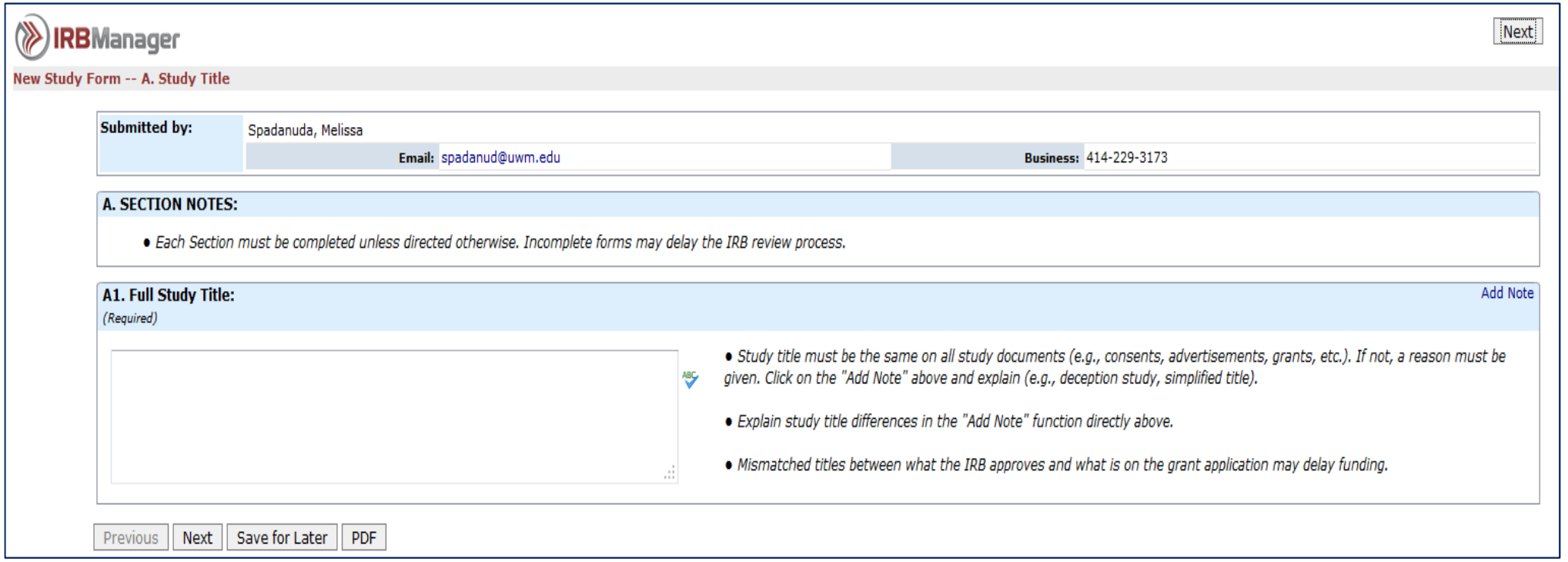
Screen Shots of IRBManager New Study xForm

Study Title Page:



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

Add Contact

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

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Level of Risk Page:

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

Submitted by:	Spadanuda, Melissa		
	Email: spadanud@uwm.edu	**Business:**	414-229-3173

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).*

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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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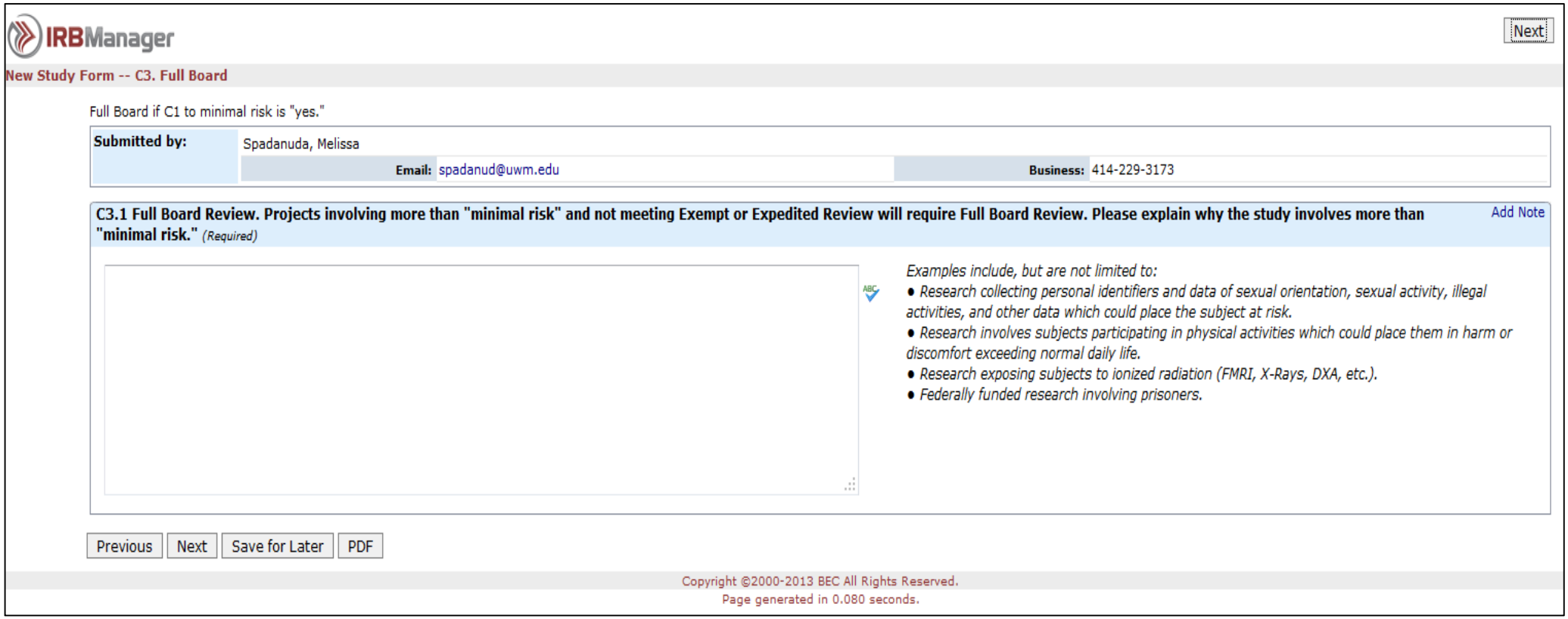
If More than Minimal Risk:



Funding Page:

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New Study Form -- D. funding details

Submitted by:	Spadanuda, Melissa		
	Email: spadanud@uwm.edu	**Business:**	414-229-3173

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

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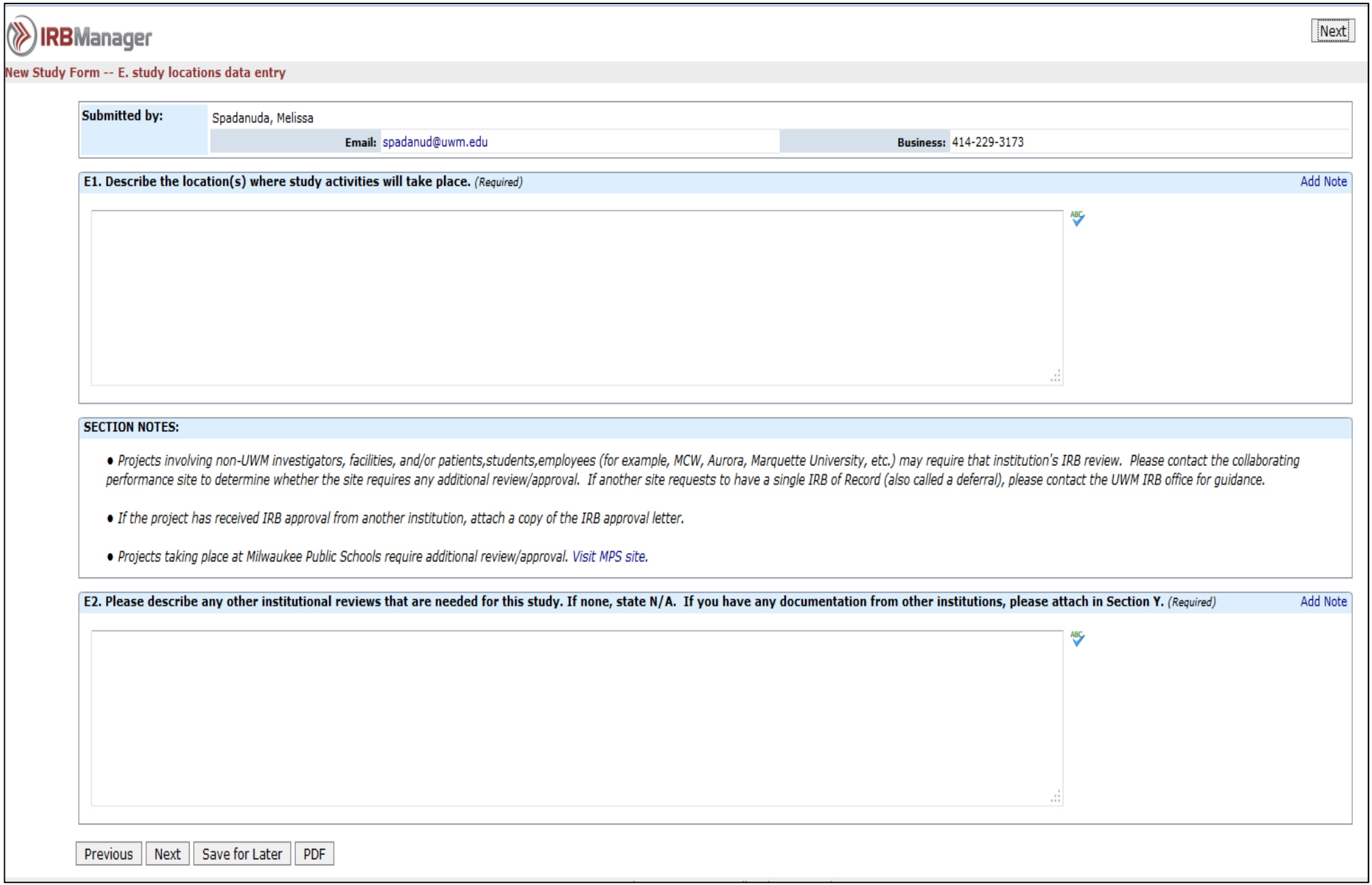
Study Locations and other approvals Page:



Study Activities Page:

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New Study Form -- F. study involvement

Submitted by:	Spadanuda, Melissa		
	Email: spadanud@uwm.edu	**Business:**	414-229-3173

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

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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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HIPAA and Conflict of Interest Page:

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New Study Form -- SECTION H: HIPAA and Conflicts of Interest

Submitted by:	Spadanuda, Melissa		
	Email: spadanud@uwm.edu	**Business:**	414-229-3173

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)* Add Note

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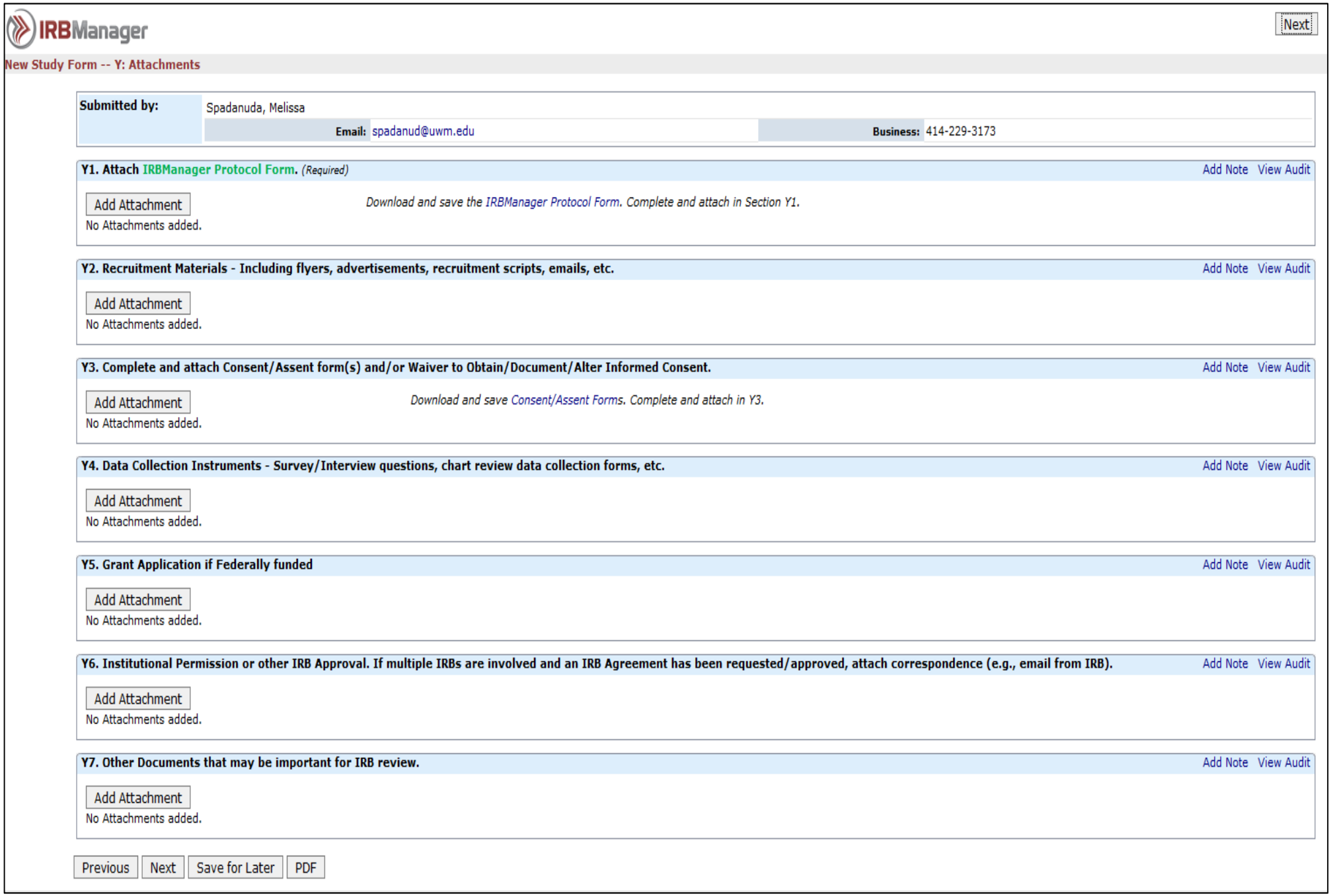
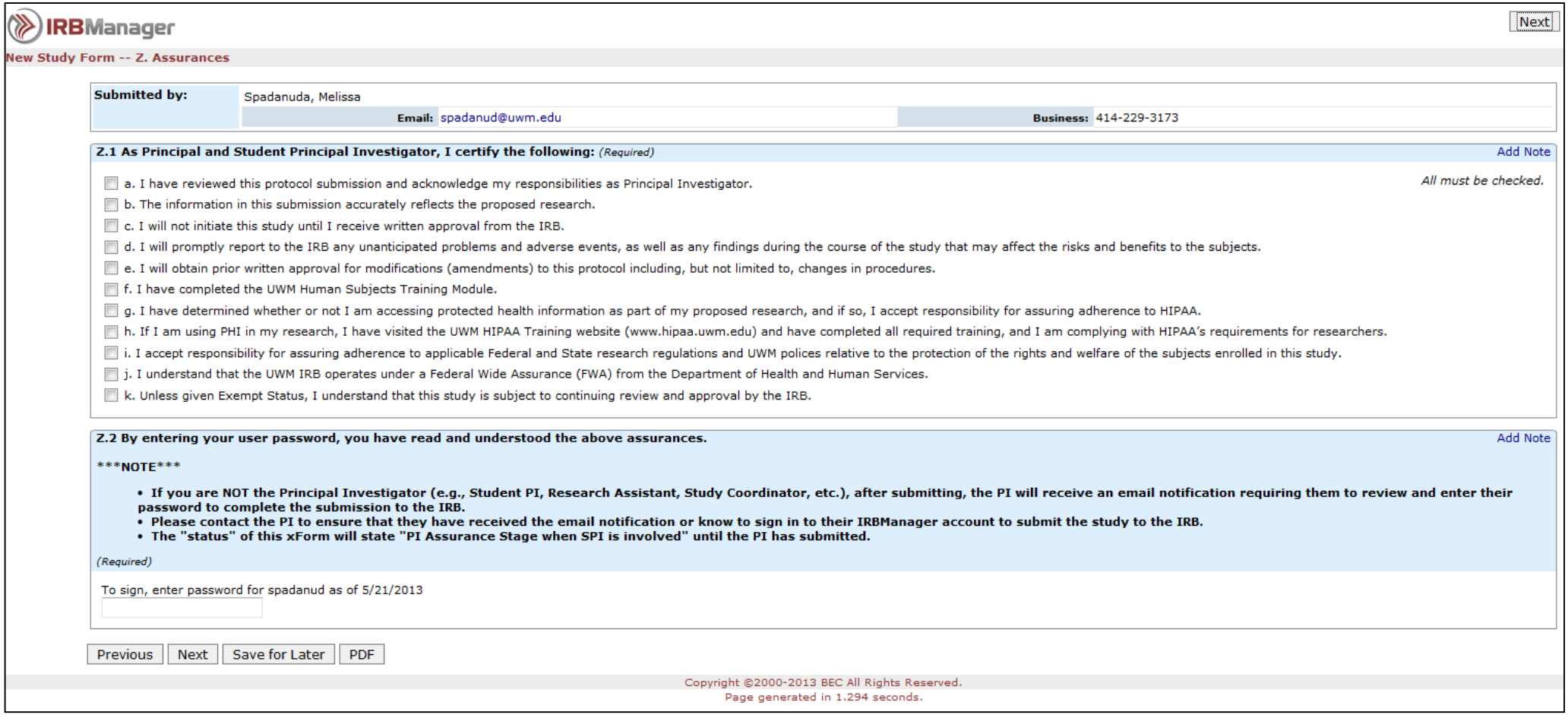
Attachments Page:



Assurances Page:



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