

DeSales University IRB Committee

Social Media Policy

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.

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.\*

1. **How Does Social Media Differ from Other Recruitment Methods? \***

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 based on 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 based on 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 based on 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.

**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. IRBs should indicate during the review process if there is any communication or specific information that must be avoided.

1. **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.

Importantly, these legal requirements do not differ when applied to social media recruitment.

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

**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. (See HHS..)
* 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.

(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>).

1. **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. If 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. If 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.

**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). 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.

1. **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.

1. **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 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.*

1. **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. (Such as those developed by the *Center for Information and Study on Clinical Research Participation*, here: https://www.ciscrp.org/primer/).**
* **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 abut risks of un-blinding).

\*Taken from Harvard Catalyst “The Use of Social Media in Recruitment to Research: A Guide for Investigators and IRBs\*

\*Taken from <http://college.emory.edu/communications/communications-resources/social-media.html>