

Screen Shots of IRBManager New Study xForm

Study Title Page:

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New Study Form -- A. Study Title

Submitted by:	Spadanuda, Melissa
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Business:	414-229-3173

A. SECTION NOTES:

- Each Section must be completed unless directed otherwise. Incomplete forms may delay the IRB review process.

A1. Full Study Title: [Add Note](#)
(Required)

- Study title must be the same on all study documents (e.g., consents, advertisements, grants, etc.). If not, a reason must be given. Click on the "Add Note" above and explain (e.g., deception study, simplified title).
- Explain study title differences in the "Add Note" function directly above.
- Mismatched titles between what the IRB approves and what is on the grant application may delay funding.

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PI, SPI, Research Personnel Page:

B. SECTION NOTES:

- IRB correspondence (e.g., Approval Letters, IRB revisions, etc.) will be sent to the email addresses listed under the PI and contact person (B1 and B3).
- Only UWM faculty and staff may be listed as PI in B1. Students may be listed as a Student PI in B3.
- The PI and SPI are required to complete Human Subjects Research training. Please visit the UWM IRB website for more details: <http://www4.uwm.edu/usa/irb/researchers/training.cfm>

B1. Principal Investigator (P.I.) (UWM faculty and staff only. Students may NOT serve as the PI.):

[Add Note](#)

(Required)

You must enter the full UWM email address including the @uwm.edu. If the person is not found, they must be added to IRBManager as a new user. The individual must request a new user account by registering on the UWM IRB website: <http://www4.uwm.edu/usa/irb/researchers/irbmanageruseraccount.cfm#uwmaccount>

B2. Department, School, or College (Required)

[Add Note](#)

B3. Student Principal Investigator (S.P.I.) and/or Other Contact than PI. These individuals will be notified on all IRB notifications.

[Add Note](#)

No answer entered.

You must enter the full UWM email address including the @uwm.edu. If the person is not found, they must be added to IRBManager as a new user. The individual must request a new user account by registering on the UWM IRB website: <http://www4.uwm.edu/usa/irb/researchers/irbmanageruseraccount.cfm#uwmaccount>

B4. Enter the names of Co-Investigators and research personnel not listed in B3 and their role in the project. If study personnel are not affiliated with UWM, identify their institutional affiliation and their role in the project.

[Add Note](#)

- These individuals will not receive IRB notifications.

Is this project being conducted as part of the Student PI's dissertation or thesis? (Required)

[Add Note](#)

New Study Form -- C1. Review Type and Miminal Risk

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C1.1 Select the type of research this project best falls under: (Required) Add Note

a. Social & Behavioral **Social & Behavioral:** Research that deals with human attitudes, beliefs, and behaviors. Studying the neurology, anatomy, and physiology that underlies perception, learning, instinctual behavior, and emotional responses.

Educational: Research in educational settings involving educational practices. For example: research on regular and special education instructional strategies; effectiveness or comparison among instructional techniques, curricula, or classroom management methods.

Biomedical: Research designed to evaluate the safety, effectiveness, or usefulness of an intervention; diagnostic procedures; preventive measures; specific disease processes; human functioning and development; and human genome and genetic markers.

Health Services: Research on how social, financial, and organizational factors, affect access and/or delivery of health care.

C1.2. Please select the risk level of the study. (Required) Add Note

- **"Minimal Risk"** is when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than the harm and discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination, so this activity would be minimal risk.
- Most survey, interview, oral history, focus group, and program evaluations are considered no greater than minimal risk. However, in some circumstances asking questions about illegal activities (such as drug use) or private and sensitive activities (such as sexual behavior) may involve more than minimal risk and require full board review.
- Studies involving x-ray emitting equipment or devices without FDA approval are considered more than minimal risk and require full board review.
- Activities that may be considered minimal risk for healthy adults may involve more than minimal risk for some populations (such as children, pregnant women, prisoners, cognitively impaired adults, or elderly).

If Minimal Risk:

C2.1. Exempt Review. For a project to qualify for Exempt Review, all of the project's activities must fall under one or more of the following categories and cannot be more than "minimal risk." Select all that apply. [Add Note](#)

- Category 1 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Category 2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) 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.
- Category 3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Category 4 Research involving the collection or study of existing data, documents, records, pathological specimens, 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.
- Category 5 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- Category 6 Taste and food quality evaluation and consumer acceptance studies.

C2.2. Expedited Review. For a project to qualify for Expedited Review, all of the project's activities must fall under one or more of the following categories and cannot be more than "minimal risk." Select all that apply. [Add Note](#)

- Category 1 Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Category 2 Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Category 3 Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- Category 4 Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- Category 5 Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- Category 6 Collection of data from voice, video, digital, or image recordings made for research purposes.
- Category 7 Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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If More than Minimal Risk:

New Study Form -- C3. Full Board

Full Board if C1 to minimal risk is "yes."

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C3.1 Full Board Review. Projects involving more than "minimal risk" and not meeting Exempt or Expedited Review will require Full Board Review. Please explain why the study involves more than "minimal risk." (Required)

[Add Note](#)

Examples include, but are not limited to:

- Research collecting personal identifiers and data of sexual orientation, sexual activity, illegal activities, and other data which could place the subject at risk.
- Research involves subjects participating in physical activities which could place them in harm or discomfort exceeding normal daily life.
- Research exposing subjects to ionized radiation (FMRI, X-Rays, DXA, etc.).
- Federally funded research involving prisoners.

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New Study Form -- D. funding details

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D. SECTION NOTES:

- Federally funded studies (e.g., NIH, CDC, NSF, etc.) require IRBs to review the grant application for consistency in human subject interaction/intervention and protections. You will be prompted to attach the grant application in Section Y5 of this form.

D1. This study's funding source is or will be: (Select all that apply.) (Required) [Add Note](#)

- a. FEDERAL: Health and Human Services (ACF, CDC, FDA, NIH, SAMHSA, etc.)
- b. FEDERAL: OTHER (NSF, DOJ, DE, DOD, DOE, etc.)
- c. State Agency, Industry, Foundation, Commercial, or Private
- d. UWM: RGI, CUPH, Graduate School, Academic Affairs, etc.
- e. OTHER
- f. NOT FUNDED

D2. Provide the funding agency's name and address. Enter N/A if the study is not funded. (Required) [Add Note](#)

D3. UWM Proposal/ grant # (if applicable): [Add Note](#)

Study Locations and other approvals Page:



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New Study Form -- E. study locations data entry

Submitted by:	Spadanuda, Melissa		
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E1. Describe the location(s) where study activities will take place. (Required) [Add Note](#)

SECTION NOTES:

- Projects involving non-UWM investigators, facilities, and/or patients, students, employees (for example, MCW, Aurora, Marquette University, etc.) may require that institution's IRB review. Please contact the collaborating performance site to determine whether the site requires any additional review/approval. If another site requests to have a single IRB of Record (also called a deferral), please contact the UWM IRB office for guidance.
- If the project has received IRB approval from another institution, attach a copy of the IRB approval letter.
- Projects taking place at Milwaukee Public Schools require additional review/approval. Visit MPS site.

E2. Please describe any other institutional reviews that are needed for this study. If none, state N/A. If you have any documentation from other institutions, please attach in Section Y. (Required) [Add Note](#)



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New Study Form -- F. study involvement

Submitted by:	Spadanuda, Melissa	
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F1. This study involves the following activities/articles (select all that apply): (Required) Add Note

- A. Data/Record/Chart Analysis
- B. Interviews/Focus Groups
- C. Questionnaires/Surveys
- D. Observations
- E. Audio, Video, Photo Taping
- F. Internet Research
- G. Blood/Specimen Collection
- H. Genetic Testing
- I. MRI, fMRI, X-Rays, DXA, etc
- X. Device (Non-Medical)
- Y. Device (Medical)
- Z. Drug
- zz. N/A
- ZZ. OTHER

- *Internet Research is subject to additional guidelines. See IRB website.*
- *Ionizing radioactive materials or radiation producing devices located here on campus requires the review and approval from the Radiation Safety Program. See Radiation Safety website.*

F1a. Specify Other Add Note

Consent Page:

SECTION NOTES:

Obtaining and documenting subject's signed (can be written or electronic) informed consent is required.

Consent forms must include elements such as the purpose of the study, study procedures, risks, benefits, alternatives, confidentiality, researcher and IRB contact information and the voluntary rights of the participant. The UWM IRB has several consent templates available on the UWM IRB website that researchers may use for guidance. Please attach consent form(s) in Section Y3.

A request to waive obtaining, altering or documenting consent may be granted if justified. The different types of consent waivers are explained below. To request a Waiver, please complete the [Waiver to Obtain/Document/Alter Consent Request Form](#) and attach it in section Y3.

I. A **waiver to obtain informed consent** can be requested for studies with no direct contact or involvement with human subjects. Examples:

- secondary analysis of identifiable dataset;
- reviewing a large number of patient charts; and
- research on identifiable specimens

II. A **waiver to alter the required elements of the informed consent** means that consent is still obtained. However, the consent does not contain all the required elements (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111>). Examples:

- Not disclosing the true purpose (a required element) of the study in the consent document because it may bias what is being tested.

III. A **waiver to document informed consent** can be requested for studies where the subject's signature is not obtained. Waiving documentation still requires that a written consent document be presented to the subject. However, the subject's signature is not obtained. Most often, the subject is presented with a consent letter (on computer screen or on paper) explaining that by clicking the "continue button" or completing and returning the survey they are consenting to participate. Examples:

- anonymous survey conducted on paper and pencil;
- confidential online survey; and
- studies where privacy and confidentiality would be compromised by having a signed document linking the subject to the study. E.g., interviews on illegal activities or HIV status

IV. A request to **obtain verbal consent** for **Exempt** research will require the IRB to approve a summary/script of what is to be said to the subject. Example:

- cases where subjects are not able to receive a written consent ahead of time, such as a random digit dialing for telephone surveys where subjects are read a brief consent script

V. A request to **obtain verbal consent** for **Expedited and Full Board** research will require: (1) the IRB to approve a summary/script containing the required elements of consent that is to be verbally presented to the subject, (2) a witness to the verbal presentation of this information, (3) the subject signs a brief document giving consent for participation, (4) the witness signs both the brief document and the summary/script, (5) the researcher obtaining consent signs the summary/script, (6) the researcher keeps all signed documents (summary/script signed by witness and researchers, and brief document signed by witness and subject), and (7) the subject keeps copies (either signed or unsigned) of the brief document. Examples:

- subject populations where many are illiterate;
- it is against one's culture to sign one's name to a document

G1. How will the consenting of subjects take place? Please attach the consent form(s) and/or the Waiver to Obtain/Document/Alter Informed Consent Request Form in Section Y3. (Required)

Add Note

- a. Written informed consent with the subject's or legal representative's signature. Use a consent template and attach in Section Y3.
- b. Waiver to obtain informed consent can be requested for studies that do not have direct contact with subjects. For example, a dataset or chart study. Complete Waiver to Obtain/Document/Alter Informed Consent Request Form and attach in Section Y3.
- c. Waiver to alter the required elements of the informed consent document may be requested when some of the required elements are not included. For example, not disclosing the true purpose (a required element) of the study in the consent document because it may bias what is being tested. Complete Waiver to Obtain/Document/Alter Informed Consent Request Form and a consent form and attach in Section Y3.
- d. Waiver to document informed consent can be requested for studies where the subject's signature is not collected but all the other required elements must be presented to the subject. For example, informed consent process is done verbally, anonymous survey conducted on paper and pencil, confidential online survey, etc. Complete Waiver to Obtain/Document/Alter Informed Consent Request Form and a consent form and attach in Section Y3.
- e. Assent for minors. Use IRB Assent Template with separate parent consent or combined parent consent/child assent template. Attach in Section Y3.

[Click here to access IRB consent templates.](#)

[Waiver to obtain/document/alter informed consent Request Form](#)

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H: Health Information Privacy & Accountability Act (HIPAA) and Protected Health Information (PHI)

What is it?

The Health Information Portability and Accountability Act (HIPAA) Privacy Rule is Federal legislation which regulates the way certain health care groups, organizations, or businesses, handle the individually identifiable health information known as protected health information (PHI). The Privacy Rule establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. Researchers seeking to use PHI from a UWM Covered Department or an external covered entity as part of their research study must comply with HIPAA. Compliance typically requires either obtaining a HIPAA Authorization during the informed consent process or obtaining a Waiver of such Authorization from the IRB.

What is PHI?

Protected health information (PHI) includes information relating to an individual's past, present or future physical or mental health or condition, the provision of health care services or the past, present or future payment for such services. It only covers information that is individually identifiable. There are 18 identifiers under the Privacy Rule, some of which include: names, dates, geographic locations, telephone numbers, medical record numbers, account numbers, biometric identifiers, and other unique identifying number or code.

If you are asking a participant to self-report his medical history outside a UWM covered department or a clinical/hospital setting and do not wish to see his/her medical record, the information is not considered PHI under HIPAA.

What are UWM's Covered Departments?

UWM is considered a "hybrid entity" under HIPAA because it has some departments and units that are covered by HIPAA and some that are not. All employees and volunteers in UWM's Covered Departments must comply with the Privacy and Security Rules, including in connection with research.

UWM's Covered Departments are currently comprised of the following entities:

A. Provider Units:

1. Athletics Trainers (Division of Student Affairs)
2. Hearing Evaluation Center (College of Health Science)
3. Norris Student Health Center (Division of Student Affairs)
4. Psychology Clinic (College of Letters and Sciences)
5. Speech and Language Clinic (College of Health Sciences)
6. Urban Health Partnerships (College of Nursing)

B. Administrative Units:

1. Bursar's Office (Division of Finance & Administrative Affairs)
2. IT Personnel in Business & Financial Services (Division of Academic Affairs)
3. Information and Media Technologies (I&MT) (Division of Academic Affairs)
4. Institutional Review Board Members and Administrative Staff (Division of Finance & Administrative Affairs)
5. Internal Audit (Division of Finance & Administrative Affairs)
6. Office of Legal Affairs (Division of Finance & Administrative Affairs)
7. Risk Management (Division of Finance & Administrative Affairs)
8. Privacy Officers

Who do I contact to for more information on this?

Contact the UWM Office of Legal Affairs (<https://www4.uwm.edu/legal/hipaa/>)

H1. Based on the information above, are you conducting this research as part of a UWM HIPAA covered department AND using Protected Health Information (PHI)? (Required)

Add Note

 

H2. Based on the information above, are you conducting this research outside of a UWM HIPAA covered department but using Protected Health Information (PHI) from a HIPAA covered entity (either at UWM or another institution)? (Required)

Add Note

 

If you answered YES to H1 or H2, you must:

1. Obtain authorization from Research Participants using an "[Authorization Form for Research For the Use and Disclosure of Patient Health Information](#)" OR Combine the [authorization language in the consent form](#) OR The IRB must approve a request to waive authorization by completing the "[Application for IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule](#)." Please attach in section Y3.
2. Complete online HIPAA training at <https://www4.uwm.edu/legal/hipaa/training/login/>.
3. If you are collecting PHI from a non-UWM HIPAA covered entity, you should verify from that institution if any additional approvals or forms are needed.

H. Conflicts of Interest

When researchers are involved with commercial ventures, there is the potential for diverting from their primary mission of research and education. Conflicts of interest can arise when the interests of the commercial venture differ from the interests and primary obligations of the researcher, or when the commercial venture consumes an undue share of employee time. Please visit the UWM Graduate School website for more details regarding the Conflict of Interest Policy and procedures:

<http://www.graduateschool.uwm.edu/research/data-policy/phs-conflicts-of-interest/>

H3. Please describe any potential conflict of interest key personnel involved in the proposed research activity may have that requires disclosure?
(If none, please state N/A.) (Required)

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New Study Form -- Y: Attachments

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Y1. Attach IRBManager Protocol Form. (Required) [Add Note](#) [View Audit](#)

[Add Attachment](#) *Download and save the IRBManager Protocol Form. Complete and attach in Section Y1.*

No Attachments added.

Y2. Recruitment Materials - Including flyers, advertisements, recruitment scripts, emails, etc. [Add Note](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

Y3. Complete and attach Consent/Assent form(s) and/or Waiver to Obtain/Document/Alter Informed Consent. [Add Note](#) [View Audit](#)

[Add Attachment](#) *Download and save Consent/Assent Forms. Complete and attach in Y3.*

No Attachments added.

Y4. Data Collection Instruments - Survey/Interview questions, chart review data collection forms, etc. [Add Note](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

Y5. Grant Application if Federally funded [Add Note](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

Y6. Institutional Permission or other IRB Approval. If multiple IRBs are involved and an IRB Agreement has been requested/approved, attach correspondence (e.g., email from IRB). [Add Note](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

Y7. Other Documents that may be important for IRB review. [Add Note](#) [View Audit](#)

[Add Attachment](#)

No Attachments added.

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New Study Form -- Z. Assurances

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Z.1 As Principal and Student Principal Investigator, I certify the following: *(Required)*

[Add Note](#)

- a. I have reviewed this protocol submission and acknowledge my responsibilities as Principal Investigator.
- b. The information in this submission accurately reflects the proposed research.
- c. I will not initiate this study until I receive written approval from the IRB.
- d. I will promptly report to the IRB any unanticipated problems and adverse events, as well as any findings during the course of the study that may affect the risks and benefits to the subjects.
- e. I will obtain prior written approval for modifications (amendments) to this protocol including, but not limited to, changes in procedures.
- f. I have completed the UWM Human Subjects Training Module.
- g. I have determined whether or not I am accessing protected health information as part of my proposed research, and if so, I accept responsibility for assuring adherence to HIPAA.
- h. If I am using PHI in my research, I have visited the UWM HIPAA Training website (www.hipaa.uwm.edu) and have completed all required training, and I am complying with HIPAA's requirements for researchers.
- i. I accept responsibility for assuring adherence to applicable Federal and State research regulations and UWM policies relative to the protection of the rights and welfare of the subjects enrolled in this study.
- j. I understand that the UWM IRB operates under a Federal Wide Assurance (FWA) from the Department of Health and Human Services.
- k. Unless given Exempt Status, I understand that this study is subject to continuing review and approval by the IRB.

All must be checked.

Z.2 By entering your user password, you have read and understood the above assurances.

[Add Note](#)

NOTE

- If you are NOT the Principal Investigator (e.g., Student PI, Research Assistant, Study Coordinator, etc.), after submitting, the PI will receive an email notification requiring them to review and enter their password to complete the submission to the IRB.
- Please contact the PI to ensure that they have received the email notification or know to sign in to their IRBManager account to submit the study to the IRB.
- The "status" of this xForm will state "PI Assurance Stage when SPI is involved" until the PI has submitted.

(Required)

To sign, enter password for spadanud as of 5/21/2013

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