Is my study Exempt?
Understanding exemption criteria

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I have no conflicts of interest to disclose.

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Agenda

- Laying the Foundation and Speaking the Same Language
- What is Human Subjects Research?
- Understanding Exempt review
- Informed Consent
- Questions?

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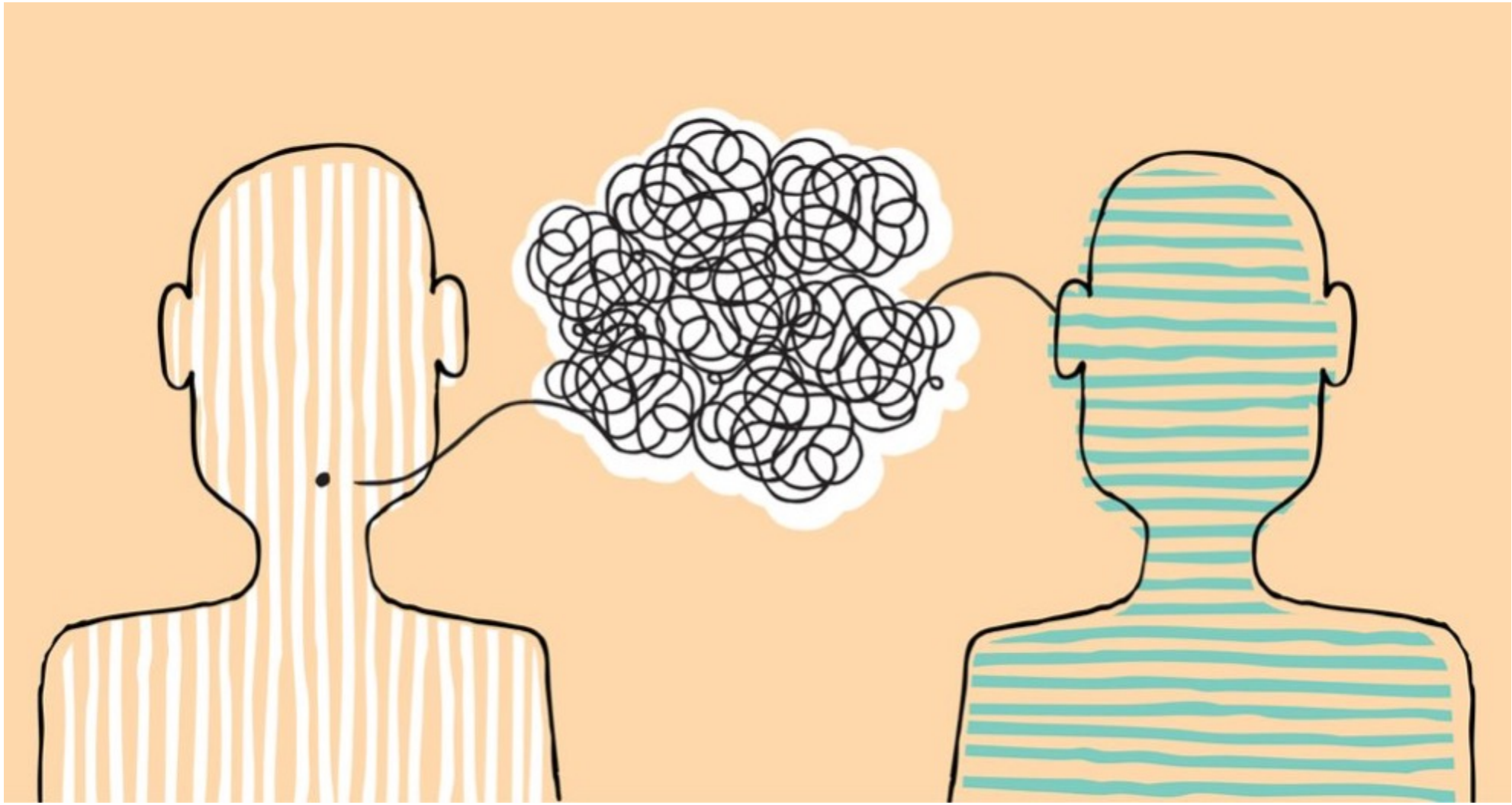

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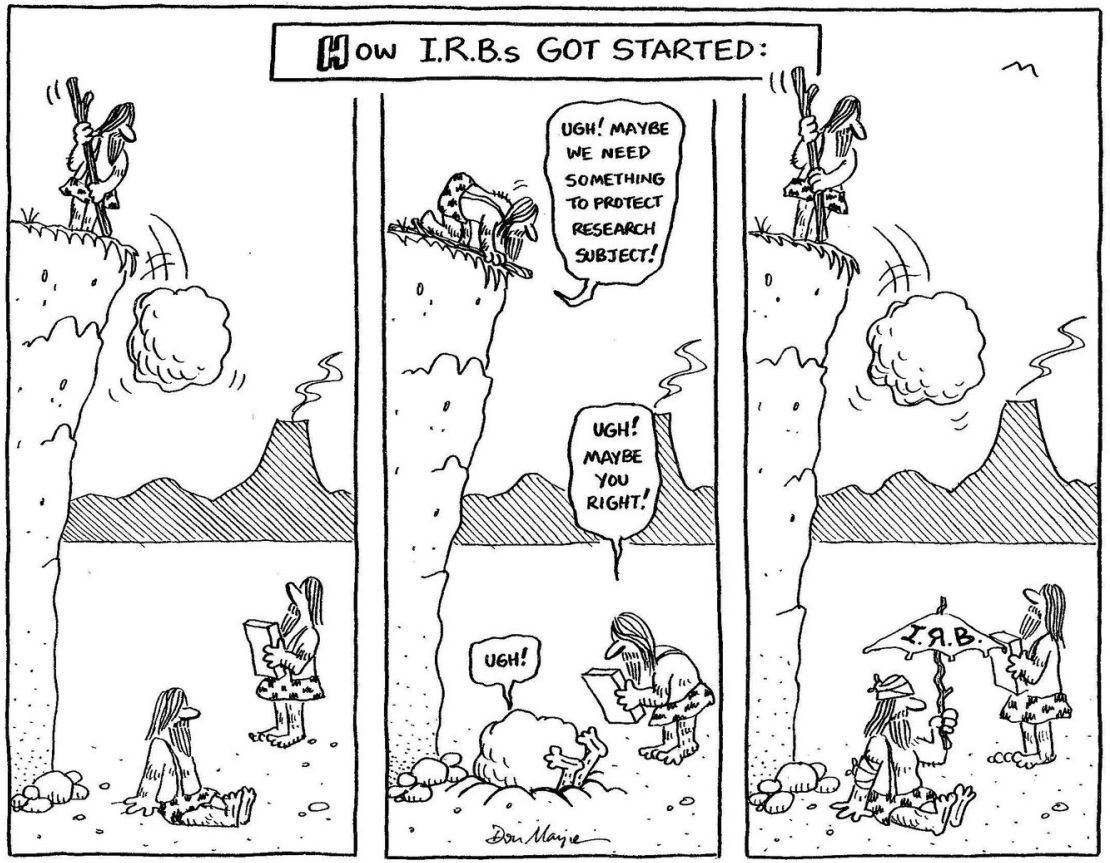
Institutional Review Board



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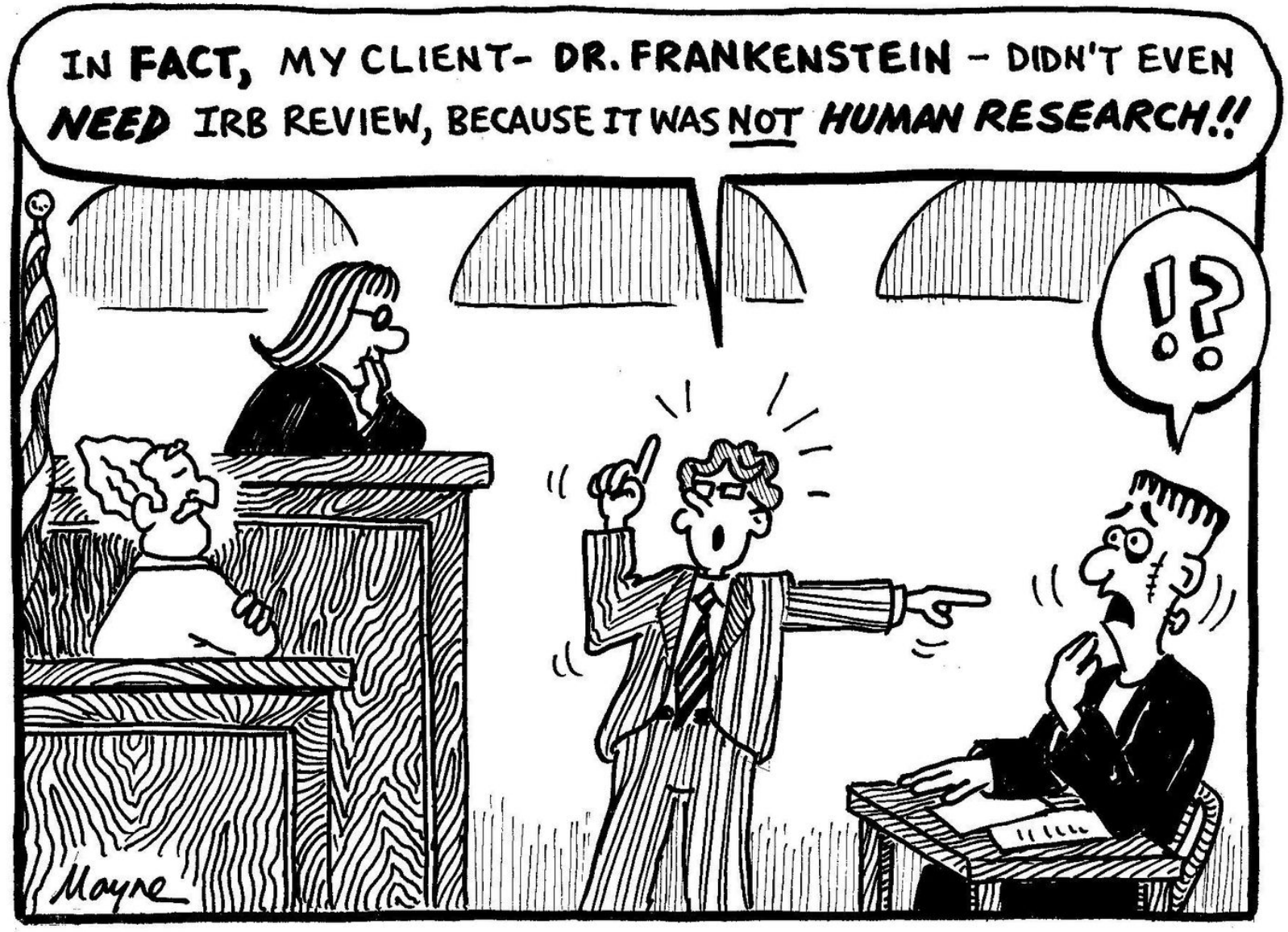

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A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102)

Is the activity an investigation?
Investigation: Searching inquiry for facts; detailed or careful examination

Is the investigation systematic?
Systematic: Having or involving a system, method, or plan

Is the systematic investigation designed to develop or contribute to knowledge?
Knowledge: Truth, facts, information

Is the knowledge the systematic investigation is designed to develop or contribute to generalizable?
Generalizable: Universally or widely acceptable.

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What is a Human Subject?

A living individual about whom an investigator conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

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Terminology

- Anonymous – collected without identifiers
- Deidentified – identifying information is removed
- Coded – data are separated from identifiers through use of a code (linking document)
- Sensitive information - information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.

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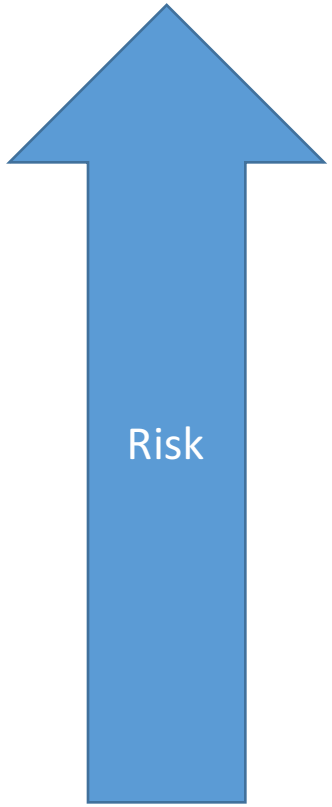
Levels of IRB Review



Full Board

Expedited

Exempt

Not Human Subjects Research (NHSR)

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Exempt Research

What Does Exempt Mean?

"Exempt" human subjects research is a sub-set of research involving human subjects that *does not require* IRB approval but are subject to review because the research activity involving the human subjects falls into one or more specific exemption categories as defined by the Common Rule.

- Minimal Risk
- Meets an Exemption Category(ies)
- Not subject to continuing review
- Amendments are still required
- Reportable New Information (RNI) are still required
- Exempt studies are NOT EXEMPT from institutional policies, the requirement to conduct ethical research, or the requirement to complete human subjects protections training.

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Exemption Limitations and Requirements

- Cannot be FDA-regulated
- Must be submitted to local IRB for review and determination (at UMB)
- Does not mean that informed consent is not applicable
- Some exemptions cannot include children (exemption 2 and 3)
- If the exempt research involves the use or disclosure of protected health information (PHI), HIPAA applies
  - If the exempt research involves the sharing of data, a data use or sharing agreement is required.

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Exempt = Human Subjects Research

Human Subjects Research = Application and Review

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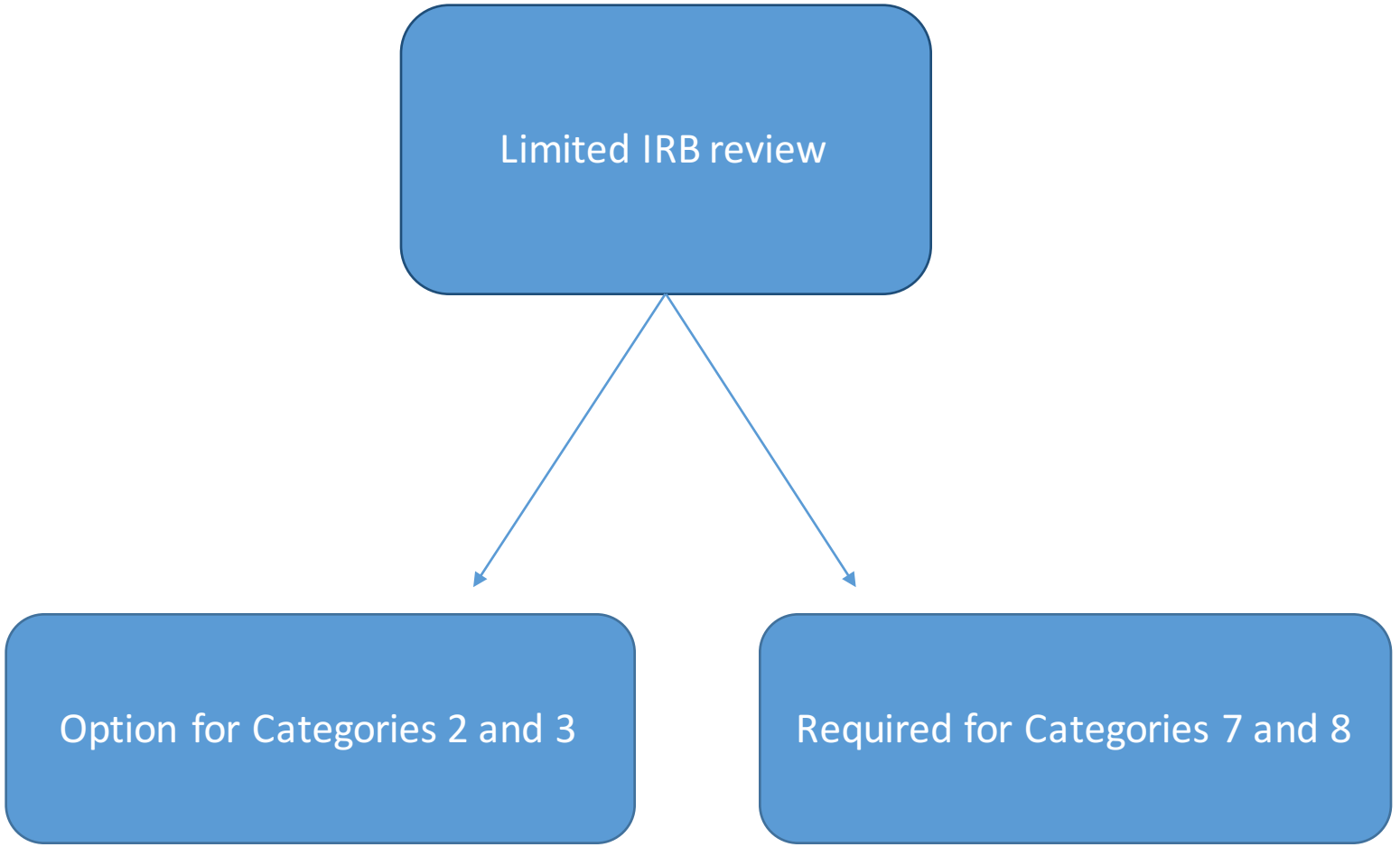
Limited IRB Review



Understanding Limited IRB Review

- Expedited procedure
- Applies to categories 2, 3, 7 and 8
- Ensure adequate provisions for protecting privacy and confidentiality
  - Extent to which identifiable private information is or has been de-identified
  - Risk for possible re-identification
  - How the information will be used or shared
  - How long the identifiable information will be retained
  - Security controls in place to protect data
  - Potential risk of harm to participants if data were to be lost, stolen, or otherwise compromised

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Exempt Category 1

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Understanding Exemption 1*

- Test development
- Collecting data about attitudes toward learning
- Assessments related to educational activity
- Research on instructional methods or classroom activities
- Collecting data related to knowledge

**FERPA may apply*

Image from: Pexels.com

Example	Exempt 1 Yes/No	Explanation
Evaluation of instructional methods and materials used for online college courses.	Yes	Evaluation of normal educational practices in an established educational setting.
Study to evaluate teacher management of undesired classroom behaviors. Findings will be reported to school leadership.	No	The study could adversely impact teachers based on findings.
Assessment of attitudes about instructional strategies used in high school courses.	Yes	Involves normal educational practice in an established educational setting.
An educational intervention is implemented in 7th and 8th grade students. The study includes a pre- and post- intervention survey with questions about mental health.	No	The focus of the research must be limited to the educational practice and NOT focus on the student, family, or teacher.

Adapted from University of Michigan Tip Sheet: Exemption 1
https://research-compliance.umich.edu/sites/default/files/resource-download/exemption_1_-_tips_and_examples.pdf

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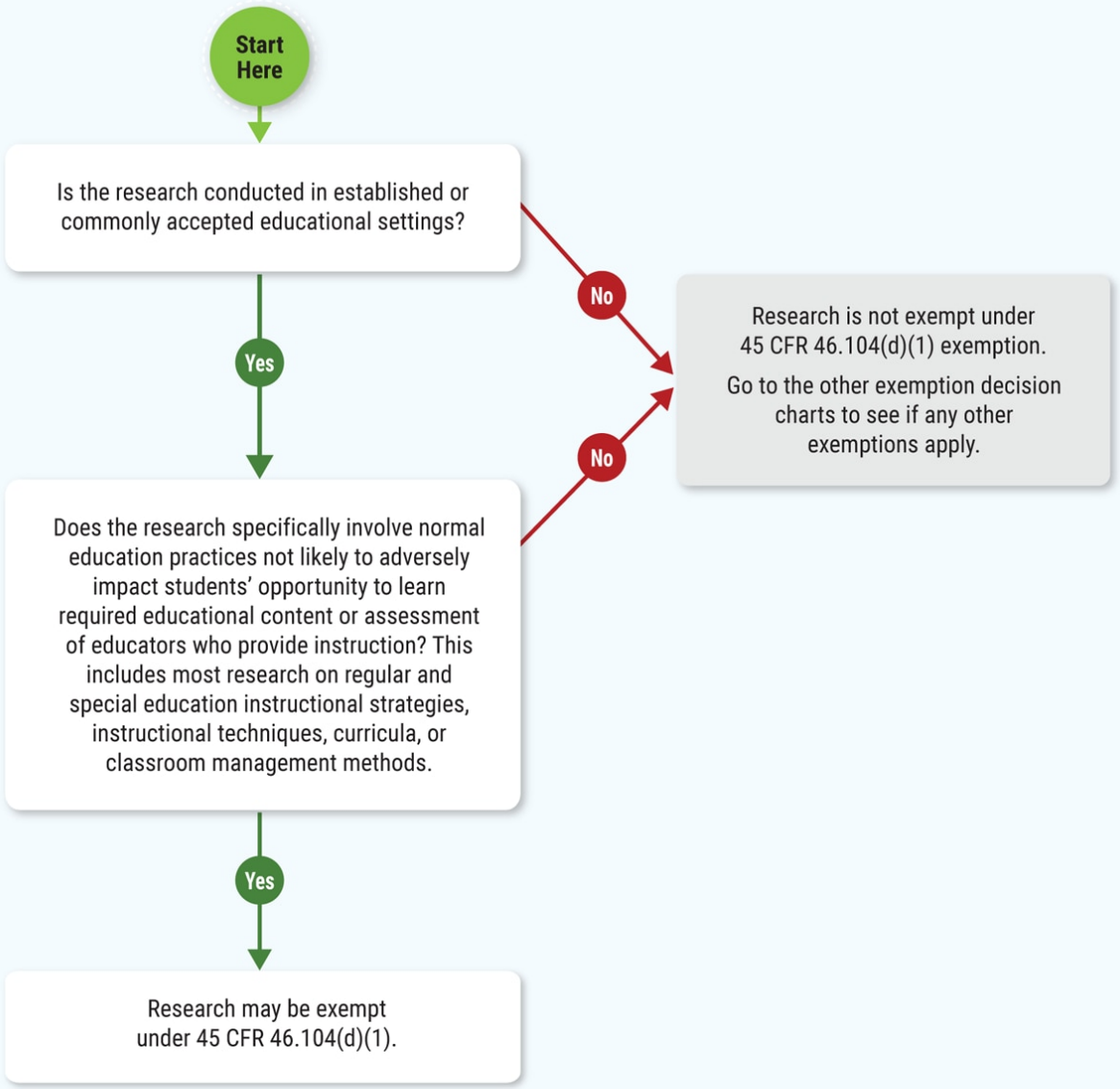
TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.



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IRB Submission Considerations

- Justify and explain normal practice and commonly establish setting
- Be clear about what is “normal” and what is “research”
- Be clear about data that will be collected
- Who are your research participants?
  - Students/teachers/parents?
- Explain how the project will not adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instructions

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Exempt Category 2

Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if **at least** one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

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Understanding Exemption 2

- Surveys
- Interviews
- Focus Groups
- Educational tests
- Observation of public behavior

Children may only be enrolled in research under Exempt 2 if the investigators do not participate in the activities being observed.

Example	Exempt 2 Yes/No	Explanation
An online survey about sexual behavior where no identifiers are collected.	YES	The data collects sensitive information BUT is anonymous (meet criteria 1).
An online survey about sexual behavior collecting email address and IP address	YES* **Limited IRB review required*	Data is sensitive (sexual behaviors) and identifiable. Limited IRB review.
An in-person, anonymous, survey assessing how women feel about Well Women visits.	YES	The data collected isn't sensitive in nature and is anonymous.
Focus group with children about mindfulness	No	Children may only be enrolled in research if the investigators do not participate in the activities being observed.

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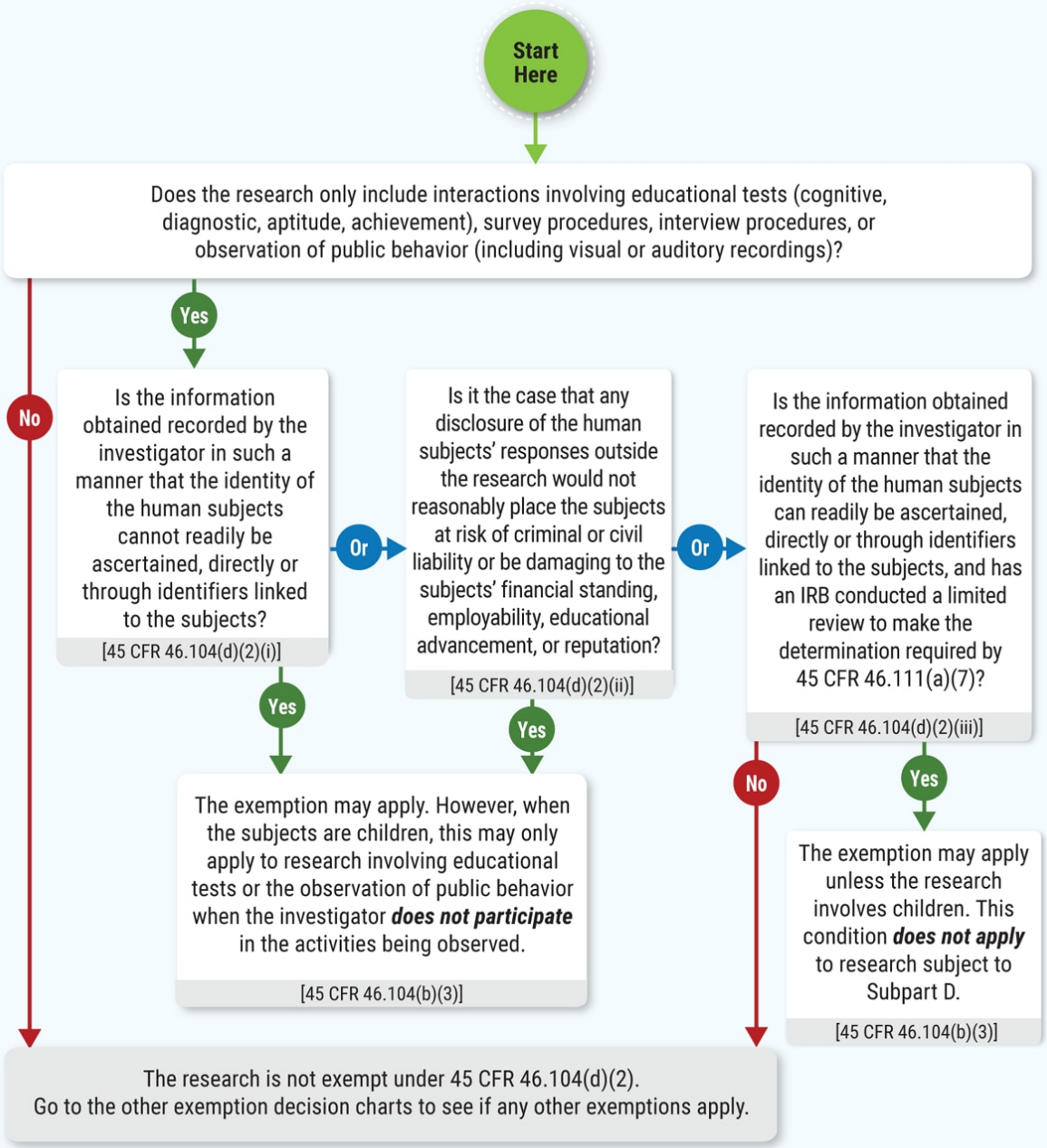

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Exempt Category 3

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

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Understanding Exempt 3

"Benign" Behavioral Intervention:

- Brief
- Harmless
- Painless
- Not physically invasive
- Not likely to have a significant adverse lasting impact
- No reason to think participants will find the interventions offensive or embarrassing

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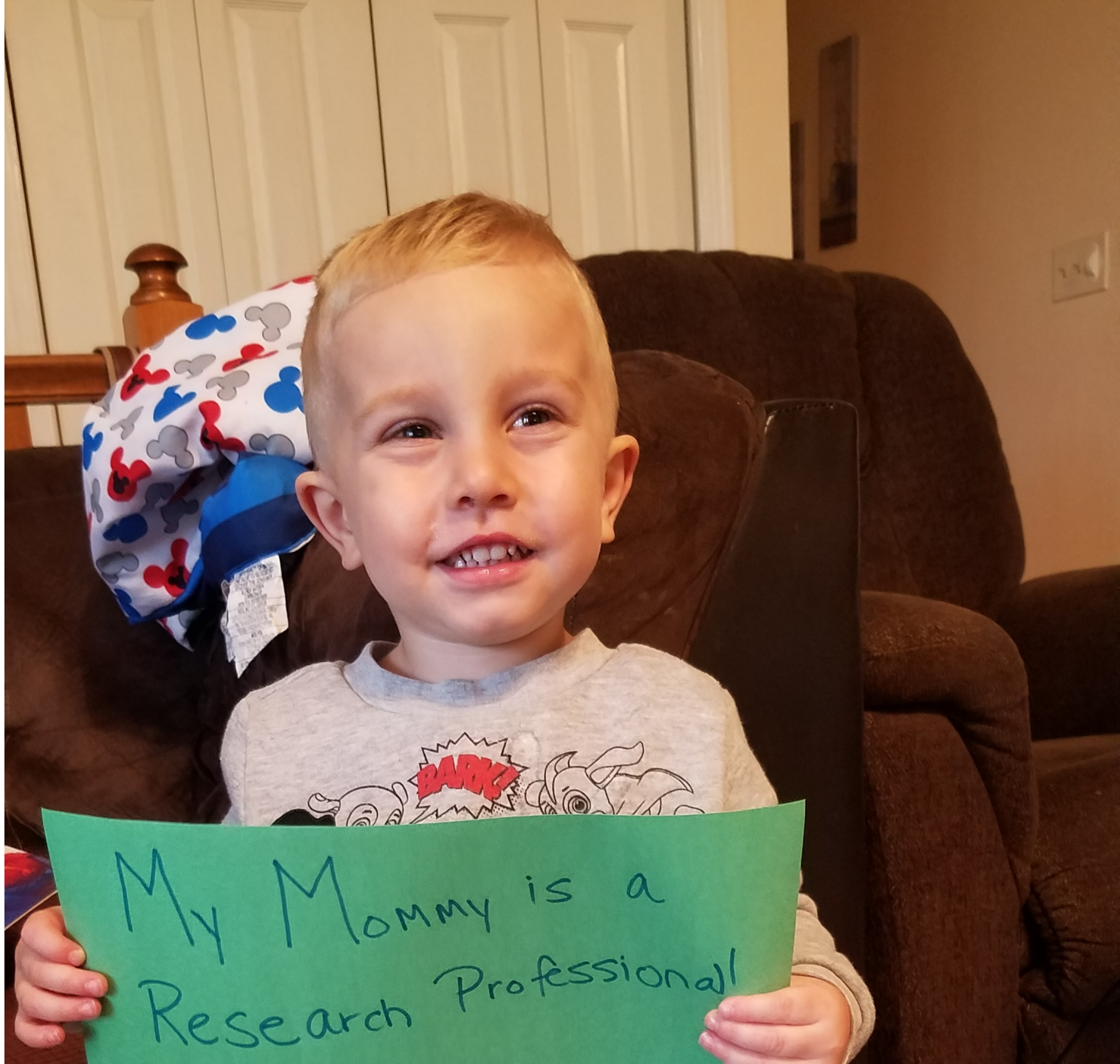
Exempt category 3 cannot enroll children



Example 1

Research study involving asking adult participants to play a game for 30 minutes and answer survey questions.

- ✓ Brief
- ✓ Harmless
- ✓ Painless
- ✓ Not physically invasive
- ✓ Not likely to have a significant adverse lasting impact
- ✓ No reason to think participants will find the interventions offensive or embarrassing
- ✓ Adults

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Example 2

Research study asking participants to complete a set of problem-solving activities with different background noises. Will last 2 hours.

- ✓ Brief
- ✓ Harmless
- ✓ Painless
- ✓ Not physically invasive
- ✓ Not likely to have a significant adverse lasting impact
- ✓ No reason to think participants will find the interventions offensive or embarrassing
- ✓ Adults

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Example 3

College students visiting the campus health center are asked to take part in a study to reduce risky sexual behaviors. Students are asked to watch a 10-minute interactive video about safe sex practices.

Participants will complete pre-and post-surveys assessing changes in attitudes and behaviors. Identifiers are not collected.

- ✓ Brief
- ✓ Harmless
- ✓ Painless
- ✓ Not physically invasive
- ✓ Not likely to have a significant adverse lasting impact

? No reason to think participants will find the interventions offensive or embarrassing

? Adults

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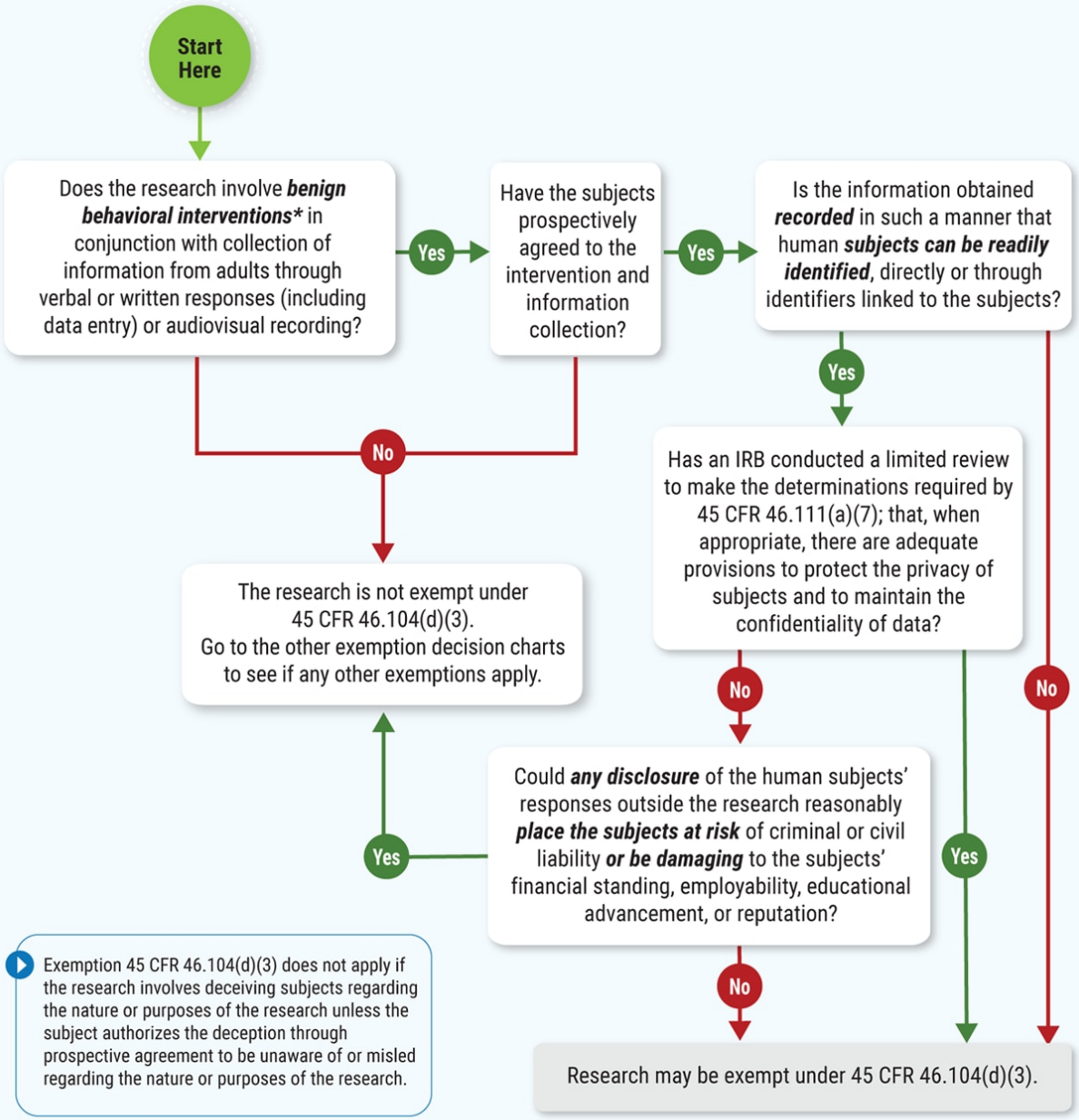
TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.



Exemption 45 CFR 46.104(d)(3) does not apply if the research involves deceiving subjects regarding the nature or purposes of the research unless the subject authorizes the deception through prospective agreement to be unaware of or misled regarding the nature or purposes of the research.

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Exempt Category 4

Secondary research for which consent is not required- Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded in such a manner that the identity of subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigators' use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (the HIPAA Privacy Rule), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined in 45 CFR 164.501, or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**

(iv) The research is conducted by or on behalf of a federal department or agency using government-generated or government-collected information obtained for non-research activities…

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Understanding Exempt 4

(i) The identifiable private information or identifiable biospecimens are publicly available:

Example: Would apply to secondary research use of archives in a public library or of government or other institutional records where public access is provided on request.

Understanding Exempt 4

(ii) Information, which may include information about biospecimens, is recorded in such a manner that the identity of subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify subjects:

Example: Would apply to research with information for which identifiers have been removed when the original collection of information or biospecimens occurs in the future or has already occurred.

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Understanding Exempt 4

(iii) The research involves only information collection and analysis involving the investigators' use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (the HIPAA Privacy Rule)*, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined in 45 CFR 164.501, or for "public health activities and purposes" as described under 45 CFR 164.512(b)

Example: Would apply to chart review studies where the data is regulated under HIPAA.

**Biospecimens are not regulated under HIPAA and therefore Exemption 4iii can not apply*

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HIPAA

- HIPAA applies to health plans, health care clearinghouses, and to any health care prov electronic form ("covered entitie
  - Hospitals
  - Doctor's offic
  - Insurance cor
- Researchers may vidual identifiable health informatic
  - Documented ration or **wavier**
  - Preparatory t
  - Research on PHI of decedent
  - Limited data sets with a data use agreement

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Considerations for Exempt 4

- Data does not need to be existing
- Only applies to the re-use of data and specimens that were or will be collected for NON-Research purposes
- HIPAA Waivers and Data Use/Sharing Agreements may be needed

Example	Yes/No	Explanation
A cardiologist wants to access medical records from his clinic to collect outcome data from his patient who have undergone or will undergo TAVR procedures between 2018-2022.	Yes	Meets criteria for exemption 3 – data regulated under HIPAA.
A researcher wants to use data collected from a previous research study and link it to data from the medical record.	No	Cannot use data collected from another study. Data is not anonymous. Data is not all regulated under HIPAA.
A researcher will receive completely de-identified data where there is no way that it could be linked back to the subject (not coded) to conduct analysis.	NHSR	Does this constitute Human Subjects Research?

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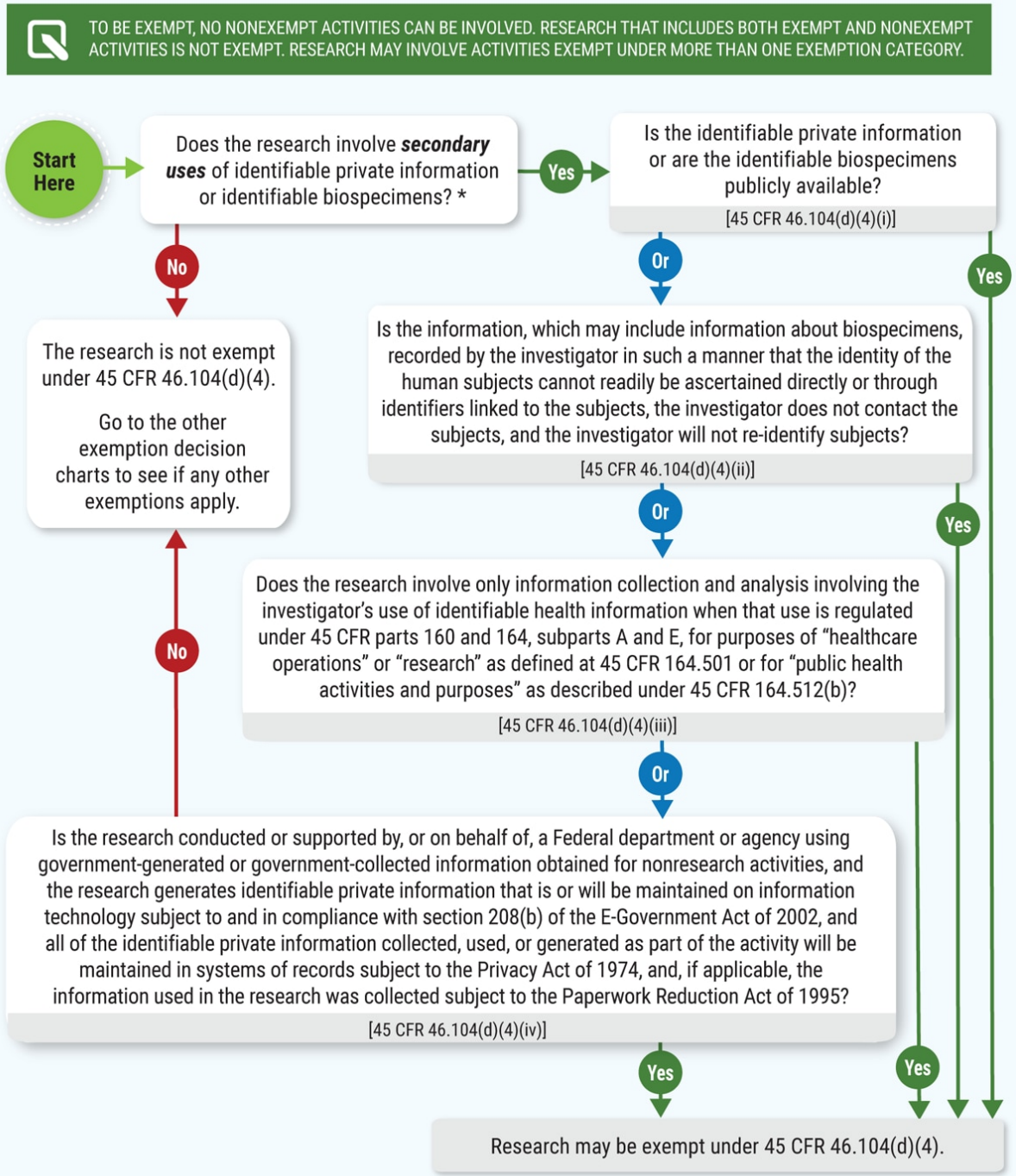

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Exempt Category 5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

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Exempt Category 6

Taste and food quality evaluation and consumer acceptance studies*:

(i) If wholesome foods without additives are consumed, **or**

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

*This category also qualifies for exemption under the FDA regulations at 21 CFR 56.104(d)(l

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Informed Consent

- **Interaction with study participant**
  - "Information sheet"
  - Email
  - Letter

- **What to include:**
  - **Required:**
    - Activity involves research
    - Voluntary participation
    - General description of study procedures and time commitment
    - Who to contact with questions

  - **Recommended:**
    - Any potential risks
    - Measures in place to minimize risk
    - What will be done with the data (confidentiality)

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SAMPLE: Anonymous Survey – Paper Information Sheet

Instructions: Statements *in brackets and italics* are instructions or examples. Do not include them in the final version of the information sheet.

We are asking you to take part in a research study being done by [*list researcher's name*] at the University of California, San Francisco.

If you choose to be in the study, you will complete a survey. This survey will help us learn more about [*briefly describe the purpose of the research*]. The survey will take about [*XX minutes or hours*] to complete.

[*Optional*: *If unclear, explain why subjects are being asked to participate and/or how they were selected.*]

You can skip questions that you do not want to answer or stop the survey at any time. The survey is anonymous, and no one will be able to link your answers back to you. Please do not include your name or other information that could be used to identify you in the survey responses.

Being in this study is optional. Please tell the researcher if you do not want to participate.

Questions? Please contact [*researcher's name*] at [*contact info*]. If you have questions or concerns about your rights as a research participant, you can call the UCSF Institutional Review Board at 415-476-1814.

https://irb.ucsf.edu/

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Exempt Reminders

- Regulatory requirements still apply
  - Regulatory document maintenance
  - Participant binders
  - Data retention and management requirements/policies
  - Good documentation practices

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Exempt Takeaways

- Provide IRB with all the information they need to make a determination
- Privacy and confidentiality still matter
- Basic ethical principles still matter
- Informed consent may still be necessary
- The IRB is the final decision maker

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Questions?

Stay Well

Stay Safe

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