

ACRIN 6666

Registration

ACRIN Study 6666 Case #
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant's Name _____ Participant's I.D. No. _____

Instructions: Complete the worksheet **prior** to consent/registration of the participant. A response coded **other than that prompted ()** renders a participant ineligible for study enrollment. If assistance is needed regarding eligibility, please contact ACRIN Data Management at 215-574-3150.

- _____ 1. Institutional person randomizing case (Name of individual randomizing case)
- _____ 2. **(Y)** Has the eligibility checklist (worksheet) been completed?
- _____ 3. **(Y)** Patient eligible for this study?
(Participant meets at least one of the six high-risk criteria defined in section 5.3)
- _____-_____-_____ 4. Date the study-specific consent form signed
mm dd yyyy (Must be prior to study entry)
- _____ 5. Participant's initials (Last, First) (L,F)
- _____ 6. Verifying physician
- _____ 7. Patient ID # (**Optional**; this is an institution's method of internally tracking a participant to a protocol case number; may code a series of 9's)
- _____-_____-_____ 8. Date of birth (must be \geq 25 years old)
mm dd yyyy
- _____ 9. Ethnic Category
 - 1 Hispanic or Latino
 - 2 Not Hispanic or Latino
 - 9 Unknown
- (10. Omitted)
- _____ 11. Gender
 - 2 Female
- _____ 12. Participant's Country of Residence (if country of residence is *other*, complete Q18)
 - 1 United States
 - 2 Canada
 - 3 Other
 - 9 Unknown
- _____ 13. Zip Code (US residents 5 digit zip code)
- _____ 14. Participant's Insurance Status
 - 0 Other
 - 1 Private Insurance
 - 2 Medicare
 - 3 Medicare and Private Insurance
 - 4 Medicaid
 - 5 Medicaid and Medicare
 - 6 Military or Veteran's Administration
 - 7 Self Pay
 - 8 No means of payment
 - 9 Unknown/Decline to answer

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_____ 15. Any care at VA or military hospital

- 1 No
- 2 Yes
- 9 Unknown

____-____-____ 16. Calendar base date (First study imaging scheduled date)
mm dd yyyy

____-____-____ 17. Randomization date
mm dd yyyy

_____ 18. Other country, specify (complete Q18 if Q12 is other)

_____ 19. **(N/Y)** Race: American Indian or Alaskan Native

_____ 20. **(N/Y)** Race: Asian

_____ 21. **(N/Y)** Race: Black or African American

_____ 22. **(N/Y)** Race: Native Hawaiian or other Pacific Islander

_____ 23. **(N/Y)** Race: White

_____ 24. **(N/Y)** Race: Unknown

Institution _____ Institution No. _____

Participant's Name _____ Participant's I.D. No. _____

- _____ 25. **(N)** Is participant enrolled in the first year of the **Digital Mammography Imaging Screening Trial (DMIST)** any contrast-enhanced breast MRI trials, tomosynthesis trial, any other trial of breast ultrasound or breast ultrasound agents, or any breast cancer screening trial?
- _____ 26. **(N)** Has the participant undergone contrast-enhanced breast MRI or bilateral whole breast ultrasound within the past 12 months?
- _____ 27. **(N)** Has the participant had any breast procedures (FNAB other than cyst aspiration, core biopsy, or other breast surgical procedure) within the past 12 months?
- _____ 28. **(N)** Is the participant aware of any palpable abnormality in the breast(s), abnormal skin changes of the breast(s) and or nipple(s), bloody discharge, or spontaneous nipple discharge?
- _____ 29. **(Y)** Does the participant meet at least one of the high-risk criteria as defined in Section 5.3 of the protocol?
- _____ 30. **(N)** Has the participant had breast cancer diagnosed within the prior 12 months or have known distant metastases from breast cancer or have known residual cancer?
- _____ 31. **(N)** Excluding breast cancer, basal cell or squamous cell skin cancer, and in situ cervical cancer, has the participant been diagnosed with cancer in the last five years or has the participant had a recurrence of cancer in the last five years or has residual disease been detected in the last five years?
- _____ 32. **(N)** Does the participant have breast implant(s) in the study breast(s)?
- _____ 33. **(N)** Is the participant pregnant, nursing, or does she have any reason to believe she may be pregnant or does she plan to become pregnant within the next 2 years?
- _____ 34. **(Y)** Does the participant understand and agree to the follow-up requirements as outlined in Section 4.10 of the protocol?
- ____-____-____ 35. Date* study mammogram scheduled (mammogram and sonogram must be within 2 weeks of each other and
mm dd yyyy performed at the same site)
- ____-____-____ 36. Date* of study sonogram scheduled (sonogram and mammogram must be within 2 weeks of each other
mm dd yyyy and performed at the same site)
- _____ 37. **(N/Y)** Is this the participant's first mammogram? (If yes, answer Q38 and skip Q39, if no, answer Q38 and Q39)
- _____ 38. **(Y)** Is this a routine annual mammogram visit?
- _____ 39. **(Y)** Are the breast(s) heterogeneously dense or dense mammographically as defined in Section 5.3 of the protocol? (leave blank if no prior mammogram)

Participant Signature _____

Signature or person responsible for the data _____
(Research Associate or Principal Investigator)

Date of form completed (mm-dd-yyyy) _____ - _____ - _____

Signature of person entering data on the web _____

* If the study mammogram and or sonogram have been scheduled please provide the dates. If the imaging appointments have not been scheduled, please leave the question blank.