



**Are you being monitored  
for low risk prostate cancer?**

**If so, you may be able to participate in  
this study of a potential new treatment.**

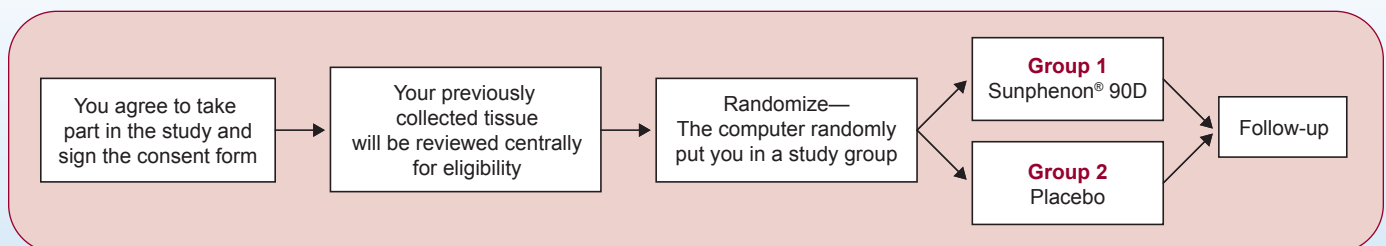
## To Evaluate if Green Tea can be Effective in Reducing the Progression of Prostate Cancer in Men on Close Monitoring

### **WHY** consider participating in this study?

- Research studies are conducted to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.
- Studies have shown that “active surveillance” is a recommended option for men who have been diagnosed with low risk prostate cancer. This involves close monitoring with a prostate-specific antigen (PSA) test, a digital rectal exam (DRE), prostate biopsies, and imaging tests.
- EA8184 will compare active surveillance alone to active surveillance with the study drug, Sunphenon® 90D (containing green tea catechins).
- The purpose of the EA8184 study is to find out if Sunphenon® 90D can help prevent the progression of prostate cancer (from a low risk stage to a higher risk stage) in men who are on active surveillance.

### **WHAT** does this study involve?

- If you decide to take part in EA8184, you will be assigned by chance (randomized) to one of the two groups listed below. Neither you nor your doctor will be told which group you are in, but your doctor can find out if it is necessary to know for your health.
  - **Group 1:** You will get the study drug Sunphenon® 90D. This will be three pills, taken by mouth two times a day for 6 months.
  - **Group 2:** You will get the placebo pills for 6 months. A placebo pill looks like the study drug, but contains no medication. This will be three pills, taken by mouth two times a day for 6 months.



- At the end of the 6 months, after you finish your study treatment with the study drug or placebo, your doctor will contact you by phone to ask how you are doing. You will also need to visit the clinic for a standard of care biopsy.
- Your doctor will follow your condition for an additional 6 months.
- You can decide to stop taking part in the study at any time, even after you have enrolled.



## WHO will take part in this study?

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- Approximately 360 people will take part in EA8184.
- Participants must be at least 21 years old, speak English or Spanish, and have biopsy-proven adenocarcinoma of the prostate.
- Only participants who are on active surveillance will be included in this study (i.e., not participants that are using radiation or surgery to treat their prostate cancer).
  - Participants must not have had previous treatment for their prostate cancer.

## WHAT are the costs of taking part in this study?

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- Just as you would if you were getting the usual care for your cancer, you and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Check with your insurance company to find out what they will pay for.
- You/your insurance provider will **not** have to pay for Sunphenon® 90D, or the following exams, tests, and procedures while you take part in this study:
  - Hepatitis B & C tests (prior to the start of the study)
  - Gleason Score confirmation and % Ki-67 expression assessment (at the start and end of the study)
  - Apoptosis by caspase and tissue Nf-kB (start and end of the study)
  - Plasma catechins (start and end of the study)
- You/your insurance provider will **not** have to pay to send your tissue from the biopsy.
- For more information on insurance coverage and clinical trials, visit the National Cancer Institute (NCI) website at: [www.cancer.gov/clinicaltrials/learningabout/payingfor](http://www.cancer.gov/clinicaltrials/learningabout/payingfor) or call 1-800-4-CANCER (1-800-422-6237).

## IF you would like to know more

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- About the EA8184 study, talk with your doctor or:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EA8184, then select the link to EA8184.
    - » If you are seeking information about the locations where the study is available, scroll down the page to Locations and Contacts.
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- About clinical trials:
  - General cancer information: visit the NCI website at [www.cancer.gov](http://www.cancer.gov)
  - Insurance coverage: visit [www.cancer.gov/clinicaltrials/learningabout/payingfor](http://www.cancer.gov/clinicaltrials/learningabout/payingfor)
- About ECOG-ACRIN:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org)
  - For a list of patient resources and links to patient advocacy groups, visit <https://ecog.org/patients/resources>

