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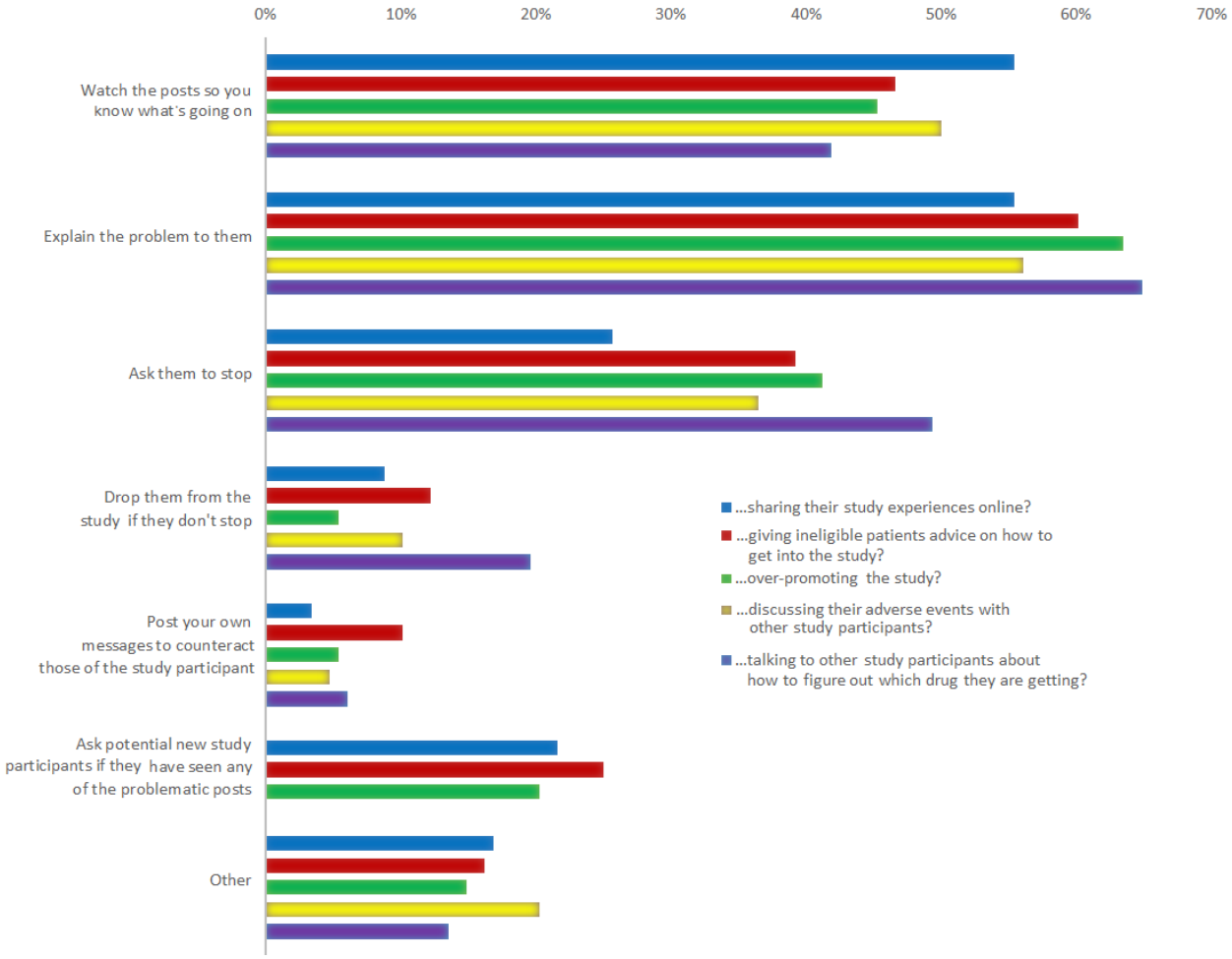
Clinical Research Ethics Question of the Month: Social Media Activity

By Norman M. Goldfarb

You are the chairperson of an IRB overseeing a study comparing three diabetes drugs. Some of the study participants have been talking about the study on social media. The sponsor believes their posts have affected study enrollment, adherence and retention. She wants your advice on how to deal with this problem ethically.

Results

The 148 respondents answered five related questions on how should the investigator should deal with study participants who are…
…sharing their study experiences online?
…giving ineligible patients advice on how to get into the study?
…over-promoting the study?
…discussing their adverse events with other study participants?
…talking to other study participants about how to figure out which drug they are getting?



The most popular interventions, in order of popularity, are to (1) explain the problem, (2) watch the posts, and (3) ask them to stop. The least popular interventions, in reverse order of popularity, are (6) post counteracting messages, (5) drop uncooperative participants from the study, and (4) ask potential participants if they have seen any problematic posts.

Respondents are most likely to monitor online activity for participants sharing their study experiences.

Respondents are most concerned about participants trying to figure out which drug they are getting, and then about posts giving advice about getting into the study.

Respondents are most likely to explain the problem when study participants are trying to figure out which drug they are getting. Respondents are most likely to ask these people to stop the postings and drop them from the study.

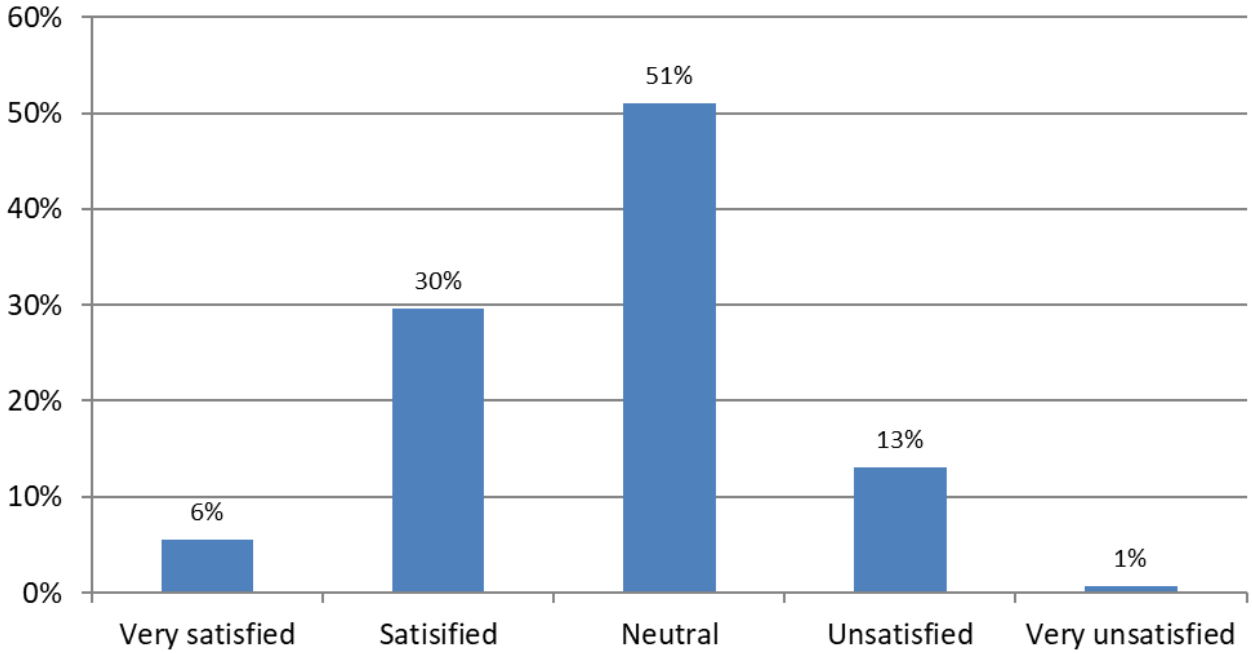
Respondents are most likely to respond to a post if it is giving advice on getting into the study. They are also most likely to ask potential study participants if they have seen posts giving advice on getting into the study.

The most pertinent of 235 comments can be summarized as follows:

- A number of respondents recommended including social media guidelines and their rationale in the consent process, since study participants might not recognize the ramifications of their social media activity. In addition, the investigator could describe his or her plans to monitor and participate in social media activity.
- A number of respondents pointed out that, if the consent form does not prohibit or social media postings, respondents are free to do as they wish.
- A number of respondents pointed out that consent forms are not legally binding on study participants.
- A number of respondents said that it is impossible to control social media activity.
- A number of respondents suggested the study was poorly designed. Other respondents recommended that the study be redesigned to minimize the impact of social media activity.
- One respondent said that study participants have First Amendment rights.
- Several respondents said that social media activity is a good thing because it reflects the real world.
- Several respondents pointed out that it could be impossible to identify the author of social media postings.
- Several respondents suggested that, if a problem arises, the investigator discuss the issues with all study participants, perhaps in a group format.
- Several respondents said that it would be unethical for the investigator to participate in social media discussions.
- Several respondents said that dropping a participant from the study would not necessarily stop their social media activity and could lead to negative postings.
- A number of respondents expressed concern about the effects of inaccurate social media postings.
- Several respondents noted that study participants can speak only to their own experience and are probably not qualified medical professionals with the necessary knowledge to give what amounts to medical advice.
- A number of respondents recommended posting to correct inaccurate information.

- Several respondents pointed out that social media postings might provide useful information (e.g., unreported adverse events, non-adherence, outcomes or issues with study conduct) for the investigator and study sponsor.
- Several respondents pointed out that posts by the investigator might have unexpected negative effects, e.g., calling more attention to the problematic posting.
- Several respondents noted that social media activity could provide useful, albeit possibly misleading, information to third parties like investors.
- Several respondents encouraged the investigator to use social media to educate and engage study participants.
- Several respondents recommended creating a private social media page for the study's participants and investigator.
- One respondent said that reading online posts could bias the investigator.
- Several respondents recommended asking potential participants how they heard about the study, so issues created by social media can be addressed.
- One respondent suggested discussing these issues with the IRB in advance.
- Several respondents pointed out that social media activity is qualitatively no different than face-to-face communications.
- Several respondents questioned whether "over promotion" is an issue, since there will still be a screening and consent process.
- Several respondents suggested that study participants might view investigator posts as "Big Brother" surveillance and interference with their rights to say what they wish.
- A number of respondents recommended keeping the IRB and/or sponsor informed about social media activity.

How satisfied are you that your advice will work?



Thirty-six percent of respondents expect their advice to work. Fourteen percent do not expect it to work. Fifty-one percent of respondents are neutral.

Discussion

Study participant social media activity is a significant and complex challenge for clinical research. Among other problems, ineligible patients can lie to gain admission, participants can perceive nonexistent adverse events or drop out if they learn they not receiving active drug, and people can take actions based on invalid information.

On the other hand, attempts to address postings that include misinformation or attempt to game the system can backfire if they are perceived as "Big Brother" surveillance and interference with basic rights. Site employees (or their friends and relatives), might take action if they discover what they consider objectionable social media activity by the investigator.

Bad or misguided behavior on social media, whatever the intent, is *qualitatively* no different than face-to-face bad or misguided behavior, so potential remedies should be considered from that perspective. However, because social media can magnify the effects by orders of magnitude, they must also be considered from the *quantitative* perspective.

Informed consent forms are odd animals: Study participants sign them but are not contractually bound by them. In contrast, while investigator signatures not required, consent forms create legal obligations for the investigator and, potentially, the study sponsor and IRB, as well.

While study participants have the legal right to say or do anything they wish, investigators have the obligation (a) to protect the health and welfare of all study participants, and (b) to protect the scientific validity of the study. If there is a study sponsor, it has the same obligations

The challenge for the investigator faced with a problematic social media posting (or any problematic participant action), is more practical than ethical: What intervention, if any, would address the problem without creating bigger problems?

To some extent, social media are governed by expectations of acceptable behavior, i.e., social norms (which might or might not be to act ethically). The problem is that many individuals feel free to violate these norms — or punish others for perceived violations — based on their own personal standards or lack thereof.

A first good step is to educate prospective participants during the consent process about the study's rules for social media activity and the possible consequences to the participant and the study for social media postings inconsistent with these rules. The guidelines can be provided as part of the consent form, in a separate document, and/or verbally. If the prospective participant agrees to follow the rules, the investigator is then free to enforce them.

Of course, the investigator would have to identify the author of an unacceptable post. If the identity is not self-evident, the investigator could research the identity. Or, the investigator could ask the participant to disclose his or her online identities in advance. Both options seem too creepy and invasive to employ. As in other areas, there has to be some assumption of trust between the investigator and the participant.

There is no ethical reason why the investigator cannot monitor a public social media venue, provided the venue permits his or her participation. However, if a group is open only to people who have a particular disease, it would be unethical for the investigator to join the group unless he or she has that disease. Neither would it be ethical for an investigator to recruit someone with the disease to join the group as his or her agent. The investigator should inform study participants of his or her monitoring plan. If an investigator wants to monitor the social media activity of study participants, their permission should be obtained because they would probably find it objectionable otherwise.

If problematic social media activity occurs, there is no *ethical* reason why the investigator cannot participate in the discussion, provided the online venue does not prohibit investigator participation. The challenge, again, is in the practical consequences of participation. In particular, public venues might have countless third-party participants who know nothing about the poster, the study, or clinical research, but believe strongly in their right to attack or defend anyone they please.

Another option would be for the investigator to respond to a problematic posting without identifying himself or herself as the investigator, or under a false identity. Using a false identity would clearly be unethical. Not identifying oneself would also be unethical if there is the intent or effect to conceal, even if everyone else is using a pseudonym. Leaving aside the ethics, the practical effects of unmasking could be severe.

One option for the investigator would be to identify social media where problems might occur and proactively say something like the following (with IRB approval, of course):

> We are starting a new clinical study to test what might be an effective new treatment for this devastating disease. If you are interested in learning more, please contact me or visit [study website]. I will be following this discussion for any mention of the study, so I can answer questions and correct any misunderstandings, as best I can.

It seems like a good idea for the clinical research enterprise to collectively draft standard language that could be used in online postings to provide useful information without giving offense. For example, the investigator might respond to a posting about how to game eligibility screening by saying something like the following:

> As the investigator in this study, I would like to point out that the purpose of this study is to find an effective new treatment for thousands of patients with this devastating disease. Therefore, we need everyone who participates in the study to accurately reflect the actual patients we want to eventually treat. If you have this disease, please talk to your doctor about your healthcare options, including clinical studies.

If you have language that could be useful during the consent process or on social media, please contact the author.

Next Month's Question

You are the chairperson of a central IRB overseeing a large phase 3 study. Based on an anonymous call, you determine that one of the investigators is not accepting homeless people who want to enroll in the study… Read the full question and give us *your* answer at: https://www.surveymonkey.com/r/X3S7K33.

Please send your ethical conundrums to ngoldfarb@firstclinical.com.

Author

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