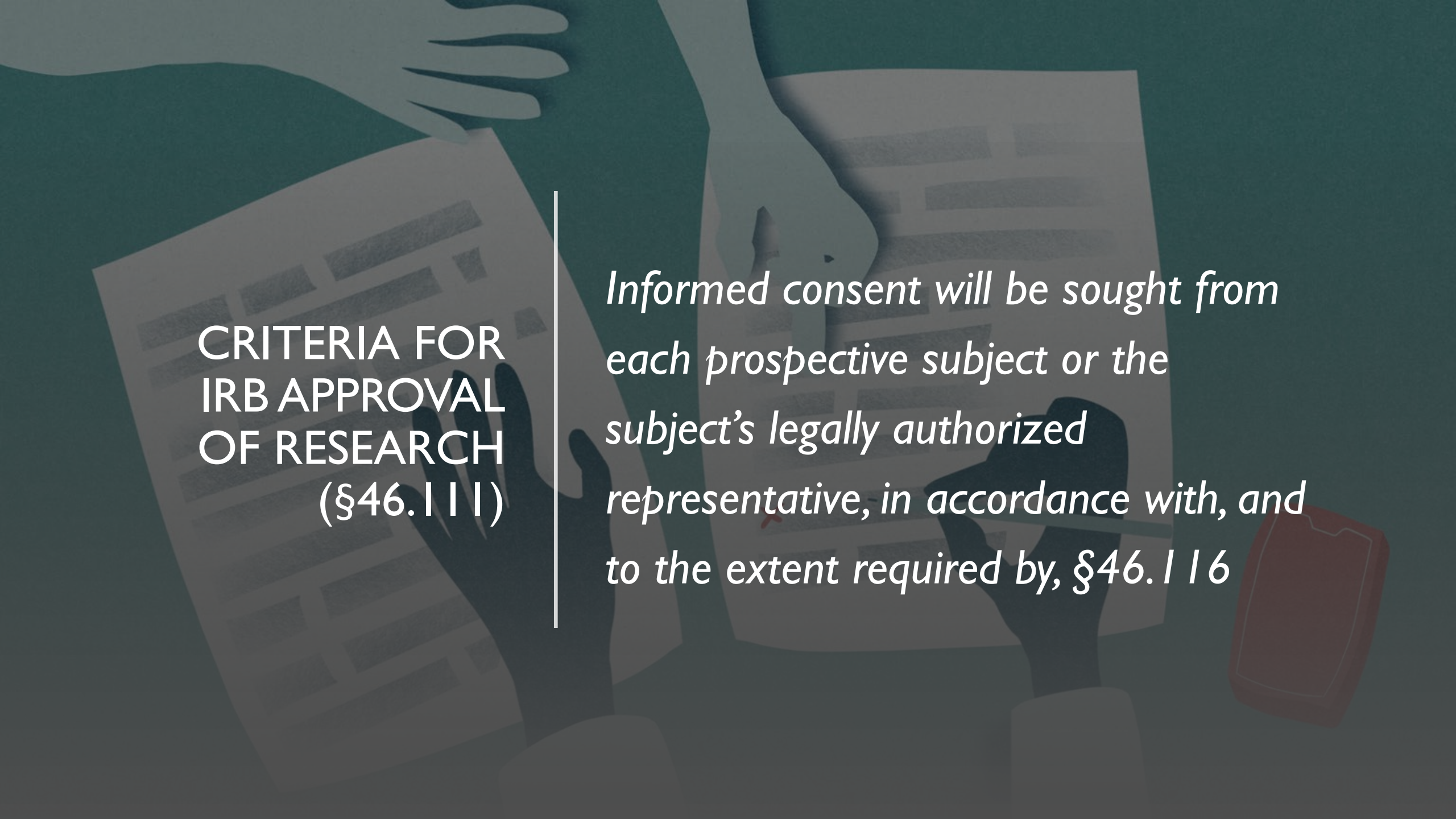
WAIVER OF CONSENT

INFORMED CONSENT

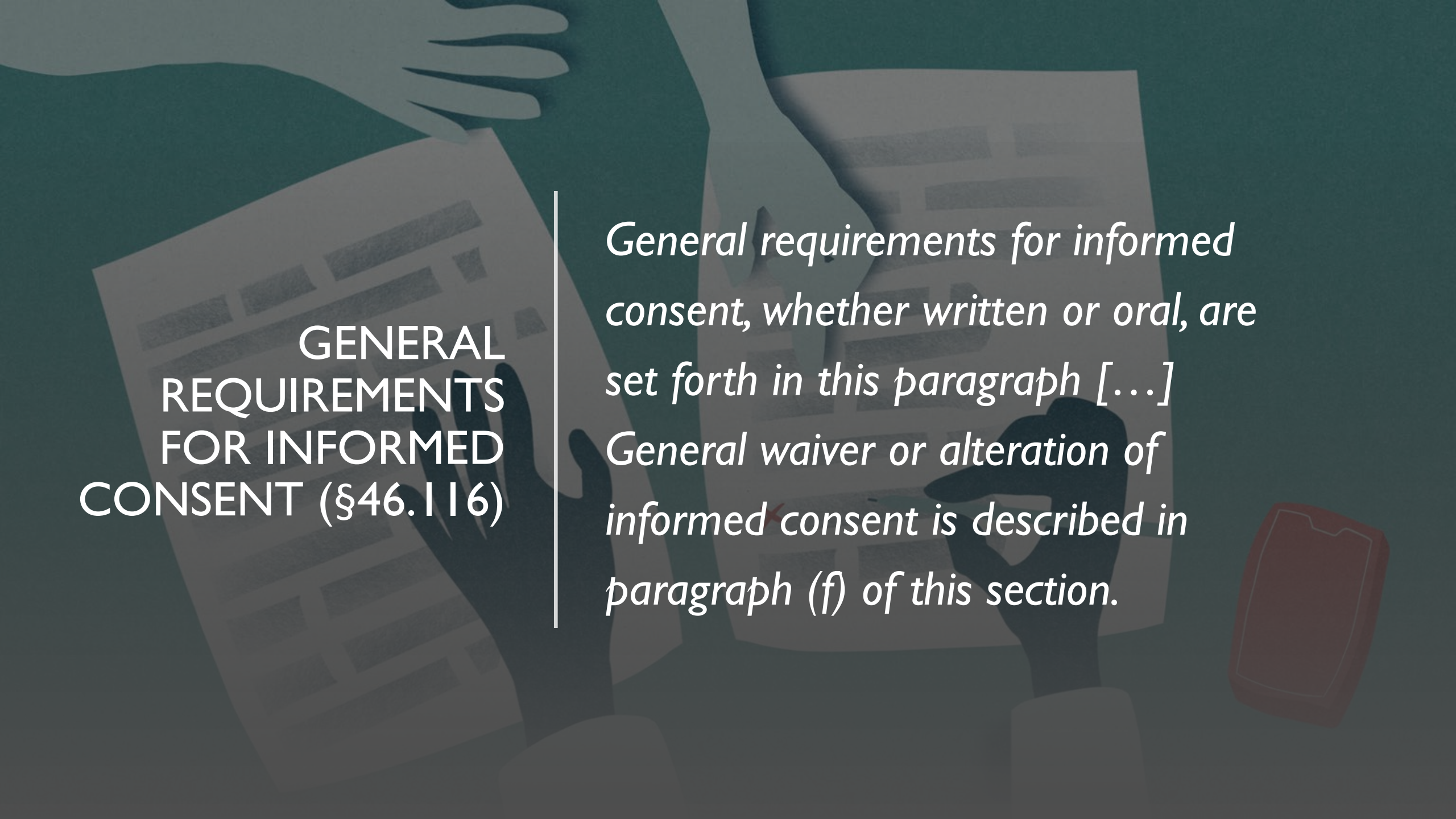
FROM PRINCIPLES TO (COMMON) RULE

- 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 sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116

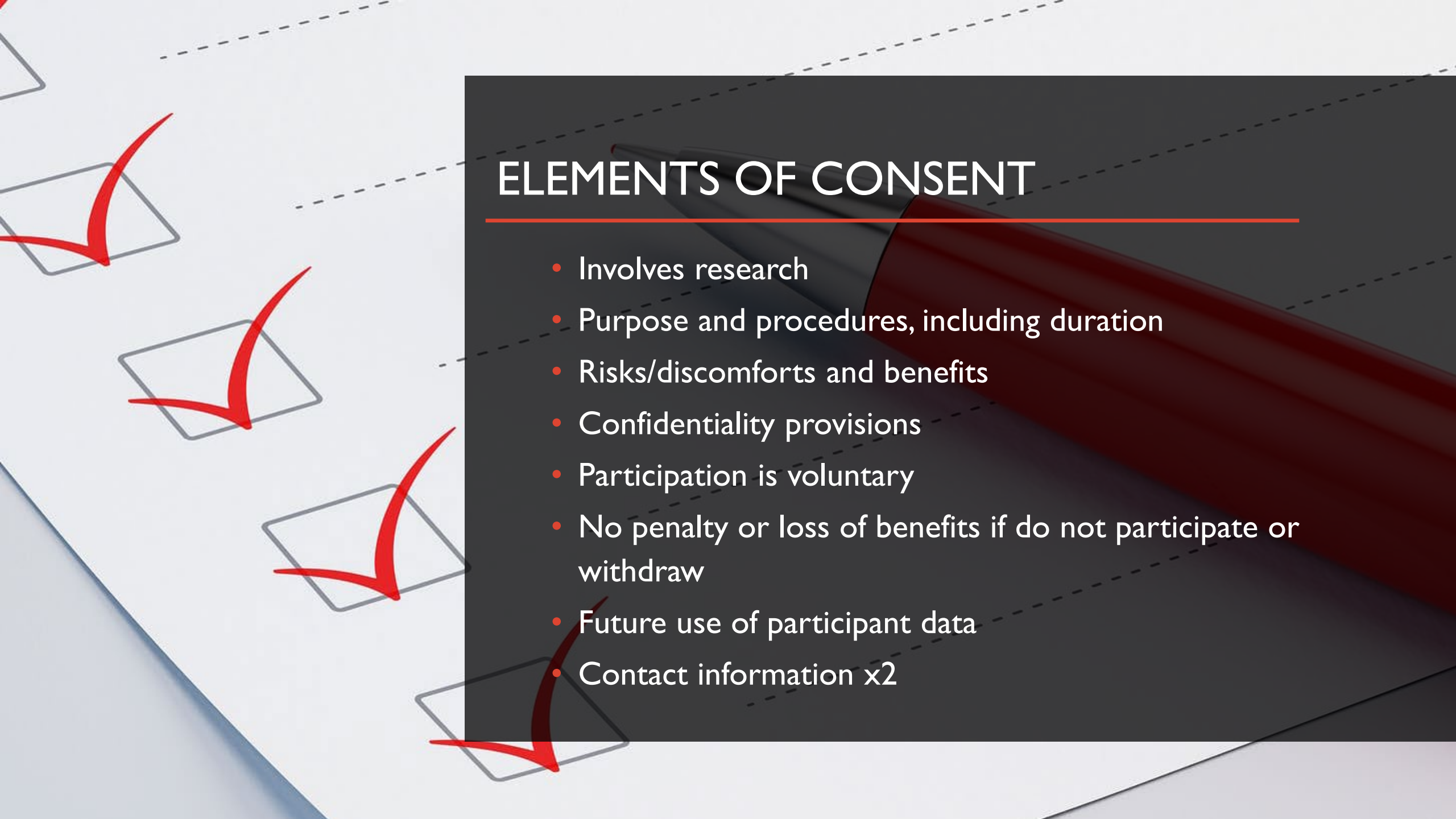


GENERAL REQUIREMENTS FOR INFORMED CONSENT (§46.116)

General requirements for informed consent, whether written or oral, are set forth in this paragraph […] General waiver or alteration of informed consent is described in paragraph (f) of this section.

GENERAL REQUIREMENTS (§46.116)

- Before research, obtain consent from participant or representative
- Appropriate circumstances, free from coercion or undue influence
- Understandable language
- "Reasonable person" standard
- Key Information and organization
- No exculpatory language



ELEMENTS OF CONSENT

- Involves research
- Purpose and procedures, including duration
- Risks/discomforts and benefits
- Confidentiality provisions
- Participation is voluntary
- No penalty or loss of benefits if do not participate or withdraw
- Future use of participant data
- Contact information x2

WAIVER VS. ALTERATION

WAIVER

*An IRB may **waive** the requirement to obtain informed consent for research under paragraphs **(a) through (c)** of this section, provided the IRB satisfies the requirements of paragraph **(f)(3)** of this section.*

Removing obligation to obtain consent

ALTERATION

*An IRB may approve a consent procedure that **omits some, or alters some** or all, of the elements of informed consent set forth in paragraphs **(b) and (c)** of this section provided the IRB satisfies the requirements of paragraph **(f)(3)** of this section.*

Removing obligation to share all required consent information

GENERAL REQUIREMENTS (§46.116)

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WAIVER VS. ALTERATION

WAIVER

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Removing obligation to obtain consent

ALTERATION

*An IRB may approve a consent procedure that **omits some, or alters some** or all, of the elements of informed consent set forth in paragraphs **(b) and (c)** of this section provided the IRB satisfies the requirements of paragraph **(f)(3)** of this section.*

Removing obligation to share all required consent information

REQUIREMENTS FOR WAIVER AND ALTERATION

RISK	The research involves no more than minimal risk to the subjects
PRACTICABILITY	The research could not practicably be carried out without the requested waiver or alteration
IDENTIFIABILITY	If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
RIGHTS AND WELFARE	The waiver or alteration will not adversely affect the rights and welfare of the subjects
DEBRIEF	Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

COMMON CASE: DECEPTION

- **Deception** is the intentional misleading of a participant about the nature of the study
- **Incomplete disclosure** occurs when certain details of a study are deliberately withheld from participants

QUESTIONS?