## Expedited Category 9

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## Outline

- What is Expedited Category 9?
- General Expedited Review Requirements
- Additional Requirements for Expedited Category 9
- References

What is Expedited Category 9?

- Allows the Expedited continuing review of minimal risk projects
- Allows continuing review to be reviewed by a single person
  Usually OIA staff
- Requires return to committee for continuing review if there are new risks identified

General Expedited Review Requirements • May not be used for classified research

- Not generally seen here at UCSD
- May be used for research involving vulnerable populations
- Subjects in the study may be of any age
- If identification of the subjects or their responses would reasonably place subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, <u>then</u> reasonable and appropriate protections must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal

Additional Requirements for Expedited Category 9

- The convened IRB must have determined that the study is minimal risk
- The study does not have an IND or IDE
- The study is not eligible for expedited review under another category
  - If it is eligible under another category(ies), should be reviewed under that category
  - May have been sent to full board to ensure it's minimal risk, impasse with the researcher, ethical issue, etc.

## References

• Federal Expedited Review Categories

• <u>OIA-313</u>