

I. POLICY FOR REVIEW OF RESEARCH FOR SCIENTIFIC OR SCHOLARLY MERIT**PURPOSE**

The University of Louisville is committed to protecting the rights and welfare of human subjects involved in research. Protection of subjects includes an assessment of the benefits of the research and of the risks, and the determination of an appropriate and favorable ratio between the two. The scientific or scholarly merit of a research activity may affect the benefits that could result from the research and therefore impact the risk benefit equation. External legal and ethical requirements* mandate the University and members of its research community to review research for which they are responsible.

POLICY

To determine that the approach is sound and the research design will yield valid results, research projects involving human subjects and conducted by University of Louisville faculty, staff, or students, or for which the University is responsible, will be reviewed prior to its initiation in accordance with the following guidelines or principles:

- Academic departments or units responsible for the research will determine a systematic and non-arbitrary review process and criteria.
- The review process and criteria will be stated in writing and be accessible.
- The review will be conducted by one or more departmental or unit peers of the researchers who are both impartial and competent to assess the scientific or scholarly merits of the university research. In situations where the University of Louisville IRB serves as the IRB of record, the external agency must provide documentation of the merit review.
- Responsibility for conducting such a review may be delegated to other agencies provided that the circumstances and the identity of the agency are specified.
- The department chair, director or unit head, will certify in writing that review has occurred and will forward a copy of the certification to the investigator. The certification will contain the identity of the researcher, the individual(s) conducting the review, the title of the research, and the outcome and date of the review.

* Examples include The Belmont Report, Principle 11 of the Declaration of Helsinki, and accreditation requirements disseminated by the Association for the Accreditation of Human Research Protection Programs.

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