QUESTIONS & RECOMMENDATIONS FOR TOOL KIT
Answered by
Segal Institute for Clinical Research

We labeled question is labeled as “general,” “site specific” or “study specific” and we gave our recommendations/answers for the questions below.

When sites are asked these types of questions, it’s important for each site to evaluate who is asking the question and why. Just because a question is asked, does not mean you have to answer it. It’s important to be honest & transparent on the important issues and keep any proprietary or confidential information safe.

QUESTIONS FOR TOOL KIT

1. How do you refer to the clinical trial participant? What does the term “volunteer" or "subject" mean as it relates to clinical research trials? *(General)*

A clinical trial participant is referred to as a “volunteer” or “participant”. The term “volunteer” is used often since participation in clinical research study is 100% voluntary.

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2. Does your site have an affiliated private practice? If so, what is the relationship between your private practice and your site? Do you share medical records from your private practice or referrer patients? In what instances? Do you get authorization from your private practice patients to market to your clinical trials? Under what authority? How does HIPAA play into this? *(Site Specific)*

Since this question is site specific, we recommend sites to outline the history & relationship between the site and private practice. Also, briefly discuss how patients are referred. It’s important to note that your practices are inline with any other health provider and abides by all relevant HIPAA regulations.

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3. Does your site have recruiters or liaisons? Are they in the hospitals? How are they paid? What are the state and federal laws regarding who can be paid and how much they can receive? What are the state and federal laws on who’s allowed to refer volunteers? *(Site Specific)*

Since this question is site specific, we recommend for sites to be transparent if they have recruiters or liaisons. It’s vital to stress the importance of their role, which is to introduce and educate the community and local health care professionals on clinical research studies and create relationships within the community. It is at the site’s discretion to share information regarding where the liaisons work and how they are paid.

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4. What is the relationship between your site and the hospitals where you conduct inpatient trials? *(Site Specific)*

Since this question is site specific, we recommend sites to outline the hospitals where they conduct clinical research studies and give a brief description of the hospital and their specialties. You can also speak about working hand in hand with the hospital administration and clinical staff. It's also important to state clinical trial participants may be admitted to that facility in order to participate in a research study and it is a common approach for conducting research.

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5. What protections are there to ensure that doctors are not referring people out of a profit motive? *(General & Site Specific)*

The site staff collaborate with physicians & providers who believe that research is an essential catalyst in advancing medicine. Physicians, whether it be a physician from an affiliated private practice or an area physician, can refer patients for clinical research studies. It's important to note, a referral does not mean the patient will automatically be enrolled – there are strict protocols and eligibility requirements for each trial that must be met for enrollment.

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6. How does the informed consent process work? What protections are in place to make sure the volunteer is capable/stable enough to give consent? If a volunteer signs ICF, can they leave the study at any moment? *(General & Site Specific)*

After a participant has qualified for a research study, the Informed Consent Form is given to the participant to read over on their own. After the participant reads over the form, a clinical site staff member will review it with them a second time to confirm their understanding of the form and answer any questions or concerns. The consent form is also written at a 6-8th grade reading level.

Qualified and trained staff members assess each participant to ensure they are capable and stable enough to give consent.

Once the participant decides that they would like to participate in a study, they will sign the Informed Consent Form and complete any necessary screening assessments.

It's important to remember that a participant is a volunteer and even if a participant signs ICF, they can still leave the study at any moment for any reason.

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7. Are volunteers compensated? How are they compensated and how much? What is it for? Many people look at this as coercive. Would this even be a question when talking about certain indications?

Study participants are compensated for their time and travel. The compensation varies for each research study, which is an industry standard and in all cases is approved by the IRB.

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8. How do you recruit and advertise to volunteers? *(Site Specific)*

Since this question is site specific, we recommend a general statement such as the following: “Making potential participants aware of current research studies is no easy task for a research site. Potential patients are made aware of trial opportunities through various advertising channels. The advertising strategy varies for each study.”

It is at the site’s discretion to share any detailed information regarding their marketing & advertising efforts.

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9. Does your site offer any additional services (i.e transportation)? Is it coercive or reasonable to offer transportation to underprivileged individuals who are easy to exploit? Does transportation enable more exploitation? Is this a possible issue nationwide? *(Site Specific)*

Since this question is site specific, we recommend to list any additional services that your site may provide and their benefits.

If your site provides transportation services, you could speak about the fact that you are working to ensure that all participants have equal access to reliable transportation. This is done to ensure volunteers make their regular study visits. Also, it gives all participants the same opportunities for participation. This is especially important for those to those who may not have reliable transportation or who live farther away.

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10. Does your site recruit volunteers who are already admitted to psychiatric hospitals or seeking admission? Under what circumstances would this be in the best interest of the patient to enter a trial? *(General & Site Specific)*

A physician refers a patient for a clinical research study when it’s deemed the best medical option by both the physician and the patient.

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11. Certain populations, such as drug addicts, the homeless, and mentally ill can be some of society's most vulnerable people. Is it exploitative to use this segment of the population to test new drugs? Why is it necessary to test on this population? *(General)*

As part of the clinical research process, investigational medications & products must be tested on the population they are intended for to ensure effectiveness. Therefore, we are unable to develop new and better treatment options for these populations if we do not conduct clinical research trials.

Furthermore, a clinical research site's mission is to play an integral role in the advancement process of medicine and help millions of people suffering from diseases.

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12. Are volunteers responsible for their own medical care if they become sick or injured from a trial? Who guarantees medical care if harmed? *(General)*

The study sponsor typically provides coverage in the event a participant becomes sick or injured from a trial. The coverage details are outlined in the Informed Consent Form.

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13. What can volunteers expect during and after the trials? What happens to volunteer after the clinical trials ends? Will they still have access to the investigational product if it was helpful for them? *(General)*

Once the study has completed, some participants may have access to an open-label extension study, which will provide the investigational medication to the participant for the duration of this extension study. If a volunteer does not continue in an extension study or a study is not available, they will be referred to a local physician or health center to resume their care.

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14. How can the public be assured that sites are operating safely and fairly? Are there any governing entities that ensure the safety of the trial process? How are trials monitored by the FDA, Sponsor and IRB? *(General)*

Clinical trials adhere to the principles of good clinical practices, and monitoring procedures mandated by the FDA. This information can be found through the following link: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/

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15. Where can the public get more information about the whole process of a clinical trial? *(General)*

The public can check out these sites below to get more information on clinical research trials:

ClinicalTrials.gov - ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws. www. ClinicalTrials.gov

The Center for Information & Study on Clinical Research Participation (CISCRP) - An independent non-profit organization whose purpose of increasing education and awareness about clinical research participation and increasing recognition of the role that clinical research participants play in advancing medical science. www.CISCRP.org

Find these links and more at www.SegalTrials.com

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16. If volunteers have the following study specific questions, where and when can they get the answers?

- What is the length of the study? *(Study Specific)*
- How many visits are required by the study? *(Study Specific)*
- What is the compensation? How does payment work? *(Study Specific)*
- What are the details about the study medication? *(Study Specific)*
- Will I definitely get the study medication during the study? What is placebo? Why is it important? *(Study Specific)*
- Will I still be able to see my own doctor? *(Study Specific)*
- Can I continue to take my own regular medications during the trial? *(Study Specific)*
- Are there any things I am not allowed to do while on the study? *(Study Specific)*
- What are the benefits & risks associated with the study? Are there any possible side effects and what would happen then? *(Study Specific)*
- What may not qualify me for a study? *(Study Specific)*
- Will I know if I was taking real drug or sugar pill/placebo during or after the trial (Study Specific)

The study participant will receive these answers while reviewing the Informed Consent Form. In addition, the clinical staff will review the Informed Consent Form with the participant to ensure that all of their questions have been answered before they decide to participate.

When giving a presentation or interview, it's important for sites to stay on track with their intended messaging/topics. If there are questions which veer from your intended message, sites can use these blocking & bridging techniques.

Block and Bridging Techniques:

1. Blocking = avoiding unwelcome or unproductive questions
    a. Another thing to remember…
    b. That speaks to a bigger point…
    c. Let's take that one step further…
    d. That's important, but the real issue is…
    e. Another way of thinking about this is…
    f. You should also know that…

2. Bridging = transitioning to an area that fits your agenda
    a. I understand your questions, but the bigger picture is this…
    b. Let's back up for a moment…
    c. You seem to have some misinformation here…
    d. I'm sorry to interrupt, but you should know that…