Addendum: DPPOS Ancillary Study Policies

1. Review Process and Timeline

The DPPOS Steering Committee recently discussed and voted on the criteria that have been used to select ancillary studies that are applying for access to data and/or stored samples. In particular, considering the very limited DPP biological samples that are available at baseline and year 1 and as a result **as of January 2014, the following principles and policies apply:**

1.1. Any investigators applying for use of biosamples will be required to first go to the NIDDK Repository and determine whether the samples available at the repository will be adequate and are available for the proposed study. The Repository samples should be used if at all possible, and the use of remaining DPP samples only requested if this is not possible. If investigators proceed with a request for remaining DPP samples they must explain in their application why the Repository samples will not satisfy the proposed study's needs.

1.2. After permission to use DPP/DPPOS stored samples for an ancillary study has been granted (by the Ancillary Studies Committee and subsequently by vote of the Steering Committee and review by DSMB), the biosamples that are approved for an ancillary study are only reserved for the approved study for ~ 1 typical NIH review cycle (~ 9 months from time of approval and submission). The expectation is that investigators will submit their approved studies at the next possible NIH submission cycle (typically within 2 months) after study approval by the Steering Committee (see review schedule below). If the study is funded, the samples will be provided to the study. If not approved, the samples will go back into the "pool" of stored samples available for other investigators to access for subsequently approved studies. If an investigator re-submits an ancillary project that has failed to garner funding support, the application, including the request for samples, will be re-considered by the Ancillary Studies Committee, in competition with other applications submitted during that cycle.

1.3. The Ancillary Studies Committee (ASC) currently reviews ancillary studies ONLY three (3) times a year. Considering the limited number of biosamples available, selection of the most deserving studies to access biosamples would be helped by performing head-to-head comparisons of submitted proposals (for scientific importance and quality). In order to accomplish this end, Ancillary Studies Committee reviews are performed three times per year. Any applications will be aggregated and reviewed in a group (similar to an NIH study section review). The review schedule will be announced well ahead of time and will be synchronized with NIH submission dates (for example, submission deadline to the ASC 10-weeks before the NIH submission deadline, allowing 6-8 weeks for ASC and SC review and addressing any questions raised and then ~6-weeks for the PI to prepare the grant for submission.) If a special RFA that would benefit potential DPP/DPPOS ancillary studies is issued with a submission schedule that makes the usual three times per year ASC review schedule problematic, the ASC would be flexible and would schedule an additional review session to accommodate submitted proposals.

Ancillary studies review schedule – Proposals due to ASC by Dec 1 (for Feb deadline), Apr 1 (for June deadline) and Aug 1 (for Oct deadline)