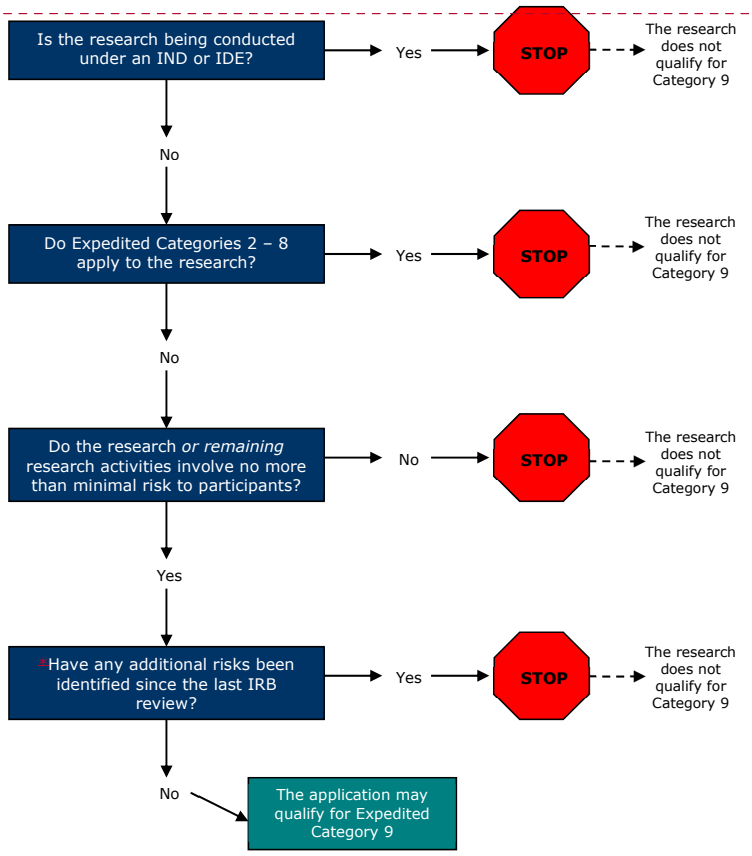
EXPEDITED CATEGORY 9 DECISION CHART

Decision Chart

Use this chart to determine whether ~~or not~~ a study being discussed at a convened board meeting may be expedited under Category 9.



~~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:~~

~~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~~

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

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~~implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal; and~~

~~2. 1. The research is not classified (i.e. research is not subject to government secrecy laws).~~

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

Description

~~*"Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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."*~~

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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:

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

~~Under Category (9), a study may be reviewed using expedited review procedures at continuing review if the research was previously approved by the IRB at a convened meeting and meets the following conditions:~~

~~1. The research is not conducted under an investigational new drug application (IND) or an investigational device exemption (IDE);~~
~~2. Expedited review categories (2) through (8) do not apply to the research;~~
~~3. The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk to the subjects; and~~
~~4. No additional risks of the research have been identified~~

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).

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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.

Documenting the Category 9 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. ~~The following language should be included in the minutes:~~

Commented [AS1]: Template language for minutes is intended for the coordinator's use. Coordinators can find language for this determination in the "Minutes Ending Language" document.

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~~If the study is **minimal risk**, add this note to the minutes, and as a Private Permanent Comment in ERICA:~~

> ~~"This research is not conducted under an IND or IDE, the research involves no more than minimal risk to subjects, and no additional risks of the research have been identified. Therefore, the convened Board determined on <<insert board meeting date>> that future continuing review of this study may be conducted using Expedited procedures under Expedited Category #9, provided no new risks have been identified."~~

~~If the study is **greater than minimal risk**, but the *remaining* research activities involve no more than minimal risk to participants, add this note to the minutes, and as a Private Permanent Comment in ERICA:~~

> ~~"This research is not conducted under an IND or IDE, the **remaining research activities** present no more than minimal risk to subjects, and no additional risks of the research have been identified. Therefore, the convened Board determined on <<insert board meeting date>> that future continuing review of this study may be conducted using Expedited procedures under Expedited Category #9, provided no new risks have been identified."~~

Determining Whether Additional Risks Have Been Identified~~* at Continuing Review~~

~~At continuing review, the pre-reviewer and designated expedited reviewer must ensure that the application still meets the criteria for Category 9. If it does not meet the requirements for the category, it must be reviewed by the convened board again.~~

The convened board should not expedite continuing review under category 9 if there is need of ongoing monitoring since expedited studies do not require subsequent continuing review.

Should ~~To determine whether~~ any additional risks ~~have~~ be~~en~~ identified, ~~the CR pre-reviewer should review all of~~ with the submission of an ~~the~~ Amendment~~s~~ or~~and~~ Report Form~~s~~, the investigator will be asked to submit a continuing review. ~~that have been submitted since the last review.~~ If any of the applications include changes that include additional risk, the application cannot be expedited using this category.

~~If the pre-reviewer does not identify any additional risks, the application may be assigned to an expedited reviewer. However, the expedited reviewer must confirm the findings of the pre-reviewer, and must make a final determination regarding the expedited category. The determination will be documented in their Board Reviewer Checklist, and in the final approval letter.~~

~~*With regard to multicenter research projects, the condition that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular institution has identified any additional risks from any institution engaged in the research project or from any other relevant source since the IRB's most recent prior review (OHRP 2009).~~

References & Links

Expected Review of Research IGS	*https://irb.utah.edu/guidelines/investigator.php~~http://www.research.utah.edu/irb/guidelines/pdf/ExpeditedReviewOfResearch-Jul09.pdf~~*
~~*OHRP 2007 & 2009 Guidance on Continuing Review of Research*~~	http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm ~~*http://www.hhs.gov/ohrp/requests/20091guidance_rev.html*~~

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