DATA SHARING AGREEMENT

This Data Sharing Agreement (this "Agreement") entered into on **EFFECTIVE DATE:** Click here to enter a date (the "Effective Date") by and between H. Lee Moffitt Cancer Center and Research Institute, Inc., a Florida non-profit corporation organized pursuant to Section 1004.43 of the Florida Statutes, located at 12902 Magnolia Drive, Tampa, Florida 33612 ("Moffitt") and **OUTSIDE PARTY'S NAME AND ADDRESS:** Click here to enter name and address of the Outside Party ("Institution"), and Moffitt and Institution are hereinafter each individually referred to as a "Party" and collectively as the "Parties."

WHEREAS, Moffitt is a National Cancer Institute designated comprehensive cancer center, a statewide research institute, and a national resource for basic science, clinical research, and interdisciplinary approaches to research and patient treatment.

The Ovarian Cancer Cohort Consortium (OC3) is an international consortium of cohort studies designed to address scientific aims important for understanding ovarian cancer risk, early detection, and survival in the context of tumor heterogeneity. The OC3 is part of the NCI Cohort Consortium, which is an extramural-intramural partnership to address the need for large-scale collaborations and provides the super-structure (but not funding) for managing the OC3. The OC3 currently has over 25 participating, on-going cohort studies and we expect there to be over 8,000 invasive ovarian cancer cases among more than 1.5 million women.

WHEREAS, Institution has asked that Data (defined hereinafter) be transferred to Moffitt for completion of the Research Project (defined hereinafter).

WHEREAS, Dr. Shelley Tworoger shall supervise the Research Project under this Agreement on behalf of Moffitt.

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein as covenants, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Moffitt and the Institution agree as follows:

1. For the purposes of this Agreement, the following words and phrases shall have the following meanings:

   a. "Data" means all data further described in Exhibit A.

   b. "Research Project" means the research described in Exhibit B.

2. Institution shall deliver to Moffitt the Data by a mutually agreed upon date for completion of the Research Project using a secure method of electronic transfer.

3. The Data shall reside at Moffitt but may be provided to a requestor upon approval by the OC3 Steering Committee and the principal investigator at the institution(s) who provided such Data to Moffitt. Any such transfer will be governed by an agreement substantially similar to the agreement set forth in Exhibit C (Data Access) or D (Data Release). Such Data request shall

comply with Exhibit E (Guidelines for proposing a new analysis using OC3 data). The requestor of the Data shall comply with Exhibit F (Ovarian Cancer Cohort Consortium (OC3) Publication Guidelines**)**.

4. Please note that Exhibits, C, D, E and F are attached to this Agreement as **"SAMPLES" only**. Exhibits C, D, E and/or F will be utilized should future agreements be needed.When required by a journal or for NIH-funded grants subject to the 2003 data sharing policy (NOT-OD-03-032), Moffitt may make available a de-identified (including no cohort identifier) dataset consisting of only the OC3 harmonized variables used to generate data for a publication outside of the guidelines outlined in Section 3 above (with no scientific or authorship requirements). Requests for these restricted datasets can be made by investigators with appropriate human subjects training at valid research or educational institutions on or after the time of manuscript acceptance. DSA would be necessary to obtain dataset. Any such transfer will be governed by an agreement substantially similar to the agreement set forth in Exhibit C (Data Access) or D (Data Release).

5. Moffitt will be able to use Data to carry out studies described in Exhibit B. Use of the Data provided by the Institution for specific analyses will be approved by the principal investigator. Moffitt has the right to aggregate Data from this Agreement with other data sources.

6. Moffitt agrees to acknowledge the source of the Data in any publications reporting use of it and follow authorship guidelines approved by the OC3 steering committee.

7. THE INSTITUTION MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

8. Institution may provide certain Protected Health Information (PHI) to Moffitt under a Limited Data Set (LDS) as defined under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). The LDS, if provided hereunder, shall be specifically spelled out in Exhibit A "Data".

9. Moffitt shall comply with all laws, statutes, and regulations applicable to Moffitt's conduct of the Research Project, including, but not limited to HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, and seek appropriate Institutional Review Board, Ethics Committee, or other similar board review, when applicable, in performing its obligations under this Agreement.

10. The Institution will abide by the Agreement that Moffitt signed with the Study as described in the DSA and Exhibit A (Data).

11. The Parties agree that this Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

IN WITNESS WHEREOF, the Parties have duly executed this Agreement on the Effective Date set forth above.

H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.

By: _____

Name: _____

Title: _____

SIGNATURE BLOCK: CLICK HERE TO INSERT THE OUTSIDE PARTY'S NAME

By: _____

SIGNATORY NAME: Click Here to Insert Name of Outside Party's Signatory

Title: SIGNATORY TITLE: Click Here to Insert Title of Outside Party's Signatory.

EXHIBIT A
(Data)

OC3 data elements

Below is a list of potential data elements that may be requested as part of the OC3 database. Note that not all cohorts will have all data elements. Please cross out any data elements that will not be shared as part of this agreement.

Exposure data from <u>baseline</u> questionnaire

- Year/age of enrollment
- Year of birth
- Known or putative ovarian cancer risk factors
    - Demographic data
    - Reproductive history
    - Contraception history
    - Family history of ovarian, breast, or other cancers
    - Hysterectomy/oophorectomy status
    - Anthropometric variables (e.g., height, weight, weight at age 18, waist/hip circumference)
    - Other diagnoses (e.g., endometriosis, other cancer, cardiovascular disease, auto-immune disease, diabetes, pelvic inflammatory disease, other cancers)
    - Lifestyle data (e.g., smoking status, physical activity, sedentary activity, diet, talc use)
    - Medication use (e.g., hormone therapy, non-aspirin NSAIDs, aspirin, Tylenol/acetaminophen, statins, metformin)
    - Previously linked geographic information system (GIS) data (e.g., census tract, exposure to pollution, green space, etc.)
    - Other variables as approved by the OC3 steering committee

Updated exposure data from <u>follow-up</u> questionnaire(s)

- Year/age of questionnaire completion
- Known or putative ovarian cancer risk factors
    - Demographic data
    - Reproductive history
    - Contraception history
    - Family history of ovarian, breast, or other cancers
    - Hysterectomy/oophorectomy status
    - Anthropometric variables (e.g., height, weight, weight at age 18, waist/hip circumference)
    - Other diagnoses (e.g., endometriosis, other cancer, cardiovascular disease, auto-immune disease, diabetes, pelvic inflammatory disease, other cancers)
    - Lifestyle data (e.g., smoking status, physical activity, sedentary activity, diet, talc use)
    - Medication use (e.g., hormone therapy, non-aspirin NSAIDs, aspirin, Tylenol/acetaminophen, statins, metformin)

- Previously linked geographic information system (GIS) data (e.g., census tract, exposure to pollution, green space, etc.)
- Other variables as approved by the OC3 steering committee

Ovarian cancer diagnosis characteristics

- Year/age of diagnosis
- Year of death
- Cause of death
- ICD code
- Tumor behavior (borderline or invasive)
- Morphology
- Histology
- Grade (abstracted from tumor registries or pathology reports)
- Stage
- Tumor dominance
- Measurements of tumor/ovary/adnexa on right and left sides
- Debulking status
- Chemotherapy
- Other tumor or treatment characteristics

Follow-up data

- Year/age of death
- Cause of death
- Year/age of last follow-up

Biologic specimen data

- Presence of biological specimens (e.g., blood, urine, cheek cells, tumor block)
- Biospecimen characteristics (e.g., date of sample collection, time of day of blood draw, fasting status)
- Genetic data (from WBCs or check cells, e.g., Oncoarray)
- Plasma/serum/urine biomarker results
- Tumor marker results

Limited Data Set (if applicable)

The Limited Data Set may include the following data elements:

- Month/year of enrollment questionnaire return
- Month/year of birth
- Month/year of diagnosis of ovarian cancer, other cancers, or other diseases
- Month/year of death
- Month/year of last follow-up
- Zip code for geographic information systems linkage

Moffitt shall use appropriate safeguards to prevent use or disclosure of the LDS other than as provided for by this Agreement. Moffitt may not use the LDS to identify the information or contact any individual who is the subject of any information contained in the LDS.

EXHIBIT B
(Research Project)

General description of the research goals of the OC3. The Ovarian Cancer Cohort Consortium (OC3) is an international consortium of cohort studies designed to address scientific aims important for understanding ovarian cancer risk, early detection, tumor heterogeneity, and prognosis. To achieve this goal, the OC3 is bringing together cohorts with ovarian cancer endpoints for pooled projects and building a focused group of ovarian cancer researchers to develop a comprehensive research approach that integrates questionnaire and pathology data with biomarkers, genetics, and tissue. The broad research goals of the OC3 are described below.

Examining risk factors by tumor subtype. One broad research goal of the OC3 is to examine whether associations of putative ovarian cancer risk factors differ by ovarian cancer subtype. Thus far, we have defined subtypes by tumor histology/grade, dominance (as a surrogate for cell of origin), and aggressiveness (tumors fatal within three years vs. all others). Risk factors that have been analyzed include contraception history, reproductive history, postmenopausal hormone therapy, family history of ovarian cancer, anthropometric variables, analgesic use, and several biomarkers, including androgens, C-reactive protein, and insulin-like growth factors. We observed unique patterns of risk factor associations across subtypes. Also, the strongest associations were observed for endometrioid and clear cell tumors (which often present as dominant tumors) as well as less aggressive disease phenotypes, while relatively few associations were observed for high-grade serous or highly aggressive tumors, which are the most common types of ovarian cancer. These results support that pre-diagnostic factors may influence ovarian cancer development and aggressiveness and that considering multiple tumor characteristics simultaneously may provide a clearer picture of disease etiology. Future research in the OC3 will continue to explore multi-faceted approaches to characterizing tumor heterogeneity (e.g., tumor immune marker profiles) and the associations of tumor subtypes with known and suspected risk factors.

Risk prediction. Although there are several known ovarian cancer risk factors, the ability to identify women at high risk remains limited. Thus, a major goal of the OC3 is to improve ovarian cancer risk prediction. On-going OC3 research is developing a risk prediction model for ovarian cancer overall. However, given the unique risk factor profiles of different ovarian cancer subtypes observed in previous OC3 research, and the poor performance of the model in predicting serous cancer (the most deadly subtype), the OC3 is focused on determining whether risk prediction models for ovarian cancer can be improved by accounting for differential associations by cancer phenotype. Research is currently underway to develop risk prediction models by tumor subtype.

Survival. Outside of surgery and chemotherapy, few factors have been associated with improved survival after diagnosis with ovarian cancer. An important goal of the OC3 is to conduct research to improve understanding of the impact of pre- and post-diagnosis exposures, and their interactions with tumor subtype, on survival. For example, we plan to characterize tumor immunosuppressive signatures related to poor prognosis, and examine their relationship with the trajectory of inflammation-related exposures before and after diagnosis. The long-term goal this research is to help focus efforts to develop novel cancer therapeutic strategies, and aid discovery of biomarkers for tailored treatment

Data repository expansion for future research aims. An important goal of the OC3 is to create an infrastructure with a core dataset of important variables for ovarian cancer epidemiology that will be available for future efforts to study ovarian cancer risk. Therefore, the OC3 plans to expand its data repository by obtaining funding to include dietary factors, updated exposure data from follow-up questionnaires, and biomarker information (both plasma/serum markers, including high-throughput omics data, and genetics) that can be used to identify new risk factors as well as early detection markers.

Overall, this systematic approach to address ovarian cancer heterogeneity in a large consortial effort will set new standards for evaluating ovarian cancer risk factors and biomarkers and thereby impact understanding of ovarian cancer etiology beyond the work conducted in OC3.

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Completed, on-going, and proposed statistical analyses in the OC3

Project
Known and putative risk factor associations by histology/grade
Risk prediction for epithelial ovarian cancer overall and by histologic subtype
Androgens and risk of ovarian cancer by tumor subtype
IGFs and risk of ovarian cancer by tumor subtype
NSAIDs and risk of ovarian cancer by tumor subtype
Known and putative risk factor associations by tumor aggressiveness
Known and putative risk factor associations by anatomic site
Known and putative risk factor associations by tumor dominance
Inflammatory risk factor associations by tumor subtypes
CRP and risk of ovarian cancer by tumor subtype
Lifetime ovulatory cycles and risk of ovarian cancer by tumor subtype
Caffeine/coffee/tea and risk of ovarian cancer by tumor subtype
Talc and risk of ovarian cancer
Inflammatory and psychosocial factors associated with long-term survival in serous ovarian cancer, overall and by tumor markers
Diabetes and risk of ovarian cancer by tumor subtype
Hypertension and risk of ovarian cancer by tumor subtype
Lifecourse adiposity and risk of ovarian cancer by tumor subtype
OncoArray (GWAS)
Proportion of subtype associations explained by known risk factors (methods paper)
Exposure-wide association study of high grade serous tumors
Telomeres in tumor tissue and survival
Immuno-proteomics for early detection – tumor-associated Abs (Taabs)
Epigenetics of ovarian cancer
CARRIERS project of high risk alleles

EXHIBIT C
(Data Access Agreement)
THIS EXHIBIT C IS ATTACHED HERETO AS A SAMPLE ONLY

This Data Access Agreement entered into on **EFFECTIVE DATE:** Click here to enter a date (the "Effective Date") by and between H. Lee Moffitt Cancer Center and Research Institute, Inc., a Florida non-profit corporation organized pursuant to Section 1004.43 of the Florida Statutes, located at 12902 Magnolia Drive, Tampa, Florida 33612 ("Moffitt") and **OUTSIDE PARTY'S NAME AND ADDRESS:** Click here to enter name and address of the Outside Party ("Institution"), and Moffitt and Institution are hereinafter each individually referred to as a "Party" and collectively as the "Parties."

WHEREAS, Moffitt is a National Cancer Institute designated comprehensive cancer center, a statewide research institute, and a national resource for basic science, clinical research, and interdisciplinary approaches to research and patient treatment;

The Ovarian Cancer Cohort Consortium (OC3) is an international consortium of cohort studies designed to address scientific aims important for understanding ovarian cancer risk, early detection, and survival in the context of tumor heterogeneity. The OC3 is part of the NCI Cohort Consortium, which is an extramural-intramural partnership to address the need for large-scale collaborations and provides the super-structure (but not funding) for managing the OC3. The OC3 currently has over 25 participating, on-going cohort studies and we expect there to be over 8,000 invasive ovarian cancer cases among more than 1.5 million women.

WHEREAS, the Institution has asked that Data (defined hereinafter) be accessed by the Institution, the OC3 Steering Committee has approved said access, and Moffitt is amenable to such access;

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein as covenants, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Institution and Moffitt agree as follows:

1. DEFINITIONS

1.1. The foregoing recitals are hereby incorporated herein by reference and acknowledged as true and correct. For the purposes of this Data Access Agreement, the following words and phrases shall have the following meanings:

a. "Data" shall mean **DATA DEFINITION:** Click here to add the description of the Data received from the Institution.

b. "Institution Investigator" shall mean **OUTSIDE PARTY INVESTIGATOR:** Click here to add the name of the Outside Party's Investigator who will supervise the Research Project under this Data Access Agreement on behalf of Institution.

c. "Research Project" means the research described in Exhibit A, which is incorporated herein in its entirety. The Research Project may only be changed or amended by prior written agreement by the Parties.

d. "Research Results" means all data and information, which are generated in the performance of the Research Project during the term of this Data Access Agreement.

e. "Third Party" means any party other than Moffitt, the Institution or their respective Affiliates.

2. ACCESS AND USE OF DATA

2.1. Access of Data. Moffitt shall allow access to Institution of the Data by a mutually agreed upon method, using a secure logon after providing proof of human subjects training. The Institution shall provide written proof to Moffitt that the principal investigator for each participating cohort has approved the Data access. Such access may occur multiple times while this Data Access Agreement is in full force and effect.

2.2. Compliance with Laws. Each Party shall comply with all laws, statutes, regulations and guidelines applicable to that Party and the conduct of the Research Project, including, but not limited to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, and seek appropriate Institutional Review Board, Ethics Committee, or other similar board review, when applicable, in performing its obligations under this Data Access Agreement. Institution may provide certain Protected Health Information (PHI) to Moffitt under a Limited Data Set (LDS) as defined under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). The LDS, if provided hereunder, shall be specifically spelled out in Exhibit A "Data".

2.3. Inadvertent Access to PHI. In the event Protected Health Information (PHI), as defined by HIPAA, as amended, is inadvertently accessed by the Institution in connection with this Data Access Agreement, the Institution will immediately notify Moffitt of such PHI, in accordance with Moffitt's instructions. Pending notification of the knowledge of any PHI, the Institution shall maintain the confidentiality of all Data (including the PHI) and use appropriate safeguards to prevent further access to, use, or disclosure of Data (including the PHI).

2.4. No Contact with Patients. Institution and Institution Investigator shall in no way attempt to identify or contact the patients associated with the Data. Furthermore, Institution and Institution Investigator shall not attempt to obtain or otherwise acquire any patient private identifiable information associated with the Data without the prior written consent of Moffitt.

3. PUBLICATION AND REPORTS

3.1. Joint Publication. Institution acknowledges that Moffitt obtained access to the Data and agrees that any publication or disclosure of the Research Results by the Institution shall be, in

collaboration with Moffitt, in the form of a jointly authored manuscript to be published in a scientific peer-reviewed journal, following the authorship guidelines set forth in Exhibit entitled "Ovarian Cancer Cohort Consortium (OC3) Publication Guidelines" approved by the OC3 steering committee.

3.2. Reporting Requirements. In consideration of Moffitt having provided access to the Data, Institution shall provide a summary of Research Results every six (6) months from the Effective Date to Moffitt and to the OC3 Steering Committee.

3.3. Final Report. Within thirty (30) days of the Research Project's completion or expiration or termination of this Data Access Agreement, whichever occurs first, Institution shall provide Moffitt and the OC3 Steering Committee with a final report which shall include a comprehensive summary of the Research Project undertaken and any Research Results or other accomplishments achieved in connection with the Research Project. The final submitted manuscript may constitute the final report.

4. WARRANTY DISCLAIMER, INDEMNIFICATION AND LIABILITY

4.1. Disclaimer. Access to the Data is provided AS IS without any WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, ACCURACY, RELIABILITY, COMPLETENESS, WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, MERCHANTABILITY, EXCLUSIVITY, RESULTS OBTAINED FROM USE, OR FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT.

4.2. Liability. Except to the extent prohibited by law, Institution assumes all liability for damages that may arise from its use of the Data. Moffitt will not be liable to the Institution for any loss, claim or demand made by the Institution, or made against Institution, by any other party, due to or arising from the use of the Data by the Institution, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Moffitt.

5. TERM AND TERMINATION

5.1. Term and Termination. This Data Access Agreement shall terminate upon completion of the Research Project or three (3) years from the Effective Date, whichever occurs first. Moffitt may terminate this Data Access Agreement on ten (10) days written notice should any human subject from whom Data was collected object to the use set forth herein, or should an Institutional Review Board or other comparable body object to the terms of this Data Access Agreement or the provision or use of the Data. The Research Project is completed when the Data has been published in a journal.

5.2. Cease Access to Data. Upon termination or expiration of this Access Data Access Agreement, whichever occurs first, the rights granted to Institution to use the Data shall terminate immediately, and Institution shall immediately cease accessing and using the data. Such determination shall be made in Moffitt's sole discretion.

6. MISCELLANEOUS

6.1. Electronic Signature. The Parties agree that this Data Access Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

IN WITNESS WHEREOF, the Parties have duly executed this Access _____ on the Effective Date set forth above.

H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.	SIGNATURE BLOCK: CLICK HERE TO INSERT THE OUTSIDE PARTY'S NAME
By: _____	By: _____
Name: _____	**SIGNATORY NAME:** Click Here to Insert Name of Outside Party's Signatory
Title: _____	Title: **SIGNATORY TITLE:** Click Here to Insert Title of Outside Party's Signatory.

EXHIBIT D
(Data Release Agreement)
THIS EXHIBIT D IS ATTACHED HERETO AS A SAMPLE ONLY

This Data Release Agreement entered into on **EFFECTIVE DATE:** Click here to enter a date (the "Effective Date") by and between H. Lee Moffitt Cancer Center and Research Institute, Inc., a Florida non-profit corporation organized pursuant to Section 1004.43 of the Florida Statutes, located at 12902 Magnolia Drive, Tampa, Florida 33612 ("Moffitt") and **OUTSIDE PARTY'S NAME AND ADDRESS:** Click here to enter name and address of the Outside Party ("Institution"), and Moffitt and Institution are hereinafter each individually referred to as a "Party" and collectively as the "Parties."

WHEREAS, Moffitt is a National Cancer Institute designated comprehensive cancer center, a statewide research institute, and a national resource for basic science, clinical research, and interdisciplinary approaches to research and patient treatment;

The Ovarian Cancer Cohort Consortium (OC3) is an international consortium of cohort studies designed to address scientific aims important for understanding ovarian cancer risk, early detection, and survival in the context of tumor heterogeneity. The OC3 is part of the NCI Cohort Consortium, which is an extramural-intramural partnership to address the need for large-scale collaborations and provides the super-structure (but not funding) for managing the OC3. The OC3 currently has over 25 participating, on-going cohort studies and we expect there to be over 8,000 invasive ovarian cancer cases among more than 1.5 million women.

WHEREAS, the Institution has asked that Data (defined hereinafter) be transferred to Institution, the OC3 Steering Committee has approved said transfer, and Moffitt is amenable to such transfer;

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein as covenants, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Institution and Moffitt agree as follows:

7. DEFINITIONS

7.1. The foregoing recitals are hereby incorporated herein by reference and acknowledged as true and correct. For the purposes of this Data Release Agreement, the following words and phrases shall have the following meanings:

a. "Data" shall mean **DATA DEFINITION:** Click here to add the description of the Data received from the Institution.

b. "Institution Investigator" shall mean **OUTSIDE PARTY INVESTIGATOR:** Click here to add the name of the Outside Party's Investigator who will supervise the Research Project under this Data Release Agreement behalf of Institution.

c. Research Project" means the research described in Exhibit A, which is incorporated herein in its entirety. The Research Project may only be changed or amended by prior written agreement by the Parties.

d. "Research Results" means all data and information, which are generated in the performance of the Research Project during the term of this Data Release Agreement.

e. "Third Party" means any party other than Moffitt, the Institution or their respective Affiliates.

8. TRANSFER AND USE OF DATA

8.1. Delivery of Data. Moffitt shall deliver to Institution the Data by a mutually agreed upon date using a secure method of data transfer. The Institution shall provide written proof to Moffitt that the principal investigator for each participating cohort has approved the Data transfer. Such delivery may occur in multiple installments while this Data Release Agreement is in full force and effect.

8.2. Compliance with Laws. Each Party shall comply with all laws, statutes, regulations and guidelines applicable to that Party and the conduct of the Research Project, including, but not limited to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, and seek appropriate Institutional Review Board, Ethics Committee, or other similar board review, when applicable, in performing its obligations under this Data Release Agreement. Institution may provide certain Protected Health Information (PHI) to Moffitt under a Limited Data Set (LDS) as defined under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). The LDS, if provided hereunder, shall be specifically spelled out in Exhibit A "Data".

8.3. Inadvertent Transfer of PHI. In the event Protected Health Information (PHI), as defined by HIPAA, as amended, is inadvertently disclosed to the Institution by Moffitt in connection with this Data Release Agreement, the Institution will immediately notify Moffitt and will return or destroy such PHI, in accordance with Moffitt's instructions. Pending return or destruction of any PHI, the Institution shall maintain the confidentiality of all Data (including the PHI) and use appropriate safeguards to prevent access to, use, or disclosure of Data (including the PHI).

8.4. No Contact with Patients. Institution and Institution Investigator shall in no way attempt to identify or contact the patients associated with the Data. Furthermore, Institution and Institution Investigator shall not attempt to obtain or otherwise acquire any patient private identifiable information associated with the Data without the prior written consent of Moffitt.

9. PUBLICATION AND REPORTS

9.1. Joint Publication. Institution acknowledges that Moffitt obtained the Data and agrees that any publication or disclosure of the Research Results by the Institution shall be, in collaboration with

Moffitt, in the form of a jointly authored manuscript to be published in a scientific peer-reviewed journal, following the authorship guidelines set forth in Exhibit entitled "Ovarian Cancer Cohort Consortium (OC3) Publication Guidelines" approved by the OC3 steering committee.

9.2. Reporting Requirements. In consideration of Moffitt having provided the Data, Institution shall provide a summary of Research Results every six (6) months from the Effective Date to Moffitt and the OC3 Steering Committee.

9.3. Final Report. Within thirty (30) days of the Research Project's completion or expiration or termination of this Data Release Agreement, whichever occurs first, Institution shall provide Moffitt and the OC3 Steering Committee with a final report which shall include a comprehensive summary of the Research Project undertaken and any Research Results or other accomplishments achieved in connection with the Research Project. The final submitted manuscript may constitute the final report.

10. WARRANTY DISCLAIMER, INDEMNIFICATION AND LIABILITY

10.1. Disclaimer. The Data is provided AS IS without any WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, ACCURACY, RELIABILITY, COMPLETENESS, WARRANTY OF FITNESS FOR PARTICULAR PURPOSE, MERCHANTABILITY, EXCLUSIVITY, RESULTS OBTAINED FROM USE, OR FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT.

10.2. Liability. Except to the extent prohibited by law, Institution assumes all liability for damages which may arise from its use of the Data. Moffitt will not be liable to the Institution for any loss, claim or demand made by the Institution, or made against Institution, by any other party, due to or arising from the use of the Data by the Institution, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Moffitt.

11. TERM AND TERMINATION

11.1. Term and Termination. This Data Release Agreement shall terminate upon completion of the Research Project or five (5) years from the Effective Date, whichever occurs first. Moffitt may terminate this Data Release Agreement on ten (10) days written notice should any human subject from whom Data was collected object to the use set forth herein, or should an Institutional Review Board or other comparable body object to the terms of this Data Release Agreement or the provision or use of the Data. The Research Project is completed when the Data has been published in a journal.

11.2. Return of Data. Upon termination or expiration of this Data Release Agreement, whichever occurs first, the rights granted to Institution to use the Data shall terminate immediately, and Institution shall immediately return or destroy any remaining Data to Moffitt, and such determination shall be made in Moffitt's sole discretion. Institution may delay destroying Data to comply with funding agency requirements if Research Project is funded by a government agency.

12. MISCELLANEOUS

12.1. Electronic Signature. The Parties agree that this Data Release Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

IN WITNESS WHEREOF, the Parties have duly executed this Data Release Agreement on the Effective Date set forth above.

H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.	SIGNATURE BLOCK: CLICK HERE TO INSERT THE OUTSIDE PARTY'S NAME
By: _____	By: _____
Name: _____	**SIGNATORY NAME:** Click Here to Insert Name of Outside Party's Signatory
Title: _____	Title: **SIGNATORY TITLE:** Click Here to Insert Title of Outside Party's Signatory.

EXHIBIT E
(Guidelines for proposing a new analysis using OC3 data)
THIS EXHIBIT E IS ATTACHED HERETO AS A SAMPLE ONLY

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).

1. Email the co-chairs of the steering committee (Drs. Shelley Tworoger: shelley.tworoger@moffitt.org and Nicolas Wentzensen: wentzenn@mail.nih.gov) 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 Dr. Tworoger and will be posted on the OC3 website in the future. They will 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 https://cedcd.nci.nih.gov/ 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.
2. After the initial conversations, please submit a proposal to the OC3 Steering Committee for approval at a steering committee meeting. Please use the NCI Cohort Consortium form at https://epi.grants.cancer.gov/Consortia/proposal.pdf (though note that studies using existing OC3 infrastructure do not have to submit to the full secretariat). Information about criteria for approval is at https://epi.grants.cancer.gov/Consortia/cohort_pooling.html.
3. 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.
4. 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.

5. 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 de-identified 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.
6. 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 Monday from 10-11am Eastern time.

Potential problems that may arise

1. What if two investigators propose the same project?

   If two investigators propose the same analysis within 6 months of each other, the steering committee will put the two investigators in contact with each other to see if they can work together to develop a joint proposal. However, if attempts to develop a joint proposal are unsuccessful, the first investigator to propose the analysis will be given precedence.
2. How long does each investigator have between proposing the analysis and getting started on the analysis?

   The status of all approved analysis proposals will be reviewed annually to assess progress toward securing funding for the analysis and toward completing the analysis and manuscript. If the steering committee determines that an investigator has not made sufficient progress on an analysis proposal within 3 years of approval, the steering committee will have the option of allowing another OC3 member to propose that topic.

EXHIBIT F
(Ovarian Cancer Cohort Consortium (OC3) Publication Guidelines)
THIS EXHIBIT F IS ATTACHED HERETO AS A SAMPLE ONLY

Guidelines for authorship and publication have been developed to ensure that results published by the Ovarian Cancer Cohort Consortium (OC3) are timely and of the highest quality, that the research projects are effectively coordinated, and that the individual researchers and centers that contribute to the projects are given fair and appropriate credit. These guidelines have been developed and approved by the OC3 Steering Committee. We anticipate that these guidelines will change over time to reflect the needs and experience of the OC3.

13. General Principles

14. One of several objectives of the Cohort Consortium is to foster multidisciplinary collaboration among genomic researchers, epidemiologists, biostatisticians, and other scientists in large-scale prospective studies of ovarian cancer. We anticipate that the OC3 will generate many high impact publications. Recognizing the contribution of a large number of scientists to the collection and analysis of data in the ovarian cancer project, the OC3 has developed the following guidelines to coordinate and facilitate publications derived from this collaboration.

15. Authorship

The general approach to authorship will be inclusive rather than exclusive, although it should meet the criteria proposed by the International Committee of Medical Journal Editors (ICMJE) (Annals of Int Med 1988; 258-304). The ICMJE specified that authorship credit should be limited to those who contribute substantially to all of the following:

a) conception and design, or acquisition of data, or analysis and interpretation of data:
b) drafting the article or revising it critically for important intellectual content:
c) final approval of the version to be published.

According to the ICMJE, none of the above contributions is sufficient by itself to justify authorship. However, in the case of the OC3, multiple centers have contributed to data collection by providing questionnaire and follow-up data on cohorts and/or by contributing to the statistical analyses. A center is defined as an institution that is participating in the OC3, while a cohort is defined as an individual study that resides at a center. Note that some centers will have multiple participating cohorts.

It is proposed that each cohort that participates in a particular analysis will have 2 co-authors (an author may represent more than one cohort), not counting the writing group, listed on that particular manuscript. Cohorts can request that the steering committee make an exception if more than two authors are required for certain cohorts. This approach is compatible with the ICMJE view that, "A test to help determine whether a center should be included in the author list is 'could the work have been completed without the center'? If not, then each center that provided data should be represented in the authorship."

The author list will begin with the members of the writing team (except the senior author). Listed after the writing team will be all other researchers (in alphabetical order) who meet the criteria for authorship. The last author will be the senior researcher responsible for that particular

manuscript/project. Additionally, if the journal permits it, the writing group should be specified in a footnote or acknowledgement.

Each writing team will consist of five or six researchers who have worked on a specific exposure of interest or proposal and/or been most active in developing the OC3. When the senior or first author circulates a proposal to the participating cohorts for approval, he/she should also solicit participation on the writing team. Cohorts participating in the project can request that an individual from that cohort be on the writing team. The person who submitted the proposal will assemble the writing team from among those who expressed interest, spreading membership across the cohorts as much as possible. One researcher (generally determined by the senior researcher) on the writing team will take primary responsibility for data analysis and writing, and will be considered first author. The senior researcher will be the person who submitted the original proposal or is the mentor of the person who submitted the proposal; their role is to edit the paper and accept full responsibility for its content. Either the lead or senior investigator will serve as the corresponding author. The remaining order in which other authors on the writing team will be listed will be determined based on contribution to the writing team.

The duties of the writing team are as follows:

1. Advice on conducting data analysis
2. Assistance/insight in interpreting results
3. In-depth reading and feedback on draft manuscripts prior to circulation to the full group

These duties should be completed in a timely fashion to ensure that an analysis is completed within the timeframe that the OC3 has put forward (see below).

If major imbalances appear between groups, and if these imbalances do not fairly reflect the level of contribution, the authorship lists will be negotiated with the Steering Committee.

Final decisions about who should be considered full authors on collaborative papers will be made by members of the Steering Committee, not by the journal or PubMed/NML. Other mechanisms for acknowledgement are discussed below.

(a) Acknowledgement of Other Contributions

All papers will acknowledge the source of funding as follows:
Dept. of Defense Ovarian Cancer Research Program (OC110197)

Any other sources of funding for participating studies will also be recognized after acknowledgement of the Consortium funding source. The Steering Committee will develop a list of acknowledgements for each cohort/center and post it on the website.

(b) Manuscript preparation, review, and approval

A major challenge in large collaborative undertakings is to ensure timeliness and effective coordination in developing manuscripts. Given the funding period, timeliness is particularly important. Accordingly, we will establish a priority list of manuscripts, mechanisms for writing and incorporating feedback, and expected dates for submission that respects competing demands on collaborating members but maintains a pace that is appropriate for the priority of the undertaking.

The following checklist is proposed to encourage each writing team to designate responsibilities and to establish a timeline for manuscript development. A number of these steps can be addressed simultaneously rather than sequentially.

- Clearly delineate the role(s) of each member of the writing team
- Work with data coordinating center to complete basic analyses; two possible options are: 1. The data coordinating center conducts all analyses under the direction of the first and senior authors or 2. The person conducting the analyses will be granted access to the data coordinating center computer system. This will require modifying or setting up a new DUA 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. There is a possible option for sending a data set to the investigator for analysis, but is dependent on agreements between the data coordinating center and the individual cohorts.
- Develop outline of main analyses, table shells, and selection and format of figures
- Identify and conduct secondary analyses
- First draft of title, abstract, results, tables, & figures
- First draft of methods
- Complete literature review and draft of introduction and discussion.
- First draft of full manuscript
- Incorporate secondary analyses
- Review and revision by authors
- Review by Consortium

We propose the following guidelines for manuscript review by the overall Consortium.

- Each of the contributing centers or group of cohorts will identify a contact for coordinating their input to any given manuscript (i.e., the designated contributor). This contact is also responsible for obtaining any signatures or other paperwork necessary for final submission to the journal.
- Preliminary tables of results will be circulated along with the outline of the paper. When a draft manuscript is circulated, co-authors are expected to provide feedback within 2 weeks of receiving the draft. Once the first author has received feedback from the group, he/she has two weeks to incorporate the feedback and produce an updated version of the manuscript.
    - The submission of comments to the first author should be coordinated by the designated contributor from each cohort group, combining input before forwarding to the writing team.
    - Ideally comments will be ranked into two levels, (a) essential analytic and factual changes, and (b) possible grammatical and other editorial changes
    - Revisions of the manuscript will specifically address responses to the category (a) items noted above. (However, changes in category (b) above will also be accommodated as appropriate in the manuscript.)
- Revised manuscripts will be circulated to all co-authors with the understanding that a timely response is essential to the overall success of this research undertaking. Any further revisions should be returned to the first author within 2 weeks.
- The final manuscript will be submitted within six to eight weeks after any final comments are sent to the first author. This will allow for all necessary cohort-specific review processes

(which will be listed on the website and in the table below) that must occur before submission. The first and senior authors are responsible for ensuring that these review processes are met.

- If comments are not sent within the appropriate time frame, these additional suggestions might be incorporated during the peer review process.
- If the journal that accepts the manuscript does not automatically deposit the manuscript into PubMed Central, the first author must take responsibility for doing so.

For this overall process to work smoothly, the writing team and all co-authors will be placing very high priority on the collaborative manuscripts. Clear communication and quick responses will be essential for success.