## Analysis Proposal Guidelines

The OC3 is a rich source of questionnaire data relating to ovarian cancer risk and survival, considering questionnaire as well as biomarker data. We anticipate that many of the OC3 participating studies will wish to propose new analyses. To ensure that these proposals are handled fairly and in a timely manner, we have established the following guidelines based upon recommendations by the NCI Cohort Consortium Secretariat (and also approved by that body).

- Complete the 'Contact Us' form found on our website with an overview of the project idea to make sure that another investigator has not already proposed your project. Ongoing projects and recently submitted proposals are maintained by staff and will be posted on the OC3 website.
- 2. After completing the contact us form, the co-chairs of the steering committee (Drs. Shelley Tworoger and Nicolas Wentzensen) will reach out to you and work to determine how many cohorts have data on the exposure of interest (if the data are already in the data coordinating center); the cohort database at <a href="https://cedcd.nci.nih.gov/">https://cedcd.nci.nih.gov/</a> can also be checked. Also provide initial thoughts on funding mechanisms and discuss potential modes of data sharing with Dr. Tworoger. The data coordinating center will require some funds to cover the cost of the work for each specific project. These should be negotiated with Dr. Tworoger.
- Following the initial conversations, please submit a proposal to the OC3 Steering Committee for approval at a steering committee meeting. Please use the <u>OC3 Project proposal form.pdf</u> found on our website. Information about criteria for approval can be found at <u>https://epi.grants.cancer.gov/Consortia/cohort\_pooling.html</u>.
- 4. Drs. Tworoger and Wentzensen will circulate submitted proposals to the steering committee approximately quarterly (i.e., once every 3 months), however, this timeline can be expedited if necessary. Proposals will be discussed and either approved or disapproved by the steering committee. If a proposal is disapproved, details will be provided as to the reason and whether the proposal can be resubmitted with revisions.
- 5. After approval is obtained, it is the investigator's responsibility to email each OC3 cohort contact person and ask if that cohort is willing to participate. Note that the OC3 operates on an opt-in basis. That is, cohorts have to officially give permission for their data or samples to be used for each project. The Data Coordinating Center requires an email from each cohort's contact person that the study agrees to participate in the analysis. A list of cohorts and contact individuals will be provided to the investigator. After approval is obtained, additional regulatory factors must be addressed including potential revisions in existing data sharing agreements between an institution and the data coordinating center to allow a new analysis (where specified), a data sharing agreement between the investigator's institution and the data

coordinating center for use of the data, IRB approval at the data coordinating center and the investigator's home institution, etc.

- 6. Once funding is secured, an analysis proposal must be written and provided to the data coordinating center for review (to ensure data are available, etc.), to any cohorts requiring an analysis proposal submission, and for approval from the writing group. At that point, the data coordinating center will provide a dataset with the required variables and studies that can be used for the analysis. Several options exist for data collaboration: 1. The data coordinating center conducts all analyses under the direction of the first and senior authors, 2. The person conducting the analyses will be granted access to the data coordinating center computer system with access to the dataset needed for that analysis, or 3. It may be possible, depending on existing agreements between the data coordinating center and individual cohorts, to send a deidentified or limited data set to the investigator for analysis. The latter two options will require modifying or setting up a new agreement to allow the analyst access to the data. The approach for each project should be discussed with Dr. Shelley Tworoger who oversees the data coordinating center.
- 7. Once analysis begins, investigators are expected to participate in a bi-weekly conference call to provide status updates on the project, share early results for input and discuss analytic challenges. Currently these calls occur every other Tuesday from 2-3pm Eastern Standard Time.