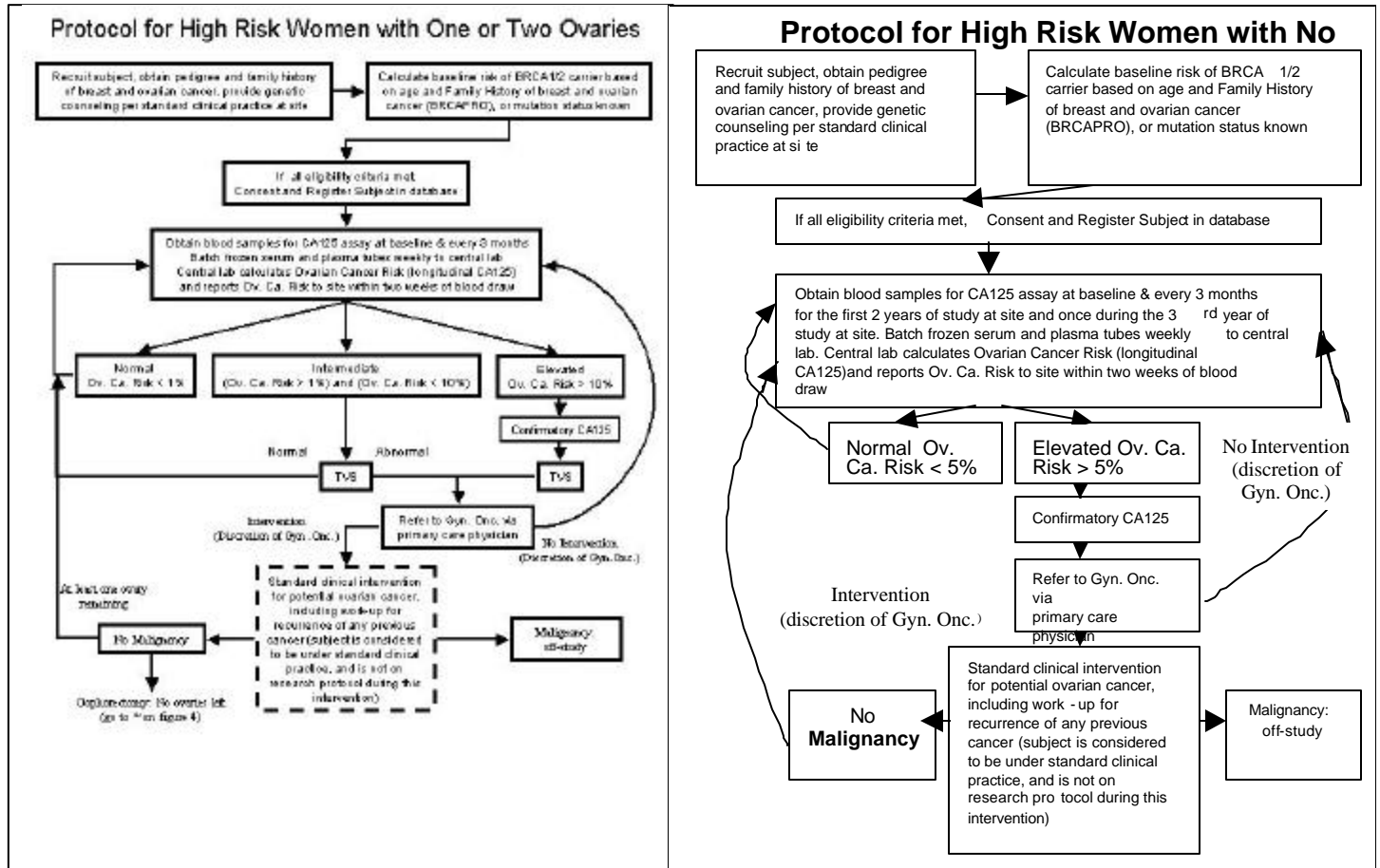


# OVARIAN CANCER SCREENING PILOT STUDY IN HIGH RISK WOMEN

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**Statistical Support:** MGH Statistical Coordinating Center  
**Funding Source(s):** CGN Pilot study; R01 submitted February 2004  
**Participating Groups:** CGN, SPORE, EDNR, GOG

**Accrual Start Date:** 5/2001  
**Accrual End Date (Projected):** 2005  
**Study End Date:**  
**Data Cut-off Date for this Report:** 1/23/2005

**Goal:** A study of feasibility and predictive value of CA125 models of screening for ovarian cancer in high risk women.



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## Study Objectives

- Determine the feasibility of prospective screening studies of high risk subjects within the CGN network, and identify the logistical issues of screening and their solutions within this framework.
- Establish normal ranges and distributions within and between high risk women for CA125 values over time, with sub-classification by pre/post-menopausal status, ERT usage (yes/no), and prophylactic oophorectomy (yes/no).
- Obtain estimates of the specificity and positive predictive value suitable for designing a definitive trial of screening for ovarian cancer in high risk women.
- Establish a longitudinal serum and plasma bio-repository for retrospective evaluation of other promising biomarkers with special relevance to inherited ovarian and breast cancer risk.

## Eligibility Criteria

### Inclusion

- Age  $\geq$  30 years
- Elevated risk of ovarian cancer, indicated by one of these criteria:
  - Proband, or 1<sup>st</sup> or 2<sup>nd</sup> degree relative has tested positive for BRCA 1/2 mutation
  - Women with a family containing at least two ovarian or breast cancers among the themselves and 1<sup>st</sup> and 2<sup>nd</sup> degree relatives \*
  - Women of Ashkenazi descent with one first degree or two second degree relatives with breast or ovarian cancer, or women of Ashkenazi ancestry and has had breast cancer \*
  - Women with a probability of carrying a BRCA1/2 mutation given family pedigree of breast and ovarian cancers exceeds 20%, as calculated by BRCAPRO <sup>2</sup>

### Exclusion

- Prior/current diagnosis of ovarian cancer or peritoneal carcinomatosis
- Negative test for same BRCA 1/2 mutation present in a 1<sup>st</sup> or 2<sup>nd</sup> degree relative
- Currently pregnant or anticipating pregnancy during the study
- Currently receiving adjuvant chemotherapy or radiation therapy for cancer (excluding tamoxifen or other hormonal therapy)
- Prior treatment for metastatic malignancy within the past five years
- Intraoperative surgery within the last 3 months (laparoscopy or laparotomy)
- Prior bilateral oophorectomy \*\*

\* If breast cancer is required to satisfy this condition, at least one breast cancer is pre-menopausal (age less than or equal to 50 if menopausal status is unknown)

\*\* As of October, 2003

## Accrual

As of January 23, 2005: 2255