# IRB Guidance for Online Research Activities

## I. Background:

The increasing frequency and complexity of online research involving human subjects accompanies with it confusion as to what, if any, research activities conducted online require UWM IRB review and approval. This guideline is intended to clarify the types of online research activities requiring IRB review.

An online research activity (e.g., using an online survey instrument, analyzing information posted on Facebook, analyzing questions/responses in online support groups) must meet two basic criteria for it to require IRB review. It must be (a) *research* and involve (b) *human subjects*. Whether a project is defined as research or not is no different if it is an online or face-to-face study (see 45CFR46.102 at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102 or a summarized statement of the federal definition of research at http://www4.uwm.edu/usa/irb/faq/#faq4). Whether an online project involves human subjects depends on the federal definition of *human subjects*, which states:

> *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.*
> *…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) in order for obtaining the information to constitute research involving human subjects.* (45CFR46.102(f))

## II. Online research involving intervention or interaction:

Similar to paper and pencil surveys or in-person interviews, a survey created online for the purpose of collecting research data would constitute data collected *through intervention or interaction*. This would meet the criteria for research involving human subjects and IRB submission/review would be required. The researcher must follow the appropriate consenting requirements. Online and abbreviated versions of consent templates are available on the IRB website, http://www4.uwm.edu/usa/irb/researchers/formsandtemplates.cfm

## III. Online research NOT involving intervention or interaction:

Research projects where the only activities consist of observations or recordings, whether in the cyber world or physical world, would not meet part (1) Data through intervention or interaction with the individual) of the federal definition. We must therefore look to part (2), *Identifiable private information* to determine whether the project requires IRB review.

Part (2) can be broken down into (a) *identifiable* and (b) *private*. If the online data is *identifiable* or the data collected could reasonably enable someone to ascertain the identity of an individual **and** it is *private*, the criteria for human subjects would be met.

A. Identifiable:

*Identifiable* should not be relegated to a person's actual name (e.g., Facebook), but should also take into consideration the fact that online user names often are derivatives of real names; are traceable from one website to another; function like real names, and therefore should be treated as

a real name. In most cases, user names should be treated as *identifiable*. IP addresses would also qualify as identifiable information if they are being collected by the researcher.

**IMPORTANT:** Even if a researcher has access to *identifiable* data, but does not record that as part of their dataset, the IRB, as directed by the Department of Health and Human Services' Office for Human Research Protections, still recognizes this activity to be *identifiable*. An example would be if a person records non-identifiable data from another individual's Facebook profile. (Identifiable data such as one's name is still available to the researcher regardless of whether these data are recorded). Having access to such data for research purposes will require IRB submission.

B. Private information

Privacy in the cyber world is untenable in the literal sense. However, for the purpose of this guidance, *private information* is:

> *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.* (45CFR46.102(f))

Websites vary on the degree to which there is an expectation of privacy. As a general guideline, the UWM IRB has identified three primary strata with regard to expected privacy. These include:

- *Fully public sites.* In these contexts, any internet user can access and search the site and no login or username is required There is a general understanding that the information shared between users within such a site is public. Thus, the information posted on such a site would *not* constitute private information and would therefore *not require IRB approval*. Examples of fully public websites include news, entertainment and classified sites as well as open access (publicly available) data repositories such as property tax/ownership information.
- *Public sites requiring user log-in.* Such a site requires users to log-in or register to post and/or read other users' comments. Anyone willing to supply personal information (e.g., name, e-mail address) can obtain a username for the site. Users vary in the degree to which their usernames provide identifying information (e.g., "Mary_Snow" vs. "bcsurvivor"). However, there is a general understanding that the information shared between users within such a site is public. Thus, the information posted on such sites would *not* constitute private information and would therefore *not require IRB approval.* Examples include topic-specific discussion fora, news websites where a login is required to comment, etc…
- *Public sites requiring invitation by site administrator.* Such a site requires users to register to gain access to information shared by a community of users. The specific parameters of usage will vary from site to site. However, the following scenarios provide examples of such parameters: the site may have a "user agreement" that community members refrain from certain activities (e.g., that they not advertise products on the site, that they refrain from using offensive language, that they not divulge personal information about other users, etc.); the site might require one to be invited by a central administrator in order to join the community; or postings might be moderated by an administrator for content. Facebook is an example of such a site when individual users act as personal administrators of their own web pages *and* when they limit access to their personal information (e.g., by virtue of "friending" certain users). In such cases, there *is a greater expectation of privacy* and information posted on such sites *may constitute*

*private information that would require IRB approval*. Moreover, if deception is needed in order to gain access to information on the site, e.g., registering with a discussion forum/group on eating disorders in order to collect data on eating disorders when there is a reasonable expectation that no observation or recording is taking place, and that individuals are providing information for a specific purpose (e.g., to gain social support) and *reasonably expect their information will* ***not*** *be made public, then this would fall under the private realm and would therefore require IRB review.*

It is important in all cases that the Terms of Service for the website be checked by the investigator to ensure the proposed research is allowable.

**V. Informed Consent:**

Informed consent is a key element to protect the rights and welfare of human subjects. When possible, informed consent must be obtained and done so in a documented fashion. However, informed consent for online research activities can be altered or waived under certain circumstances. The following details the various forms of waivers and alterations of informed consent.

A. Waiving Informed Consent: Consent not obtained for any human subjects.

- The collection of non-sensitive data through observational techniques. For instance, researcher collects private data from a discussion forum regarding health and fitness. The researcher does not interact with any of the subjects and plans to minimize risk by keeping the data on a secured password protected computer.
- Secondary data analysis of private identifiable data. The researcher plans to minimize risk by keeping the data on an encrypted file, computer or device.

B. Waiving Documentation of Informed Consent: Consent is obtained but not documented (e.g., participant does not provide an electronic signature).

- The collection of data through an online survey tool, such as Qualtrics, UWM's online survey tool (https://www4.uwm.edu/survey/). The first page contains the informed consent document but in lieu of signatures, the bottom contains a statement where completion of the survey indicates consenting to participate. Or clicking the "next" button means that the participant understands and consents. Please review the Online Survey Consent template to ensure the correct language is included in the consent document (http://www4.uwm.edu/usa/irb/researchers/formsandtemplates.cfm )

C. Alteration of Informed Consent: Consent is obtained but the information provide for consent does not contain all of the required elements (e.g., study purpose, risks, benefits, alternatives, etc.).

- Collection of data from a private online teacher support group. The researcher announces his/her presence and states, "I'm conducting a study about how teachers share and communicate teaching methods for my thesis project. I've started a discussion topic titled 'Thesis Project-Teachers Share' with a list of questions if anyone is interested in participating." Because certain required elements are not present, a request to alter informed consent will be required.
- An alteration of informed consent may be combined with waiving the documentation of informed consent.

In requesting a waiver/alteration, the researcher must provide adequate justification (see Section G of the New Study x-Form). To grant the waiver/alteration, the IRB will consider the following criteria:

1) sensitivity level of the data being collected;
2) use of deception;
3) procedures to minimize risk of privacy and confidentiality breaches; and
4) level of interaction or intervention with the subject.

Visit the IRB website for template examples (http://www4.uwm.edu/usa/irb/researchers/formsandtemplates.cfm).

**IV. Other considerations:**
Consult the IRB website (www.irb.uwm.edu) or use the Determination of UWM IRB Submission form if you are uncertain about the criteria for IRB review (http://uwm.edu/irb/submission/do-you-need-to-submit-to-the-irb/). Even if a research project does not meet the criteria for IRB submission, the researcher is still responsible for the ethical conduct of his or her project. Researchers are encouraged to follow the principles of respecting the subject's rights by obtaining consent and maintaining confidentiality; making sure the study is designed to minimize risks; and subjects are selected equally. Even if IRB approval is granted, it is the researcher's responsibility to comply with all appropriate website policies.