Brief Overview of Regulations that Govern Research Involving Human Participants

The regulations for conducting research involving human participants in the U.S. are determined by the U.S. Department of Health and Human Services (HHS) and codified in the Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (45 CFR 46). These regulations require all human subjects research that is either directly or indirectly supported by the federal government to be reviewed and monitored by an IRB.

Researchers must also adhere to regulations or policies set forth by other HHS agencies, such as the Food and Drug Administration (FDA), Title 21, Food and Drugs, Part 50, Protection of Human Subjects, and 56, Institutional Review Boards, which relates to the conduct of clinical research with drugs or devices, or the National Institutes of Health (NIH), the agency primarily responsible for biomedical and public health research in the U.S.

Another federal regulation applicable to human subjects research is the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which protects the privacy of patient health information.

Finally, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (ICH E6) are international ethical and scientific standards for the conduct of clinical research, which researchers are encouraged to follow and may be required by a funding agency, study sponsor, or the IRB.

*******Although no regulations speak directly to the use of social media in research, to help guide researchers and oversight bodies, the Secretary's Advisory Committee on Human Research Protections (SACHRP), which provides expert advisement on human subjects protections to OHRP, as well as detailed considerations and recommendations for human subject research using the internet. In short, SACHRP recommends researchers to be mindful of the unique issues with regards to privacy, confidentiality, and ability to confirm participant identities that internet-based research presents.

Privacy & Confidentiality Considerations When Using Social Media to Recruit Study Participants

Per federal regulations, private information is defined as "Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record)" (U.S. Code of Federal Regulations).

SACHRP recommendations indicate that "If an activity (textual, visual, auditory) is legally available to any Internet user without specific permission or authorization from the individual being observed, or from the entity controlling access to the information, the activity should be considered "public behavior" (Secretary's Advisory Committee on Human Research Protections 2013). Therefore, social media posts made publicly viewable would be considered public behavior.

However, SACHRP recommendations note that research using public information in an identifiable way (i.e., the participant's identifying information is associated with the data), should be reviewed by the IRB. Accordingly, <u>using social media to locate and track participants falls within the domain of gathering identifiable information, indicating that the IRB would need to review these activities</u>.

Informed Consent and Transparency Considerations When Using Social Media to Recruit Study Participants

Federal regulations and Good Clinical Practice guidelines (U.S. Code of Federal Regulations and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), require study participants to be informed of the research procedures, risks, and protections of confidentiality. However, social media users are often not aware of platform terms of service or potential privacy and confidentiality issues related to platform functionality. Therefore, it is the responsibility of the researchers to acknowledge that participants may not understand these issues. Thus, researchers must clearly explain how the social media sites will be used, the intended purpose and use of information gleaned from the social media sites, the potential risks to participants and how they will be mitigated, and the outcome of data collected during participant involvement in the study.

Recommendations for Investigators Considering Social Media to Recruit Study Participants

1. The research team should develop a study protocol that accounts for social media use and follow-up methods. All aspects of the social media platform/website's functionality should be considered in line with applicable federal and state laws and other regulations.

2. The researcher should determine whether the study will or will not utilize each specific functions such private messaging, friend requests, profile access, etc. (see Table 1 for an example). For each function, researchers should specify how and when that function will be used, what, if any, participant information will be retained, and who will have access to the information.

3. Confirm the planned research is compliant with the platform/website's terms of use.

4. Determine appropriate safeguards to ensure confirmation of a potential participant's identity to avoid contacting false profiles or other users (e.g., confirmation of two or more identifiers based on information provided by the participant).

5. Similarly, the researcher and/or study team members should confirm the participant's identity before accepting friend requests (i.e. from Facebook®). Relatedly, if accepting friend requests via Facebook®, ensure that the study Facebook® site privacy setting restricts friends from viewing each other, ensure that the study Facebook site privacy setting restricts friends from viewing each other.

6. Create a safety monitoring plan for any issues that arise due to a message from a participant or a viewed public post. Even if the researcher does not intend to view public posts, the safety monitoring plan should recognize that due to many social media displays, researchers may inadvertently view posts when looking for contact information, such as through the *About* section on Facebook®.

7. Consider if the research may require using social media to view, locate, contact, or monitor participants' collaterals (e.g., Friends, associates, etc.). If so, additional procedures will need to be established and participants' collaterals may need to be given the opportunity to consent.

8. Develop and maintain standard operating procedures for locating and tracking participants via social media and ensure all researchers are trained in appropriate procedures and are adherent to them. For example, this could include internal guidance regarding communication to ensure data and/or protected health information is not communicated over messaging systems that may or may not be secure per the social media website terms of use and policies.

9. Study recruitment activities involving citizens residing in the European Union are subject to complying with the personal data protections of the General Data Protection Regulations (GDPR) (see https://ec.europa.eu/info/law/law-topic/data-protection/eu-data-protection-rules_en)

10. Recognize that social media may change, particularly over the course of a study, and that procedures may need to be reviewed and updated accordingly.

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