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My Responsibilities as a Clinical Study Participant

By Kiran Bahrus and Norman M. Goldfarb

The informed consent process focuses on the study participant's rights and protections. However, for a clinical study to be successful, study participants must also do their part. As a study participant, the following are my responsibilities:

Informed Consent. I have read the informed consent form, discussed its contents with the study team, and believe I understand the study well enough to participate in it.

My Information. I will provide full and truthful information about my health and anything else the study team should know about.

Contact information. I will keep the study team's contact information with me at all times. I will make sure the study team always knows how to find me. If they try to contact me, I will respond as soon as I can.

Questions and Problems. If I ever have a question about the study, I will ask the study team about it and keep asking until I am satisfied with their answer. If I forget something I want to know, I will ask the study team to explain it to me again. If I have a problem with the study, I will tell the study team about that too. If my problem is with the study team itself, I will call the IRB/Ethics Committee at the telephone number in the consent form.

Visits, Medications and Records. To the best of my ability, I will keep all visit appointments, take all medications, record all information, and follow any other instructions the study team gives me. If I cannot — or forget to — do any of these things, I will tell the study team as soon as possible.

Health Problems. If, for any reason, I have any health problem at all during the study, I will tell the study team right away. Also, if I see a doctor for any reason, I will tell the study team about that, too.

Medications, Devices and Paperwork. I will take good care of any medications, devices and paperwork entrusted to me by the study team.

Information Sharing. I will not share information on social media that could interfere with the success of the study. For example, I will not coach other people on how to get into the study or help other study participants figure out whether they are getting the active medication or the placebo.

Dropping Out of the Study. If I decide to drop out of the study, I will tell the study team right away. To the extent I am comfortable, I will tell them why I am dropping out and answer their questions.

End of Study. After the study ends for me, I will return all medications, devices and paperwork to the study team right away.

Talk to the Study Team. If I am unwilling or unable to meet the above responsibilities, I will discuss the situation with the study team.

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