CUNY HRPP Policy: Extended Approval for Non-Federally Funded Minimal Risk Human Subject Research

1. Background
   CUNY has decided to limit the terms of its Federalwide Assurance (FWA) to federally funded or supported research. In general, CUNY's approach is to base all CUNY HRPP policies on federal regulations, and to apply these to all human subject research regardless of funding. However, limiting the scope of our FWA gives us flexibility to make exceptions where appropriate.

2. Purpose
   The purpose of this policy is to allow extended approval, i.e. approval period of greater than one year, for certain non-federally funded minimal risk research and to define the criteria for research to which extended approval may be applied.

3. Criteria
   The CUNY UI-IRBs may grant an extended approval to research that meets the following criteria:

   3.1. The IRB has determined that the human subject research meets the criteria for review via the expedited review procedures

   3.2. The human subject research is not subject to direct or indirect federal oversight by any federal agency, including the FDA

   3.3. The research does not involve prisoners or parolees

   3.4. The research does not involve children

   3.5. The research does not involve adults who lack the capacity to consent

   3.6. The research is not covered by a Certificate of Confidentiality

   3.7. There are no contractual obligations or restrictions that disqualify the research from receiving an extended approval

4. Approval Period
   Unless otherwise indicated, the extended approval will be granted for 3 years from the date of approval. This 3-year approval period is consistent with the period for which CUNY HRPP issued exemptions from IRB review are valid.

5. Applicability of Other CUNY HRPP Policies
   All extended approvals are subject to all other CUNY HRPP policies, including those for timely submission of amendments and continuing review.

Effective Date: July 18, 2016