



Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

Expedited Review

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What is Expedited Review?



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Expedited Review Process

- Per regulations at 45 CFR 46.110 and 21 CFR 56.110
 - Performed by the Chair or experienced IRB member
 - Outside of the convened meeting
 - Can be used for:
 - Initial review
 - Continuing review
 - Minor changes to a study approved by the convened IRB
 - Criteria for approval are the same
 - Expedited review may NOT disapprove research
 - Method for keeping all members advised



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Review Categories

- Categories 1-7 apply to initial review
- Categories 8 and 9 apply to continuing review
- Research activities must be in a category on this list
 - Should not be considered minimal risk just because it is on this list



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Expedited Review Category 1

1. Clinical studies of drugs and medical devices when:
 - a) An IND is not required
 - b) An IDE is not required, or the device is approved for marketing and is being used in accordance with its labeling.



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Expedited Review Category 2

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

- a) Healthy, non-pregnant adults who weight at least 110 lbs \leq 550 ml/8 week period and not more than twice a week
- b) Adults and children, \leq the lesser of 50ml or 3ml/kg in 8 weeks; collection not more than twice a week



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Expedited Review Category 3-4

3. Prospective collection of biological specimens by non-invasive means

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation)



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Expedited Categories 5-7

- 5. Research involving materials that have been collected, or will be collected 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 research employing survey, interview, focus group, program evaluation, human factors evaluation



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Expedited Category 8

8. Continuing review of research previously approved by the convened IRB under any of the following conditions:

- a) Where (i) research is permanently closed to enrollment of new participants, (ii) all participants have completed all research related interventions, and (iii) the research remains active only for long term follow up of participants.
- b) Where no participants have been enrolled and no additional risks identified
- c) Where the remaining research activities are limited to data analysis



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Expedited Category 9

9. Continuing review of research,

- Not conducted under and IND or IDE application, where categories 2 through 8 do not apply
- 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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Thank you.



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