GUIDELINE FOR RESEARCH USING SOCIAL MEDIA

The basic principles of the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations regarding Research Subjects Review Board (RSRB) oversight for review and approval of subject directed materials will be followed as pertains to the use of social media. This guideline provides additional responsibilities and requirements for Investigators regarding the use of social media in human subject research, in order to ensure that the risks to human subjects are minimized and privacy and confidentiality are maintained when utilizing such methods of interaction or communication.

Definitions used within this guideline:

a) Social Media - An interactive platform for electronic communications, used by groups of people to create, share and exchange information. An Internet-based mode of communication that allows users to interact with the medium (e.g., a website) and/or other users of the medium. Also referred to as social networking.

b) Platform – A framework on which interactive applications may be run. For purposes of this guideline as pertains to social media and commonly used applications, will include but is not limited to mobile technology, Facebook, Twitter, Skype, YouTube, Blogs and Forums.

c) Recruitment – A process for raising awareness and informing the public about research opportunities in order to select prospective subjects for an approved protocol.

d) Retention – A process for maintaining subject participation in a study, which may include, but is not limited to communications about study progress, updates or study reminders.

e) Investigator – Individual responsible for the oversight and conduct of the study per University policy. Includes study staff who have been delegated responsibilities for study activities pertaining to the use of social media.

Investigators are responsible for minimizing the risks to human subjects posed by use of the internet or social media, as well as for maintaining subject privacy and confidentiality. In doing so, an Investigator should ensure that a proposed social media platform is in compliance with requirements set forth by URMC Marketing and URMC Public Relations & Communications (refer to the URMC Social Media Toolkit for further information).

See Table 1 for a quick reference guide to determine whether a proposed activity may be acceptable.

Considerations When Proposing Use of Social Media

1. Weigh the risks/benefits to the particular type of electronic communication and make sure to address these in the consent and authorization (if applicable) in order to protect the subject's privacy and confidentiality.
2. Understand the risks associated with the collection of protected health information (PHI) from a social network site that could lead to privacy, confidentiality, and potentially HIPAA concerns (i.e., expectations of privacy versus the reality of privacy in a public environment).
3. Unless documented evidence of permission exists, avoid collection of PHI or personal identifying information (PII) over social media since the information on social media sites is usually not encrypted and, in most cases, shared with other companies for marketing purposes.
4. Understand what happens to any personal information that may be obtained, in particular whether data are obtained by a third party (e.g., marketing company) and whether names/information may be sold to or shared with others.
5. When using social media, no sensitive information (whether PHI or PII) should be published (shared) through the social media platform.
6. When sending ads or promotional messages, ensure that the platform or medium being used is appropriate to the (common) user and won't appear intrusive to potential subjects.
7. If a communication is made using a social network site or Twitter group (e.g., breast cancer support group), ensure the message is appropriate to the members of those groups.
8. Understand the purpose of the proposed use of social media (e.g., will the platform be used for dissemination of information, engagement with individuals, or both).
9. Keep information and messages generic when possible (i.e., be aware of including information tied to a specific health condition).

RSRB Review and Approval of Social Media in Research

The RSRB will review social media plans and uses to ensure the rights and welfare of subjects are protected.

1. The Investigator will include information about any proposed uses of social media in the protocol, consent and any other study related materials, as applicable, at the time of an initial submission. The RSRB application will also indicate the use of social media, be it for recruitment, retention or post-study activities (see below).

Social Media and Recruitment:

a. *RSRB Review Required:* Direct advertising to prospective subjects to solicit participation such as display or banner ads on a web page, paid search ads, in-text ads (an add that pops up when user scrolls over a keyword), social network ads, social network pages, blogs, tweets and texts containing direct advertising.

b. *RSRB Review Generally Not Required:* As with other recruitment materials, communications intended to be seen or heard by health professionals (e.g., similar to doctor-to-doctor letters), news stories, information about related research conducted outside of the study, pictures, videos or other information posted by a subject, and basic study information such as that posted to clinicaltrials.gov or URMC's Health Research Website.

   NOTE: RSRB should be consulted for any questions regarding requirements for review.

Social Media as Research:

When conducting an internet based research study that utilizes a social media platform to conduct the research (e.g., Skype), both this guideline, as well as the *Guideline for Computer and Internet Based Research* should be referenced as appropriate.

Social Media and Subject (Retention) Communications:

a) The RSRB will review subject communications involving social media or other technologies (e.g., online or phone-based diaries/questionnaires, reminders sent through email, Facebook message or text message, information about study progress).
   - Appointment reminders may or may not require RSRB review; for example, a phone script for calling a subject regarding a visit reminder generally does not need review, versus a text message reminder that would impact subject privacy. To mitigate privacy concerns, text message reminders should only have basic information similar to what would be included on a reminder postcard.

b) These types of communications should be described in the protocol.

c) These types of communications should also be described in the consent form or information letter, in particular to address whether there may be any costs associated with the communication (e.g., text messages) and also in regard to the increased risk to privacy with use of any of this technology. Determine whether an opt-out provision is necessary.

Social Media and Study Results:

a) If study results are communicated while a study remains open, the information and method of communication require RSRB review.

b) If study results are communicated once the study is closed, RSRB review is generally not required; however, depending on the context and content of the information, RSRB review may be necessary in the following scenarios:
   i. Communication functions as a recruitment tool (e.g., a YouTube video presenting study results and providing information about an extension study);
   ii. Communication re-initiates study activity (e.g., Facebook message to a subject providing his/her individual study results if subject has documented permission to do so, YouTube video providing information required for medical or regulatory purposes that is related to the subject's participation in the study); or,
   iii. Implications for HIPAA (e.g., release of identifiable information when reporting study results).

2. If social media was not planned at the time of the initial protocol submission, proposed use(s) must be submitted as an amendment. Ensure that the RSRB application and study documents are revised as applicable.
   - The Investigator will not implement any new or modified uses of a social media platform without prior approval by the RSRB and ensuring compliance with URMC Professional Use of Social Media requirements.

Use of Social Media in an Established Non-Study Specific Platform

1. Investigators intending to utilize an already established and URMC approved social media platform (e.g., Golisano Children's Hospital Facebook page, Wilmot Cancer Center Twitter account) will ensure the RSRB application and applicable study documents are amended to indicate the new method of subject communication (i.e., a general statement regarding the type and intended use of social media is sufficient).

2. Additional documentation of the proposed communication, such as an outline or description of possible messages or communications that would be posted.

3. New postings that fall outside the context or essence of previously approved communications will require resubmission for RSRB review and approval.

4. The informed consent (or HIPAA authorization as applicable) should include reference to the third party providers or collaborators who will collect and retain the data by the nature of the service used (e.g., MTurk, Survey Monkey), as applicable.

Use of Social Media in an Established Study Specific Platform

1. The Investigator will ensure that the protocol describes the proposed use of social media, including the purpose, the platform to be used, and addressing any issues pertaining to

subject privacy, confidentiality and minimizing risks associated with the use of social media for a study specific platform. See Appendix 1, the Social Media Communication Plan worksheet that may be used as a tool to ensure all elements are considered and addressed accordingly within the protocol.

- An outline or description of possible messages or communications that would be posted or used within the social media platform should be included in the recruitment materials section of ROSS for RSRB review.

2. The Investigator will also need to complete the University required applications to ensure compliance with University policies regarding professional use of social media (refer to the URMC Social Media Toolkit to locate the Social Media Application and Content Owner Agreement). RSRB approval for use of social media will be contingent on completion of these forms.

3. New postings that fall outside the context or essence of previously approved communications will require resubmission for RSRB review and approval.

4. The informed consent (or HIPAA authorization as applicable) should include reference to the third party providers or collaborators who will collect and retain the data by the nature of the service used (e.g., MTurk, Survey Monkey), as applicable. A statement regarding the data retention policy of the third party provider and whether data will be used for any future use/analysis by others should also be stated within the consent form.

Protecting Privacy and Confidentiality

1. The Investigator is prohibited from posting any content that is PHI or PII, including but not limited to images or videos, without prior consent from the subject.

2. Measures should be taken to ensure communications protect the privacy of a subject; for example, avoid answering an individual's question in a public forum.

3. The use of system automated interactions with prospective subjects should be avoided (i.e., spam messages or solicitations distributed to a group).
   - If automated communications are to be used, any list should be obtained from a public source or with documented permission of the list owner. Additional details of the communication should be outlined for the RSRB to review.

Data Storage and Security

In order for the RSRB to adequately review and assess any potential issues regarding subject confidentiality and privacy, the following information regarding data collection, storage and use should be addressed in the protocol:

- How sensitive is the data or what is the risk to the subject if the data were released?
- How will the data be collected (e.g., web, email, laptop)?
- How will the data be protected during transfer (e.g., encryption during transmission)?
- Where will the data be stored and who has access to the stored data?
- Is the data de-identified?
- How will the data be protected at rest (e.g., stored on University secured server, encryption of data on portable devices, two factor authentication, removal of unnecessary/identifiable information)?
- Where else does the data go (e.g., backups, analysis)?
- Where does the data go when the study is over?

Example of generalized statement in protocol:
We will be using an internet survey platform to administer anonymous surveys.

Example of improved statement in protocol:
Researchers will be using [survey software name]. No identifying information will be collected within the survey; however, [survey software name] will collect IP addresses as a part of their normal data collection. The research team for this project requested that [survey platform name] not collect this identifier.

Table 1. Is the Proposed Use of Social Media Acceptable?

Generally Acceptable	Probably, if done thoughtfully	Generally Not Acceptable
Creating a study specific Facebook page	Interacting with subjects using Skype	Contacting individuals using Facebook, based on their information (e.g., spam messages/solicitations)
Tweets to research or related group about new studies	Approaching/Contacting members of a condition-specific blog in accordance with the blog site policies	Misrepresenting self as a person with a condition to gain access to potential subjects
Using secure internet-based survey methods to collect PHI*	Sending informative Tweets to study followers and/or study subjects	Looking for lost-to-follow-up subjects on Facebook

*See Guideline for Computer and Internet Based Research

Appendix 1

Social Media Communication Plan for Research

(For use when proposing interactive social media platforms such as Facebook, Twitter and YouTube for recruitment, retention and/or dissemination of research results.)

Purpose

Why are you establishing a social media presence?

Objectives/Goals

What do you plan to achieve with this social medium? Recruit? Inform? Encourage dialogue?

Disseminate study results?

Share information? What kind of information?

Who is the target audience reading and commenting on your social media? Whom are you trying to engage?

Platform

What type of social media platform will be used (e.g., Facebook, Twitter, YouTube)?

Access or privacy settings required?

Is any PHI being recorded? Partial HIPAA Waiver required?

Address how the confidentiality of collected information will be maintained?

Describe type(s) of communication and methods to minimize privacy risks.

Execution & Maintenance

Who will establish your presence?

Who will be the administrator?

Who will maintain it?

How often will it be updated? (Depending on the type of social media, updates at least daily are typical.)