IRB Review and Digital Data Considerations

Many protocols make use of digital data and apps in recruitment, data collection, and data analysis. These protocols deal with all of the issues that non-digital research deals with, but also have special considerations that are unique to them due to the amount of data, the unique properties of the information studied, and the complex perception of subjects when it comes to their online data. The following are examples of questions and concerns that one should consider when reviewing protocols involving digital data and apps.

Population Perceptions

Users' perceptions of the technology are important components of digital research because different levels of technological and data privacy literacy exist in the public so users' perceptions can be drastically different depending on their level of understanding. The following questions will assist in developing an understanding of how potential subjects may perceive the study's technology and its impact on their data.

1. What is the study population's expectation of privacy when using the app or website? As an example of users' expectations, when a group of Twitter users was asked about whether researchers should use their tweets in research, only 35% said "yes." However, the 65% who said "no" did make qualifications about when it would be acceptable; when getting their permission first, when the tweets are part of a large group so their tweets are not singled-out, and depending on the value of the research.
2. What is the technological literacy of the study population?
3. How can user expectations of privacy be assessed?
    a. Examine the terms of use or service to see if there is a description of the intended use of the content. For example, the agreement could say the content is not meant for the public domain or that any reproduction of the content must have written permission from the individual who created the content or the hosting entity who runs the platform.
        i. There is some risk in this method since it is well known that users do not read the terms of service and can be misinformed about the level of protection that the terms of service provide against researchers. When asked in the same Twitter study mentioned above, approximately 10% of participants said they thought researchers could not use their tweets without their permission for research because of Twitter's terms of service. In reality, Twitter's terms of service explicitly allow researchers to use them.
    b. Does the site have a membership requirement (i.e., log in) to see the content? If there is a log in, there is an expectation of privacy.
    c. Does the site have an explicit or implicit target membership (e.g., grieving parents, dating sites for specific populations/groups)? If so, this could create a sense that only individuals from that specific group will see the content, even if there are no restrictions.

App functions

How an app functions is very important to the ethics of a protocol, just like any other tool used in the study. Any app used in a protocol must have a description of how it works included. The following questions should be considered in order to make sure all possible issues are addressed. If the protocol does not address relevant issues, ask the PI for clarification. If the app has any medical function(s), please also review the FDA mobile app guidance.

1. Does the consent form describe the app and its function in the study?
2. Is the use of the app mandatory or optional for the participant? If optional, what is the alternative means of participation? If the app is mandatory, does the consent process explain that?
3. Is there a plan for technical support for the app and the participants? Technical support can ensure that subjects use the app properly and prevent breaches of privacy and confidentiality.
4. Will participants need to provide their own devices or will the study provide them? If participants must provide their own device, the study population could be limited to only those with a compatible device. This could create a question of equity if the study could provide a benefit for participants.
5. Will participants need to pay to use the app?
6. How will use of the app impact subjects' data plans, if they have one?
7. Is the app custom-made? If so, has it undergone quality assurance testing for functionality, compatibility, performance, stability, and security?
8. Is there a license agreement, terms of use, privacy policy, or any other document(s) that subjects will have to agree to with a third party in order to use the app?
    a. How does the consent form compare to those documents? For example, does the language in the consent refer to any third party document that has exculpatory language? If so, there should be language in the consent form that indicates the exculpatory language does not apply in the context of the research.
    b. Will someone review the app's documents for future updates that could affect the protocol?
    c. Will the subject be encouraged to review the app documents in the consent process?
    d. Will subjects be notified if there are any changes to the app's documents that could affect their willingness to participate in the research?
9. Does the app create identifiable or linkable information? Keep in mind that re-identification is possible with information as trivial as zip codes and web search queries.
10. Will data be provided to any third parties, including the app developer?
11. Is the app using text messages to communicate with subjects? If so, the protocol must explain that during the consent process and in the consent form due to federal law, which requires consent to receive text messages.
12. Will patients' health care providers use the data collected?
13. Are the app developer and other entities that use the app as a source of information HIPAA compliant?
14. Could the app gather data on persons other than the subject (e.g., an app gathering data on social contacts of the subject)? If so, does the protocol explain how this will be prevented and what will be done if it does happen?

Website functions

Protocols that use websites as a part of the research need to describe how the website functions in order to allow reviewers to better understand user expectations, data management, and the relationship the website will have with the research. The following questions are considerations to assist reviewers in assessing the risk level.

1. Can the researcher see the information online without having to register a membership?
2. Does the website have a policy against research being done on the site?
3. Is there any indication that communication on the site is private, confidential, and/or selective in viewership?
4. How likely is it that there might be unknown minors involved on the site? What, if anything, can be done to identify and/or filter them out of recruitment and data retrieval?
5. Does the website create identifiable or linkable information? Keep in mind, re-identification is possible with information as trivial as zip codes and web search queries. In addition, IP address is a new type of identifier with different countries declaring it private information.
6. Does the site have a comment section that could compromise subject confidentiality or privacy? Can this section be turned off or moderated to protect subjects?

Data protocols

Data management is even more important in protocols using websites and apps because of the potential amount of data to be gained and the number of subjects involved. The following questions can help reviewers think through the potential problems and issues.

1. Is the app or website third party? If so, consult with legal when necessary.
2. How do participant termination and withdrawal procedures work with the app or website?
    a. Will the app automatically delete from their device(s)?
    b. Can they still use the app or website after withdrawing?
    c. Are protections in place to stop gathering data from these (former) subjects?
3. Does the context of the website create an expectation of privacy that differs from what would ordinarily be expected? For example, is an online chatroom the same as conducting a conversation in a public place or does the login requirement imply that it is private?
4. Is the use of archived content (even in discussion venues open to non-members) considered secondary use of data?
    a. Users post digital content for a specific purpose (e.g., to provide or seek new information, to communicate with members of a specific community, and/or to possibly seek general public attention). It would be rare for users to expect their digital content will be used in an unknown person's research project. Thus, all content used for research purposes without the user's knowledge or expectation of such could be considered secondary data use.
    b. In many cases, users' content is archived indefinitely on the website to which it was originally posted. Users may or may not be aware that comments they made are archived for many years afterwards. In this respect, these archives of user content are also secondary data because the content is going to be used for a purpose other than originally intended. Being used in an unknown person's research study would qualify as such a purpose.

5. Where is the data stored?
    a. Mobile app data can be stored on the participant's device(s) or on a server. Either option has risks involved regarding breach of confidentiality. The device could be stolen or the transmission of the data from the device to the server could be intercepted. Encryption should be done in either case to protect participants' confidentiality. Devices should also be password protected.
    b. How long will the data be stored in each storage type/format that will be used (i.e., how long will the data remain on a subject's device, how long will it be on the server, and/or how long it will remain in the PI's possession)?
    c. Is the data stored in multiple locations with different laws? For example, European countries have different regulations and standards for digital privacy that may conflict with local standards.
6. If the researchers are using a third party server, does that third party also have access and right to use the data? Is this clearly stated in the protocol?
7. Does the protocol describe any password protection or data encryption for data obtained from digital sources?
8. Does the PI have any experience with the app software? The PI needs to know if the app gathers any data not specified in the study protocol and describe how the protocol will deal with this additional data.

Digital data coming from websites and apps can create unanticipated problems and/or violations of confidentiality and privacy. Some types of data can seem perfectly safe on an individual level but, when taken to the scale that is possible with digital data gathering methods, they can create problems. Even data that is completely de-identified can be dangerous. An example of completely de-identified data creating a breach in privacy involved an exercise-tracking app called Strava. The app released a map of their users' data that tracked their exercise routes to show the global impact of their app. The map had more than three trillion GPS data points that, inadvertently, created a map detailed enough to reveal the outlines of military bases in Afghanistan (identifiable to the level of individual buildings) which even Google Maps had greyed out for security purposes. For more information, hold down the control button and click here.

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