PROTOCOL TITLE:

Northwestern Ovarian Cancer Early Detection & Prevention Program: A Specimen and Data Study

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1.0 Objectives

The aim of the Northwestern Ovarian Cancer Early Detection & Prevention Program (NOCEDPP): A Specimen and Data Study is to establish an effective, early detection program employing state-of-the-art science and technology in collaboration with other nationally recognized clinicians and scientists. This proposed research study will foster collaboration between clinicians and scientists that will facilitate the rapid identification of a set of molecular, biochemical, functional, and genetic markers which can be employed to effectively detect and manage ovarian cancer and other gynecological malignancies.

- To identify and develop highly sensitive and specific tumor markers for the detection and management of ovarian cancer and other gynecological malignancies.
- To identify new prevention approaches and therapies.
- To identify measures to improve the quality of life for women at increased risk for developing ovarian cancer and for women diagnosed with ovarian cancer.

2.0 Background

In the United States more women die annually from ovarian cancer than all other gynecologic malignancies combined, predominantly because the majority of women continue to be diagnosed with disseminated epithelial ovarian carcinoma (Stage III or IV). However, if ovarian cancer is detected when disease is confined to the ovary (Stage I) the 5-year survival of approximately 93%, requires less radical surgery and often does not require adjuvant chemotherapy. According to the American Cancer Society, the incidence of ovarian cancer decreased by 0.7% per year between 1985 and 2003. Of the women who will develop ovarian cancer in their lifetime, 18.8% are between the ages of 45 and 54. Twenty-one percent (21%) are between the ages of 55 and 64. For women who have one close relative with ovarian cancer, the lifetime risk of developing the disease is increased to approximately 4%. In families where the pattern of ovarian cancer and possibly other associated cancers (i.e. breast cancer) appears to be inherited, the chance for a woman to develop ovarian cancer increases up to 54%.

Also, women with hereditary syndromes have other associated risks. Hereditary Breast and Ovarian Cancer syndrome is most often caused by an autosomal dominant mutation in the *BRCA1* or *BRCA2 (BRCA1/2)* genes. Female carriers of a *BRCA1/2* mutation have up to 87% lifetime risk for developing breast cancer and up to 54% lifetime risk for developing ovarian cancer. *BRCA1/2* mutations are also associated with a somewhat elevated risk for prostate, melanoma, pancreatic, gastric, and male breast cancer. Hereditary non-polyposis colorectal cancer (HNPCC), aka Lynch syndrome is an autosomal dominant hereditary cancer syndrome. Individuals with HNPCC have an approximate 80% lifetime risk of developing colon cancer, up to 60% risk for endometrial cancer, up to 19% risk for gastric cancer, and up to 12% risk for ovarian cancer. There is also an increased risk for cancers of the hepatobiliary tract, urinary tract, small bowel, brain, and skin. Less than 10-15% of all patients diagnosed with ovarian cancer have an inherited disease.

3.0 Inclusion and Exclusion Criteria

The study population will be derived from **two** separate populations. Study subjects will be recruited from the clinical program with the same name and from the clinical practices of co-investigators. Patients participating in the NOCEDPP clinical program may choose not to participate in the research study.

NOCEDPP Population

Eligible subjects will have at least one of the following risk factors:

- One or more first degree relatives (mother, sister, daughter) with ovarian cancer, primary peritoneal cancer or fallopian tube cancer
- One first degree relative, or two or more second degree relatives diagnosed under the age of fifty with either ovarian, primary peritoneal, fallopian tube, and/or pancreatic cancer who have tested positive for hereditary cancer syndrome or have increased risk as deemed by a certified genetic counselor
- A personal or family history of a hereditary cancer syndrome that includes an increased risk of gynecologic cancer
- Increased risk as deemed by a certified genetic counselor

Gynecologic or Gynecologic Oncology Population

Eligible subjects will have at least one of the following:

- A diagnosis of a reproductive cancer, including borderline tumors (cervical cancer excluded).
- Planned risk-reducing salpingo oophorectomy

Age Requirement

- Women must be between the ages of 18 and 80.

Consent

- Women must have the ability to understand and the willingness to sign a written informed consent document and authorization permitting the release of personal health information.

Pregnant women can be consented to the study. We will not be including children or prisoners in this study.

4.0 Study-Wide Number of Subjects

4000 subjects are expected to participate in this study.

5.0 Study-Wide Recruitment Methods

Potential research subjects contact the NOCEDPP directly after seeing the informational website, or their physician refers them to the clinic and research program. The NOCEDPP research coordinator will discuss the program with the potential subject and review eligibility criteria. If subject is eligible to participate, the coordinator will further discuss the research study. If interested, a consent is mailed prior to their clinic visit. The patient will then meet with the study investigator/physician and the research coordinator at the first visit. The patient has the opportunity to ask questions, and if, after all questions are answered, and the patient remains interested, a consent will be signed. A copy is given to patient.

Patients will be recruited via the following:

- Websites
- Program and Referral letters
- Brochures
- Newsletter

6.0 Multi-Site Research – N/A

7.0 Study Timelines

The study will remain open until patient numbers have been accrued and data analysis is complete.

8.0 Study Endpoints

The primary study end points are Identification and development of highly sensitive and specific tumor markers for the detection and management of ovarian cancer and other gynecological malignancies.

The secondary primary endpoints are Identification of new prevention approaches and therapies. Identification of measures to improve the quality of life for women at increased risk for developing the disease and for women diagnosed with ovarian cancer.

There are no designated primary or secondary safety endpoints for this study.

9.0 Procedures Involved

This study will collect clinical specimens (including but not limited to blood, tissue, urine, ascites, and pleural fluid) and relevant clinical information. The NOCEDPP, in collaboration with other nationally recognized clinicians and scientists, will analyze clinical specimens for molecular, biochemical, functional, and genetic markers that can be

employed to effectively detect and manage ovarian cancer. Markers identified include, but are not limited to: lysophosphatidic acid, LPA; epidermal growth factor receptor (EGFR/ErBb), soluble urinary-type plasminogen activator (suPAR); and other matrix metalloproteinases (MMPs).

Collaborators and Biomarker Development Laboratories include but are not limited to the following: National Cancer Institute/EDRN Investigators, Abcodia, Inc, and Atairgin Technologies, Inc

Potential study subjects will be screened to determine eligibility. Potential NOCEDPP clinic participants will be sent an introductory letter and a copy of the informed consent for the research study to review prior to the appointment. The day of the patient's appointment, the physician or PI will discuss the research and consent the patient if they are still interested.

The research participants may have samples of blood, tissue, or body fluids (such as ascites, pleural fluid or urine), or any combination of the aforementioned samples, obtained to develop tumor markers to detect early stage or recurrent ovarian cancer.

Subject data will be retrieved through the Enterprise Data Warehouse (EDW). Research investigators will review the information in the electronic medical record, EPIC, to determine those who match the inclusion criteria. EPIC medical records will be identified by the patient's name and medical record number.

Participants from the NOCEDPP population and from the Gyne or Gyne/Onc population may be asked to complete a combination of questionnaires such as:

- Impact of Events Scale (IES),
- Profile of Mood States (POMS),
- Functional Assessment of Cancer Therapy Scale, General (FACT-G)
- Medical Outcomes Study, Short Form-36 (SF-36)
- CES-D
- State/Trait Anxiety Inventory
- Cope Scale
- Patient Satisfaction Questionnaire

As necessary, Psychological, Social, and Physical Well-being Studies may be added to or deleted from the above list.

These questionnaires will be completed to examine psychological functioning among women enrolled in a comprehensive ovarian cancer early detection program who are at increased risk of developing ovarian cancer as compared to those women currently diagnosed with ovarian cancer. Psychosocial evaluation will be completed on 4000 participants, 2000 from the NOCEDPP population and 2000 from the Gyne or Gyne/Onc population. Each clinical site will be asked to administer these studies to participants. Participants may be asked to meet with a clinical psychologist or a research assistant for a brief interview (15-30 minutes in length) immediately prior to their appointments. Follow-up assessments will be completed at variable time intervals. Questionnaires may be administered in person, by mail, and/or by telephone. If participants fail to respond to questionnaires that are sent by mail, they will be made aware that they will be contacted by telephone and asked to complete the questionnaires over the phone.

Socio-demographic data and information pertaining to personal and/or family history of ovarian cancer will be obtained from subjects' clinical records and in person interviews.

10.0 Data and Specimen Banking

The consent that will be used to obtain blood and/or urine on women who decide to participate in this research study is titled **"NU 99G8: Northwestern Ovarian Cancer Early Detection & Prevention Specimen and Data Collection Study-Women at Increased Risk (NOCEDPP population)"**.

The consent that will be used to obtain ovarian tissue from women having a prophylactic oophorectomy is titled **"NU 99G8: Northwestern Ovarian Cancer Early Detection & Prevention Specimen and Data Collection Study-Surgical Subjects for Tissue and/or Fluid Donation"**.

Blood Specimens:
Approximately 20 milliliters of blood will be withdrawn from each study participant at the time of each clinic visit which will occur one to four times annually, based on risk factors for developing cancer. The blood will be tested for the presence of experimental serum and plasma tumor markers. The blood may also be tested for the presence of tumor marker CA-125. CA-125 is a protein that circulates in the blood and may be elevated in women with ovarian cancer, as well as, many other conditions such as pregnancy and liver disease. The results of the experimental serum and plasma tumor markers will not be reported to the study participant or her physician since they are experimental with uncertain meaning.

Urine Specimens:
Urine specimens may be obtained from the NOCEDPP population to study potential tumor markers in urine for ovarian cancer and gynecological malignancies. Urine specimens may be obtained from each study participant at each semi-annual visit.

Ovarian Tissue:
Ovarian tissue obtained at the time of surgery will be from women found to be appropriate for prophylactic BSO. These specimens are to be critically evaluated for evidence of atypical hyperplasia or occult malignancy, as 40% of the NOCEDPP population at Northwestern has been found to have atypical hyperplasia while none have had a malignancy.

Women deemed appropriate for prophylactic BSO, who are participants in the NOCEDPP, may continue to be followed per clinical standard of care recommendations for continued participation with the experimental blood test evaluations.

Tissue will be collected after routine pathologic evaluation is completed. This tissue would normally be discarded. No additional tissue will be surgically removed for research purposes.

Genetic Assessment:
Individuals in NOCEDPP receive a consultation with a genetic counselor. The genetics consultation, that is a standard part of the clinical program, provides individuals with an estimate of their cancer risk. The genetic counselor will work with individuals who request genetic testing. Genetic testing will not be performed as part of the NOCEDPP clinical or research program.

Gynecologic or Gynecologic Oncology Population

The consent that will be used to obtain blood is titled **"NU 99G8: Northwestern Ovarian Cancer Early Detection & Prevention Specimen and Data Collection Study-Women with a Suspected or Diagnosed Gynecological Condition".**

Blood Specimens:
Approximately 20 milliliters of blood will be withdrawn from each study participant at each visit. No more than approximately 40 milliliters of blood will be drawn over a one-month period. The blood will be tested for the presence of experimental serum and plasma tumor markers. The amount of blood for experimental purposes will be in addition to the routine blood work (including a CA-125) ordered by the physician. If routine blood work is not ordered by the physician, no experimental blood work will be withdrawn. Only the CA-125 result will be reported to the study participant, as the experimental serum and plasma tumor marker results are experimental with uncertain meaning.

Tissue and Body Fluid Specimens:
Tissue and body fluid, such as urine, ascites, and pleural fluid, will be collected from the Gyne or Gyne/Onc population for molecular, genetic, biochemical, and pathological analysis. Tissue and body fluids (or any combination of these samples) may be obtained at the time of any surgical intervention or during routine PAP smears. Body fluids, such as ascites and/or pleural fluid may be obtained at the time of any procedure(s) intended to aspirate or drain such fluids (such as a pararacentesis and/or thoracocentesis). Urine specimens may be obtained from the Gyne or Gyne/Onc population to study potential tumor markers in urine for ovarian

cancer and gynecological malignancies. Urine specimens may be obtained from each study participant at each visit.

11.0 Data and Specimen Management

A signed informed consent and authorization for research document must be obtained from all study participants prior to the initiation of any study procedures. Each study participant will receive a copy of the informed consent.

Every consented study participant will be assigned a subject number from the Subject Identification Log (Appendix 2). Subject numbers should be assigned sequentially. No subject number should be skipped. Subjects will be identified as follows: an abbreviation of the clinical site, i.e. NW denotes Northwestern University, followed by a four digit number beginning with 0001. NW-0001 will be the first subject number assigned at Northwestern, followed by NW-0002, NW-0003 etc. Once a study participant has received a subject number, that number will always identify the patient even if more than one type of specimen (such as blood, tissue, ascites, pleural fluid, urine) is obtained.

Blood Collection

Approximately 20ml of blood will be withdrawn from each NOCEDPP study participant at each visit.

- Approximately 20 ml of blood will be withdrawn from each study participant in the Gyne or Gyne/Onc population when routine blood tests are being done.
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Blood Identification

Assign each tube of blood collected from a study participant a sample number**.** Sample numbers should be assigned sequentially. No sample number should be skipped. Each tube should be labeled with the NW identification number and sample number.

Blood Processing for Serum

- After collection of sample, invert the tubes several times to mix well, and let the tubes stand in an upright position, at room temperature, for at least 30 min to allow clotting.
- Transport the specimen to the laboratory for processing.
- Centrifuge the specimen at the specified speed for the stated period of time.
- If necessary, transfer the centrifuged specimen in refrigerator for the stated temperature and period of time.
- Transfer supernatant from each serum tube to one, 3cc cryovial.
- Label each cryovial with one pre-numbered cryo-tag. Cryo-tags must be attached to clean, dry cryovials before they are frozen. All cryo-tags must be accounted for on the tracking log. Labels that are damaged, lost, or not used, should be documented as such on the tracking log.
- Store vials at least at -20°C.

Blood Processing for Whole Blood

- After collection of sample, invert the tubes several times to mix and let the tubes stand in an upright position at room temperature.
- Transport the specimen to the laboratory for processing.
- Centrifuge the specimen at the specified speed for the stated period of time.
- If necessary, transfer the centrifuged specimen in refrigerator for the stated temperature and period of time.
- Transfer supernatant from each EDTA tube to one, 3cc cryovial.
- Label each cryovial with one pre-numbered cryo-tag. Cryo-tags must be attached to clean, dry cryovials before they are frozen. All cryo-tags must be accounted for on the tracking log. Labels that are damaged, lost, or not used, should be documented as such on the tracking log.
- Store vials at least at -20°

Blood Processing for Plasma

- After collection of sample, invert the tubes several times to mix and let the tubes stand in an upright position at room temperature.
- Transport the specimen to the laboratory for processing.
- Centrifuge the specimen at the specified speed for the stated period of time.
- If necessary, transfer the centrifuged specimen in refrigerator for the stated temperature and period of time.
- Transfer supernatant from each EDTA tube to one, 3cc cryovial.
- Label each cryovial with one pre-numbered cryo-tag. Cryo-tags must be attached to clean, dry cryovials before they are frozen. All cryo-tags must be accounted for on the tracking log. Labels that are damaged, lost, or not used, should be documented as such on the tracking log.
- Store vials at least at -20°C.

TISSUE COLLECTION, IDENTIFICATION and PROCESSING PROCEDURES

Tissue Collection and Processing

Ideally, we would like to obtain ovarian tissue pieces from all ovaries (malignant and benign) removed by the physicians and in the cases of ovarian cancer, would like to obtain tissue pieces from as many metastatic sites as possible. Specimens need to be placed in saline **immediately** after tissue resection. The amount of tissue and the sites from which it is obtained is at the discretion of the Attending Physician.

Tissue specimens not needed for pathological evaluation will need to be cut in approximately ½ cm x ½ cm pieces. The ½ cm x ½ cm pieces are placed in cryovial(s) and immediately placed in OCT. Only 2-3 pieces of tissue should be placed in each cryovial. Tissue from different sites requires different cryovials for storage.

Cervical cells will be obtained from the brush and spatula that are discarded after PAP smears are performed.

Store vials/slides at least at -20°C.

Tissue Identification

Each cryovial/slide will be assigned a sample number. All sample numbers must be accounted for on the tracking log. Sample numbers should be assigned sequentially with no number skipped. Each cryovial should be marked with the sample number and NW number.

BODY FLUID COLLECTION, IDENTIFICATION and PROCESSING PROCEDURES

Body Fluid Collection

Once body fluid is obtained, place it in an appropriate container. There is no need to add transfer medium, OCT etc. Transport the labeled body fluid specimen(s) to the laboratory for processing. If unable to transport the body fluid specimen(s) to the laboratory, immediately place it in the refrigerator until it becomes possible to do so. (May refrigerate the specimens for up to 24 hours.)

Body Fluid Identification

A body fluid sample number should be assigned and accounted for on the tracking log. The containers should be labeled with the NW identification number and sample number.

Body Fluid Processing

Ascites

- Once the ascites fluid is in the lab, divide fluid into 50 ml sterile centrifuge tubes. Use a maximum of 5 sterile centrifuge tubes. Remaining ascites can be divided fluid into 200 ml sterile tubes/containers.
- Store tubes at least at -20°C.

Urine

- Once the urine specimen is in the lab, transfer urine to 15 ml vials.
- Store vials at least at -20°C.

Pleural Fluid

- Once the pleural fluid is in the lab, divide fluid into 50 ml sterile centrifuge tubes. Use a maximum of 5 sterile centrifuge tubes. Remaining pleural fluid can be stored in bulk.
- Store tubes at least at -20°C.

Subject Identification: Once a study participant has received a subject number, that number will always identify the study participant even if more than one type of specimen is obtained. The subject's NW number, name, date of birth, phone number, address, which consent was signed by the participant, the date the consent was signed, and if a participant has refused further participation will be entered into the Northwestern Oncology Trial Information System (NOTIS) of the Robert H. Lurie Comprehensive Cancer Center.

Specimens: The subject's NW number and sample numbers will be maintained in the Pathology Core Facility specimen tracking database.

Clinical data: Demographic and clinical data collected from the subject's medical records and questionnaires will be maintained in a password-protected software program with access limited to study investigators and research team.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

All study participant information will be stored in a password-protected computer software and in locked file cabinets in the PI's Division Academic office area with access limited to research investigators and personnel.

Records will be kept confidential. During their required reviews, representatives of the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) may have access to medical records that contain the identity of a study participant. Study participants will not be personally identified in any publication having to do with this research study.

13.0 Withdrawal of Subjects*

Subjects will be withdrawn from research without their consent if the patient is found to not meet the inclusion criteria. Their data will be removed from the database and their samples will be destroyed.

Subjects that choose to withdraw from research will have their data removed from the database and their remaining specimens may be destroyed (if requested by the subject), and no further data or specimens will be collected.

14.0 Risks to Subjects*

The potential risks are:

- Those associated with a potential breach of confidentiality. To minimize this risk, questionnaires and specimens will be labeled with a unique patient de-identified study number.
- Those associated with questions that may be upsetting or cause emotional distress. To minimize this risk, patients are given the option to not answer questions that they do not feel comfortable with.

- Those associated with taking blood include a bruise at the point where the blood is taken, redness and swelling of the vein and infection. Care will be taken to avoid these complications.

- Those associated with being identified due to the uniqueness of DNA.

15.0 Potential Benefits to Subjects

There may be no direct benefit to the subject by participating in this research project. However, use of blood specimens may contribute to researchers' understanding of cancers which may, in turn, help others in the future. There is no guarantee that the procedures involved in this research study will detect early stage ovarian cancer or recurrent ovarian cancer.

16.0 Vulnerable Populations

The research may recruit pregnant women

17.0 Community-Based Participatory Research – N/A

18.0 Sharing of Results with Subjects

Any results conducted on specimens will not be shared with the subjects since this is considered research with uncertain meaning. Data collected from medical records are readily available to the patient via the Northwestern Health Information System (medical records).

19.0 Setting

Potential research subjects contact the NOCEDPP directly after seeing the informational website, or their physician refers them to the clinic and research program. The NOCEDPP research coordinator will discuss the program with the potential subject and review eligibility criteria. If subject is eligible to participate, the coordinator will further discuss the research study. If interested, a consent is mailed prior to their clinic visit. The patient will then meet with the study investigator/physician and the research coordinator at the first visit. The patient has the opportunity to ask questions, and if, after all questions are answered, and the patient remains interested, a consent will be signed. A copy is given to patient.

Patients will be recruited via the following:

- Websites
- Program and Referral letters
- Brochures
- Newsletters

20.0 Resources Available

All study investigators are physicians with the clinical knowledge to perform this research. Only individuals listed on the IRB application will have data access. The statistical analysis will be performed by an experienced researcher who has completed statistical analyses to other research studies. The researchers have a relationship with consulting PhD-level academic statisticians as needed. All clinical personnel are trained to perform all procedures associated with this study.

21.0 Prior Approvals – N/A

22.0 Recruitment Methods

The study population will be derived from **two** separate populations. Study subjects will be recruited from the clinical program with the same name and from the clinical practices of co-investigators. Patients participating in the NOCEDPP clinical program may choose not to participate in the research study.

Potential research subjects contact the NOCEDPP directly after seeing the informational website, or their physician refers them to the clinic and research program. The NOCEDPP research coordinator will discuss the program with the potential subject and review eligibility criteria. If subject is eligible to participate, the coordinator will further discuss the research study. If interested, a consent is mailed prior to their clinic visit. The patient will then meet with the study investigator/physician and the research coordinator at the first visit. The patient has the opportunity to ask questions, and if, after all questions are answered, and the patient remains interested, a consent will be signed. A copy is given to patient.

Patients will be recruited via the following:

- Websites
- Program and Referral letters
- Brochures

- Newsletters

23.0 Local Number of Subjects

5000 subjects are expected to participate in this study.

24.0 Confidentiality

All study participant information will be stored in a password-protected computer software and in locked file cabinets in the PI's Division Academic office area with access limited to research investigators and personnel.

Records will be kept confidential. During their required reviews, representatives of the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) may have access to medical records that contain the identity of a study participant. Study participants will not be personally identified in any publication having to do with this research study.

Data will be stored for 7 years after the study is terminated and all manuscripts are published. At the time, paper files will be shredded and electronic data will be deleted.

Data and biological samples from this study may be shared with clinical affiliates, including but not limited to the Northwestern Medical Group (NMG), Northwestern Medical Group (NMG), Northwestern Memorial Hospital, Prentice Women's Hospital (PWH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) and/or other University research centers outside Northwestern University, commercial entities, or international organizations.

Before sharing any patient data or biological samples with other researchers conducting separate research, all investigators will need to obtain approval from the NU IRB or the IRB of their institution. for any such collaboration and before any data or samples obtained under this protocol are shared. Sample requests will require an executed Material Transfer Agreement (MTA) with other researchers conducting separate research.

To facilitate collaborations, a Data Sharing Process standard operating procedure (SOP) and application was created to ensure HIPAA and IRB compliance. Each request will be reviewed by the internal Data Use Committee comprised of the lead research coordinator and principle investigator(s).

25.0 Provisions to Protect the Privacy Interests of Subjects

All study participant information will be stored in a password-protected computer software and in locked file cabinets in the PI's Division Academic office area with access limited to research investigators and personnel.

Records will be kept confidential. During their required reviews, representatives of the National Cancer Institute (NCI) and the Food and Drug Administration (FDA) may have access to medical records that contain the identity of a study participant. Study participants will not be personally identified in any publication having to do with this research study.

Data will be stored for 7 years after the study is terminated and all manuscripts are published. At the time, paper files will be shredded and electronic data will be deleted.

Study subjects are assigned a unique number which is used on all specimen samples. Study investigators and research staff will serve as the gatekeepers and have access to subject identifiers.

26.0 Compensation for Research-Related Injury

The study is of minimal risk to subjects, so there will be no compensation for research-related injuries.

27.0 Economic Burden to Subjects

The research procedures will not be of any economic burden to the subjects.

28.0 Consent Process

Potential study subjects will be identified from practices of physicians at Northwestern. The study name and number may appear on certain approved websites, such as Northwestern, with number to contact for additional information. The subject will be able to take the consent form home to discuss participation with family. To further assist the subject with understanding the details of participation in their research and their subject rights, time will be arranged for follow-up discussion or a conference with the subject and family members. If the patient then agrees to research, a consent will be signed and a copy with be given to the patient for their record keeping.

Following is a list of the two populations, the type of sample that may be obtained from each population and the **status** to use for each type of sample.

NOCEDPP Population:

Sample Type	***Status***
Blood	NOCEDPP clinic visits
Urine	NOCEDPP clinic visits

Gyne or Gyne/Onc Population:

Sample Type	***Status***
Blood	Pre surgery-pre treatment
	Post surgery-pre treatment
	Post surgery- current treatment
	Post surgery-post treatment-recurrent disease-pre treatment
	Post surgery-post treatment-recurrent disease-current treatment
	Post surgery-post treatment-follow up appointment- no evidence of disease
	Intra-op
Tissue (such as ovarian, endometrial, omentum)	Intra-op
Ascites	Intra-op/Procedure (such as paracentesis)
Pleural Fluid	Intra-op/Procedure (such as thoracentesis)
Urine	Pre-op/intra-op
	Post-surgery visits

Patients may choose not to participate in this research study and still be seen in the NOCEDPP clinic.

29.0 Process to Document Consent in Writing

We will follow SOP: Written Documentation of Consent (HRP-091).

30.0 Drugs or Devices – N/A