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Is This Confidential?

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If you work at a clinical research site, you sign — or are bound by — agreements with confidentiality requirements on a regular basis, but do you really know what they mean? To find out, should you disclose the requested information in the following circumstances?

1. **You are recruiting a study participant. She asks for a copy of the protocol and investigator's brochure.**

2. **A customer service person from the central IRB received a voice message from a study participant complaining about a treadmill test yesterday, but the message was garbled. He asks you for the person's name and contact information.**

3. **A local physician is conducting a study and suspects someone is trying to enroll under a false identify. The person might be participating in one of your studies. The physician asks for identifying information to find out if that is the case.**

4. **The laboratory for a previous study is being sued by a study participant. It asks for the person's study records to help its defense in the case.**

5. **A friendly study coordinator at another site is looking for new studies. She asks if you know of any that are recruiting sites and a copy of the study questionnaires.**

6. **The state health department is investigating the potential diversion of medications for sale at flea markets. It asks for your drug accountability records for any marketed products.**

7. **You are having difficulty using a study's EDC system. You ask your 15-year-old son for assistance.**

8. **A study participant is traveling overseas. She asks for you to fax a copy of her signed consent form, care of the hotel.**

9. **You are teaching a medical school class on antiviral treatments. You are co-authoring the first, multicenter article for a study. A student asks about new treatments being developed.**

10. **You are ready to submit a study application to your local IRB. One of the IRB members is the lead investigator for a study on a competitive product.**

Answers to these questions are on the following page.

Answers

1. **Disclose the information with precautions.** Disclosure of the protocol and investigator's brochure should be permitted, so long as the request is in connection with a sincere interest in learning more about and potentially participating in the study. Disclosure can certainly help participants become more informed about the study. However, even after signing an informed consent form, study participants have no legal obligation to maintain the confidentiality of study documents.

   Before sharing these documents, the investigator and site should read the confidentiality provisions of the clinical trial agreement (CTA). The CTA probably does not have an explicit exception for this specific disclosure.

   If the site determines that the potential participant's request is legitimate, it should contact the sponsor and/or the CRO asking for permission to provide copies of these documents. The sponsor's/CRO's response should be documented in an email or other written form. Providing the documents to the potential participant in hard copy in the site's offices allows the site to answer questions and prevents further dissemination of the documents. The potential participant might also be satisfied with only part of the documents.

2. **Do not disclose the information.** The participant might not have consciously wanted to disclose his or her identity to the IRB or might have changed his or her mind about doing so. Instead, contact the participant and ask him or her to contact the IRB again.

3. **Disclose information that does not constitute Protected Health Information (PHI) under HIPAA.** For example, height, weight and eye color alone are probably not PHI. If, based on this data, it does appear to be the same person, the local physician should explain the circumstances to the person and ask for his or her written permission to share definitive identifiers (e.g., name and driver's license number) with you.

4. **Do not disclose the information.** The laboratory can obtain the records through the legal discovery process. Although most confidentiality provisions in CTAs allow for disclosure in connection with a court order or regulatory requirement, with prior notice to the sponsor/CRO (if reasonably practicable), those exceptions are between the site and the sponsor/CRO, not the site and the laboratory.

5. **Review your confidentiality obligations before disclosing the information.** Information that is publically available on ClinicalTrials.gov or other public websites is not confidential. However, the study questionnaire may be covered by an existing CTA or confidential disclosure agreement (CDA), or a statement about confidentiality in the questionnaire or cover letter.

6. **Review your confidentiality obligations before disclosing the information.** Most CTA's provide for disclosures of confidential information to governmental authorities upon receipt of a court or administrative order, so confirm that the request arrived in that form. Verify that the provision is broad enough to cover disclosures of this type. The CTA might require you to notify the sponsor prior to disclosure. If you disclose the information, ensure that it is free from PHI.

7. **Do not give your son access to the EDC system.** Leaving aside the fact that he is not trained on the system, giving him access will also give him access to confidential study information and the PHI of study participants, unless you understand the system

well enough to obtain his assistance without revealing any data in the system. You could obtain his signature on a confidentiality agreement, but since he is a minor, he would not be legally bound by the agreement. A better approach is to obtain additional training on the EDC system.

8. **Provide the consent form with precautions.** Study participants should have access to their signed consent forms. Presumably, the participant in this case has a good reason for wanting a copy of the document. However, sending the consent form by fax exposes it to disclosure to and by hotel personnel. Presumably, the participant is aware of this risk, but you should obtain explicit acknowledgment in writing. The foreign country's data protection laws may bear on this situation. It would be more secure to send the document by express courier or electronically, protected by a password that is transmitted separately, perhaps by fax.

9. **Answer the question, but say that your role as co-author prevents you from commenting on results from that study.** Some academic institutions require a CTA provision that allows internal, non-commercial use of study data for teaching and educational purposes. However, that exception is normally limited to data originating from the specific site, not all the data you would see as co-author of a multicenter article. Multicenter data is normally covered by the CTA's publication provision, which probably does not permit disclosure prior to publication of the multicenter article. In theory, you could answer the question based on data generated just by your site, but a student could deduce that you would not do so unless that data was consistent with the multicenter data, thus constituting a prohibited disclosure.

10. **Submit the application if confidential information can be protected.** 21 CFR 56.107(e) states: "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." In this case, the IRB member appears to have a clear conflict of interest (COI), but ask the Sponsor/CRO for its position. It may decide that the information in the application is not confidential or can be disclosed to the conflicted member with additional precautions. If the local IRB agrees that there is a COI, the member can be recused and the application kept confidential from him or her. If the IRB does not agree, it may be possible to submit the application to another IRB.

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