



RESEARCH ETHICS CONSULTATION SERVICE

Standard Operating Procedures

Purpose

The University of Miami (UM) Ethics Programs' Research Ethics Consultation Service (RECS) is a resource for addressing ethical issues that arise during the development, conduct, analysis, or reporting of research.

RECS consultations are provided without charge to UM faculty, staff, and trainees involved in the conduct of research. RECS Consultants will provide persons requesting consultations with a non-binding advisory response, which will be documented.

RECS complements but does not supersede the work of other entities at UM that are involved in the supervision of research, such as the Human Subjects Research Office (HSRO) and its Institutional Review Boards (IRB), the Institutional Animal Care and Use Committee (IACUC), or the Office of the Vice Provost for Research (VPR). In particular, interactions with RECS consultants do not supplant any reporting requirements to/for these other UM entities (e.g., reporting to the anonymous 'Cane Watch hotline).

UM Ethics Programs has since its inception provided research ethics consultation services on a variety of topics. This document describes an expansion and formalization of the RECS process under the auspices of UM's Clinical and Translational Science Institute (CTSI).

Current information on RECS services is posted at www.miami.edu/recs.

Scope

University-wide

Responsibility and Reporting

The Director of the UM Bioethics Program is responsible for supervising the service. RECS activities will be reported annually to the Bioethics Program Director, to the UM Vice Provost for Research, and other such persons in UM research or CTSI leadership as appropriate.

Operational Policies and Procedures

1. Director(s) of RECS will be appointed by the Director of the UM Bioethics Program to serve as administrators of the RECS Program and as Primary Consultants. Additional persons may be invited by the RECS Director(s) to serve as Consultants. All will serve without term.

2. RECS consultations will be provided upon request and without charge to UM faculty, staff, and trainees involved in the conduct of research. Estimated response times and the level of confidentiality that can be afforded will be established as part of the initial contact with the Requestor.
3. Responses to Requestors will be advisory, and will generally consist in recommendations of one or more appropriate courses of action as well as, when appropriate, contact information for other relevant organizations or services at UM. Requestors will be advised that that they retain responsibility for their decisions regarding actions taken or not taken.
4. RECS Consultants will document all responses to Requestors, including but not limited to: the name, title/position, and department of the Requestor; date(s) of interaction with the Requestor; the facts to the extent known; and the advice provided to the Requestor. In general, one or more written response(s) should be provided to the Requestor, which response(s) will be kept on file in RECS archives.
5. RECS Consultants may provide responses to Requestors for uncontroversial matters before informing other Consultants, but should notify the Directors as soon as possible thereafter and provide documentation (as described in #4) of the consult. The documentation must be completed by the lead/sole Consultant. Consults will be logged upon submission of standard documentation.
6. RECS Consultants should contact the RECS Director(s) and other Consultants as needed for consults for which group discussion (or expertise outside of the RECS consultation group) is appropriate before responding to Requestors. See Appendix flowchart.
7. Consult requests regarding questions of law, regulation, or institutional policy will generally elicit a recommendation that the Requestor contact the appropriate UM organization for an authoritative response.
8. RECS Consultants will maintain confidentiality to the maximum extent permitted by law, regulation, and UM policy. As with likely response times, the limits of confidentiality for a particular consult will be made clear to the Requestor as early as possible during the consult process, and will be updated should the parameters change significantly.
9. Periodic reports of general characteristics of RECS activities will be provided to the UM Bioethics Program Director, the UM Vice Provost for Research, and other such persons in UM research or CTSI leadership as appropriate.

Reports will include a categorization and counts of all consultations for the period of the report. Details of individual consults will be disseminated only among the RECS Consultants, in support of formulating a response to Requestors and for purposes of quality assurance.

10. Appropriate information about RECS services will be made available to the UM community, and will include: a listing of RECS Director(s) and other Consultants; their contact email addresses and telephone numbers; a general contact email and telephone number for RECS; an Overview of Services and Frequently Asked Question (FAQ), including the procedures for initiating a consult request; and such other materials as deemed necessary and appropriate by the RECS Director(s).

The website URL used for this purpose is: www.miami.edu/recs.

History

Initial version: 12 August 2011

Last update: 18 June 2014

Appendix – RECS Process

