Human Subjects/Institutional Review Board (IRB)

Clark University has an Institutional Review Board (IRB) which is responsible for ensuring research conducted by faculty, staff, and students, protects the rights and welfare of human subjects. The point of contact for IRB matters is Linda Cote, Grant and IRB Coordinator, at x3880.

**NOTE:** Some committee determinations may require review of a revised proposal at a subsequent meeting of the full committee. It is strongly urged that research planned for summer be submitted for review NO LATER THAN APRIL to allow time for resubmission if required.

- **a. Human Subjects Policy**
- **b. Revised IRB Proposal Application with Required Checklist (.doc)**
  
  (This downloadable document can be completed using Microsoft Word, saved and then emailed back to the research office with other supporting documents as required to: humansubjects@clarku.edu) **REQUIRED:** Completed application, checklist, consent forms, CITI training certificate, study instruments and other attachments must be merged and submitted to the IRB as ONE Word document. **Information on CITI and/or RCR training**
- **c. Anonymous Survey Application** (Anonymous surveys are conducted on a rolling basis. You do not need to wait for a regular IRB meeting. This application is completed online.)
- **d. Course Approval Form**
- **e. Exemptions**
- **f. Sample Request for Exemption Application**
- **g. Exclusion Application**
  
  All work with human subjects or identifiable information on human subjects must be reviewed by the IRB. If you think that your project might be excluded from further IRB oversight, you MUST submit this Exclusion Application, and the IRB will make this determination.
- **h. Continuing Review Form**
  
  (This downloadable form may be used to extend an approval or close an approval. To extend the approval, form should be completed and returned to the humansubjects@clarku.edu email address 14 days prior to the approval expiration date. If a continuing review form to extend an approval for ongoing research is not received by the expiration date, the approval will expire.)
- **i. Sample Recruiting Text**
- **j. Sample Consent Form**
- **k. Sample Assent Form - paragraph style. Sample Assent Form - question style**
- **l. Sample Translator Confidentiality Agreement form**
- **m. Examples of Human Subjects Protocols to Clark IRB**

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CITI Resources for January 21, 2019 (expected) compliance date of revisions to the Common Rules:

<table>
<thead>
<tr>
<th>Overview of Common Rule revisions</th>
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<tbody>
<tr>
<td>Changes to Exempt Determination process</td>
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</table>
Guide to Informed Consent changes

New and revised definitions

Additional Information:

- United States Department of Health and Human Services
- National Institutes of Health - Office of Human Subjects Research
- National Institutes of Health - IRB Protocol
- National Science Foundation: Federal Policy for the Protection of Human Subjects
- Public Responsibility in Medicine and Research
- The Nuremberg Code
- Tutorial and certification program for research involving human subjects

The Chair of the IRB is Robert Johnston. Inquiries should be addressed to rjohnston@clarku.edu and cc humansubjects@clarku.edu.