

## PATIENT RECRUITMENT SCRIPT

### Cell Genesys: VITAL-1 and VITAL-2 Protocols

Hello, thank you for calling about the prostate cancer research study. As we proceed, please know that this call may be monitored or recorded for quality assurance purposes.

**Q1.** My name is \_\_\_\_\_. How may I help you?

1. Patient or other calling for information about study: go to **Q2**
2. Physician/nurse: go to **Physician Script**
3. Other, general info, media: go to **General/Media Close**
4. Patient callback (for possible reasons below): go to **Special/Follow-up Close**
  - Site Issues: Needs site address, Appointment change
  - Personal information change
  - Wants to complete the phone screen
  - Other

**Q2.** Are you interested in the studies for yourself or someone else?

If self, go to **Q4 – Patient Call Flow**

If for someone else, go to **Q3 – Caregiver/Family Member**

**Q3.** I'm sorry, but privacy and confidentiality rules do not allow for someone other than the participant to answer our pre-screening questions. We will have to talk directly with him about participation in this trial. Is the patient there with you (can the patient come to the phone)?

- No: go to **Non-Patient Close**
- Yes: *If the patient is there, but cannot talk due to disability or does not speak English, then go to **General/Media Close***
- Yes: Patient is put on the phone and finish rest of call with patient: go to **Q4.**

**Q4.** First, may I ask how or where you heard about our toll-free number?

1. Doctor:
  - May I get the doctor's name, please (including spelling): \_\_\_\_\_
  - The doctor's address or clinic location or facility name: \_\_\_\_\_
  - The doctor's phone number: \_\_\_\_\_
2. Friend/family member
3. Other: \_\_\_\_\_
4. Don't know

[go to **Q5**]

**Q5.** Before we continue, I would like to get your name and contact information. Could I please have your...

Name \_\_\_\_\_  
Address 1 \_\_\_\_\_

Address 2 \_\_\_\_\_  
 City, State, Zip \_\_\_\_\_  
 Daytime telephone number \_\_\_\_\_  
 Evening telephone number \_\_\_\_\_

**Q6.** In order to determine if you qualify for this research study, I'm going to ask you some confidential questions about your health history and present condition. These questions may take 5-10 minutes. Do I have your permission to continue?

If yes, go to **Q7**

If no, and indicates lack of time, respond:

We do need to ask these questions before we can refer you to the nearest clinical study center. As I mentioned, it should take 5-10 minutes to complete.

If caller continues to indicate no time, respond:

I understand. Is there a convenient time when I could call you to complete this questionnaire?

- Yes: record date and time for call back. \_\_\_\_\_
- No: but would like to pre-screen, continue:

Please feel free to call back at your convenience. We would be happy to complete the questions with you then. Please call us at 1-866-687-0725 when you have time to complete the screening process. We look forward to speaking with you soon. [go to **Short Close**]

**Q7.** The questions I will ask you require answers that contain specific health information about you. This pre-screening information may be forwarded to a study site participating in the clinical trial so that the site can contact you about the trial. All information will be transferred in a secure file format to protect your privacy according to government regulations. The information you give will be used only for the purpose of evaluating you for this study; it will not be shared or sold to other organizations or used for marketing purposes. Do I have your permission to continue?

- Yes: go to **Q8**
- No: go to **Declined Participation Close**

**Q8.** If you have any questions during our discussion, please feel free to ask at any time.

[If patient asks questions, read from **Patient FAQs**]

[If patient requests written materials be sent to them, go to **Q8-A.**]

- If patient wishes to continue or has no further questions, go to **Q9**
- If patient expresses disinterest, go to **Declined Participation Close**

**Q8-A.** I'd be happy to send you more information. How would you like it sent?

- Email: get email address: \_\_\_\_\_
- Fax: get fax number: \_\_\_\_\_
- Regular mail: verify mailing address \_\_\_\_\_ (from **Q5**)

**Q9.** To verify eligibility, I need to ask your date of birth.

Date of birth: Month \_\_\_\_ Day \_\_\_\_ Year \_\_\_\_

Age (in years): \_\_\_\_\_

If > 18 years old, go to **Q10**

If under 18 years old, patient is **Unqualified**, but continue with **Q10**.

- Q10.** Have you been diagnosed with prostate cancer?
- Yes, go to **Q11**
  - No, patient is **Unqualified**, but continue with **Q11**
- Q11.** Have you been treated with hormone therapy for prostate cancer? Are you now or have you at any time taken any of following drugs: Lupron, Eulexin, Proscar, Casodex, or Nilandrone?
- Yes: go to **Q12**
  - No: patient is **Unqualified**, but continue with **Q13**
  - Don't know: go to **Q13**
- Q12.** Has the hormone therapy stopped working? For example, has your PSA increased or your cancer spread to other parts of your body?
- Yes: go to **Q13**
  - No: patient is **Unqualified**, but continue with **Q13**
  - Don't know: go to **Q13**
- Q13.** Are you able to walk on your own or with a cane or walker?
- Yes: go to **Q14**
  - No: patient is **Unqualified**, but continue with **Q14**
  - Unsure/Don't Know: go to **Q14**
- Q14.** Have you been treated with docetaxel (taxotere) or taxol?
- Yes: patient is **Unqualified**, but continue with **Q15**
  - No: go to **Q15**
  - Don't know: go to **Q15**
- Q15.** Have you been treated with any other chemotherapy agent for prostate cancer other than docetaxel (taxotere) or taxol?
- Yes: unqualified for Vital 1, but might qualify for Vital 2, go to **Q16**  
Do you remember the name of the chemotherapy drug? [Record name if known]
  - No: go to **Q16**
  - Don't know: go to **Q16**
- Q16.** Do you have pain caused by prostate cancer?
- Yes, go to **Q17**
  - No, go to **Q18**
  - Don't know, go to **Q18**
- If **yes** to **Q15** and **Q16**, patient may be eligible for Vital 2 only, go to **Q17**.
  - If **yes** to **Q15** and **no** for **Q16**, go to **Unqualified Close**.
  - If **no** to **Q15** and **yes** to **Q16**, patient may be eligible for Vital 1 or 2, go to **Q17**
  - If **no** to **Q15** and **Q16**, patient may be eligible for Vital 1 only, go to **Q17**.

**Q17.** Please tell me what medications you are currently taking for your cancer related pain. Please tell me all of your pain medications, even if you take them only once in a while.

- Record List: \_\_\_\_\_, go to **Q18**
- Doesn't know: go to **Q18**.
- Refuses to provide: go to **Declined Participation Close**

**Q18.** In order to be screened for this study, you will need to visit a study site where you will be evaluated to determine whether you qualify for this study. During the study, you will need to go to the study site every 2-3 weeks for 6 months to receive study medication. Can your schedule accommodate this?

- Yes: go to **Q19**.
- No: go to **Declined Participation Close**

**Q19.** Do you have questions about this clinical trial that I can answer at this time?

[if patient asks questions, read from **Patient FAQs**]

[If patient requests written materials be sent to them, go to **Q19-A**.]

- If patient wishes to continue or has no further questions, go to **Q20**
- If patient expresses disinterest, go to **Declined Participation Close**

**Q19-A.** I'd be happy to send you more information. How would you like it sent?

- Email: get email address: \_\_\_\_\_
- Fax: get fax number: \_\_\_\_\_
- Regular mail: verify mailing address \_\_\_\_\_ (from **Q5**)

[If patient wishes to continue or has no further questions, go to **Q20**]

*[Based on patient's zip code, and answers to questions 15 and 16, the closest appropriate study site will be suggested. If yes to Q15 and Q16, a Vital 2 site will be suggested. If no to Q15 and Q16, a Vital 1 site will be suggested.]*

**Q20.** The study site closest to you is \_\_\_\_\_. Would you be willing to travel to this site?

- Yes: note site selection, go to **Qualified Close**.
- No: Continue to offer other "next nearest" appropriate site. If none are convenient to patient, go to **Inconvenient Site Close**

## CLOSES

### Short Close

Thank you. Goodbye.

### General/Media Close

For questions regarding the trial please call Cell Genesys, Inc. at 1.650.266.3200. Thank you for calling and we appreciate your interest. Goodbye.

**Non-Patient Close**

Thank you for contacting us. Please have the patient (your \_\_\_\_\_) call us back toll-free at (866) 687-0725 between the hours of 8am to 8pm Eastern time. Thank you. Goodbye.

**Inconvenient Site Close**

I'm sorry that those locations are not convenient for you but I thank you very much for calling today. Should you reconsider, please call us again at (866) 687-0725. We will be very happy to continue with you in the preliminary screening process. New sites may be opening in the future. With your permission, we would like to keep this information about your health on file for possible qualification if new sites open in the future. Do we have your permission to retain the information we collected in this telephone conversation?

- ☐ Yes
- ☐ No – say: We will destroy this information at the conclusion of this call.

Again, thank you for your interest and for calling today. Goodbye.

**Unqualified Close**

We certainly appreciate your interest in this study. However, based upon the information you have given us, it appears that you do not qualify for this research study. *[If caller wants to know which answer was wrong, say you don't know.]* With your permission, we would like to keep this information about your health on file for possible qualification in a future research study. Do we have your permission to retain the information we collected in this telephone conversation?

- ☐ Yes
- ☐ No – say: We will destroy this information at the conclusion of this call.

Again, thank you for your interest and for calling today. Goodbye.

**Declined Participation Close**

We certainly appreciate your interest in these studies. I'm sorry you have declined to participate. If you have any future interest or have additional questions regarding these studies, please feel free to contact us toll-free at (866) 687-0725. With your permission, we would like to keep this information about your health on file for possible qualification in a future research study. Do we have your permission to retain the information we collected in this telephone conversation?

- ☐ Yes
- ☐ No – say: We will destroy this information at the conclusion of this call.

Again, thank you for your interest and for calling today. Goodbye.

**Qualified Close**

Someone from the study site will contact you within a couple of days to set up an appointment. You may also contact them directly at \_\_\_\_ [provide site phone number and contact]. During this first appointment, the study doctor and clinic staff will ask you specific questions, perform a study-related physical examination and run some tests to determine whether you are eligible for the study. The study will be explained to you in detail, and you will be able to ask questions. If you are interested in participating in the study, you will be asked to sign an informed consent document. You will not be asked to take the study medications during this first visit - it is for screening purposes only. Let me confirm your phone number (*Confirm patient's phone number*). Let me also again confirm the study site: (*Verify site address, zip code, and site's phone number*). If you are unable to keep an appointment for any reason, please call the study site at \_\_\_\_ [*site's phone number*]\_\_ to re-schedule. We appreciate your willingness to participate and also your time spent on the phone today. With your permission, we would like to keep your information about your health on file. Do we have your permission to retain the information we collected on this phone conversation?

- ☐ Yes
- ☐ No – say: We will destroy this information at the conclusion of this call.

Thank you for calling. Goodbye.

**Special/Follow-up Close**

May I have your name and phone number, please: *look up patient in system and find status.*

What can I help you with today?

- Needs site address, appointment change or missed appointment: *provide patient with study site info (address & phone number).*
- Personal information change: *update info in database.*
- Wants to complete the phone screen: go to **Q2**.
- Wants information sent to them: go to **Q19-A**.— update database to indicate **Patient FAQ** needs to be sent. [Schedule a follow up call for 1 week away.]
- Questions about study: use **Patient FAQs** to answer questions if possible. If patient already has a screening appointment scheduled, then advise them to ask the questions at that appointment. Otherwise, provide patient with phone number of study site.

End with: Thank you for your call today. Goodbye.