Social Media for Research Recruitment: Ethical and Practical Aspects

Luke Gelinas, PhD
Senior Researcher, Petrie-Flom Center at Harvard Law School
Schulman IRB Member
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- Compliant with FDA, OHRP and Health Canada requirements

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About Today’s Presenter

Luke Gelinas, PhD
Senior Researcher, Petrie-Flom Center at Harvard Law School
Schulman IRB Member

- PhD in Philosophy/Ethics from University of Toronto; MA in Religion from Yale Divinity School
- Most recently completed a Postdoctoral Fellowship in Bioethics at National Institutes of Health and training in Clinical Ethics at Albany Medical College
- Research currently focused on regulatory, ethical, and practical aspects of recruiting and retaining research participants
- Work has been published in several academic journals, including Hastings Center Report, American Journal of Bioethics, and Journal of Medical Ethics
Learning Objectives

- Apply relevant Federal regulations to the context of social media recruitment
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- Utilize sound methodology for evaluating social media recruitment techniques
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- Understand how research ethics principles apply in the social media context, particularly the norms of respect for privacy and investigator transparency
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- Utilize sound methodology for evaluating social media recruitment techniques
- Understand how research ethics principles apply in the social media context, particularly the norms of respect for privacy and investigator transparency
- Understand potentially unfamiliar ethical aspects of social media recruitment techniques
Case Study 1: Open Facebook Group

- Researcher A is performing a study on effective support mechanisms for people with depression.

- A is having trouble meeting recruitment targets. One day A encounters an online Facebook support group for people with depression, many of whom are likely to meet inclusion/exclusion criteria.

- The group is ‘open’ and has no restrictions on joining.
Case Study 1

- Would it be advisable to contact this group, given that it is not geared toward research and members may not be expecting it?

- How (if at all) should recruitment proceed?

- What ethical and regulatory considerations apply?
Is it ethically acceptable for the investigator to target this online group for research recruitment?

A. Not acceptable
B. Acceptable to post a general announcement to entire group
C. Acceptable to individually solicit members based on their profile or online conversations/activity
D. Both B and C
Recruitment to research is challenging

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  - As of 2011, of all trials registered as closed on clinicaltrials.gov, over 47,000 subjects participated in under-powered studies

Social media holds promise as a research recruitment tool

- Social media use has increased exponentially and is now extremely common
- According to PEW Internet Research, as of 2016, 70% of ALL U.S. adults use at least one social media site, up from 5% in 2005
Ever-growing body of literature documenting social media’s effectiveness as recruitment medium across a variety of different contexts…
Background

- For example...
  - HIV vaccine trials (Sitar et al. 2009)
  - Occipital nerve studies (Goadsby et al. 2013)
  - Pediatric cancer research (Akard et al. 2015)
  - Depression prevention (Morgan et al. 2013)
  - Smoking cessation (Heffner et al. 2013, Frandsen et al. 2014)

- Also among historically hard-to-reach populations
  - Gay Latino couples (Martinez et al. 2014)
  - Young cancer survivors (Gorman et al. 2014)
  - Low incidence diseases (e.g., spontaneous coronary artery dissection, Tweet et al. 2011)
Potential Barriers

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  - What exactly should researchers designing social media strategies, and IRBs reviewing them, focus on?
Potential Barriers

- Currently no specific regulatory guidance on social media recruitment and very little in the bioethics literature
- Can lead to uncertainty among IRBs and investigators and risk of under-utilization
  - What exactly should researchers designing social media strategies, and IRBs reviewing them, focus on?
  - Are the risks different from more familiar recruitment? Are new ethical principles or review processes required?
Relevant Regulatory Requirements
U.S. regulatory bodies, notably the Office for Human Research Protections (OHRP), has consistently interpreted the regulations to provide IRBs authority and responsibility for review of study recruitment material

- Recruitment = beginning of informed consent process
- Thus, recruitment plan must receive IRB review/approval prior to initiation
Exceptions

- For exempt research, IRB has discretion over whether to review recruitment materials
  - Many IRBs request recruitment materials for exempt research and have standard processes for reviewing

- May be more relevant with expanded exemptions under new Rule
  - Educational tests, survey, interview, observation of public behavior; secondary research exemptions conditioned on broad consent (new .103(d)(7)-(8))
Regulatory Considerations

OHRP, “IRB Review of Clinical Trial Websites”
http://www.hhs.gov/ohrp/policy/clinicaltrials.html

- **When Is IRB Review of Clinical Trial Websites Not Required?**
  
  “Clinical trial websites that provide *only* directory listings with basic descriptive information about clinical trials in general...do not need to be reviewed by an IRB.”

- ‘Basic descriptive information’ = study title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), how to contact the study site for further information
  
  - Examples: ClinicalTrials.gov, the NIH National Cancer Institute's cancer clinical trials listing, AIDS Clinical Trials Information Service (ACTIS)
When Is IRB Review of Clinical Trial Websites Required?

“When information posted on a clinical trial website goes beyond directory listings with basic descriptive information, such information is considered part of the informed consent process and therefore requires IRB review and approval.”

- Information goes beyond basic = descriptions of clinical trial risks and potential benefits, solicitation of identifiable information, incentives

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Regulatory Considerations

- Implication of OHRP’s guidance …
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- Study websites created specifically for recruitment purposes should receive IRB review.

- What needs to be reviewed:
  - Recruitment plan
  - Typically, actual webpage also reviewed
    ◇ Screen shots may be helpful to the IRB
Collecting PHI Online

- In some cases, researchers may wish to identify potential subjects online, which could involve collecting/recording protected health information (PHI) for recruitment purposes.

- Consent for gathering PHI online for recruitment purposes must be obtained from individuals, or waived by IRB via the ‘preparatory to research’ clause...
  - Similar to how consent for access to PHI may be waived when researchers scan medical records for recruitment purposes.
(g) Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens
Ethical Considerations
How Should Social Media Recruitment Be Evaluated?

- Three part methodological recommendation…
How Should Social Media Recruitment Be Evaluated?

1. Begin by comparing online to off-line scenarios
   - E.g., approaching FB support group analogous to approaching in-person support group
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2. Apply relevant ethical principles
   – How would we typically evaluate the analogous off-line scenario?
How Should Social Media Recruitment Be Evaluated?

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   - How would we typically evaluate the analogous off-line scenario?

3. Identify differences that require further scrutiny
When evaluating recruitment proposals, should the IRB evaluate background risks of general social media use?

- Such as risks of social media platforms collecting and selling their data
Research versus Background Risks

- When evaluating recruitment proposals, should the IRB evaluate background risks of general social media use?
  - Such as risks of social media platforms collecting and selling their data

- Recommendation: IRB not required to assess background risks of social media generally
  - These have already been accepted in personal lives
  - *Best practice*: Researchers may wish to clarify with site how information will/not be used and disclose to individuals as part of IC
What Are the Relevant Ethical Principles in This Context?

- Belmont principles of respect for persons, beneficence, and justice
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- Belmont principles of respect for persons, beneficence, and justice
- Applied in this context particularly demand
  1. Respect for *privacy* of social media users
  2. Researcher *transparency*
Substantive Ethical Principles

- Respect for privacy
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  - Ensure that potentially sensitive health information is handled by research team in ways that minimize embarrassment, stigmatization, or harm
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- **Respect for privacy**
  - Ensure that potentially sensitive health information is handled by research team in ways that minimize embarrassment, stigmatization, or harm
    - Even if it is already available on social media.
    - Some/many users may not understand privacy settings or realize privacy implications.
    - Obligation not to compound privacy risks (e.g., by further publicizing sensitive information)
    - Acceptable to target individuals using available personal information, if done respectfully (similar to use of medical records in recruitment)
A Concern…

No matter how respectful researchers might be when recruiting people on social media …

- Some people are likely to be annoyed or off-put by their advances

- Doesn’t this caution against the use of social media as a recruitment tool? Particularly for targeting specific individuals?
A Distinction

- True that some people will *in fact* be annoyed
  - People can be annoyed by lots of things (almost anything, really)
A Distinction

- True that some people will *in fact* be annoyed
  - People can be annoyed by lots of things (almost anything, really)

- Ethically, the important question is whether they *are reasonable* or have *a right* to be annoyed
  - Sometimes annoyance is unjustified, in which case it has little or no ethical weight
A Guiding Question

- Ask …

- Would individuals in this particular social media/online context be reasonable to assume or expect that they will *not* be approached for recruitment? Would they be *reasonably* annoyed?
A Guiding Question

- Ask …

- Would individuals in this particular social media/online context be reasonable to assume or expect that they will *not* be approached for recruitment? Would they be *reasonably* annoyed?
  
  - If so, their annoyance may be reasonable and have ethical weight—Caution!
  - If not, annoying them is not inherently unethical
Imagine that a recruitment coordinator for a study on arthritis encounters the following Tweet: ‘arthritis medicine not working. Looking for new options #clinical trial.’

Would it be ethically acceptable to tweet back at this person information about the study?

A. Yes
B. No
Imagine that a recruitment coordinator for a study on arthritis encounters the following Tweet: ‘arthritis medicine not working. Looking for new options #clinical trial.’

Would it be ethically acceptable to direct message this person with information about the study?

A. Yes
B. No
Substantive Ethical Principles

- Transparency
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  - Studies must be accurately represented
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  - Recruiters should not ‘creep’ or ‘lurk’ online spaces where there is an expectation of privacy
    ◊ Some spaces may be analogous to ‘public’ spaces (e.g., Twitter) and may not require proactive disclosure—err on side of caution
Substantive Ethical Principles

- **Transparency**
  - Studies must be accurately represented
  - Recruiters should not ‘creep’ or ‘lurk’ online spaces where there is an expectation of privacy
    - Some spaces may be analogous to ‘public’ spaces (e.g., Twitter) and may not require proactive disclosure—err on side of caution
  - In general, researchers should not use deception to gain access to online communities
    - When online communities have membership criteria such as having certain illness, etc.
    - Exceptions possible: Both current and revised Common Rule allow deception in research if IRB waives/alters informed consent
Researcher A is performing a study on effective support mechanisms for people with depression.

A is having trouble meeting recruitment targets. One day A encounters an online Facebook support group for people with depression, many of whom are likely to meet inclusion/exclusion.

The group is ‘open’ and has no restrictions on joining.
Case Study 1: Issues to Consider

- Compare to off-line scenario
  - Is there a moderator who can give sense of group’s expectations and culture/norms?
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- Privacy
  - Treat personal information on the site confidentially.
  - Do not amplify privacy risks (e.g., do not ask users to indicate interest by responding to public post or group)
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- **Compare to off-line scenario**
  - Is there a moderator who can give sense of group’s expectations and culture/norms?

- **Privacy**
  - Treat personal information on the site confidentially.
  - Do not amplify privacy risks (e.g., do not ask users to indicate interest by responding to public post or group)

- **Transparency**
  - Is there an expectation of privacy? If so, proactively announce presence and intent
  - Communicate truthfully, and respectfully
Investigator C is a clinical investigator conducting HIV research. To expedite enrollment, he considers using a location-based social and dating application directed towards gay and bisexual men.
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Investigator C downloads the application to his smartphone, where he creates a profile that gives him access to information from other users, and observes that User M has a profile identifying him as age 29, gay, HIV+, and living in zip code 77777.
Case Study 2: Location-based Dating/Social App

- Investigator C is a clinical investigator conducting HIV research. To expedite enrollment, he considers using a location-based social and dating application directed towards gay and bisexual men.
- Investigator C downloads the application to his smartphone, where he creates a profile that gives him access to information from other users, and observes that User M has a profile identifying him as age 29, gay, HIV+, and living in zip code 77777.
- This information suggests that User M may satisfy the eligibility criteria for Investigator C’s clinical trial. Investigator C wonders if it would be permissible for him to contact User M to see if he is interested in enrolling in the protocol.
Would approaching User M over the site about participation in the research be ethically acceptable?

A. Yes
B. No
C. Depends on further details
Case Study 2: Issues to Consider

- Compare to off-line scenario
  - Would targeting users of this app differ from other methods of seeking out the relevant population, e.g., approaching individuals leaving an establishment frequented by gay men?
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Compare to off-line scenario

- Would targeting users of this app differ from other methods of seeking out the relevant population, e.g., approaching individuals leaving an establishment frequented by gay men?

Privacy

- Would the user be justified to assume that this app is exclusively for dating/social purposes and that researchers will not be approaching them using it?
  - If so, probably not ethically justified
Case Study 2: Issues to Consider

- **Compare to off-line scenario**
  - Would targeting users of this app differ from other methods of seeking out the relevant population, e.g., approaching individuals leaving an establishment frequented by gay men?

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- **Transparency**
  - Requires investigator to make it clear from start why he is approaching user (research, not social reasons)
Potentially Novel Aspects of Social Media Recruitment

- Ethical/regulatory significance of website business rules or ‘terms of service’
- Recruiting from the networks of others
- Online participant communication
Website Business Rules and ‘Terms of Use’

- Social media sites are typically governed by ‘terms of service’ stating rules of site
Website Business Rules and ‘Terms of Use’

- Social media sites are typically governed by ‘terms of service’ stating rules of site
  - **Regulatory consideration**: neither current nor revised Common Rule requires that research must be conducted consistent with terms of service
    - IRB must consider risks to subjects posed by this aspect of the research in making the determinations
Case Study 3

- Investigator A wishes to conduct research on racial discrepancies in hiring over a job-seeking website, such as Monster.com.

- Researchers will fabricate profiles of minority and non-minority job-seekers and gauge differential responses. (Imagine the IRB is willing to permit deception in this case.)

- The ‘terms of service’ of this and other similar websites forbid research over the site. Thus, breaking terms of use is likely the only way this research will get done.
Website Business Rules and ‘Terms of Use’

- Failing to abide by terms of use does not show respect for website and website owners, but this doesn’t necessarily mean it disrespects users of the site or research participants
  - Is ensuring respect for websites, in addition to participants, within the purview of the IRB?
Website Business Rules and ‘Terms of Use’

- Failing to abide by terms of use does not show respect for website and website owners, but this doesn’t necessarily mean it disrespects users of the site or research participants
  - Is ensuring respect for websites, in addition to participants, within the purview of the IRB?

- Ethically, terms of service might function as one source of reasonable expectations among users
  - However, there is good evidence that hardly anyone reads them
Website Business Rules and ‘Terms of Use’

- Recommendations
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  - If there is a conflict with terms of use, seek an exception from the site
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  - IRB should carefully consider with input from institutional and legal counsel
Recruiting from the Networks of Others

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- These networks may provide promising recruitment pools for researchers
- Especially when the network is based on shared characteristics that match inclusion criteria for particular study (e.g., disease status, social group identification)
Recruiting from the Networks of Others

- Recommendations
Recruiting from the Networks of Others

Recommendations

- Regulatory considerations: IRB must review and approve such a recruitment strategy prior to initiation
  - What are the risks to the initial target presented by this approach?
Recruiting from the Networks of Others

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- Regulatory considerations: IRB must review and approve such a recruitment strategy prior to initiation
  
  What are the risks to the initial target presented by this approach?

- To avoid inadvertently disclosing PHI about currently enrolled subjects, research team should either…
  
  i. Seek consent from subjects before contacting members of their online networks, or
  ii. Invite subject themselves to refer networked ‘friends’ to the study
Online Participant Communication

- Social media can facilitate post-enrollment communication between research team and study participants as well as among study participants themselves
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- **Risks**
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    - Risk of un-blinding when participants describe experiences
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    - When participants post false/misleading information
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    - Risk of un-blinding when participants describe experiences
  - Undermine understanding of other participants
    - When participants post false/misleading information
  - Influence public perception of experimental agents
Online Participant Communication

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  - Explore possible technical solutions (e.g., disable comment features on pages connected with study)
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  - **Regulatory consideration:** neither current nor revised Common Rule requires investigators to monitor such responsive posts (although a routine check may be prudent)
  - Cannot ask subjects to sign away First Amendment rights to free expression
  - Explore possible technical solutions (e.g., disable comment features on pages connected with study)
  - Educate subjects about the importance of blinding and scientific integrity and risks of online communication
    - Add language or own section to consent form
Further Guidance and Checklists

- Harvard Catalyst and Petrie-Flom Center
- The Use of Social Media in Recruitment to Research: A Guide for Investigators and IRBs


- Martinez et al. “Still a hard-to-reach population? Using social media to recruit Latino gay couples for an HIV intervention adaptation study.” *Journal of Medical Internet Research*, 16/4 (2014), e113


- Sitar et al. “Social media as a tool for engaging and educating audiences around HIV vaccine research and clinical trial participation.” *Retrovirology* 6 (Supplement 3): 218.


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