**INSTITUTIONAL REVIEW BOARD (IRB) FOR**

**THE PROTECTION OF HUMAN SUBJECTS**

**POLICIES AND PROCEDURES MANUAL**

#  UNIVERSITYOF WISCONSIN‐GREEN BAY

Updated May 2019

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## INTRODUCTION

The University of Wisconsin‐Green Bay encourages and supports free and responsible investigation by faculty, staff, and students. The policies and procedures of the Institutional Review Board (IRB) of the University of Wisconsin‐Green Bay have been developed to protect the rights and welfare of human subjects. Researchers are required to 1) obtain certification of their understanding of the research process, 2) submit a research protocol specifying human subject participation and the methodology used to insure that ethical procedures are adhered to, and 3) follow up reports on the status of their research. This guide contains instructions to assist you in the preparation of a protocol for submission to the IRB. The instructions on the following pages will help you to determine which parts of the protocol to complete and will explain the review process in detail.

## UNIVERSITY OF WISCONSIN‐GREEN BAY IRB REVIEW

Research projects that involve human subjects will require review by the University of Wisconsin‐Green Bay (UW‐ GREEN BAY) Institutional Review Board (IRB) for the Protection of Human Subjects to determine if you have employed adequate measures to protect the subjects involved in your study.

The Office for Human Research Protection (OHRP) has published regulations governing Institutional Review Board (IRB) authority of research involving human subjects [Federal Register (June 18, 1991, 45CFR46), revised January 15, 2009 and effective July 14, 2009]. The University of Wisconsin‐Green Bay adheres to these regulations.

For the purpose of IRB review, Federal Register defines *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Likewise, Federal Register defines a *human subject* as 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.

RECENT REVISIONS TO THE COMMON RULE

According to the Federal Register, human subjects and research are collectively known as the Common Rule. The regulation is 45 CFR 46, Subpart A). The Common Rule was recently revised and is in effect as of January 19, 2019. These changes are important for researchers seeking federal funding. The table below provides a comparison how the changes pertain to federally funded research and to the review of UW-Green Bay research protocols that do NOT receive federal funding:

|  |  |
| --- | --- |
| **Federally Funded Research – Contact the Office of Grants and Research for further guidance** | **Non-Federally Funded Research** |
| New exempt status for research | UWGB adheres to prior exempt definition of research. |
| No continuing review for federally funded research. | All research conducted at UWGB will be subjected to a yearly progress report. See section on when reports are due. |
| Single IRB for multisite studies | Single IRB for multisite studies |
| Definition of clinical trials | Social science experimental research will not be considered a clinical trial. |

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## HUMAN SUBJECTS’ PROTECTION TRAINING

The National Institutes of Health (NIH) requires all investigators or key personnel whose NIH‐sponsored projects involve human subjects, or who assist in the design or execution of NIH‐sponsored projects that involve human subjects, to complete training in human subjects’ protection. The University of Wisconsin–Green Bay extends this policy by requiring all personnel with human subject involvement to take training, regardless of the nature of their involvement and regardless of who sponsors the project. As of August 1, 2017 all UW-Green Bay researchers must be certified via the Collaborative Institutional Training Initiative (CITI). The certification is valid for four years. For additional information about the implementation of the CITI training on our campus, please consult:



Please note that if a researcher is federally funded they should take the Responsible Conduct of Research and Conflict of Interest modules in addition to all the other modules that are relevant to their project.

If a researcher is certified by the NIH training module, please note that these are valid for five years. The last date for when an NIH certification may be accepted is July 31, 2017 with an expiration date of July 31, 2022. All researchers must have CITI training after this date.

All researchers must be recertified after their expiration date.

A copy of all certificates of all researchers involved in the project must be attached to all protocols submitted to the IRB.

All CITI training modules are available on the IRB website. The website is available to UW-Green Bay faculty, staff and students. Should your research project include a researcher outside of the UW-Green Bay community, they may also obtain the training through our CITI training website. They should click on the link labeled “Other Researcher.”

<https://www.uwgb.edu/institutional-review-board/preparing-a-protocol/>

## RESEARCH CONDUCTED AT ANOTHER FACILITY

COLLABORATION WITH ANOTHER INSTITUTION: if you are submitting a collaborative protocol with another facility and/or faculty/staff employed by another institution, that institution's IRB must approve the protocol prior to submission to UW‐GREEN BAY's IRB, UNLESS you are the principal investigator on the project. Once you have obtained approval from the collaborating institution, submit a copy of the approved protocol, a copy of your instrument(s), UW‐GREEN BAY's Coversheet, and the letter stating that the collaborating facility's IRB has approved your protocol. If you are the principal investigator on the project, it should first be submitted to UW‐GREEN BAY's IRB.

OBTAINING DATA FROM ANOTHER INSITUTION: If you are planning on collecting data from another institution/organization (but not collaborating with any researchers from this institution/organization) please obtain a letter of affiliation and attach it to your IRB protocol. The letter should be on institutional letterhead and include a statement by a person in a position of authority (e.g., someone from Human Resources) granting permission to conduct research at their institution.

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## QUALITY IMPROVEMENT PROJECTS

Not all projects constitute research. Some projects are conducted with the intent of providing in-house information for improvement of procedures and practices. Examples of “in-house” may include a hospital setting, a classroom, or a business, etc. In this case, the findings are not presented nor published so that others can use the findings either in application or research. Such projects, known as “Quality Improvement” projects, or QI, do not need to undergo the IRB review process. UW-Madison Health Sciences IRB Office has developed an online tool to determine if a project qualifies as QI or needs to go through the IRB process. Researchers who think that they may qualify should undergo the QI certification process for each particular project by accessing the following link:

## <https://uwgreenbay.ca1.qualtrics.com/jfe/form/SV_bj9ceHcZX4eadKJ>

## REVIEW CATEGORIES

Please note that researchers applying for federal funding must follow the new NIH changes to the common rule (see [https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html%22%20%5Cl%20%22c1)). Questions for federal grants may be directed to the Office of Grants and Research. UW-Green Bay’s IRB has determined to follow a more conservative approach its review categories. All research subjected to UW-Green Bay IRB approval must follow the following categories of review:

### EXEMPT Protocol Submission

#### Introduction/Definition

EXEMPT means that the research, once approved, is exempt from further IRB oversight. Any protocol that suggests greater than minimal risk to research participants will not be reviewed as exempt.

EXEMPT research is a category of research involving human subjects, defined by Title 45 Code of Federal Regulations Part 46 that does not require FULL BOARD review and approval. Please review the EXEMPT categories to determine if your research qualifies for EXEMPT status. You will be asked to cite the appropriate exemption number next to the EXEMPT box on the Protocol Submission Form.

#### EXEMPT Categories

These exemptions do NOT apply to research involving vulnerable groups (e.g., minors, prisoners, fetuses, pregnant women, human in vitro fertilization).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures [if minors are involved, full board review is required], interview procedures [if minors are involved, full board review is required], or observation of public behavior UNLESS
	1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is NOT already EXEMPT under #2 if:
	1. The human subjects are elected or appointed public officials or candidates for public office, or (ii) Federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
3. Research and demonstration projects which are conducted by or subject to the approval of [Federal] Department or Agency heads and which are designed to study, evaluate, or otherwise examine:
	1. Public benefit or service programs, (ii) procedures for obtaining benefits or services under these programs,

(iii) possible changes in or alternatives to those programs or procedures, or (iv) payment for benefits or services under those programs.

1. Taste and food quality evaluation and consumer acceptance studies,

If wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### Submission of EXEMPT Project Protocols

EXEMPT protocols must include the following:

1. A completed [Protocol Submission Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/Protocol-WordForm-V2-0.docx) (found on the UW‐Green Bay IRB Website).
2. [A Consent Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/sample-consent-form.docx) (as appropriate; see page 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.).

**Note:** Members of the IRB that review research proposals may request “view-only” access to electronic surveys, e.g., Qualtrics. Please include the survey link in the IRB Protocol (approved by the IRB 12/14/15).

1. Researchers need to attach their CITI certification to all protocols submitted as exempt.
2. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

#### Review of EXEMPT Research

1. Completed protocols should be submitted to the Institutional Review Board Chair for review by the Chair or designee. The Institutional Review Board will notify you when your protocol is approved. You may not begin your research until you receive the approval notification from that office.
2. If the IRB places a conditional approval on your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.

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1. Once approved, you will not need additional review of your protocol unless you make modifications to your original protocol submission (see Protocol Modifications, page 8).
2. If the IRB Chair or designee determines that your protocol is not EXEMPT or needs clarification/modification, you will be notified and given instructions on how to proceed.

### EXPEDITED Protocol Submissions

#### Introduction/Definition

If your project involves only minimal risk, but does not meet one of the six exemption criteria, your project may qualify for EXPEDITED review. Federal Register defines *minimal risk* to mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

#### Submission of EXPEDITED Project Protocols

EXPEDITED protocols must include the following:

1. A completed [Protocol Submission Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/Protocol-WordForm-V2-0.docx) (found on the UW‐Green Bay IRB Website)
2. A Consent Form (as appropriate; see pages 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.) **Note:** Members of the IRB that review research proposals request “view-only” access to electronic surveys, e.g., Qualtrics. Please include the survey link in the IRB Protocol (approved by the IRB 12/14/15).
4. Researchers need to attach their CITI certification to all protocols submitted as expedited.
5. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

#### Review of EXPEDITED Research

1. Completed protocols should be submitted to the Institutional Review Board Chair for review by the Chair or designee. The Institutional Review Board will notify you when your protocol is approved. You may not begin your research until you receive the approval notification from that office.
2. If the IRB requires you to revise and resubmit your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.
3. If the IRB Chair or designee determines that your protocol does NOT qualify for EXPEDITED review and requires FULL BOARD review, you will be notified and given instructions on how to proceed.
4. If at any time you modify your protocol, you must submit those changes to the Institutional Review Board for review and approval by the IRB (see Protocol Modifications, page 8).
5. If your project continues for longer than one year, you will need to submit an [ANNUAL PROGRESS REPORT](https://www.uwgb.edu/UWGBCMS/media/irb/files/Annual-Progress-Report_final.pdf) (see Annual Progress Reports, page 8) and [a request for an extension.](https://www.uwgb.edu/UWGBCMS/media/irb/files/Modification-and-Extension-Form.pdf)

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### FULL BOARD Review Protocol Submissions

#### Introduction/Definition

If your project involves more than minimal risk to subjects as defined previously, your project requires a FULL BOARD review. Protocols involving any of the following will also require FULL BOARD review:

* Minor subjects (children 17 years of age or younger)
* Special populations (prisoners, pregnant women, individuals with disabilities) Please note that NIH changes to the Common Rule effective as of January 19, 2019 affect who is considered to be a member of a special popularion. These changes will only pertain to protocols receiving federal funding.
* The use of video‐ or audiotape to record subjects
* Asking questions that may be highly embarrassing or compromising (e.g., sexual behavior, sexual orientation, alcohol consumption, illegal drug use, medical conditions, violations of the law, personal finances, problems in the workplace, etc.)
* Exposing subjects to graphically violent or pornographic materials
* Inflicting physical pain upon, attaching electrodes to, or injecting any substance into subjects
* Creating high levels of stress, fear, discomfort, or tension
* Threatening subjects in any way
* Causing subjects to violate laws or official university regulations
* Providing some subjects with benefits denied to others (this includes payments or rewards for participation, e.g., offering extra credit to participants, etc.)
* Causing physical or mental exhaustion or engaging subjects in intense exercise
* Placing individuals in confining physical settings or attaching other devices
* Exposing subjects to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movement, etc.)
* Leaving minors alone for periods of time longer than 20 minutes
* Taking hair samples or nail clippings from subjects
* Taking human tissue samples, drawing blood, or sampling any other bodily fluid

#### Submission of FULL BOARD Project Protocols

Protocols for projects, which require FULL BOARD review, must contain the following:

1. A completed [Protocol Submission Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/Protocol-WordForm-V2-0.docx) (found on the UW‐Green Bay IRB Website)
2. [A Consent Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/sample-consent-form.docx) (as appropriate; see pages 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.) Note: Members of the IRB that review research proposals request “view-only” access to electronic surveys, e.g., Qualtrics. Please include the survey link in the IRB Protocol (approved by the IRB 12/14/15).
4. Researchers need to attach their CITI certification to all protocols submitted as full.
5. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

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### Review of FULL BOARD Protocols

1. If your project requires FULL BOARD review, you must submit your protocol to the IRB Chair two weeks before the IRB meeting when you would like it considered. The IRB encourages you to attend the FULL BOARD review to provide any clarification the board may need. At the meeting, the IRB may approve, conditionally approve, disapprove, or table (e.g. due to insufficient information, concern about the research, etc.) your protocol. All meetings are contingent upon a quorum (including at least one member whose primary concerns are in nonscientific areas) of members attending.
2. After the meeting, the Institutional Review Board will notify you of the status of your protocol. If the IRB places a conditional approval on your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.
3. If at any time you modify your protocol, you must submit those changes to Institutional Review Board for further review by the IRB (see Protocol Modifications, page 8).
4. If your project continues for longer than one year, you will need to submit an [ANNUAL PROGRESS REPORT](https://www.uwgb.edu/UWGBCMS/media/irb/files/Annual-Progress-Report_final.pdf) (see Annual Progress Reports, page 8) and [file for an extension](https://www.uwgb.edu/UWGBCMS/media/irb/files/Modification-and-Extension-Form.pdf).

## PROTOCOL MODIFICATIONS

If you make any changes to your protocol, you must submit a [Protocol Modification Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/Modification-and-Extension-Form.pdf)  the Institutional Review

Board. If the modifications are minor (i.e., changing several questions on existing surveys, title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review the protocol. If the modification entails adding or substituting new and different questionnaires or surveys, that protocol may have to be resubmitted as a new protocol. If the modifications include more than minimal risk (see definition on page 5), the protocol will be included on the next IRB agenda for FULL BOARD review.

## PROTOCOL RENEWALS

If you need to more time to finish your research, you must submit a [Request for Extension Form](https://www.uwgb.edu/UWGBCMS/media/irb/files/Modification-and-Extension-Form.pdf) to the Institutional Review Board. NOTE: If the request is made after the original ending date, it is still possible to obtain an extension. “The IRB will allow a one year grace period (beyond the original research expiration date) in which an investigator can request an extension of research. However, the research must have not changed significantly, the request must be made via a request for extension/modification form, and the reviewer will have the option to deny the request if other factors, e.g., changes in laws/policy, would suggest that the research is no longer consistent with current principles of protection of human research subjects.” (approved by the IRB 12/14/15)

## ANNUAL PROGRESS REPORTS

The IRB is required by 45CFR46 to conduct an annual review of every EXPEDITED or FULL BOARD IRB‐approved protocol within 12 months of the original approval date. For protocols approved in the Fall semester, a request for a progress report will be sent prior to the August 30th deadline for the report. For protocols approved in the Spring semester or during the summer, a request for a progress report will be sent prior to the January 31st deadline for the report. Complete the [Annual Progress Report](https://www.uwgb.edu/UWGBCMS/media/irb/files/Annual-Progress-Report_final.pdf) form and return it to Institutional Review Board. All expedited and full-board approved studies must submit the progress report. Exempt protocols do not have to submit a progress report.

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Annual Progress Reports are reviewed by the IRB Chair or designee. However, if modifications are made that include more than minimal risk (see definition on page 5), the protocol will be included on the next IRB agenda for FULL BOARD review.

## INFORMED CONSENT PROCEDURES

### Basic Elements of Informed Consent

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental. If UW-Green Bay students are awarded course research credit (as in the Psychology/Human Development ERLP program) the procedures and credits awarded must be described.
2. A description of any reasonably foreseeable risks or discomforts to the subjects.
3. A description of any benefits to the subjects or to others, which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (if applicable).
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. In the case of electronic data story, participants must be assured that the data will be stored on password protected servers.
6. For research involving more than minimal risk, an explanation as to whether any compensation is to be given and an explanation as to whether any medical treatments for injuries or counseling/psychological services for mental stress are available and, if so, what they consist of or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and who to contact to access the results of the study (include the principal investigator/faculty advisor’s name, Email address, and telephone number).
8. An explanation of whom to contact for answers to pertinent questions about the research subject’s rights/treatment (include the IRB Chairperson’s name, Email address, and telephone number).
9. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. A statement that the participant is over 18 years of age also is required (unless the study involves minors which requires a Full Board review).
10. Informed consent may also require the following
	1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
	2. A statement of anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
	3. A description of any additional costs to the subject that may result from participation in the research.
	4. An explanation of the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
	5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.
	6. Unless specifically studying minors, informed request should have a statement that the participant is at least 18 years of age.

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## AFFILIATION LETTERS

Projects involving cooperating institutions must include an affiliation letter with each cooperating institution. The affiliation letter(s) should be written on institutional letterhead by a supervisor at the particular agency and serve as evidence that the primary investigator has been given permission to conduct research at the institution. You may not begin participant recruitment or data collection until you have submitted the signed affiliation letter(s) to the Institutional Review Board.

## COURSE RESEARCH PROJECTS

If an activity or projects being conducted as part of a class qualifies as research with human subjects (see the definitions of *research* and *human subjects* on page 3), then IRB approval is required. However, in‐class presentations do not constitute a contribution to generalizable knowledge. Thus, unless the intention is to present to an audience outside the institution, IRB approval is not required.

All course assignments involving human participants that do not fall under the category of research must still be planned and carried out with due consideration of the University’s ethical and legal responsibility to protect individuals involved in these activities.

## USING MODELS IN PROJECTS

If an investigator generates photographs or video tapes of models to be used in their research, e.g., an image that will be rated, the researcher must provide a signed “image-release” form from those models. Audio recordings must also have a media release. The investigator is required to use [the UW-Green Bay approved form](https://www.uwgb.edu/UWGBCMS/media/irb/files/pdf/photo-release.pdf) (available on IRB web page) (approved by the IRB 3/12/13).

**Policy on Outside Institutional Access to**

**UW-Green Bay Participants**

This policy pertains to requests from institutions other than the University of Wisconsin-Green Bay (including other UW System Institutions). The IRB Chair, in consultation with the full IRB Board, shall review the approved IRB document. If approval is granted, the Chair of the UW-Green Bay IRB Board shall request that the UW-Green Bay Dean of Students randomly select up to 1000 student email addresses to forward to the requestor. Upon completion of the project the researcher of the outside institution shall submit a copy of the completed report to the current IRB Chair.

Approved by the UW-Green Bay Institutional Review Board, December 14, 2015. Note to IRB: Review this policy

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**Guidance for Use of the Internet and Social Media in Research**

 *The purpose of this document is to specify what is important for investigators to consider when using social media in research, to provide definitions and examples of social media terms and policies, and to outline the Institutional Review Board’s policies in regards to social media.*

(*adapted with permission from Lindenwood University IRB)*

# How are the Internet and Social Media tools to be utilized in research?

Researchers use the internet in a variety of ways to collect data and interact with participants. While reviewing applications, the IRB finds it helpful to make the following broad distinctions:

* **Internet-Based Research:** Researchers often observe research participants and collect data in online spaces. However, an immense amount of primary and secondary research data are now available on the internet in other modes and sources. It is possible to collect observational or interventional data in online spaces where users provide comments and information, such as online forums, chat rooms, gaming environments, and marketplaces. In such cases, the Internet effectively functions as the research “site.” Research conducted through said method should be identified as Internet-Based Research.
* **Social Media in Research:** All social media applications (e.g. Facebook, Twitter, Instagram, WhatsApp, Baidu, SnapChat) utilized in a study should be identified as tools used for data collection from participants.

# What is the difference between Publicly Available and Private data?

Data are available on the internet in a wide array of formats and degrees of identifiability. When collecting data online, a researcher should be aware of how participants typically use a given space, forum, or platform and what expectations they have for observations or analysis of their data. Failure to adhere to the federal or local regulatory definitions of the difference between private and public can pose significant risks to participants or others in the research process. Regulations imply a difference between data collecting from **public observation** and **private data** collected from interaction or intervention with a research participant.

* **Private Information**: data accessed through special permission, password protection, or registration of a user. 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.*” Researchers should clearly outline their expectations of the participants and their right to privacy throughout the study. A website or platform’s Terms of Service often outline privacy expectations on behalf of users.
	+ Requires Informed consent.
* **Public Observation:** occurs in spaces where a reasonable person does not have an expectation of privacy. This definition of public observation applies in online spaces when there is no assumption of privacy by those using, contributing to, or interacting in the online space. When publicly available sources are used, the data only remain publicly available if the researcher does not attempt to trace user names or profiles back to identifiable information.

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The following is a set of examples (not exhaustive) of Private and Public sources:

|  |  |
| --- | --- |
| **Examples of Private sources** | **Examples of Public sources** |
| Facebook | Twitter (unless “locked” by user) |
| Listservs | Comments at news sites, blogs, etc… |
| Anything made private by the user | Forums with no registration requirement |
| When use violates Terms of Service | Blogs |
| Chat spaces in online games | Crowdsourcing sites (e.g. GoFundMe) |
| Live chat platforms | LinkedIn (excepting personal connections) |
| Messenger | Comments on Federal Notices |
|  | YouTube (unless locked by user) |
|  | Freely available Federal and State databases |
|  | WeChat (Chinese messaging, social media & mobile payment app) |

1. **How do Terms of Service apply to researchers?**

The researcher is obligated to maintain compliance with the Terms of Service for any resource they access for data collection.

# How can a researcher use social media to recruit research participants?

Researchers must follow the same UW-Green Bay IRB policies for recruiting participants through social media that apply to traditional media (e.g. flyers, bulletin boards, etc...).

*The following are acceptable methods used to recruit participants online:*

* Posting flyers or advertisements on social media platforms:
* Posting recruitment scripts in forums and social media spaces dedicated to specific causes or conditions:
	+ If a researcher is collecting data on a specific condition or interest, it may be possible to recruit participants directly from online spaces frequented by participants meeting those criteria. In these cases, researchers should seek permission to post information from site moderators, and adhere to all community guidelines set by the group.
* Initiating interactive recruitment on social media platforms:
	+ Researchers may initiate two- way communication through social media with potential participants.

# How can a researcher obtain consent from participants online?

Performing a consent process online can pose interesting challenges, though the same regulations and policies for consenting participants in human subjects research apply regardless of the format or venue. If obtaining consent in an online forum or chatroom, *a researcher must ensure that the consent process does not alter the flow of conversation or use of that space.* There are two strategies used for obtaining and documenting informed consent for an online survey or data collection process:

1. **Obtaining Written Documentation of Consent:**
	1. If the IRB determines that written documentation of consent is required, a researcher will share a consent document with participants, which they will then sign and return by mail, email, or a similar format. In such cases, researchers will return a fully executed consent form, which also includes the researcher’s signature and date, to participants.

\*\*If consenting minors as research participants, researchers will providing an assent and consent form for the minor participant ***and parent*** to sign and return ***prio****r* to receiving the survey or participating in the research. Researchers should use survey questions to confirm that participants are either adults or minors during this process.

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* 1. In online surveys, researchers should create a landing page for the survey, which includes an Information Sheet or Consent Form. At the bottom of this page, the researcher will include buttons or checkboxes for participants to indicate that they agree or do not agree to continue with the survey. It is also acceptable to include a statement that clicking “next” constitutes consent to continue with the survey. If participants agree, they will be taken to the survey(s).

# What are important Privacy and Confidentiality issues to consider?

A researcher should not assume they understand expectations for privacy in online environments. Notions of privacy can vary widely based on the type of online communication and nature of data presented. In addition, individual participants may have different senses of privacy in their online interactions. Researchers at UW-Green Bay may use **Qualtrics** or alternative survey research platforms to perform online survey research. UW-Green Bay considers IP addresses identifiable information. Researchers are advised to turn off the IP address on Qualtrics and other survey platforms.

* + If using social media to perform a research protocol, researchers should use options available to eliminate potential disclosure of information about participants.
	+ User names, online avatars (such as Bitmoji or Profile Picture) are often identifiable, and researchers should use traditional IDs (typically a number) to preserve anonymity of participants during the data collection process.
	+ If a researcher is offering compensation for participation, it is advisable to offer gift certificates from online retailers that use a certificate redemption number after the survey is completed. This will permit compensation without having to collect identifiable information from participants.
	+ All data should be stored on a password protected secure server.
	+ Links to names should be changed as soon as possible.

# What are additional important ethical and regulatory issues to consider?

Consent **must attest** to participants being at least 18 years of age.

If minors are studied:

* If researchers are communicating with children online, these interactions are subject to the Children’s Online Privacy Protection Act (COPPA). Researchers may not collect personal information from minors without a verifiable parental consent. It is best practice to exclude minors from internet-based research by using programs like SafeSurf or AdultCheck systems.

Research in Forums and Chatrooms:

* Researchers may encounter information about risky or illegal behaviors. It is important to consider prior to conducting the research how this kind of data will be treated, and when, if applicable, it would need to be reported to state or federal agencies.
* If collecting data in a forum or chatroom, the researcher will need to consider their own identifiability.

# What information should be included in the IRB Application?

In cases of internet-based research, researchers **must define** the nature of the recruitment and consent process, and the scope of their data collection very specifically in the IRB application. For example, the application should identify precisely what blogs or site comments they will access, and what additional information will be considered based off participant’s profiles. The following information should be presented in the IRB application:

* + An itemized description of specific sources used during the research.
	+ A description of how the researcher will obtain consent or provide appropriate consent information to participants.

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* + A description of a user’s typical expectation of privacy for data accessed or obtained during the research.
	+ A description of how the researcher will minimize privacy and confidentiality risks during the research process.
	+ A description of how the researcher will obtain, code, transfer, and store data.
	+ Affirmation that research use of the source does not violate the Terms of Service. The obligation for compliance with Terms of Service lies with each principle investigator, including compliance with any changes to Terms of Service during the research process.

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