

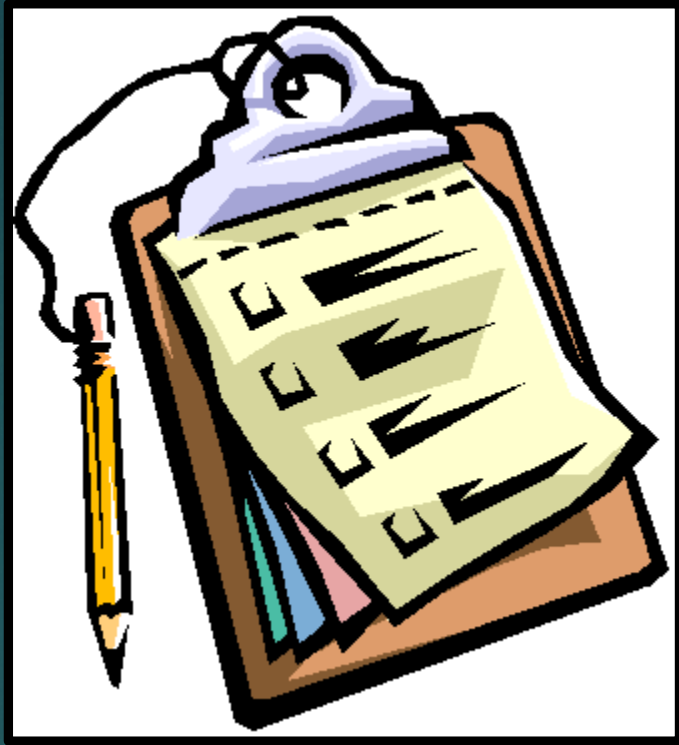


IRB Review of Social Media

ROSA SOBER

MANAGER, HRPP

Agenda



- ▶ What is Social Media & Why it is Important
- ▶ Social Media Use in Research
- ▶ IRB Review Considerations

What is Social Media

- ▶ Broad term including social networking (facebook, twitter, linked in)
- ▶ Social photo and video sharing (Shutterfly and YouTube)
- ▶ Interactive websites (Blogs, Geisinger Exchange)

An INTERACTIVE platform for electronic communications, used by groups of people to create, share, and exchange information.



This ability to identify, connect, and potentially align individuals can significantly amplify communication.

Social Media & Research



POWERFUL
TOOL

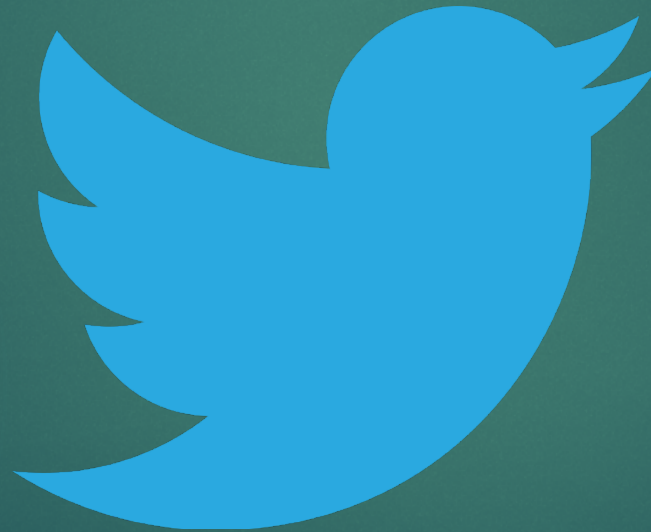
- ▶ Research depends on robust Recruitment and Retention
- ▶ Social media is being viewed as an increasingly popular and effective tool for recruitment and for communications during research
- ▶ Opportunity to extend the reach of recruitment area, not only allows direct and continuing contact but the opportunity to build a community around a research project

Research Opportunity

- Align and build engaged communities on specific health areas
- Access to public that was previously not possible



1 Billion
Users



500 Million
Users



300 Million
Users



70 Million
Users

Why underutilized?

- ▶ Little guidance
- ▶ Lack of certainty in terms of:
 - Review and approval
 - Enforcement
 - Understanding the technology
 - IRB requirements



Regulatory Framework

Regulations predate social media

Left with the broad principles to follow:

- IRB's authority to review and approve all research activities
- Requirement to ensure that IC is appropriately sought
- Requirement to ensure that adequate provisions are taken to ensure privacy and confidentiality of participants



Regulatory Framework

- ▶ Not fit easily with the many questions that social media presents
- ▶ What we need is more specific examples of how social media should be handled from a human subjects protections standpoint



Until Then

Letter and spirit of the regulations to determine what and how to review

Social Media Research Use

- ▶ In general, 3 purposes that researchers utilize social media for:



Recruitment



Component of
research intervention
or data collection
method



Updating and
informing

Social Media and Recruitment

Informed consent



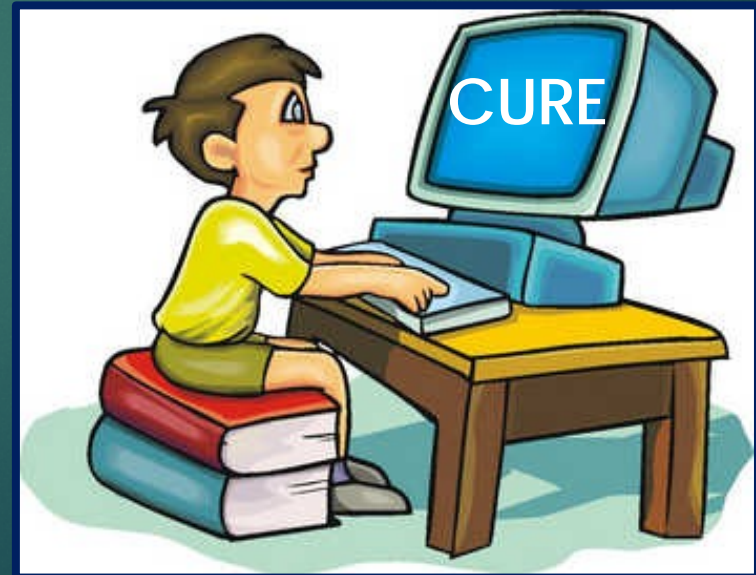
Recruitment
Activities

- Advertising and recruitment plans must be reviewed by IRBs
- Social media recruitment component
- Same as our review of printed recruitment materials
- Centered around how they are presented

Social Media and Recruitment

- ▶ Review of Advertisements – IRB needs to review social media advertising and recruitment to ensure advertisements:
 - Are not unduly coercive (influential)
 - Do not promise or imply a unrealistic favorable outcome or other benefits not likely to occur
 - Doesn't imply investigational product is safe or effective if unknown
 - Does not cause therapeutic misconception ("treatment" implies benefit if not further explained)
 - Payment not emphasized
 - Does not include misleading statements

Based on FDA guidance



Which advertisements require review?

- ▶ IRB's will review social media ads as they have print ads
- ▶ No IRB review needed for descriptive information (generally accessible information online, any available trials)
 - Study Title
 - Purpose of Study
 - Protocol Summary
 - Basic Eligibility criteria
 - Study Site Locations
 - How to contact the study for further information

Based on OHRP guidance

Which advertisements require review?

- ▶ Direct advertising for research – advertising that is intended to be seen or heard by prospective subjects to solicit their participation in a study
- ▶ Intent to recruit subjects
- ▶ Includes – newspaper, radio, flyers, posters, TV ads, etc.
- ▶ Social Media – Display or Banner Ads (top of webpage side)
- ▶ Social Network Ads, pages

[Click here to join our study](#)

Which would be most appropriate?

- ▶ Free medicine!
- ▶ Join study, for \$\$\$
- ▶ More frequent monitoring and doctor visits
- ▶ New research for diabetes
- ▶ New treatment for diabetes #cures

Social Media - Participant Communications

- ▶ From regs – IRB has authority to approve/ require mods/ or disapprove all research activities
- ▶ Also references reviewing “specific research activities” as IRB function
- ▶ IRB must ensure that there are adequate provisions to protect privacy of subjects and to maintain the confidentiality of data
 - ▶ heightened concern when using social media compared to traditional communication
- ▶ So we have a responsibility to review communications and their avenues

Social Media – Participant Communications

- ▶ Online diaries, questionnaires
- ▶ Reminders through email, facebook, etc.
- ▶ Information about study progress, updates

When do communications require IRB Review?

- ▶ IT DEPENDS!
- ▶ We have decided posting/ sending already approved IRB language does not need review
- ▶ If new language that is not approved, streamlined amendment
- ▶ Example: user posts a question and study team can answer with approved language



Review Considerations

- ▶ No social media site can provide absolute anonymous, confidentiality or privacy
- ▶ Up to the researcher when designing a protocol to understand the various privacy and data security plans of the social media platform
- ▶ Investigators must understand the privacy provisions in their policies and be able to explain that information to the potential research participants and the IRB



Social Media Management Plan

- ▶ Plan can take the mystery out of social media
- ▶ Corporate Communications requires this development – assure attached to IRB submission
- ▶ From the plan depending on the social media application should be able to see planned posts, messages, content and timing
 - Plans for timely monitoring the user entered information for accurate information, non-offensive – removed if needed
 - Plans for timely responses to research participants questions
 - Planned responses
- ▶ Streamlined amendment



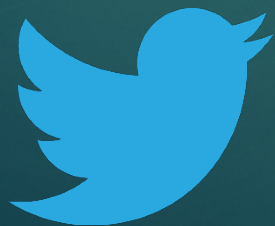
What's
the
plan?

IRB Review – other points to consider

- ▶ The rationale for the use of social media in the research project
- ▶ Social media can have a lasting and long impact on users. The choice of social media should be carefully considered and justified.
 - Target population frequently uses the application and it represents an opportunity to identify and consent with the target population
- ▶ Consider which social media application chosen in rationale



Widely used by public and provides administrators options that help ensure the risks are minimized. Private groups, private posts, etc. Fairly good reputation.



Only provides the option of public tweets versus private tweets, is not widely used, and generally is viewed as less authentic.

IRB Review – other points to consider

- ▶ Are privacy and confidentiality concerns addressed?
- ▶ All privacy protections should be explained
- ▶ Privacy measures taken should be addressed proactively and the privacy settings should be explained
- ▶ IT or expert consultation with the study team and/or IRB may be necessary



Summary

- ▶ Social Media proves to be a powerful tool that has potential to benefit research recruitment, engagement and retention
- ▶ IRBs currently have to use the law and the spirit of regulations to review material (SOP development)
- ▶ Best approach is to request a comprehensive social media plan to review

Questions

