Cornell University
Office of
Research Integrity and Assurance

Human Research Participant Protection Program

POLICY 21: TRIENNIAL (THREE YEAR) APPROVAL FOR RESEARCH STUDIES

1. Subject:

Current Federal Regulations for research involving human participants (45 CFR 46) require that studies undergo a continuing review of the research at least annually. In its Federalwide Assurance (FWA 00004513) with the U.S. Department of Health and Human Services (DHHS), Cornell University commits to complying with these federal regulations for all federally funded research. Limiting the scope of its FWA to federally funded research allows Cornell's Human Research Protection Program (HRPP) and its Institutional Review Board (IRB) some flexibility in its application of federal regulations to studies that are not federally funded. In doing so, Cornell does not compromise its commitment to following the ethical principles of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research) and applying the highest ethical standards for the protection of all human participants for all Cornell research.

Since many research studies conducted at Cornell University Ithaca campus pose no more than minimal risk to the participants, annual continuing reviews of such projects does not materially increase the protection of research participants' rights and welfare. A Triennial (three-year) Approval for such studies will reduce the administrative burden on investigators while continuing to maintain high standards for the protection of human participants in Cornell research. This policy describes the criteria under which a Triennial Approval may be granted and the corresponding initial and ongoing review and approval procedures.

2. Policy statements

2.1. IRB approval for a study will be valid for a (3) three-year period (Triennial Approval) if the study meets the following conditions:

- **Poses no more than minimal risk or harms** to human participants. Risks/harms in this context include the probability or magnitude of harm or injury (physical, psychological,

social, or economic) occurring as the result of participation in a research study. Although most social and psychological risks are minimal and transitory, investigators must be aware of the potential for harm.[i]

- **Does not include any** of the following:
  - Federal funding for the project including federal training and program project grants
  - Flow through funding from a Federal sponsor
  - Student projects funded on federal funds received by the Faculty sponsor/advisor
  - Federal no-cost extensions
  - A sponsor or funder that requires annual IRB review as part of the agreement
  - Prisoners as subjects
  - Receipt of an NIH issued Certificate of Confidentiality to protect identifiable data
  - Certain minimally invasive bio medical procedures that are considered by regulations to be no more than minimal risk, such as blood collection, clinical interventions or FDA-regulated components; or use of devices or methods that are normally used for medical diagnosis or treatment, such as blood pressure measurements, EKGs, EEGs, ultrasounds, blood sugar measurments, magnetic resonance imaging, thermography, detection of naturally occurring radioactivity, , diagnostic infrared imaging, etc.. Studies involving such procedures will continue to be subject to Annual review by the Cornell IRB, as we continue to develop IRB and institutional practices for the conduct and monitoring of human health and safety related to these procedures.

NOTE: ***Studies involving the following types of quasi-biomedical procedures may be eligible for trinennial review. The final determination of eligibility for Triennial Approval will be made by the IRB reviewer and IRB staff*****:**

- Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings in a nondisfiguring manner; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

- Collection of data through certain noninvasive procedures. Examples: anthropometric measurements (height, weight, circumference, etc.) and other non-invasive external measurements; physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy, such as pedometer, eye tracker, pulse monitor, perspiration measurements; weighing or testing sensory acuity; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

2.2. IRB applications granted a three year approval may not be used to support proposals or future awards involving federal funding. PIs should contact the IRB office for instructions if federal funding is anticipated.

2.3. All other research projects not granted a three year approval are subject to the full terms of the Cornell University Ithaca FWA and are subject to annual continuing review.

2.4. Principal Investigators (PI) are responsible for reporting to the IRB changes in funding or sponsor status that make the project ineligible for Triennial Approval.

2.5. If during the course of the three year approval of the study any changes occur that make the project ineligible for Triennial Approval, the study will be subject to the annual review and approval process.

2.6. At the end of the three years of approval, PIs must submit a Request for Renewal of Triennial Approval to the IRB so the project can receive a comprehensive review prior to the expiration of the Triennial Approval.

2.7. All other regulatory requirements, including requirement to submit and receive IRB approval for protocol amendments before implementing modifications to the study, and adverse event and reporting, and the requirements, guidelines and expectations outlined in the Cornell IRB policies, continue to apply to all Cornell research.

3. Procedures

3.1. For new research projects involving human participants, the PI will complete the Initial Approval Request form (www.irb.cornell.edu/forms) and submit it for review by the IRB. If the IRB office determines that the project is eligible for Triennial (three-year) Approval, the

protocol will be granted approval of the type "IRB Approval – No Federal Funding". The PI will be notified accordingly.

3.2. A PI may request in the IRB application, that her/his study be granted an annual review and approval, even if the study qualifies for a triennial review.

3.3. IRB staff will check the protocol information against the grant information for the PI in the sponsored portal to ensure that there is no current federal funding associated with the protocol.

3.4. **Annual reminder: As a courtesy, an annual notice will be sent to the PI** asking if there are changes to the project that would require reconsideration of the three year approval. PIs must carefully review the conditions for the three year approval and take one of the following actions:

- If no such changes have occurred, confirm via email (not required, but highly recommended).
- If one or more changes have occurred that would require reconsideration of the three year approval, submit an Annual Continuing Review application for IRB review. The subsequent approval could be for one year or three years, depending on the changes that have occurred in the sponsorship or risk profile of the study.

4. Quality Assurance for protocols approved under Triennial Approval

The IRB office will review a random sample of studies approved for three years to confirm that the funding status has not changed to being federally sponsored or that the level of risk has not increased to more than minimal, and that any changes made to the protocol have been reported to the IRB prior to implementation.

5. Reporting Requirements

Research projects that are not supported by Federal funds are not subject to the terms of Cornell University's FWA and, therefore, are not subject to federal reporting requirements. Nevertheless, for such projects, Cornell's IRB follows the same internal reporting requirements for serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risks to participants or others, as described in Cornell's (HRPP) Policy XYZ

6. References

6.1. Federal Policy for the Protection of Human Subjects (Common Rule) http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html

6.2. Cornell IRB SOP 3: Initial and Continuing Review by the IRB: Requirements for Submission of Applications, Approval Criteria, and Expedited and Convened Committee Review Procedures

6.3. OHRP Guidance on Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Approved by the IRB: October 4, 2013

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