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Seventeen Questions an IRB Should Ask About a Research Site's Communication System

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The personnel at a research site might need to communicate quickly with a study participant if there is a problematic lab test, a safety issue with the study drug or device, or a natural disaster like a hurricane. Communications might be incoming, from the study participant, or outgoing, to the study participant.

If a study participant is injured, incapacitated, cognitively debilitated, or just unavailable, the site might need to communicate with the participant's family member, caregiver, physician or other designated person. Such communications are most likely during a study but might also be necessary afterwards.

A communications plan requires knowing who communicates with whom, what information is communicated, how, when and in what form it is communicated, and how communications are documented.

Given that good communications are often essential to protect study participants, IRBs should ensure that sites have an adequate communication plan by asking the following questions:

1. What site contact information will the site provide to the study participant and other persons?
2. What contact information for the study participant and other persons will the site maintain?
3. From what family member, caregiver, physician and/or other persons will the site obtain contact information?
4. How will the site verify the identity of a person who contacts the site on behalf of a study participant?
5. What information will the site provide to the study participant and other persons about the study that can later be provided to emergency care providers?
6. Will the site store the participant's contact information in a secure place, safe from fires, natural disasters, etc.?
7. In case of a natural disaster, will the site be able to post messages to study participants on its website?
8. Will the site obtain the study participant's permission to contact such people and share personal health information with them?
9. How will the site educate the study participant and other persons about medical issues that appear to be unrelated to the study but might, in fact, be caused by the study drug or device?
10. How will the site provide 24/7 attention to incoming telephone calls?
11. Who will the site's primary contact(s) be, and how will their incoming telephone calls, emails and texts be handled when they are unavailable, e.g., on vacation?
12. What information, e.g., abnormal lab values, will be provided routinely to the participant's physician(s)?
13. What information will the site provide to whom in case a medical or other issue arises?

14. Are there any obstacles to the site sharing information about the study or participant with emergency care personnel?
15. How will medical emergency communications be expedited?
16. How will the site follow up on communications that require action by the participant or other person?
17. How will the site test its communications system?

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