Protocol Title: A Novel Method of Screening for Ovarian Cancer Using Gynecologic Fluids and Mucus

Target Population: Women with an Adnexal Mass or suspicion of Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Summary: In this Phase II biomarker validation study we will further refine and validate biomarkers using a new collection of samples from at least 200 Ovarian Cancer cases with Epithelial Ovarian Cancer (Endometroid and Papillary Serous histology, most common) and comparing these against 600 patients with a diagnosis of a benign Adnexal Mass that enter the clinics during the same time period. Patient samples will be collected on their first visit to the gynecologic oncologist at a number of collaborating clinics. Final processing of all of the samples will be performed within the proteomics research facilities of the Mitchell Cancer Institute using Selected Reaction Monitoring based on the refined set of markers statistically selected within the first aim. Biomarkers validated within this study will be compared with the well accepted CA-125 data for the patients. The research involves a 3 Year validation and may allow detection of this cancer at a very early stage when the survival is as high as 90%. One aim examines a self-taken test that could allow its use in medically underrepresented and rural areas.

Key Inclusion Criteria:
- Age Criteria:
  - Women age 50 and older who are post-menopausal (defined as 12 Months since last menstrual period).
- Must have diagnosis of:
  - Adnexal Mass
  - Suspicion of Ovarian Cancer
  - Suspected Fallopian Tube or Primary Peritoneal Cancer
- Must have a Uterus and Cervix.
- Surgery for the Adnexal Mass must be anticipated.
  - Note: Only patients with an Adnexal Mass requiring surgery will be eligible.

Key Exclusion Criteria:
- Any subject who has a condition that would increase the risk associated with the standard sampling procedures (e.g., Pap Smear, or Cotton Swab in Vagina).
- Prior Hysterectomy.
- Absence of Adnexal Mass.
- Primary diagnosis of a cancer other than Ovarian, Primary Peritoneal, or Fallopian Tube.
- Patients with grossly visible Cervical Cancer.
- Previous / recent treatment for any invasive gynecologic cancer.
- Recent chemotherapy within the prior 2 Years.
  - Note: Recent neoadjuvant chemotherapy for Ovarian Cancer would exclude the patient from participation.
- Cervical conization within the prior 6 Months.
- History of Radiation therapy to the Pelvis, Vagina, or Cervix.
- Obvious Advanced Stage Cancer (Stage III or IV) on presentation, if known prior to specimen collection.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT01787656

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