OHRP Educational Workshop Protocol Review

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Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP)
November 15, 2017

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The materials used in our protocol review have been created solely for educational purpose and should not under any circumstances be mistaken as representative of any actual research study.

REVIEW USING THE PRE-2018 COMMON RULE

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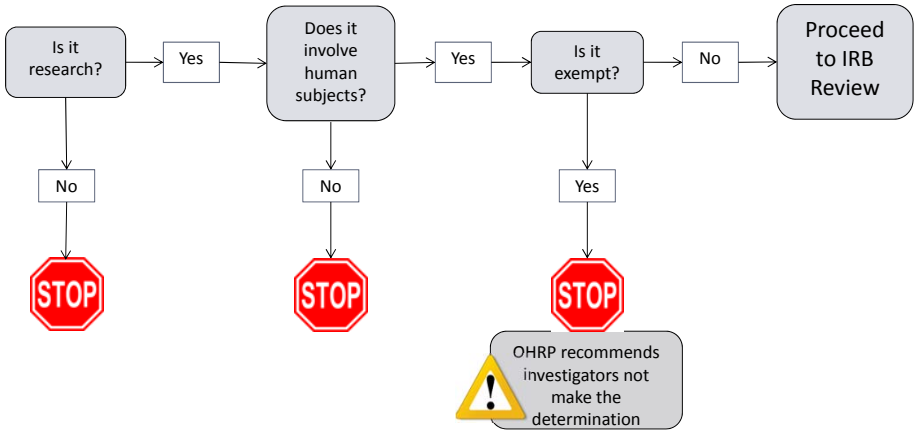
Determining When the Common Rule Applies



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Reminder: Definition of Research

Research refers to a **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**

§46.102(d)

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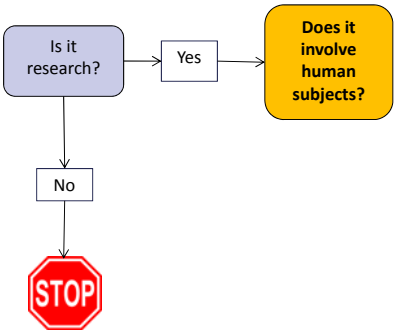
Research Requiring IRB Review



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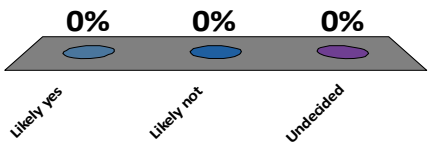
Would this study meet the regulatory definition of "human subject"?

A. Likely yes
B. Likely not
C. Undecided



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Reminder: Definition of Human Subjects

Human subject – a living individual about whom an investigator obtains:

1) data through intervention or interaction with the individual, **or**
2) **identifiable private information**

§46.102(f)

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Table Discussion

Would you consider the data collected in this study to be "identifiable private information"?

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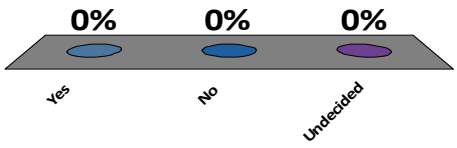
Would you consider the coded data collected in this study to be "identifiable private information"?

A. Yes
B. No
C. Undecided



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Reminder: Identifiable Private Information

- Information provided for specific purposes under the reasonable expectation that it will not be made public (e.g., a medical record)
- Private information must be individually identifiable
  - The identity of the subject **may be readily ascertained by the investigator**.

§46.102(f)

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Research Requiring IRB Review

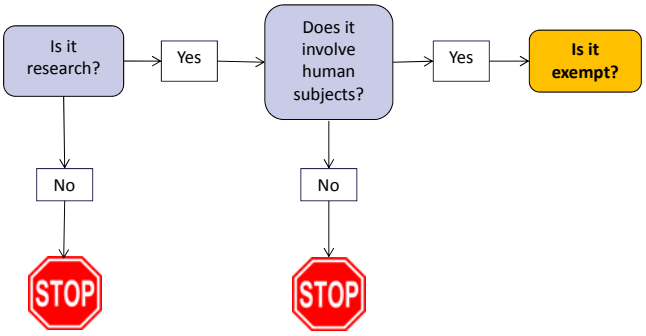

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Table Discussion

Is this Study Exempt?

- **Part 1:** Analyzing and Separating coded records into groups
  - Medical records review to find DRD2-YES and DRD2-NO
  - Analysis of left over blood samples of DRD2-YES to determine the presence of the ANKK1 SNP
- **Part 2:** Tracking treatment outcomes (i.e., methadone intake, opioid use relapse, and recovery success) and linking it to Step 1 data

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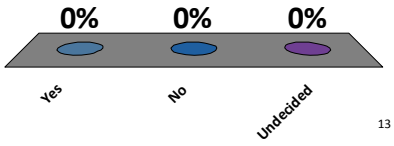
Does analyzing medical records and left over blood samples to separate subjects into groups qualify for exemption?

A. Yes
B. No
C. Undecided



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Reminder: Exemption 4

- Collection or study of existing data if:
  - Publicly available, or
  - **Recorded** by the investigator in such a manner that subjects cannot be identified, directly or **through identifiers linked to the subjects**

§46.101(b)(4)

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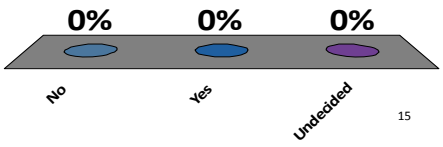
Does tracking treatment outcomes through chart review qualify for Exemption 4?

A. No
B. Yes
C. Undecided



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  - Publicly available, or
  - Recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

§46.101(b)(4)

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Revised Common Rule: Exemption 4 Expanded

- **Requirement that all data be pre-existing at the time of submission has been removed**
- Exemption 4 will apply if:
  - publically available, **or**
  - Information is recorded in an unidentifiable manner, **or**
  - Activity is protected under HIPAA, **or**
  - Certain research conducted by a Federal agency

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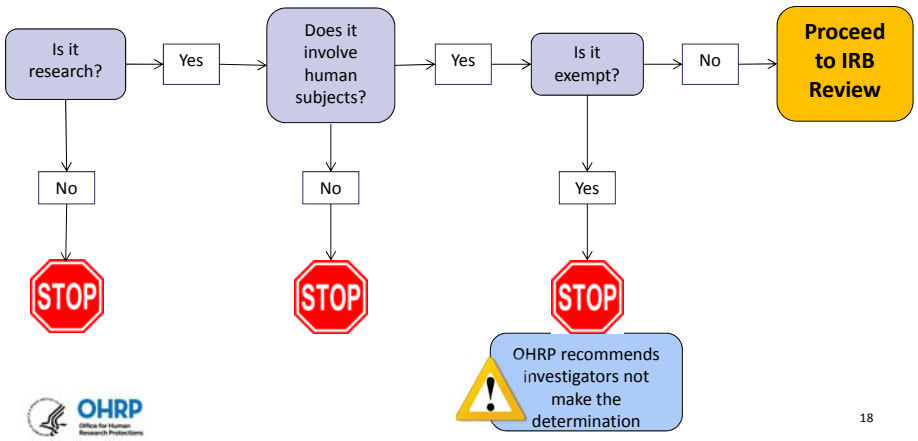
Determining When the Common Rule Applies



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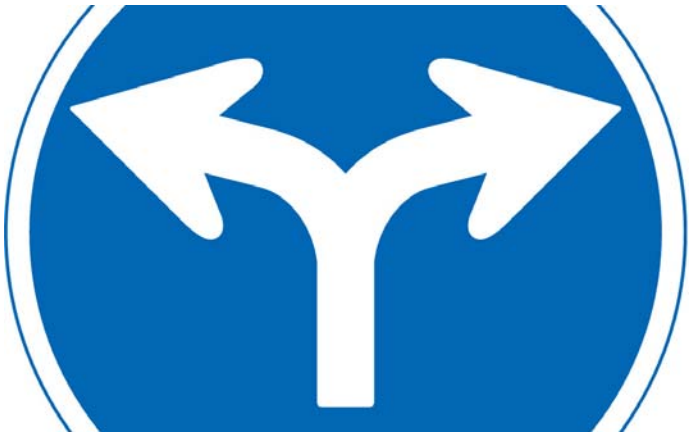

EXPEDITED OR FULL-BOARD?

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Table Discussion

Can this study be reviewed under the expedited mechanism?

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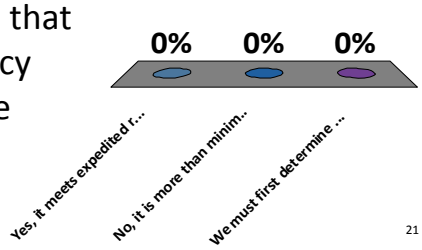
Can this study be reviewed under the expedited mechanism?

A. Yes, it meets expedited review category # 5
B. No, it is more than minimal risk
C. We must first determine that the protections for privacy and confidentiality of the data are appropriate



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Reminder: Qualifying for Expedited Review

All research procedures in the protocol must meet one or more of the categories of research that qualify for expedited review

&

Research must present no more than minimal risk to subjects

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Research on Secretary's List Eligible for Expedited Review (Initial Review List)

1. Certain clinical studies of drugs and medical devices
2. Certain collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures routinely employed in clinical practice
5. **Research involving data, documents, records, or specimens that have been collected or will be collected solely for non-research purposes**
6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, … and social behavior)

http://www.hhs.gov/ohrp/policy/expedited98.html

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Reminder: Item (C) in Expedited review Category List

- **No expedited review** where "identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing"
- "**UNLESS** reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal"

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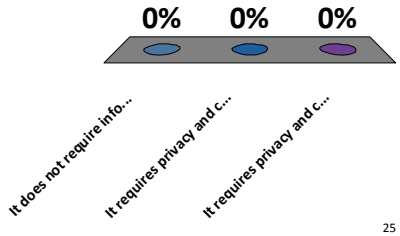
Are the protections for privacy and confidentiality in this protocol appropriate?

A. Likely yes
B. Likely not
C. Undecided



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Case Study # 2

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REVIEW USING THE PRE-2018 COMMON RULE

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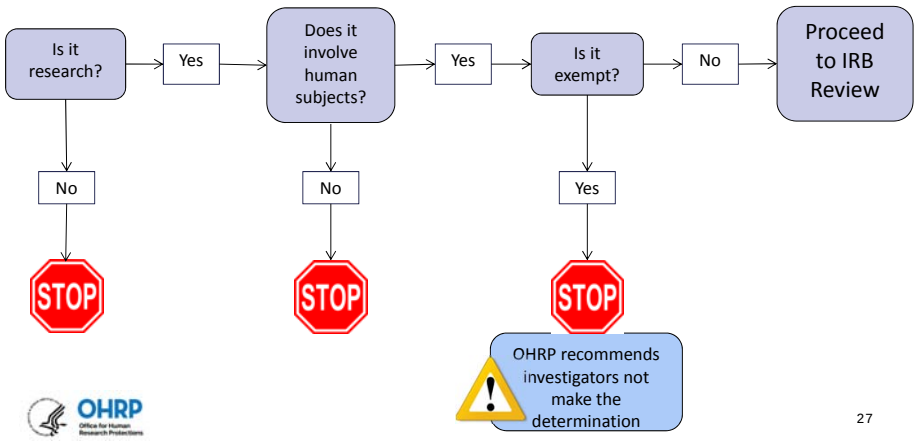
Applying the pre-2018 Common Rule



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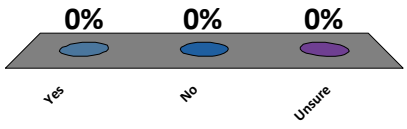
Is this Human Subjects Research Under the Regulations?

A. Yes
B. No
C. Unsure



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Is this Exempt Human Subjects Research?

Exemption 2

Educational tests, surveys*, interviews*, or observation of public behavior

UNLESS

- Identifiable **and**
- Any disclosure could put subject at risk of liability or financial, employment, or reputational harm

§46.101(b)(2)

* Does not apply to children

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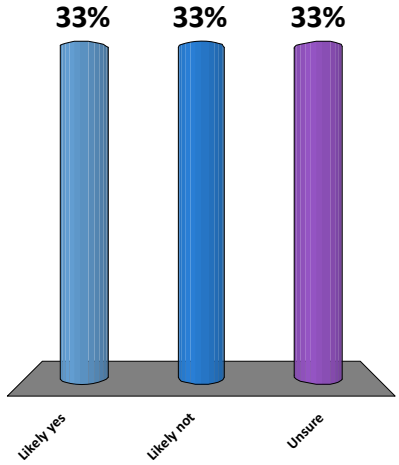
Is this Exempt Human Subjects Research Under the Regulations?

A. Likely yes
B. Likely not
C. Unsure



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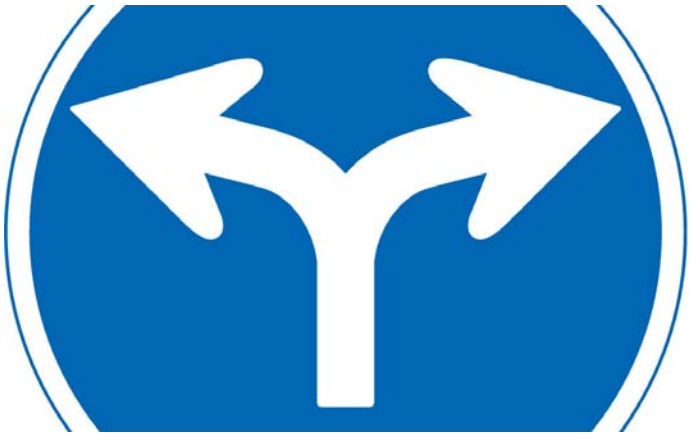

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6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. **Research on individual or group characteristics or behavior (…)or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

http://www.hhs.gov/ohrp/policy/expedited98.html

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Expedited Review Requirement 2

Research poses no more than minimal risk to participants

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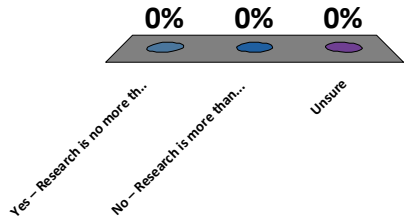
Is the current research ***no more than minimal risk research***?

A. **Yes** *(Research is no more than minimal risk)*
B. **No** *(Research is more than minimal risk)*
C. **Unsure**



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Making a Minimal Risk Determination

"The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (§46.102(i))

1. Identify risks that could reasonably result from the study procedures
2. Estimate the **probability** (how likely) and **magnitude** (how severe), and
3. Compare to risk:
   a. In daily life, or
   b. In routine physical or psychological examinations or tests

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Reminder: Item (C) in Expedited review Category List

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- "**UNLESS** reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal"

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Regulatory Criteria to Approve Research

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is appropriately documented

When appropriate:

- Data collection is monitored to ensure subject safety
- Subject privacy and data confidentiality protected
- Additional safeguards are included for vulnerable populations

§46.111

Note:
Additional findings – Subparts B, C, & D

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Table Topics for Discussion

1. Risks
2. Privacy and confidentiality
3. Informed consent

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TABLE DISCUSSION 1:

WHAT ARE THE RISKS?

HAVE THEY BEEN MINIMIZED?

IS THE RISK/BENEFIT RATIO REASONABLE?

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Points to Consider: Determining if Risks Have Been Minimized (Examples)

- Select the most appropriate population for the study
- Consider inclusion and exclusion criteria
- Use procedures consistent with sound research design
- **Review available empirical research to help think about risks**
- **Include concrete plans to handle foreseeable risks and respond to emergencies**
- **Maintenance of data, storage, handling, sharing, destroying records**
- **When appropriate, collect data anonymously**
- Select the most appropriate setting (controlled lab vs. field studies)
- Appropriate post intervention monitoring
- Be competent in the area being studied or associate with a competent team

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TABLE DISCUSSION 2:

IS PRIVACY AND CONFIDENTIALITY ADEQUATELY PROTECTED?

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Points to Consider: Protecting Privacy and Confidentiality

- Recruitment procedures – what measures are included to protect privacy?
- Study settings, how data are being collected, do participants need to be involved in protecting privacy and confidentiality?
- The kind of data being collected, their sensitivity – what measures are being undertaken by investigators to ensure data security?
- Can waiver of documentation be used here to further protect confidentiality?

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TABLE DISCUSSION 3:

HAS INFORMED CONSENT BEEN OBTAINED AND DOCUMENTED?

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Points to Consider: Informed Consent

- Are the required elements appropriately addressed? What information needs to be included?
- Is informed consent appropriately documented?
- What is the acceptability of e-consent?

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HOW MIGHT THE REVIEW CHANGE UNDER THE REVISED COMMON RULE?

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List of Exemptions in the Pre-2018 Rule

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior, unless identifiable and sensitive
3. Research on public officials or candidates for public office
4. Research using existing data, if publicly available or recorded without identifiers
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

§46.101(b)

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Revised Common Rule: Summary of Changes in Exemptions

Pre-2018 Rule (Current)	Revised Common Rule
• Exemption 1	Restrictions added
• Exemption 2	Expanded
• Exemption 3	Deleted Replaced by a new exemption 3
• Exemption 4	Expanded
• Exemption 5	Expanded
• Exemption 6	No change
	✓ New exemption 7
	✓ New exemption 8
	*** (Also new - limited IRB review)**

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Note: exemptions may not apply to subpart populations

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Revised Common Rule Exemption 2: Expanded

Research that **only includes interactions** involving educational tests, surveys, interviews, and observations of public behavior, exempt when

i. Information recorded cannot be readily linked back to subjects, **OR**

ii. Any information disclosure would not place subjects at risk of harm, **OR**

iii. Identifiable information recorded with limited IRB review for privacy and confidentiality protection under §_.111(a)(7)

§_.104(d)(2)

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Revised Common Rule
Exemption 3: New

Research involving benign behavioral interventions with collection of information—verbal or written (including data entry) or audiovisual recording—from adults who prospectively agree when

A. Information recorded cannot be readily linked back to subjects, **OR**
B. Any information disclosure would not place subjects at risk of harm, **OR**
C. Identifiable information recorded with limited IRB review for privacy and confidentiality protection under §_.111(a)(7)

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Revised Common Rule
Exemption 3, cont.

- Does not apply to children (subpart D research)
- Benign behavioral interventions

  These are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and there is no reason to think the subjects will find the interventions offensive or embarrassing
- Includes authorized deception research

§_.104(d)(3)

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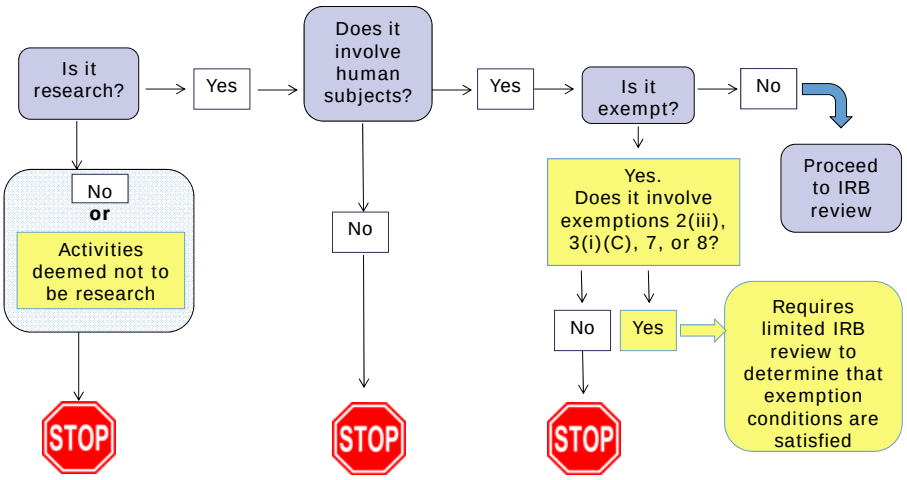
Applying the Revised Common Rule



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Revised Common Rule: General Improvements to Informed Consent

Explicitly establishes new standard: to provide the information needed *to make an informed decision about whether to participate*

- *Reasonable person* standard used to determine more specifically what information to include
- Certain *key information* provided first
- Information presented in *sufficient detail*, and *organized and presented* in a way that facilitates subject's understanding of reasons why one might or might not want to participate

§_.116(a)

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Revised Common Rule: New Elements of Informed Consent

One new *basic* element:

- Notice about possible future use of data stripped of identifiers

§_.116(b)(9)

New *additional* elements:

- Notice about possible commercial profit
- Notice about whether clinically relevant research results will be given to subjects
- Notice about whether research might include whole genome sequencing

§_.116(c)(7)-(9)

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Revised Common Rule Electronic Signature

Signatures in electronic format are permissible

§_.117(a)

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Please refer to the text of the revised Common Rule available on OHRP's website for a complete and accurate description of the regulatory requirements.

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PLEASE COMPLETE YOUR EVALUATIONS

PLEASE RETURN YOUR CLICKERS

CERTIFICATE OF ATTENDANCE AVAILABLE

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THANK YOU FOR PARTICIPATING IN OUR PROTOCOL REVIEW

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