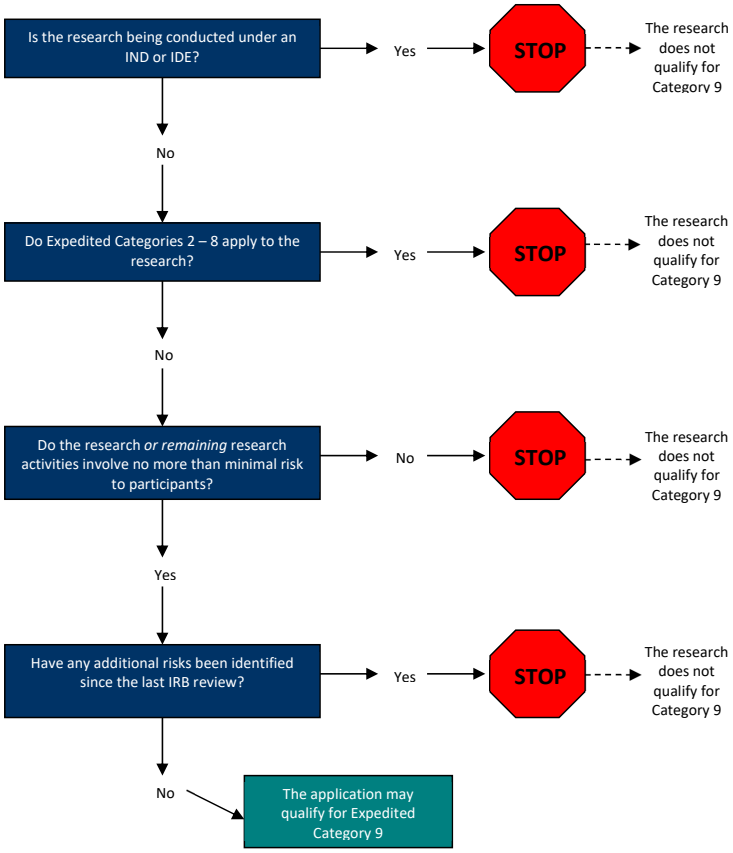
EXPEDITED CATEGORY 9 DECISION CHART

Decision Chart

Use this chart to determine whether a study being discussed at a convened board meeting may be expedited under Category 9.



Description

After using the decision chart above to determine whether a study is eligible to be expedited under Category 9, the following additional items must also be verified:

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

1. The research or the remaining research procedures do not involve procedures where the identification of the subjects or their responses will place them at risk of criminal or civil liability or be damaging to their 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; **and**
2. The research is not classified (i.e. research is not subject to government secrecy laws).

If ~~all of~~all the above requirements are satisfied, the study may be eligible to be expedited under Category 9 at the next continuing review.

In 2007, OHRP released the following guidance on this topic:

> "Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified."
>
> "The determination that "no additional risks have been identified" does not need to be made by the convened IRB" (http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm).

At the New Study Application initial review or at a subsequent Continuing Review, the convened board may determine when the research involves no more than minimal risk, that the application may be reviewed at the next Continuing Review using expedited procedures, provided that 1) the research is not being conducted under an IND or IDE, 2) Expedited Categories 2-8 do not apply, 3) the research or *remaining* research activities involve no more than minimal risk to participants, and 4) no additional risks have been identified.

Determining and* Documenting ~~*the*~~ *Category 9 and the Approval Period~~Determination~~
When the convened board determines that an application is eligible for review using Category 9, the determination must be documented in the meeting minutes and in ERICA.

~~Determining Whether Additional Risks Have Been Identified~~

In some cases, if a study is eligible for expedited review, continuing review is not required. The IRB staff typically makes a recommendation for the board to consider regarding the approval period and whether continuing review is required. The convened board should consider whether ~~not expedite continuing review under category 9 if~~ there is need of ongoing monitoring. If the board determines that ongoing monitoring by continuing review is recommended (even if continuing review is not required), the justification for requiring continuing review must be documented ~~with~~in ~~the board reviewer checklist and~~ the meeting minutes. ~~since expedited studies do not require subsequent continuing review.~~

Monitoring of Additional Risks
Should any additional risks be identified with the submission of an Amendment or Report Form, the investigator will be asked to submit a continuing review. If any of the applications include changes that include additional risk, the application cannot be expedited using this category.

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References & Links

Expedited Review of Research IGS	*https://irb.utah.edu/guidelines/investigator.php*

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