



**Human Subjects**

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# Scientific and Scholarly Validity

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# Why Scientific Review?

Study design review considers

- The least risky procedures
- Achievability of study aims
- Sufficient importance to justify the risks
- Adequate resources



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# Criteria for Approval

“Risks to subjects are minimized by using procedures which are consistent with sound research design”



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# Student Research

- Must work under the supervision of a PI
- PI should provide review for scholarly validity
- Thesis or dissertation projects are reviewed by advisory faculty/committee



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# Funded Research

Examples of Federal Sponsors:

- National Institute of Health
- National Science Foundation

Examples of Non-Federal Sponsors:

- American Cancer Society
- American Heart Association
- March of Dimes



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# Expedited Review

- Designated Reviewer
- Subject Matter Expert
- Consultant



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# Examples of Expedited Studies that require scientific or scholarly review

- Studies where biological samples are collected
- MRI/EEG/NIRS/Ultrasound procedures
- Studies that involve genetic analyses
- Studies with physical interventions (e.g., cold stressor or pressure tasks, electrical shock, exercise or nutritional intervention)



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# Continued:

- Studies with psychological manipulation (interaction or deception) used to obtain sensitive information
- Studies with the potential for group harm
- Studies that involve vulnerable or special populations such as prisoners, individuals with cognitive impairment, children with disabilities, pregnant women, neonates or infants, and undocumented aliens



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# Committee Review

- Primary Reviewer
- Secondary Reviewer
- Consultant



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# IRB Composition

- Each IRB must be appropriately constituted for the types of human research to be reviewed in accordance with federal regulations.
- Included are members with diverse experience and expertise to assure the professional competence necessary to review the university's research, as well as knowledge of community attitudes.



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# Roles and Qualifications of IRB Members

- Scientific Members
- Nonscientific Members
- Non-Affiliated (Community) Members



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# Use the Scholarly Review Checklist

This will ensure that

- The research conducted at UGA is up to standard for research publication
- UGA's research program is on par with our peer and aspirational institutions



Thank you



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