

Subject Name: \_\_\_\_\_

History # \_\_\_\_\_

### INCLUSION CRITERIA – Random FNA

- Subject is between 30-55 years of age (or within 10 years of youngest age at diagnosis of first degree relative. If >55, may be aspirated if clinical evidence of generalized proliferative breast disease or on HRT. Subjects between 18-30 are eligible if within 10 years of age of youngest age at diagnosis in a first degree relative.)  Yes  No
- Subject must be willing to have a mammogram performed at Duke University Medical Center within 12 months prior to RPFNA. Mammograms must be read as not suspicious for breast cancer (ACR Class I-III). Subjects with a class IV mammogram may be entered once they have been evaluated by a breast surgeon.  Yes  No
- Subject must be at least one year from pregnancy or lactation.  Yes  No
- Must be >30 days from cytotoxic chemotherapy and if have had chemotherapy within 60 days have recovery of white blood and platelet counts (ANC>1500, platelet count >100,000).
- Subject must be willing to discontinue aspirin, NSAIDs, fish oil, and vitamin E use 3 days prior to the procedure to decrease soft tissue bleeding.  Yes  No
- Subject must be willing to have about 40 cc of blood (approximately 3 tablespoons) drawn at each aspiration visit.  Yes  No
- Subject must be willing to complete demographic, family history and psychosocial questionnaires, as well as informed consent.  Yes  No

### EXCLUSION CRITERIA – Random FNA

- Metastatic malignancy of any kind  Yes  No
- Age <30 or >55 (except subjects whose 1<sup>st</sup> or 2<sup>nd</sup> degree relative <40 at diagnosis or subjects over 55 with diffuse epithelial hyperplasia or on HRT (other high risk subjects will be evaluated on a case-by-case basis).  Yes  No
- Subject on coumadin or other anticoagulant  Yes  No
- Subject with breast implants or tram flap reconstruction  Yes  No
- Subject has had radiation to both breasts  Yes  No
- Subject cannot give informed consent  Yes  No
- Subject has a use of amphetamines either oral or patch as documented by the presence on the medication list prior to RPFNA  Yes  No
- Subjects who are on amphetamine like medications, (eg. Ritalin) will be asked to stop these medications for 24 hours prior to the RPFNA  Yes  No
- Subject has uncontrolled or untreated hypertension as evidenced by a systolic blood pressure greater than or equal to 140 and a diastolic pressure greater than or equal to 90  Yes  No
- Subject with mammographic or clinical breast exam mass suspicious for breast cancer (ACR Class IV) who are not currently undergoing evaluation by a breast surgeon.  Yes  No

---

Signature: \_\_\_\_\_

Date: \_\_\_\_\_