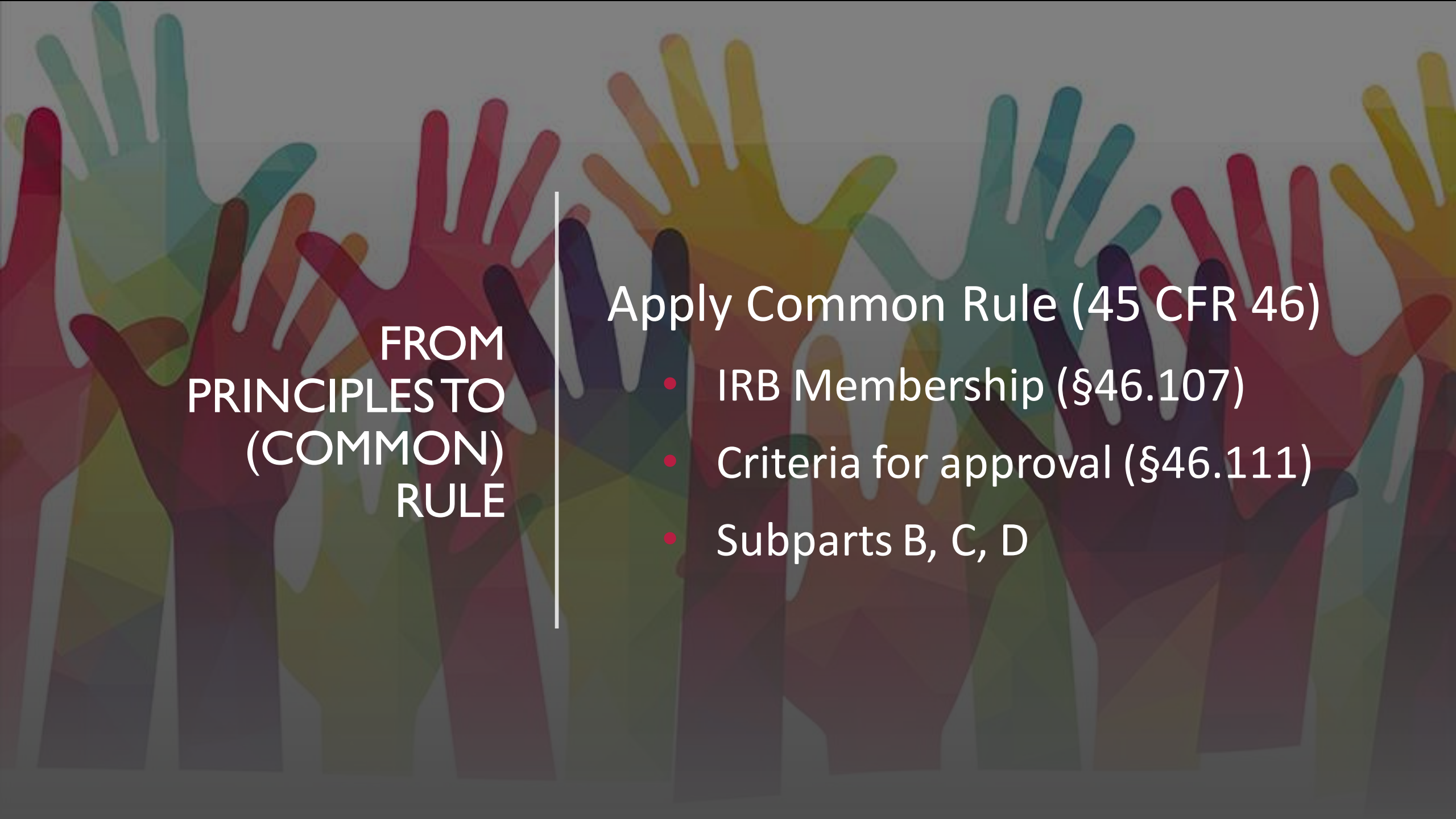
INFORMED CONSENT

THE BELMONT REPORT

- Respect for Persons
  - 1) Individuals should be treated as autonomous agents,
  - 2) Persons with diminished autonomy are entitled to protection.
- Beneficence
  - 1) Protecting the individual subjects against **risk** of harm
  - 2) Consideration of not only the **benefits** for the *individual*, but also the *societal* benefits that might be gained for research
- Justice
  - Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved."

PRINCIPLES APPLIED





FROM PRINCIPLES TO (COMMON) RULE

Apply Common Rule (45 CFR 46)

- IRB Membership (§46.107)
- Criteria for approval (§46.111)
- Subparts B, C, D

COMMON RULE

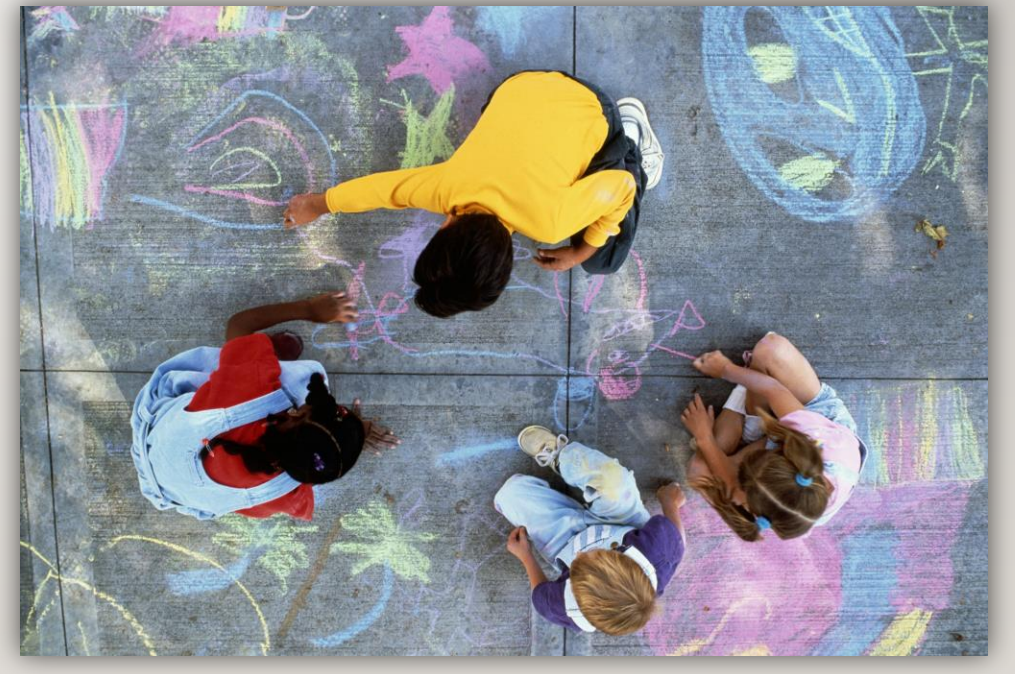
§46.107 IRB membership

If an IRB regularly reviews research that involves a category of subjects that is vulnerable to ***coercion or undue influence****, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.*

COMMON RULE: CRITERIA FOR IRB APPROVAL

§46.111(a)(3)

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be ***particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence,*** *such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.*



COMMON RULE: CRITERIA FOR IRB APPROVAL

§46.111(b)

*When some or all of the subjects are likely to be vulnerable to **coercion or undue influence**, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, **additional safeguards** have been included in the study to protect the rights and welfare of these subjects.*

COMMON RULE SUBPARTS

POTENTIALLY VULNERABLE POPULATIONS

- In addition to protected populations:
  - Economically disadvantaged
  - Cognitively impaired
  - Low literacy
  - Racial and ethnic groups
  - LGBTQ+
  - Students/employees of investigator
  - Undocumented status, refugees

CONSIDER: CONSENT

How will you inform participants about your research (e.g., orally, in writing, in person, by phone, by email)?

Is consent language straightforward and appropriate for the population?

Is there a language barrier or cultural factor that may influence the consent process?

SPECIAL POPULATIONS

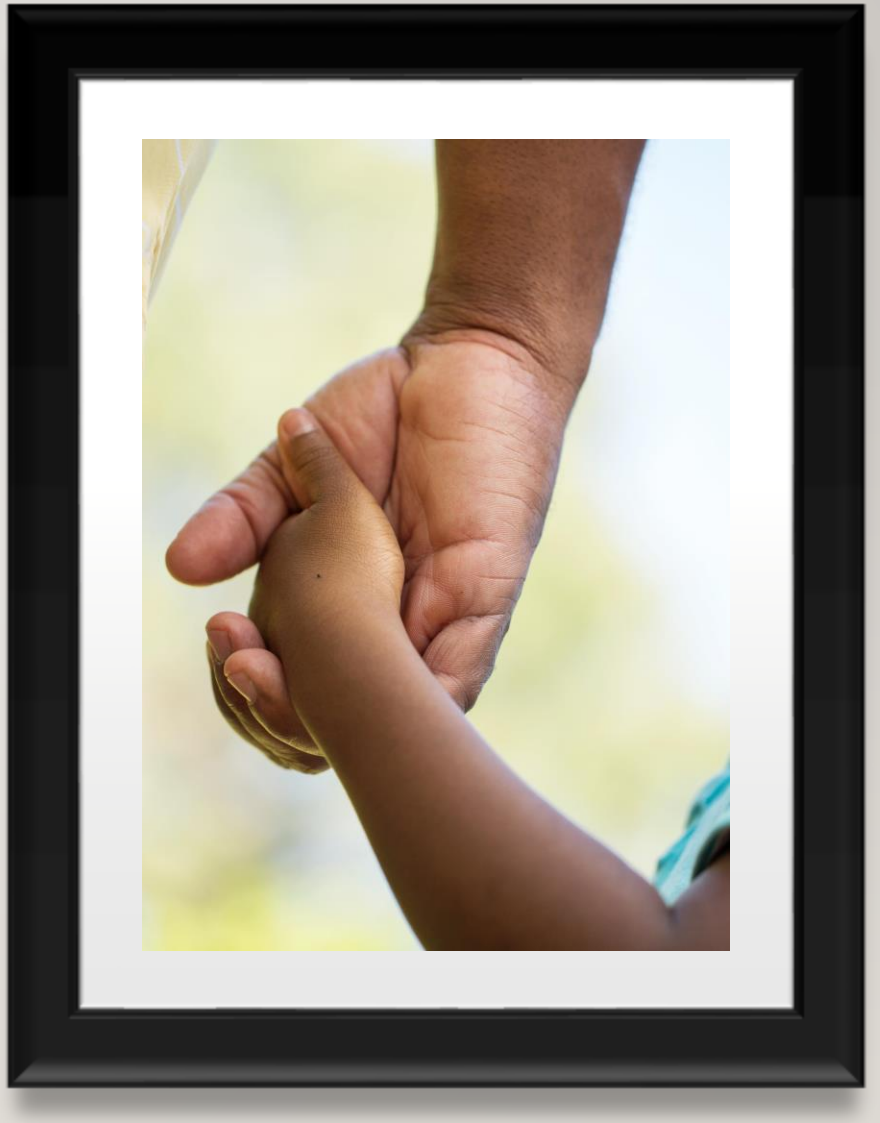
CHILDREN

§46.408 Requirements for permission by parents or guardians and for assent by children

☐	Adequate provisions are made for soliciting the **permission** of parents or guardians. **(Complete Section 7)**
☐	Adequate provisions are made for soliciting the **assent** of the children. **(Complete Section 13)**

Regarding assent: *In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.*

Regarding permission: *Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.*



ADULTS WITH DIMINISHED CAPACITY

HHS **regulations are silent** on the consent procedures specific to subjects with impaired decision-making capacity, but…

☐	The proposed plan for the assessment of the capacity to consent is adequate. *Provide protocol specific findings justifying this determination:*
☐	The subject will be informed about the research to the extent compatible with the subject's understanding. *Provide protocol specific findings justifying this determination:*
☐	Assent will be obtained from: **(One of the following must be checked)** ☐ All subjects. ☐ Some subjects, specify: ☐ None of the subjects
☐	The consent document includes a signature line for a Legally Authorized Representative (LAR).
☐	If capable, the subject will sign and personally date the written informed consent.

NOTE: Longitudinal studies involving **progressive** disorders or aging populations → potential intermittent or declining capacity → identify LAR

NON-ENGLISH-SPEAKING SUBJECTS

From the Principal Investigator Assurance Language:

I will ensure that IRB-approved study documents, including recruitment materials, consent forms, and study tools, are accurately translated in a language **understandable** to study participants. If applicable, I will submit locally-approved versions of these materials to the IRB when they become available

ILLITERATE ENGLISH-SPEAKING SUBJECTS

Person who can understand and comprehend spoken English, but physically unable to talk or write, can be entered into a study if

(1) the person retains the ability to **understand** the concepts of the study and **evaluate** the risk and benefit of being in the study when it is explained verbally (still competent) and

(2) can **indicate approval** or disapproval to study entry