20.0 Internet Based Research

20.1 Purpose

The purpose of this document is to provide guidance to Pennington Biomedical research investigators, research staff and IRB members concerning responsibilities and considerations related to Internet or mobile technology based human subject research.

20.2 Applicability

This policy applies to the use of the Internet or other technology as a tool for subject recruitment or as a tool for data collection.

20.3 Definitions

Internet Research: The broad and overarching term "Internet research" includes both the Internet as a tool for research and the Internet as a locale or venue for conducting research. For the purposes of this policy, this also includes mobile technology and devices.

Examples of Internet Research[1]

- Study of data already available on the internet without direct interaction with human subjects (harvesting, mining, profiling, scraping—observation or recording of otherwise-existing data sets, chat room interactions, blogs, social media postings, etc.)
- Research that uses the Internet as a vehicle for recruiting or interacting, directly or indirectly, with subjects (Self-testing websites, survey tools, Amazon Mechanical Turk®, etc.)
- Research about the Internet itself and its effects (use patterns or effects of social media, search engines, email, etc.; evolution of privacy issues; information contagion, etc.)
- Research about Internet users—what they do, and how the Internet affects individuals and their behaviors.
- Recruitment in or through Internet locales or tools, for example social media, push technologies

Note: Use of the PBRC web screener by itself does not constitute internet research.

[1] Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions, Final document, approved at SACHRP meeting March 12-13, 2013.

Research: systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(b)

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. DHHS 45 CFR 46.102(f) (1&2)

Private Information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for obtaining the information to constitute research involving human subjects. DHHS 45 CFR 46.102 Definitions

If individuals intentionally post or otherwise provide information on the Internet, such information should be considered public unless existing law and the privacy policies and/or terms of service of the entity/entities receiving or hosting the information indicate that the information should be considered —private. This determination is subject to IRB approval.

Intervention: includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. DHHS 45 CFR 46.102 Definitions

Examples of *Intervention*; Mimicking “real-world” manipulations through avatars, Responses to web queries, recording internet-based activities or behaviors for subsequent analysis, Using the internet as a reminder or interface for the performance of some physical activity (e.g., reminder to take medicine or perform a task).[2]

Interaction: includes communication or interpersonal contact between investigator and subject. DHHS 45 CFR 46.102 Definitions

Examples of *Interaction*; Virtual worlds, Guilds to social media sites to chat rooms, Newsgroups, Mobile platforms, Interviews, Focus Groups

[2] Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions, Final document, approved at SACHRP meeting March 12-13, 2013.

Individually Identifiable: Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (Definitions: Federal Register.45 CFR 46)

Private Information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (Definitions: Federal Register.45 CFR 46)

Social Media: includes online and mobile resource that provides a forum for generating, sharing, or discussing ideas and content. Specific applications and web tools are variably grouped as online communities (e.g., patient support groups, population-specific dating services); social networking (e.g., Facebook; Twitter); professional networking (e.g., LinkedIn); content production and sharing (e.g., YouTube, Tumblr, blogs); location-based services (e.g., Google Maps); and others.

20.4 Regulatory Review of Internet Research

20.4.1 Policy

Any internet research conducted by an investigator that obtains data through an intervention or interaction with the individual or obtains identifiable private information must be reviewed by the IRB. Some research may be exempt from IRB oversight; however, the IRB will exempt research based upon categories allowed as per 45 CFR 46.101. Exemption Categories can be found in Policy 3.

20.5 IRB Considerations

20.5.1 Privacy and Confidentiality Considerations

IRBs must ensure that adequate provisions are in place to maintain confidentiality of research data and privacy of research subjects.

IRBs will consider:

- The implications of the researcher and the public's ability to re-identify subjects; and
- Provisions for accurately informing subjects of mechanisms in place for ensuring confidentiality of research data as opposed to ensuring anonymity.

20.5.2 Informed Consent Considerations

- When appropriate, the IRB may grant a waiver of informed consent or waiver of documentation of the informed consent as per HRPP Policy 5, Obtaining Informed Consent from Research Subjects and DHHS 45 CFR 46.116.
- For research that meets the criteria for a waiver of documented informed consent, the internet site should provide potential subjects with information about the research, and a button to click to agree to participate. The contents of the information site must receive Pennington Biomedical IRB review and approval prior to implementation.

20.6 Investigator Responsibilities

Investigators should be familiar with the terms of service and privacy policy for each Internet research technology to be used in their research prior to the research being approved.

20.6.1 Protocol Considerations

- Providing the IRB with the investigator's assessment of how subject's privacy and confidentiality will be protected using the Internet research.
- Providing the IRB with the safeguards the investigators will use to protect subjects from an invasion of privacy or breach of confidentiality.
- Providing the IRB with a plan on how subjects will be informed of their risks of invasion of privacy and breach of confidentiality associated with the specific use of Internet research.

20.6.2 Informed Consent Considerations

- Investigators should include all the required elements of informed consent as stated in the federal regulations when generating consent documents for online research. When online research is being employed, the PBRC online consent form template should be followed, unless a waiver or alteration of informed consent is granted by the IRB.

20.6.2 Email Address for Investigators

Pennington Biomedical investigators are required to use their Pennington email address or a Pennington Biomedical departmental email address for communications

related to research in which Pennington Biomedical consider the institution engaged in research. Investigators should register with their Pennington email address when registering with on-line services, databases and cloud services for research-related purposes.

20.7 Research with Minors in Internet Research[3]

- PBRC does not allow internet research to be conducted in children under the age 13 to comply with Children's Online Privacy Protection Act (COPPA) regulations.
- The protocol needs to describe methods to verify age of minor.

20.8 Data Security and Data Collection

- It is strongly recommended that any data collected from subjects over computer networks be transmitted in encrypted format. This helps ensure that any data intercepted during transmission cannot be decoded and that individual responses cannot be traced back to an individual respondent.
- It is recommended that the reasonable and appropriate be used as determined by the IRB. This may require that the study participants be encouraged or required to use a specific type or version of browser software.
- Researchers are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside US boundaries.

20.9 Recruiting Through the Internet

Subject recruitment using the internet must follow the IRB guidelines for advertisements that apply to any traditional media, such as newspapers and bulletin boards. (See Advertisements section in Policy 3 for further information.) [4]

- Investigators should check that their proposed recruitment strategies comply with the policies and terms of use of the sites they wish to use and should provide documentation of HIPAA compliance with the assistance of Legal and Regulatory Compliance before submission to the IRB.

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[3] COPPA – Title XIII, Sec. 1302 (1) child means "age 13" and Title XIII, Sec. 1303 (a) (1) (ii)

[4] The available federal guidance: (1) OHRP, Guidance on Institutional Review Board Review of Clinical Trial Websites (http://www.hhs.gov/ohrp/policy/clinicaltrials.html); (2) SACHRP, Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations (http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf); and (3) FDA Information Sheet, Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm)

20.10 Miscellaneous

20.10.1 Characteristics of Purely Public Sites

- Sites containing information that, by law, is considered —public.
- News, entertainment, classified, and other information-based sites where information is posted for the purpose of sharing with the public.
- Open access data repositories, where information has been legally obtained (with IRB approval if necessary) and is made available with minimal or no restriction.
- Discussion fora that are freely accessible to any individual with Internet access, and do not involve terms of access or terms of service that would restrict research use of the information.

20.11 HIPAA

20.11.1 Definitions

PHI - Protected Health Information: for purposes of this policy means individually identifiable health information that relates to the past, present or future research services provided to an individual.

Authorization: a written document completed and signed by the individual that allows use and disclosure of PHI for purposes other than treatment, payment or health care operations.

20.11.2 HIPAA Policy

Any protected health information (PHI) collected is subject to the Pennington Biomedical HIPAA policies and requires a HIPAA authorization. The following identifiers which constitute PHI:

20.11.2.1 Protected Health Information Identifiers

a. Names (this includes initials)
b. All geographic subdivisions smaller than a state including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial 3 digits of a ZIP Code if according to the current publicly available data from the Bureau of the Census:
c. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people AND

d. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
e. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge data, date of death, and all ages and elements may be aggregated into a single category of age 90 or older.
f. Telephone numbers
g. Fax numbers
h. Electronic mail addresses
i. Social Security numbers
j. Medical Record numbers
k. Health plan beneficiary numbers
l. Account numbers
m. Certificate/license numbers
n. Vehicle identifiers and serial numbers, including license plate numbers.
o. Device identifiers and serial numbers
p. Web Universal Resource Locators (URLs)
q. Internet Protocol (IP) address numbers
    1. Biometric identifiers, including finger and voice prints.
    2. Full face photographic images and any comparable images
r. Any other unique identifying number, characteristic or code, except as permitted by 45 CFR 164.514(c).[5]

20.11.3 De-Identification

PHI may be de-identified by removing all the identifiers listed above. Once the identifiers are removed, the information is no longer subject to HIPAA protection.

20.11.4 Waiver of HIPAA Authorization.

20.11.4.1 PBRC may use or disclose PHI for research if it obtains IRB approval of an alteration to or waiver, in whole or in part, of the individual's authorization required for use or disclosure of PHI.

20.11.4.1.1 Waiver Criteria

A statement that the IRB and/or Privacy Board have determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

[5] Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, U.S. Department of Health and Human Services

a) The use or disclosure of PHI involves no more than minimal risk to the individuals based on, at least, the presence of the following elements:
    i. There is an adequate plan to protect the identifiers from improper use and disclosure.
    ii. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law.
    iii. There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI is permitted.
b) The research could not practicably be conducted without the alteration or waiver; and
c) The research could not practicably be conducted without access to and use of the PHI.

20.11.4.1.2 PHI Needed

A brief description of the PHI for which use, or access has been determined to be necessary and without which the research could not practicably be conducted as determined by the IRB and/or Privacy Board.

20.11.5 Notice of Privacy Practices

As per Pennington Biomedical policies the Notice of Privacy Practices should be available for subjects to print when conducting internet surveys.