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Harvard Clinical & Translational Science Center

The Use of Social Media in Recruitment to Research: A Guide for Investigators and IRBs¹

Harvard Catalyst Regulatory Foundations, Ethics, & Law Program

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I. Scope and summary

Purpose and motivation

Recruitment to research remains a perennial challenge. Delays in recruitment slow the progress of socially valuable research and sometimes lead to studies being canceled altogether, resulting in enrolled participants being exposed to risk for no benefit. Social media has shown early signs of effectiveness as a recruitment tool, including among historically hard-to-reach populations, and its popularity as a recruitment tool is growing.² The aim of this guidance document is to facilitate the use of social media as a valuable recruitment tool in ways that are ethically and legally appropriate. As such, it seeks to provide institutions, IRBs, and investigators with the tools to evaluate the ethical and regulatory acceptability of research protocols that propose to recruit study participants through the use of social media. It also briefly covers issues that may arise when study participants utilize social media to discuss a trial after enrollment.

Definitions

Social media can be defined as any online and mobile resource that provides a forum for generating, sharing, or discussing ideas and content. Specific applications and web tools, many of which are free, are based on different, sometimes overlapping, themes and purposes, variably grouped as *online communities* (e.g., patient support groups, population-specific dating services); *social networking* (e.g., Facebook; Twitter); *professional networking* (e.g. LinkedIn); *content production and sharing* (e.g., YouTube, Tumblr, blogs); *location-based services* (e.g. Tinder, Grindr); and others. Many social media web services contain one or more platforms that allow users to view one another's networks and interact with each other in real-time. These include comment spaces, chat rooms, discussion fora, and the like.

Existing Guidance

The federal regulations do not explicitly address the use of social media in human subjects research. Under the regulations, social media recruitment is held to the same standards as other types of recruitment efforts, including the requirement for prospective IRB review.³ Other than this basic acknowledgment, however, there has been little regulatory guidance available to IRBs and investigators for evaluating social media recruitment. Moreover, while several papers

² See Puffer and Torgersen 2003; Gorman et al. 2014; Martinez et al. 2014; and Kobayashi et al. 2013, cited here in Appendix C.

³ The available federal guidance can be gleaned from the following four documents: (1) OHRP, *Guidance on Institutional Review Board Review of Clinical Trial Websites* (<http://www.hhs.gov/ohrp/policy/clinicaltrials.html>); (2) SACHRP, *Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations* (http://www.hhs.gov/ohrp/sachrp/mtginqs/2013%20March%20Mtg/internet_research.pdf); (3) FDA Information Sheet, *Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators* (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm>); and (4) OIG, *Clinical Trial Websites: A Promising Tool to Foster Informed Consent* (<http://oig.hhs.gov/oei/reports/oei-01-97-00198.pdf>). None of these sources offers explicit guidance on the use of social media in study recruitment.

in the bioethics literature mention the potential regulatory and ethical challenges raised by social media recruitment, to date there has been no in-depth evaluation of these issues or attempts to provide investigators and IRBs with concrete ethical guidance on the issues.

What Is New Here?

An important assumption of this guidance is that the ethical issues and concerns characterizing social media recruitment are *substantially the same* as those characterizing more traditional recruitment methods. Social media recruitment is subject to the same regulatory and ethical norms as traditional recruitment, including the requirements of prospective review and approval, compliance with all applicable federal and state laws, fair and equitable subject selection, respect for the privacy and other interests of potential participants, sensitivity to the norms and values of different communities, and consideration for the impacts of different recruitment techniques on public trust in the research enterprise. Nonetheless, social media provides a new context for the application of these norms, where their operational implications may differ. Thus, rather than reiterating existing ethical and regulatory principles of recruitment in general, this document pays close attention to the potentially unfamiliar aspects of social media recruitment, providing examples and concrete guidance to help investigators and IRBs navigate this terrain.

Executive Summary

Key Point: Social media recruitment does not require new regulatory or ethical principles.

Investigators proposing and IRBs evaluating social media recruitment should approach it in substantially the same way they do traditional recruitment methods.

- **Step 1:** Ensure that social media recruitment methods comply with all pertinent laws and federal regulations, including HIPAA and HITECH. This is initially the investigator's responsibility, with oversight by the IRB and assistance from institutional legal counsel, as needed.
- **Step 2:** Ensure that proposed social media recruitment techniques comply with the policies and terms of use of the relevant websites; certain exceptions may be possible (see below, sec. IV). This is initially the investigator's responsibility, with oversight by the IRB and assistance from institutional counsel, as needed.
- **Step 3:** Ensure that the proposed recruitment strategy: (1) is sensitive to the privacy of potential participants; (2) is respectful of the norms of the community being recruited; and (3) will not undermine public trust in the research enterprise, including via deceptive practices or lack of transparency. This is a joint responsibility of the investigator and IRB.
- **Additional Steps, as Needed:**
 - Investigators should typically obtain consent from currently enrolled research participants before attempting to contact and recruit members of their online networks, or request that enrolled participants facilitate introductions directly.
 - Investigators should take steps to discourage enrolled participants from engaging in online communication that threatens to un-blind the study or otherwise jeopardize scientific validity.

II. How does social media differ from other recruitment methods?

Evaluating social media recruitment techniques does not require new ethical or regulatory principles, but rather sensitive application of these principles in the more ‘embedded’ and interconnected context of social media.

There are two types of social media recruitment, which mirror two types of traditional recruitment:

- *Passive recruitment*: distributing recruitment materials (ads, posters, flyers) with the aim of attracting potential participants to contact the research team for enrollment. Passive recruitment can be targeted to specific audiences, by selecting sites for poster or ad placement that are likely to be trafficked by the population sought for recruitment.
 - **Traditional passive recruitment**: For example, posting flyers in subways or buses.
 - **Online passive recruitment**: For example, placing advertisements in health or patient support group websites.
- *Active recruitment*: approaching and interacting with specific individuals with the aim of enrolling them in research, usually on the basis of knowledge of characteristics that would make them suitable candidates for particular trials.
 - **Traditional active recruitment**: For example, approaching an oncology patient in clinic for trial enrollment on the basis of the research staff’s knowledge of their disease state.
 - **Online active recruitment**: For example, emailing or “friending” a member of a patient support website for breast cancer on the basis of their online activity and membership in the group.

Point 1. The online versions of active and passive recruitment have strong corollaries to traditional forms of active and passive recruitment.

Guidance 1. When evaluating online versions, investigators and IRBs should imagine their ‘off-line’ equivalent and ask how that equivalent situation would be assessed.

Example A. Investigator A wishes to recruit from a Facebook patient support group to increase enrollment for her clinical trial. The Facebook support group is ‘open,’ that is, there are no restrictions on joining the support group, no registration, and no assumption that all members online are somehow afflicted with a common disorder. Anyone, including the research team, can identify and contact members of the group through it. The question is whether contacting people in this way would be ethically advisable, given that the group is not specifically geared toward clinical research.

Analysis. This case resembles a physician-investigator in a clinical setting attending an open patient support group for oncology patients in order to make them aware of the opportunity to participate in a trial. An IRB might appropriately advise the investigator to seek permission to attend the in-person support group in order to protect patient privacy and preserve trust. In the online setting, however, such groups are often less personal and intimate, and there is less continuity to them; the nature of

the group is more fluid. Thus, an IRB might consider (but not necessarily require) asking the investigator to notify the moderator (if such a moderator exists) that they intend to participate in the virtual support group, and to be sensitive to any concerns expressed by the moderator. In addition, the IRB might ask the investigator to record any negative comments or feedback received about this recruitment approach from the Facebook support group members, tabulate that information, and report back to the IRB at continuing review or earlier. Other steps to ensure transparency, as described below, might be equally important and respectful.

Example B. Investigator B wishes to use online ‘banner ads’ to increase targeted recruitment for her clinical trial. Banner ads deliver customized online messages for specific individuals or subgroups of individuals based on their search and browsing history, online profile information, and the like.

Analysis. The first step is to ask whether this case differs from the familiar practice of strategically placing flyers in physical spaces likely to be frequented by the study population (e.g., placing flyers for a study on depression in college students around college dorms). The only difference is that online banner ads utilize an individual’s search history and other online activity to target relevant populations. However, this information is generally not shared with investigators, but is rather part of an algorithm used by the site or advertising company.⁴ So long as these algorithms comply with applicable law, and investigators receive no information about individuals, online banner ads should be evaluated in the same way as strategically-placed traditional posters and flyers.

Point 2. The possibility of unanticipated interactions and dialogue between the research staff and potential participants over social media during the recruitment process does not warrant special IRB concern, because this can occur in traditional ‘off-line’ recruitment as well.

Guidance 2. Investigators should consider providing the IRB with a formal communication plan that includes responses to likely questions that may arise during the recruitment process, for both traditional and social media recruitment; a detailed script is unnecessary (see also below, sec.VII). IRBs should indicate during the review process if there is any communication or specific information that must be avoided.

Example C. Investigator C plans to use Facebook to recruit women between the ages of 18-35 for a clinical study on pregnancy. In order to identify participants, Investigator C joins an open Facebook page, which is not moderated and on which there are no restrictions for joining, that is updated weekly with resources and helpful information for pregnant women. Investigator C decides to approach women who have ‘liked’ the page via a private, direct message inviting them to participate in the clinical trial, and also intends to establish a Facebook page for the trial once it begins. There is some concern

⁴ While the site or advertising company may wish to consider their legal, regulatory and ethical exposure (e.g., concerning access and use of individual private information) in this instance, third party concerns are beyond the scope of this guidance.

about the amount of online interaction Investigator C proposes, both in terms of initial contact of participants and continuing interaction with them on the trial's Facebook page, given how dynamic, fluid, and fast online communication can be. The worry is that Investigator C may be tempted in the moment to communicate in ways that make the trial look more appealing than it is and that either induces or puts subtle pressures on the women to enroll.

Analysis. The IRB should ask how Investigator C's strategy for online recruitment would differ from approaching the same population in person and facilitating continuing interaction and support throughout the course of trial. While online interaction can be fast-paced and unpredictable, the same is true of in-person communication. Investigator C should submit a communication plan that contains the description of the study that will be used for recruitment purposes, states answers to any common questions likely to arise, and outlines a plan for handling participant posts or communications on Facebook that may threaten to un-blind the study or jeopardize its scientific integrity (see sec. VI below). The IRB should flag the types of communication that would be considered problematic in this context. The IRB may also advise the investigator to notify people contacted in this way of how they were identified (i.e., based on their 'liking' this Facebook page).

III. Laws and regulations

In addition to the Common Rule and FDA regulations governing human subjects research, trial recruitment may trigger legal requirements under HIPAA and HITECH, when research is undertaken by 'covered' or hybrid entities (or their employees) under these statutes and is also subject to state laws.⁵ Importantly, these legal requirements do not differ when applied to social media recruitment.

Point 3. As with all human subjects research, federal and state laws govern social media recruitment activities.

Guidance 3. Investigators and IRBs should determine which federal and state laws are applicable to particular social media recruitment activities and ensure compliance with them.

- Certain requirements imposed by applicable laws may be eligible for waivers during the recruitment stage of research.
 - For example, the requirement imposed by HIPAA to obtain consent before using an individual's protected health information may be eligible for waiver when the use of PHI is restricted to initial contact and offers of enrollment.⁶

⁵ For the purposes of HIPAA 'covered entities' are defined as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information during transactions for which HHS has adopted standards (https://privacyruleandresearch.nih.gov/pr_06.asp).

⁶ See HHS, *Can the preparatory research provision of the HIPAA Privacy Rule at 45 CFR 164.512(i)(1)(ii) be used to recruit individuals into a research study?* (Available here: http://www.hhs.gov/ocr/privacy/hipaa/faq/research_disclosures/317.html); and SACHRP, *Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations* (available here: http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf).

- Institutional legal counsel should be sought whenever there is uncertainty about the applicability of federal and state laws, whether a protocol complies with them, or whether and under what conditions certain legal requirements can be waived.

Example D. Investigator D wants to access a patient support group website to search for prostate cancer patients to enroll in a clinical trial. There are no restrictions on joining the support group, though most of the members in fact suffer from prostate cancer or are connected to someone with prostate cancer.

Investigator D will join as an authorized member of the website, which will allow him to search by gender, age, and medical condition. All members of the site have the ability to click on specific individuals and see the personal medical information members have made available over the site, including in many cases their medical history and treatment plans. Investigator D will not record or use the information that he sees, other than for identification purposes. Once he successfully finds patients that appear to meet the study criteria, he will join specific support chats where he can contact them directly. There, Investigator D will truthfully identify himself as an investigator seeking patients for a clinical trial.

Analysis. In this scenario the information the investigator seeks to access via online profiles constitutes protected health information (PHI) under HIPAA, if accessed by a covered entity. If PHI will be accessed, but not collected or stored, then HIPAA may not apply, which appears to be the case in this scenario. If HIPAA does apply, compliance would typically require the investigator to obtain consent from the social media users before collecting and using their PHI as part of a research protocol, although a waiver of authorization may be possible in these situations.

In addition, the Common Rule may also apply to investigators passively viewing and collecting information on the site, even if there is no interaction between researchers and the site's users. The Common Rule applies if identifiable information on the site is considered 'private,' 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 (for example, a medical record)."⁷ Whether social media users have such a reasonable expectation of privacy is a contextual issue that will vary from case-to-case depending on how public or private the site is. If, as perhaps in the example above, it is common knowledge among the site's users that there are no restrictions on joining the site and that their information may be observed by any member, this may not be a context where they can reasonably expect privacy. On the other hand, for sites where there are stricter requirements on who may join and access information, users may have a valid expectation of privacy, in which case the Common Rule would apply.

⁷ 45 CFR 46.102(f)(2).

Similarly, the expectations of the site's members help to determine appropriate precautions when actively approaching them for recruitment purposes. Researchers must always be transparent, respectful, and sensitive when approaching people for recruitment (see below, Sec. V). If there is an expectation that a site is private, or that recruitment advances may be experienced by members as intrusive or insensitive, it may also be appropriate for the IRB to require additional precautions. For example, the IRB may require the investigator to contact the site's moderator to gain insight into and gauge user expectations. If there are concerns that recruitment advances would be experienced as unduly burdensome by members of the site, the IRB might require investigators to post an announcement on the site (or otherwise inform its members) that they could be approached for research purposes and provide them a chance to opt-out of being so contacted.

IV. Website policies and terms of use

Social media sites are typically governed by policies or 'terms of use' to which users must agree, at the risk of being removed from a site for noncompliance and/or subject to legal consequences. Terms of use state the rules of the website on a range of possible issues, including what types of interactions are expected and tolerated on the site, how personal information shared over the site may be used, which outside entities will have access to personal information for what purposes, and so on.

Point 4. Terms of use may vary from site to site, and the terms may be revised over time. There may also be different terms of use for different types of users and different groups.

Guidance 4A. Investigators should check that their proposed recruitment strategies comply with the policies and terms of use of the sites they wish to use and should document and certify this compliance for the purpose of IRB review. In the event that terms of use are absent or unclear, the investigator should document that the proposed recruitment strategies are not known to be in conflict with them.

Guidance 4B. If the recruitment strategy is approved, investigators should re-confirm compliance or absence of conflict at each continuing IRB review. In the event that the terms of use are revised in the interim in a way that is relevant for the protocol's continuing compliance, investigators should be responsible for notifying the IRB.⁸

Guidance 4C. If a recruitment strategy conflicts with a site's stated policies or terms of use, investigators should seek an exception and obtain explicit written permission from the site to engage in the recruitment activity in question. If permission is granted, investigators should provide documentation and IRBs should allow the recruitment activity to proceed (absent other reasons for concern).

⁸ Many sites send email notifications when their terms of use change, so this should not be too burdensome for investigators to track.

Guidance 4D. In some cases, investigators may ask the IRB to approve a recruitment strategy that conflicts with a site's terms of use and for which no exception has been sought and/or granted. Different IRBs may approach this situation differently. Some IRBs may have a policy of categorically refusing to approve strategies that conflict with terms of use when no exception has been granted and/or an exception has been explicitly denied. Other IRBs may be willing to consider the request with input from institutional legal counsel, to determine whether the investigator's reasons for breaking the terms of use are justifiable in a particular case and to ensure that institutional considerations are accounted for. Depending on circumstances and institutional perspectives, either approach is reasonable. Note, however, that there may be practical consequences for violating terms of use, ranging from being blocked from using a site (with obvious implications for recruitment) to legal action.

Example E. Investigator E wishes to recruit over a patient support site, but the stated terms of use restrict access to 'Patients and Friends and Family only.' However, a section of the website features prominent navigation (e.g., a dropdown panel or caption heading) for 'Emerging and Experimental Therapies and Trials.' In this part of the site there are numerous postings from researchers offering enrollment to members of the site, and archived posts clearly indicate that it is a well-traveled, active area. Investigator E's study offers participants the prospect of direct benefit, but he anticipates difficulty meeting recruitment targets by other means.

Analysis. The proposed recruitment strategy does not comply with the site's explicit terms of use. An investigator who nonetheless wishes to pursue the strategy should begin by noting this conflict to the IRB and articulating why they believe it is nonetheless appropriate to pursue. The IRB may request that the investigator contact the website to seek an exception to its stated policies, especially since in this case the site appears to permit researchers to use the site under certain conditions. If the request for an exception is granted, the investigator should document and submit this to the IRB, which should allow the recruitment strategy to proceed, barring other concerns. In the absence of an exception, the IRB should assess whether it will treat compliance with terms of use as non-negotiable, or whether to consider the particular circumstances and reasons presented by the investigator, in close association with institutional legal counsel.

Example F. Investigator F wishes to conduct a study on racial bias in online hiring practices. The study would involve posting fabricated resumes to online job sites such as Monster.com. Some of these resumes will identify the job-seeker as belonging to a racial minority group, while others will not, allowing the researcher to gauge the effects of race in the hiring process. However, the terms of use of Monster.com and the other job sites forbid the posting of fabricated resumes.

Analysis. Investigator F should begin by informing the IRB that what he is proposing conflicts with the stated terms of use of the relevant websites and articulating why they nonetheless think it is appropriate to pursue. The IRB may request that the investigator contact the website to seek an exception to the terms of use. If the exception is granted, the investigator should document and submit to the IRB, who should allow the proposed

plan to proceed, barring other concerns.

Suppose, however, that the sites do not respond to Investigator F's requests for an exception, and that Investigator F subsequently asks the IRB to consider approving the study despite the fact that no exception has been granted. The IRB should then assess whether it will treat the terms of use as non-negotiable, or whether it will, in close association with institutional legal counsel, consider approving the investigator's request. In this case that would involve asking, first, whether it is possible and feasible to conduct research on racial bias in online hiring in other ways, without fabricating resumes or violating website terms of use. If it is not feasible to conduct research on this topic without fabricating resumes and breaking website terms of use, the IRB must then ask whether the value and possible benefits of the knowledge we stand to gain from the study outweighs the risks of breaking the relevant terms of use. Again, we emphasize that reasonable IRBs may differ on these issues and cases.

V. Privacy, trust, respect

Even when social media recruitment satisfies legal requirements and complies with relevant terms of use, if it violates the norms of privacy, trust, or respect for the population recruited, it is ethically problematic and as a practical matter likely to backfire, failing to adequately recruit and potentially causing damage to the research enterprise.

Point 5. Different social media sites may have different cultures and expectations among users.

Guidance 5A. Investigators and IRBs should ensure that the proposed recruitment strategy is respectful of the community being recruited and will not undermine public trust in the research enterprise.

- Investigators should not employ deception or fabricate online identities in order to gain access to online communities.
- Investigators should be fully transparent about the aims and details of a study when approaching potential participants.
- Recruiters should not 'creep' or 'lurk' on social media sites collecting data about potential participants in ways unknown to the site's users.

Guidance 5B. Investigators and IRBs should ensure that the proposed recruitment strategy is sensitive to the privacy interests and expectations of potential participants on social media.

- Investigators should not communicate with potential participants online in ways that threaten to reveal sensitive or embarrassing information about them.

Point 6. So long as these norms are respected, online recruitment advances are not inherently offensive, intrusive, or worrisome, any more so than being approached actively in person, via mailing, by telephone, etc., or passively by posters, flyers, and the like.

Guidance 6. There should not be a presumption against recruitment using social media. So

long as recruitment advances are undertaken transparently and with due respect for the privacy rights and interests of social media users, they will typically satisfy relevant ethical requirements.

Example F. Investigator F is conducting a clinical trial on frontotemporal dementia (FTLD). Investigator F knows that this is a difficult patient population to access, given that it is a very rare disease. The research team discovers an online support group for individuals recently diagnosed with FTLD and their family members. The site's terms of use do not explicitly require users of the site to be FTLD sufferers or their family members, though there seems to be a presumption among members of the site that this is the case. Neither do the terms of use forbid researchers from recruiting over the site. The research team proposes to contact members of the site and offer them the chance to participate in the study, but some members of the IRB have reservations, stemming from the belief that research recruitment overtures would conflict with the presumed intent of the site, which is to foster emotional support among people personally affected by FTLD, and that some members of the site may feel embarrassed, stigmatized, or alienated by recruitment advances.

Analysis. While some members of the site may feel annoyed or embarrassed by recruitment advances, the same may be true for recruitment that does not use social media methods, and by itself does not make such recruitment ethically problematic. While the research team has an obligation to interact with potential participants in ways that are transparent, respectful, and sensitive to their circumstances, recruitment advances on their own should not be considered inherently problematic or intrusive in any ethically significant sense. Moreover, while some may feel embarrassed or alienated by recruitment advances, other users of the site may welcome the opportunity to participate in clinical research, particularly if it holds the prospect of direct benefit.

That said, because the purpose of the site is emotional support, it is appropriate for the IRB to ensure that the site's users are not alienated or burdened. The IRB may, for example, advise the investigator to contact the site's moderator (if there is one) for an introduction to the group, and to gauge the level of precaution necessary. Additional substantive protections might include posting an announcement or otherwise informing members of the group that they may be contacted for research recruitment and giving them the opportunity to opt out of being contacted for research purposes. Note that these steps may also have the added benefit of improving recruitment rates by making a site's users more comfortable with research contacts.

VI. Recruiting from the networks of current or potential participants

One of the key features of social media sites is that individual users are often networked with 'friends,' 'followers,' and the like. In many cases these networks can be accessed with relative ease, particularly when an initial participant was recruited using social media. This dynamic can facilitate recruitment of individuals who match inclusion criteria for particular studies via the

online networks of current study participants or potential participants with whom the research team has interacted.

Point 7. Recruiting from the social networks of current or potential research participants has the potential to reveal sensitive information about them to members of their network.

Guidance 7A. Investigators and IRBs must protect the privacy rights and interests of current or potential participants when considering recruiting via their online networks.

- Investigators should never reveal anything to a current or potential participant's networked 'friends' or 'followers' that could let sensitive information be inferred about them (including their status as current or potential research participant), without the consent of the current or potential participant.

Guidance 7B. The IRB should typically require investigators to obtain consent from current or potential research participants before contacting members of their online network for recruitment purposes, or to enlist participants themselves to approach members of their network on behalf of the research team.

- If consent to contact is given, such consent should be documented in the research record and is sufficient to remove concerns that an IRB might otherwise have about protecting privacy rights and interests.
- If consent is requested and denied or withheld, however, investigators may not approach members of a participant's social network through their social network.

Guidance 7C. The IRB may and should make an exception to the requirement for consent if the investigator independently identifies the relevant individuals for study recruitment without using the online network of the current or potential participant.

Example G. Researchers have successfully recruited Participant G for a study involving drug use in the LGBTQ community, and now wish to use her social media network to recruit other participants for the same study. Participant G often frequents a LGBTQ bar where there is known drug use, and she sometimes posts pictures of herself and her friends at the bar on Facebook. The researchers want to use this information to contact the friends tagged in one of participant G's photos and offer them the chance to participate in the study.

Analysis. The research team has an obligation to be transparent about how they identify potential participants for study inclusion. In this case transparency would require telling Participant G's friends that the research team has identified them for possible study inclusion using Participant G's online network. However, the research team also has a strong obligation not to disclose Participant G's sensitive personal information to members of her online network—including information that would allow Participant G's friends to infer her personal health information, such as her current enrollment in the research protocol. This obligation would prohibit the research team from disclosing Participant G's status as a research participant to her friends, and thus prevent

researchers from being transparent with Participant G's friends about how they were identified.

Because of this, the IRB should require one of two things. First, the IRB may allow the research team to connect with members of Participant G's social media network only if Participant G is willing to facilitate an introduction herself. Alternatively, the IRB may allow the research team to contact Participant G's friends directly provided that Participant G has provided her consent for the research team to do so, acknowledging that this would entail disclosing Participant G's status as a research participant (and other possible private health information). This would allow the research team to be transparent with Participant G's contacts about how they were identified while respecting Participant G's privacy rights and interests.

Suppose, however, that in this situation one of Participant G's tagged Facebook friends, whom the research team wishes to recruit, is also independently referred to the study by her primary care physician. In that case the IRB should allow the research team to pursue enrollment of this individual without seeking Participant G's consent or asking her to facilitate a direct introduction.

Because Participant G's friend is identified and approached about study enrollment independently, by her primary care physician, not by way of Participant G's network, transparency in this case does not require disclosing Participant G's status as research participant, and so Participant G's consent is not required. To be clear, the mere presence of a potential participant in another current or potential participant's social media network is not itself a barrier to recruiting that individual. The key issue is whether the social media network is directly used for recruitment purposes, or whether recruitment occurs by other means.

VII. Managing post-enrollment online communication

Social media may facilitate post-enrollment communication between researchers and study participants, as well as communication between study participants (and potential participants) themselves. This is possible even when social media is not utilized for recruitment but may be even more likely when it is. Although participants in any study may speak with one another, the use of social media decreases the barriers to connectivity and has the potential to dramatically extend the prevalence and reach of communication between participants.

Point 8. While online interactions may be beneficial, for instance by promoting enrollment in the trial when participants have positive experiences, the following risks are incurred:

- Participants posting online descriptions of their experience may jeopardize the scientific integrity of the trial by including information that threatens to un-blind themselves, other participants, or the research team. This may occur, for example, when different participants describe in-detail the interventions they are receiving and speculate online about what arm of the trial they are in. Participants posting explicitly incorrect information about the trial can undermine the understanding of other participants (and potential

participants) and possibly introduce bias into the study.

- Participants portraying their experiences in an unduly negative light may harm study recruitment and retention and thereby introduce selection bias into the trial. This may also be of import to the IRB.
- Participants reporting their experiences with certain drugs or devices may unjustifiably influence the public perception and worth of these products.

Guidance 8A. Investigators should be aware of, and IRBs should help educate about, the risks of un-blinding and misinformation in participants' online communications.

Guidance 8B. Although investigators cannot—and should not be expected to—routinely monitor all online communications by their participants, investigators should take reasonable steps to minimize the risks of these communications. Possibilities include:

- Development of educational materials explaining the importance of maintaining blinding during the trial, and how social media communications may jeopardize the integrity of the trial.⁹
- A specific request to each participant to refrain from communications about the trial that could result in un-blinding (e.g., online postings containing detailed descriptions of the intervention and how it is affecting them, speculations about which arm of the trial they are in, and so on).

Notably, these protections might be useful to prepare for any type of communication between research participants, on- or off-line.

Guidance 8C. When social media communication among participants is likely, as when social media is used for recruitment but in other cases as well, investigators should develop a communication plan for addressing these risks, to be submitted with the original protocol. This plan should identify triggers (e.g., participant speculation on social media about which arm they are in) for interventions from the research team (e.g., corrections of misinformation or reminders about risks of un-blinding).

Example H. Investigator H starts to monitor Twitter posts related to migraines and finds that participants in his study are providing specific health information to others based on their study experience, and incentivizing others to join (e.g. “Currently doing a #migraine study, this #Lupron is great. Join this study -- it pays and it works! #clinicaltrial”).

Analysis. A tweet of this nature may influence individuals to enroll on the basis of expectation of medical relief, or to misrepresent themselves in order to appear eligible for the trial and receive compensation. It may also threaten to un-blind the research team or other participants. When the integrity of a trial is jeopardized by the dissemination of misleading information, investigators and research institutions have a strong interest in correcting it. In such cases

⁹ Such as those developed by the Center for Information and Study on Clinical Research Participation, here: <https://www.ciscrp.org/primer/>. See also the McNair citation in Appendix C.

the investigator should post a reminder that the trial is in progress and that this type of speculation can damage the integrity of the trial. Such communication could be part of the IRB-approved communications plan or may require an amendment to authorize this and similar communications during the trial.

VIII. Conclusion

The prevalence and popularity of social media is only likely to grow, and with it the appeal of using social media as a recruitment tool, particularly if early signs of effectiveness bear out. Proposing and evaluating social media recruitment requires sensitivity to the dynamics of online communities, and may involve some potentially unfamiliar issues, but these should not be exaggerated. This document has strived to put social media recruitment in regulatory and ethical perspective and to function as a roadmap for investigators and IRBs navigating its potentially unfamiliar aspects.

The pages directly following contain further resources in the form of three Appendices:

- A checklist for investigators proposing to recruit via social media, which they should be encouraged to complete and submit to the IRB
- A checklist for IRBs reviewing social media recruitment
- A list of readings that investigators and IRB members may find helpful for further consideration

Appendix A: Investigator checklist for proposing social media recruitment

Investigators proposing to recruit via social media should take the following steps:

1. Provide the IRB with a statement describing the proposed social media recruitment techniques, including:
 - A list of the sites to be use.
 - A description of whether recruitment will be passive and/or active.
 - If utilizing active recruitment, a description of how potential participants will be identified and approached, and their privacy maintained.
2. Ensure that the social media recruitment strategy complies with applicable federal and state laws.
3. Provide the IRB with a statement certifying compliance (or lack of noncompliance) with the policies and terms of use of relevant websites, OR if proposed techniques **conflict** with relevant website policies and Terms of Use:
 - Seek an exception from the website to its terms of use; provide the IRB with written documentation of the exception, if granted.
 - Depending on IRB policy, in compelling circumstances make the case that the recruitment strategy should be allowed to proceed in the absence of an exception from the site.
4. Ensure that the proposed recruitment strategy respects all relevant ethical norms, including:
 - Proposed recruitment does not involve deception or fabrication of online identities.
 - Trials are accurately represented in recruitment overtures.
 - Proposed recruitment does not involve members of research team 'lurking' or 'creeping' social media sites in ways members are unaware of.
 - Recruitment will not involve advancements or contact that could embarrass or stigmatize potential participants.
5. If the research team intends to recruit using the online networks of current or potential study participants:
 - Provide the IRB with a statement explaining this approach and describing plans either to obtain consent from participants before approaching members of their online networks, or to enlist enrolled participants to facilitate introduction between members of network and research team.
6. Consider whether a formal communication plan is needed for managing social media activities among enrolled participants, including:
 - Steps to educate participants about the importance of blinding and how certain communications can jeopardize the scientific validity of a study (e.g., a section in the orientation or consent form)
 - Triggers for intervention from the research team (e.g., misinformation or speculation among participants on social media that could lead to un-blinding)
 - Interventions from the research team (e.g., corrections of misinformation or reminders about importance of blinding on social media)

Appendix B: IRB checklist for evaluating social media recruitment proposals

IRBs evaluating protocols that propose to recruit via social media should take the following steps:

1. Seek to normalize social media recruitment to the extent possible, drawing analogies to traditional recruitment efforts.
2. Ensure that the proposed online recruitment strategy complies with all applicable federal and state laws.
3. Check that the investigator has certified compliance (or lack of noncompliance) between recruitment techniques and policies/terms of use of relevant websites.
 - If a proposed technique conflicts with website policies and terms of use, request that the investigator seek a written exception from the site, OR
 - Depending on IRB policy, request a written statement from the investigator explaining why the recruitment strategy warrants approval without an explicit exception, to be evaluated by the IRB with input from institutional legal counsel.
4. Ensure that proposed social media recruitment strategies respect all relevant ethical norms, including:
 - Proposed recruitment does not involve deception or fabrication of online identities
 - Trials are accurately represented in recruitment overtures
 - Proposed recruitment does not involve members of research team 'lurking' or 'creeping' social media sites in ways members are unaware of
 - Recruitment will not involve advancements or contact that could embarrass or stigmatize potential participants
5. Ensure that investigators will obtain consent from current participants before they approach members of their online network for recruitment via their network or enlist enrolled participants to facilitate introduction between members of their network and the research team.
6. Ensure that a communication plan is in place for how the research team will handle online communication from enrolled participants that threatens the integrity of study.

Appendix C: Bibliography and further reading

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