



Key Responsibilities of the Direct Care Nurse in Clinical Trials

Helping patients understand clinical trials

- Read the informed consent document to learn more about the clinical trial. This may help answer questions that patients and caregivers have.
- Reinforce the information given to the patient about the clinical trial. Begin by assessing their understanding.
- Use open ended question to encourage discussion and assess comprehension. These questions require explanation and cannot be answered with a yes or no. Examples include:
 - "Please explain to me what the doctor said you would need to do while you are on the clinical trial."
 - "Tell me in your own words the purpose of the clinical trial."
 - "What more would you like to know about the clinical trial?"
 - "What is the possible benefit to you of participating in this study? What are the possible risks?"
 - "How often you will need to come to visit us in the clinic?"
- If the patient has questions, review the informed consent document for the information or refer them to the research team for more information.
- Know who to contact if you or the patient has questions you are not able to answer.

Helping patients find appropriate clinical trials

- When patients express interest in finding out about clinical trials and what might be available for them, start by asking them what they have been told about their cancer and treatment.
- The following steps have been recommended by the American Cancer Society for patients interested in exploring clinical trials.
 - Step 1: Gather details about the patients cancer, such as type, stage, previous treatment and performance status.
 - Step 2: Find clinical trials by using clinical trial search sites, such as clinicaltrials.gov, disease specific search sites (usually run by advocacy organizations) and institution specific search options.
 - Step 3: Take a closer look at the details about trials that might affect the choice of the patient to participate, such as trial objective, eligibility criteria, location and requirements.
 - Step 4: Contact the team running the trial. This can be done by the patient or a member of the healthcare team – including the nurse.
 - Step 5: Ask questions. Help the patient come up with a list of questions to ask the research team about the clinical trial they are interested in learning more about.
 - Step 6: Help the patient make an appointment as needed.

Maintaining the informed consent process

- Know where to locate the signed informed consent document – it should be in the patient's medical record.

- Support the patient and family decision-making process, including making sure they have the information they need and encouraging them to discuss any concerns.
- Advocate for the patient, including supporting their right to make their own decision and withdraw from the study at any point.
- Serve as a witness if requested. Know what you are witnessing (signature of participant or the actual IC discussion). Know your organization's policies.

Administering the study drug or intervention

- Be certain that you have access to the information you need to safely administer the study drug. If you have access to the protocol, locate the study drug section and review the treatment plan and drug information. The protocol will be used to write the medical orders.
- Determine if other medications are needed (i.e., specific antiemetic regimen before chemotherapy administration)
- Know how to identify, handle, store, administer and dispose of the study drug.
- If the study drug is self-administered, ensure that the patient understands how to take the drug, what to do for a missed dose, how to store the drug and how to dispose of the drug.

Monitoring response to intervention

- Understand the definition of an adverse event: any unwanted sign, symptom, or disease that was not seen before receiving an intervention on a clinical trial or, if present before the intervention, appears to worsen. Adverse event is the term used in research instead of side effect or toxicity.
- Ask open-ended questions about how the patient is tolerating the intervention. DO NOT question the patient about specific adverse events that might be anticipated as this can bias the information collected.
- Know how to report an adverse event to the research team

Documentation/data collection:

- Record **all** medications that the patient is taking including how long they have been taking it. This includes prescription, over the counter (OTC), complementary and alternative medications.
- Record the start and stop time of an intravenous study drug administration.
- Record details of an adverse event including start date and time, description, treatment required, and resolution.
- If biospecimens are to be collected, know when and how to collect and handle them. Document that the biospecimen was collected and the time of the collection.

Adapted from:

American Cancer Society (ACS). (2016). Steps to Find a Clinical Trial. Accessed from

<https://www.cancer.gov/about-cancer/treatment/clinical-trials/search/trial-guide>

Parreco, L.K., Ness, E., Galassi, A., O'Mara, A.M. (2012). Care of clinical trial participants: What nurses need to know. *American Nurse Today*, 7(6), available online at

<http://www.americannursetoday.com/article.aspx?id=9170&fid=9138>.

