Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: III.C.1
Section: IRB Review Procedures
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: January 5, 2004
Revision Dates: February 9, 2004; May 28, 2004; August 30, 2004; December 14, 2004; May 21, 2010; June 30, 2010; July 1, 2015

Subject: Procedure for IRB Review of Human Subjects Research – Exempt

Procedure:
This procedure provides guidance in accordance with regulations to review and approve human subjects research in an exempt category.

I. Investigator Responsibilities.
   A. The “Request for Exemption” is completed in its entirety and submitted to the HRPP along with any background information. The application and instructions to complete the application are located on the HRPP website: http://www.mc.vanderbilt.edu/irb/.
   B. The Investigator replies to all requests for revisions and/or clarifications requested by the pre-reviewers or reviewers, when applicable.
   C. Certain changes may disqualify the research from exempt status; therefore, all changes in the research plan must be reported to the HRPP for review and approval, prior to implementation. Any proposed changes in the exempt study initiated after the first anniversary of the HRPP approval date that have the potential to alter its exempt status are submitted in a new “Request for Exemption”.
   D. The Investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate participant protections (i.e., confidentiality).

II. IRB Committee Responsibilities.
   If needed, the Chairperson or the designated Committee Member is available to assist the RCA in determining if the study meets the exemption criteria.

III. HRPP Regulatory Compliance Analyst (RCA) II or Higher Responsibilities.
   A. The RCA II or higher will review the proposed project to determine if the research qualifies for exemption in accordance with HRPP Policy III.C “HRPP Review of Human Subjects Research – Exempt.”
   B. The RCA II or higher will also review the proposed project to determine if the research meets the ethical standards of the Belmont Report and that the following criteria are met where applicable.
      1. The research presents no more than minimal risk to participants.
      2. Selection of participants is equitable.
      3. If there is recording of identifiable information, provisions for maintaining the confidentiality of data are adequate.
      4. If the research involves interactions with participants, the circumstances of consent minimize coercion and undue influence.
      5. If there are interactions with participants, a determination of the need for a consent process that disclose such information as:
         a) The activity involves research;
         b) A description of the procedures;
         c) That participation is voluntary;
         d) Name and contact information for the researcher;
         e) HRPP contact information; and/or
         f) There are adequate provisions to maintain the privacy interests of participants.
   C. The RCA II or higher may:
      1. Approve the request;
      2. Request minor revisions to the submitted documents in order to approve the request, and review and approve the revisions prior to granting final approval; or
3. Disapprove the request.
   D. The RCA II or higher will document the determination and its justification on the Reviewer Comment Form.
   E. If the RCA II or higher disapproves the request, the RCA will determine the appropriate level of review, communicate this to the Investigator, and guide the Investigator in submitting the necessary documentation.
   F. If the RCA II or higher approves the request, the RCA signs and sends a letter of final approval using the appropriate template.
   G. Appropriate database entries are completed, including notification of approval on the next available agenda.