Subject: Procedure for Human Subject Research/Non-Human Subject Research Determination

Procedure:
This procedure provides guidance for the determination of non-human subject or non-research projects.

I. Investigator Responsibilities.
A. Investigators must submit the “Request for Determination of Non-Human Subject Research” to the HRPP. The form and corresponding instructions are located on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
B. The Investigator will reply to all requests for revisions and/or clarifications requested by the pre-reviewers or Reviewers, when applicable.
C. Investigators must submit any changes to the research, which occur within the first year of HRPP approval, to the HRPP as a “Request for Amendment”.
D. Any proposed changes to a non-human subject or non-human determination occurring after the first anniversary date of the initial HRPP approval date must be submitted to the HRPP as a new “Request for Non-Human Subject/Non-Research Determination”.

II. IRB Committee Responsibilities.
If needed, the Chairperson or his/her Designee will be available to assist the RCA in determining whether an activity meets the definition of “Human Subject Research.”

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will review the proposed project to determine if the research qualifies as “Non-Human Subject Research” in accordance with HRPP Policy III.I, “Human Subject Research/Non-Human Subject Research Determinations.”
B. The RCA 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 approval determination; or
3. Defer the request.
C. The RCA will document the determination and its justification on the Reviewer Comment Form.
D. If the RCA disapproves the request, the RCA will determine the appropriate level of review, communicate this to the Investigator, and guide the Investigator with the resubmission.
E. If the RCA defers the request, the RCA will sign and send a determination letter using the appropriate template.
F. Appropriate database entries will be completed, including notification of approval on the next available agenda.