

# Coordinator Training

## Scenario 1

A patient expressed interest in participating a clinical trial. However, when his daughter came to the ED, she said that she did not want her father to take part in the trial.

*What would YOU do?*

### Speak with the patient individually

- You are placed in a tricky position. Although you do not want to cause conflict between the patient and his daughter, it is necessary to speak to the patient one on one.
- Emphasize that participating in a clinical trial is a personal and private decision. It is ultimately up the patient, not his family members or friends, to decide whether or not to join the study.
- However, stress that social support from family and friends can be a helpful tool for managing one's health.

### Speak with the patient's daughter

- Remember that a patient's admission to the ED can be stressful for family members and friends. Understand that the patient's daughter is simply concerned about her father.
- Although the patient's daughter has her own ideas about her father's involvement in the trial, it is ultimately up to him to decide whether or not to participate.
- During the conversation with the patient's daughter, stay neutral and state the facts. Try not to stir up a family feud!



## Scenario 2

You approached a patient about a potential clinical trial, and he responded angrily. He expressed that both he and his wife have been through a lot and do not have time to consider a trial.

### *What would YOU do?*



#### Maintain respect and empathy for the patient

- Respect and empathy are important for initiating conversations and successfully engaging with patients.
- Demonstrate respect for the patient's confidentiality and decision to not participate in research.
- Express empathy for the patient's difficult situation.
- Thank the patient for considering participation in the clinical trial.
- Never pressure a patient to participate in a study!

## Scenario 3

A patient expresses interest in being a part of your clinical trial. However, she demands that she receive the drug intervention rather than standard care.

### *What would YOU do?*



#### Discuss the importance of randomization

- Though you understand your patient's desire to participate in the intervention arm, you must explain how randomization works and its significance in clinical trials.
- An infographic or visual aid can be helpful when explaining randomization to patients (e.g. Clinical Trial Participants and Community Members toolkit, Clinical Trial Basics infographic, etc.)

## Facilitate an open discussion and clarify misconceptions



- Take 3-5 minutes to discuss the purpose and significance of conducting clinical trials. It is imperative for the patient to understand that we do research to answer questions and that it is unknown whether the intervention will lead to a "better" result than usual care or standard practice.
- After discussing randomization and other clinical trial definitions, ask if the patient is still interested in participating in the clinical trial.



A patient who is involved in a clinical trial no longer shows up for appointments or answers phone calls.

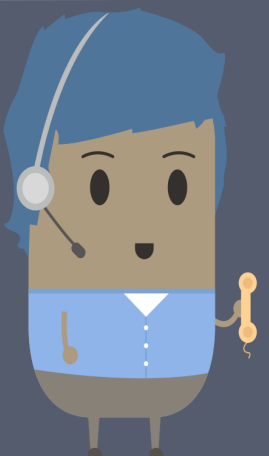
## *What would YOU do?*

### Try to get in contact with the patient

- Provide patients with consistent reminders of upcoming appointments via mail, phone, and/or email.
- Plan simple solutions for missed appointments and other deviations from the clinical trial protocol.

### Implement participant retention strategies

- Remind patients of upcoming visits.
- Maintain an environment that is patient-friendly and comfortable.
- Accommodate patients' schedules as much as possible.
- Respond to patient inquiries quickly.
- Explain the importance of patient participation.



## Understand that inconsistent participation is inevitable!



- Unfortunately, participants cannot be forced to follow instructions or keep appointments.
- Many factors that contribute to clinical trial dropout rates cannot be avoided. For example, patients might have financial constraints or schedule conflicts that prevent their participation in the study.
- It is important to understand why participants choose to discontinue a study. This information can be used to improve patient retention in the future!



A patient is interested in participating in a clinical trial, but expresses concern about the side effects of an experimental drug.

*What would YOU do?*

## Explain anticipated side effects

- Provide details about potential side effects that the patient may experience if he or she is randomized to the intervention arm.
- Explain that the degree to which the patient may experience side effects can range from mild to severe.
- Remind the patient that side effects will be appropriately managed by a health care team throughout the entirety of the clinical trial.



Discuss the benefits and risks of participation



- Explain that every clinical trial has associated benefits and risks.
- Explicitly state the degree of risk associated with the experimental drug used in the clinical trial. If there are unpleasant or serious side effects associated with treatment, share this information with the patient.
- Although it is imperative to discuss possible risks, it is also important to review the potential benefits of participating in the clinical trial with the patient. This may include gaining access to new treatments and helping future patients by taking part in medical research.



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