Social Media Recruitment and Advertising

It’s not surprising that the researchers have begun to tap into the potential power of social media for research advertising. Social networks based on shared characteristics provide promising recruitment pools. In addition to being effective, proposed recruitment activities using social media should be respectful and not undermine public trust.

Generally, the IRB considers the same criteria in all recruitment ads whether the format is in print or on social media:
- Accurate information;
- Clearly identified as research;
- Respectful and appropriate;
- No unproven therapeutic claims; and
- No over-emphasis on rewards that could unduly influence potential subjects?

The challenge with social media advertising, is maintaining control of the information once it is released into cyberspace.

The following are some considerations when reviewing recruitment plans involving social media advertising.

- **Ask for detail.**
  In describing the recruitment plan on the IRB Research Description Form, simply stating, “we will advertise on social media”, may not be enough information. Investigators may purchase targeted advertising which appears on sites based on user searches, demographics, or geographic location. They may create a page specific for a study, or simply post advertising on their own personal page or account. With the variety of platforms and options, you may want to ask the investigator to provide some detail regarding where, what, and how social media will be used.

- **Don’t forget about hashtags (#).**
  Seeing a screen shot or copy of an ad as it will appear in print allows the IRB to check what message is conveyed by photos or what information is emphasized by text size. However, the researcher should also indicate if the ad or post will be accompanied by search terms, keywords or hashtags. Hashtags, (keywords or phrases preceded by the hash mark), make the post searchable by other social media users. A hashtag can send a strong message with very few words. An appropriate ad can be misconstrued when accompanied by “#freemedTx”.

- **Managing user-generated comments.**
  When posting ads where users can comment, investigators should identify a process and person to manage user-generated content. Users are not always aware of privacy and confidentiality policies or settings. If the media platform doesn’t have an option to disable external comments, ads may need to instruct potential participants not to post personal or confidential information. Viewer comments could undermine reader understanding or be counter to the intended message. A current subject’s speculation on whether they are on the study drug or placebo could even bias study results.

- **What other rules apply?**
  Social media platforms and online advertising venues have their own Terms of Use (TOU), policies or procedures that users agree to. Advertising sites such as Craigslist, have information in the FAQ regarding prohibited content or limitations on frequency or category of ad placement. Posting on support-group social media pages may not be allowed if the ad could be perceived as intrusive or inappropriate. According to the UK Social Media Policies and Guidelines (AR 1-.4), employees are accountable for any institutionally related content they post to social media sites. Since the use of social media may blur the lines between personal voice and
For additional guidance on advertising and other other types of recruitment activities, see the 'UK Investigator’s guide to Identification and Recruitment of Human Subjects’.

Additional Sources:
Quorum Review IRB: Using Social Media in Research: Regulatory and IRB Considerations
UK CCTS, Using Social Media for Participant Recruitment
http://www.ccts.uky.edu/ccts/sites/default/files/Presentations/ParticipantRecruitment_social_media.pdf

The FDA Informed Consent FAQ provides answers to unique situations like the one below. Such situations would either need to be described in the initial IRB submission or submitted as Modification Request for a single-subject deviation.

35. May informed consent be obtained by telephone from a legally authorized representative?
A verbal approval does not satisfy the 21 CFR 56.109(c) requirement for a signed consent document, as outlined in 21 CFR 50.27(a). However, it is acceptable to send the informed consent document to the legally authorized representative (LAR) by facsimile and conduct the consent interview by telephone when the LAR can read the consent as it is discussed. If the LAR agrees, he/she can sign the consent and return the signed document to the clinical investigator by facsimile.

Notice that the FDA did not offer Waiving Documentation of Informed Consent as an optional solution. The reason, as noted on the IRB Form F, is FDA regulations only allow an IRB to consider waiving documentation under Option #2 “minimal risk research involving no procedures for which written consent is normally required outside of the research context.”
It is hard to imagine any FDA regulated studies that would actually meet that condition, particularly those that involve seeking consent from a LAR. Therefore, the proposed solution involves use of technology to obtain valid and signed informed consent.
Can consent or parental permission ever be "passive"?

“Passive consent” is not referenced in IRB regulations and the process is not consistent with the regulatory requirement for seeking and obtaining parental permission.

IRB regulations state that no investigator may involve a human being as a subject unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

However, under conditions specified in the regulations an IRB may:
- approve a consent procedure that does not include, or that alters some or all of the elements of informed consent/parental permission, or
- waive the requirement for documentation of informed consent.

For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. The risk is that subjects may become unwitting participants if, for example, they never receive the letter, don't read English, or are simply confused by the instructions. This approach also raises privacy concerns for certain types of research on sensitive topics.

For such a study, the IRB considers and may only approve this “passive” procedure if the federal criteria for waiving informed consent are met.
- The research involves no more than minimal risk to the subject.
- The rights and welfare of subjects will not be adversely affected.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever possible, the subject will be provided with additional pertinent information after they have participated in the study.

So an IRB may apply the informed consent waiver criteria and allow the proposed process for a low-risk study, without privacy concerns, where it is not practicable to obtain parental permission.

Adapted from OHRP FAQ on Informed Consent & UK IRB Guidance for Enrolling K-12 Students as Research Subjects

The Journal of Clinical Research Best Practices, available on line at www.firstclinical.com, shared an article on FDA’s perspective of safety reporting which supports the recent update to the UK unanticipated problem and safety reporting policy. The article references the issue of sponsor over-reporting of all serious events when only a small fraction would meet the current regulatory guidelines originally issued in 2012. FDA Guidance released in December 2015 encouraged industry sponsors to develop safety assessment committees to review cumulative events from all trials, perform un-blinded comparisons and make recommendations to help the sponsor determine which events meet the criteria for IND safety reporting.