UNIVERSITY of WISCONSIN UWMILWAUKEE

Use this form when submitting a new study to the IRB.

New Study data entry

A. Study Title

Submitted by:	Kraft, Patrick		
	Email: kraftp@uwm.edu	**Phone:**	

A. SECTION NOTES:

- *To give another user access to this form for reviewing, editing or submitting, select the "**Collaborators**" option at the top of any page. If appropriate, please add any collaborators as PI, SPI and/or other contact in Section B because this will not be done automatically. For more detailed instructions about collaboration, please read the collaboration instructions.*

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

A1. Full Study Title:

Media Usage and News Consumption

- *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).*

- *Mismatched titles between what the IRB approves and what is on the grant application may delay funding.*

B. PI and SPI and Other Contact

B. SECTION NOTES:

- *To give another user access to this form for reviewing, editing or submitting, select the "**Collaborators**" option at the top of any page. If appropriate, please add any collaborators as PI, SPI and/or other contact in Section B because this will not be done automatically. For more detailed instructions about collaboration, please read the collaboration instructions.*

- *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 every 3 years. Please visit the UWM IRB website for more details: http://uwm.edu/irb/training/human-subjects-training-citi/*

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

Kraft, Patrick

Email: kraftp@uwm.edu **Phone:**

● *You must enter the full UWM email address including the @uwm.edu. If the person is not found, s/he will need to create an IRBManager account by logging into IRBManager with his/her UWM Panther ID and password. An account will automatically be created.*

● *If you are not the PI, you may give the PI access to this form for reviewing, editing or submitting by selecting the "**Collaborators**" option at the top of any page. For more detailed instructions about collaboration, please click here.*

B2. Department, School, or College

Department of Political Science, College of Letters & Science

B3. Student Principal Investigator (SPI) and/or Other Contact than PI. These individuals will be notified on all IRB notifications. Be sure to list the submitter of the form.

Neumeyer, Jason

Email: neumeye6@uwm.edu **Phone:**

Heideman, Amanda

Email: heidem24@uwm.edu **Phone:**

Davis, Nicholas

Email: nrdavis@uwm.edu **Phone:**

Park, Shin Young

Email: parksy@uwm.edu **Phone:**

● *You must enter the full UWM email address including the @uwm.edu. If the person is not found, s/he will need to create an IRBManager account by logging into IRBManager with his/her UWM Panther ID and password. An account will automatically be created. If the person does not have a Panther ID, s/he can request an account on the UWM IRB website: http://uwm.edu/irb/irbmanager/*

● *If you are not the Student PI or other contact, you may give the SPI or other contacts access to this form for reviewing, editing or submitting by selecting the "**Collaborators**" option at the top of any page. For more detailed instructions about collaboration, please click here.*

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.

No answer provided.

● *These individuals will not receive IRB notifications or have access to this study's information in IRBManager.*

B5. Is this project being conducted as part of a student project, dissertation, or thesis? (If the student should have access to this study in IRBManager, please list in Section B3.)

No

C1. Review Type and Risk Level

C1.1 Select the type of research this project best falls under:

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. Includes behavioral and psychological interventions.*

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 a medical 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.

Minimal Risk

● ***"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).*

C2. Exempt or Expedited

C2. SECTION NOTES:

● *Select the review type and category (more than 1 category may be selected) you believe the study falls into. Upon review, the IRB office may change the requested type of review.*

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.

No answer provided.

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.

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.

D. Funding Details

D1. This study's funding source is or will be: (Select all that apply.)

d. UWM: RGI, CUPH, Graduate School, Academic Affairs, etc.

D2. Provide the funding agency's name and address. Enter N/A if the study is not funded.

UWM College of Letters & Science, new faculty start-up funds

D3. Grant # / UWM Proposal # (if applicable):

No answer provided.

E. Study Locations

E1. Describe the location(s) where study activities will take place.

Online survey via Amazon's Mechanical Turk

E2. Will any of your research occur outside the US?

No

If yes, complete the International Research Supplemental Form and attach in section Y7. For guidance on international research, see our website.

SECTION NOTES:

- ***IMPORTANT:*** *Projects involving non-UWM investigators, facilities, patients, students, and/or employees (for example, MCW, Aurora, Marquette University, etc.) may require that institution's IRB review. To prevent delays in review, contact the collaborating performance site* ***BEFORE*** *submitting to UWM 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 in Section Y7.*

- *Projects taking place at Milwaukee Public Schools require additional review/approval. Visit MPS site.*
- *For international research, check local requirements for ethics/regulatory review and approval.*

E3. 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.

N/A

F. Study Involvement

F1. This study involves the following activities/articles (select all that apply):

A. Data/Record/Chart Analysis
C. Questionnaires/Surveys

• *Internet Research is subject to additional guidelines. See IRB website.*

• *Ionizing radioactive materials or radiation-producing devices located here on campus require the review and approval from the Radiation Safety Program. See Radiation Safety website.*

F1a. Specify Other

No answer provided.

F1b. Please describe any devices that are being used as part of this research study (Select all that apply.)

N/A

Upload information about the device (user manual / instructions for use, information about the risks of the device, any other relevant documentation) in Section Y.

F1c.Please provide a brief description of each device and how it is used in the study (if applicable).

No answer provided.

G. Informed Consent

SECTION NOTES:

Obtaining and documenting subject's signed 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. Consent templates are 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). Example:*

- *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 **minimal risk (Expedited & 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 **more than minimal risk (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;*
- *a researcher unexpectedly encounters a potential participant who does not speak English, and a translated consent document cannot be made available*

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.

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.	*Click here to access:* *IRB consent templates* *Waiver to obtain/document/alter informed consent Request Form*

H: HIPAA and Conflicts of Interest

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. Community Audiology Services (College of Health Science)
2. Institute for Urban Health Partnerships (College of Nursing)

B. Administrative Units:
a. Privacy Officers for Covered Departments (See current List of UWM's Privacy Officers.)
b. UITS Selected Support Staff (Division of Finance & Administrative Affairs)
c. Other (Non-UITS) IT personnel serving Covered Departments
d. Internal Audit (Division of Finance & Administrative Affairs)
e. Office of Legal Affairs (Division of Finance & Administrative Affairs)
f. Risk Management (Division of Finance & Administrative Affairs)

Who do I contact to for more information on this?
Contact the UWM Office of Legal Affairs (http://uwm.edu/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)?

No

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)?

No

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 http://uwm.edu/hipaa/.
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.

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. Describe any potential conflict of interest requiring disclosure for any key personnel involved in the proposed research activity.
(If none, please state N/A.)

N/A

I: Clinical Trial Questions

General Information about Clinical Trials

What defines a Clinical Trial?
Federally Funded Studies (all of the following)
1. The study must involve human participants.
2. The participants are prospectively assigned to an intervention.
3. The study is designed to evaluate the effect of the intervention on the participants.
4. The effect being evaluated is a health-related biomedical or behavioral outcome.
FDA studies
Clinical trials, also known as clinical studies, test potential treatments in human volunteers to see whether they should be approved for wider use in the general population. A treatment could be a drug, medical device, or biologic, such as a vaccine, blood product, or gene therapy.

What are Clinical Trial Requirements?
1. All investigators and staff involved in the conduct, oversight, or management of clinical trials mustbe trained in Good Clinical Practice (GCP). The training is available through the CITI program.
2. NIH funded, FDA Regulated product, and/or ICMJE publications require registration and posting of study results at clinicaltrials.gov
3. Federally Funded studies require posting of the informed consent form at clinicaltrials.gov
The PI is responsible for clinical trial registration at clinicaltrials.gov

More information about clinical trials, training and registration can be found at the following sites:
http://uwm.edu/irb/guidance-documents/clinical-trials/
https://clinicaltrials.gov/ct2/manage-recs/background
https://grants.nih.gov/policy/clinical-trials/reporting/index.htm
https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

I1. Does your study meet the definition of a clinical trial? Please select all that apply:

a. The study involves human participants.
b. Participants are prospectively assigned to an intervention.
c. The study is designed to evaluate the effect of the intervention on the participants.

If the study is a clinical trial, all study personnel will need to complete GCP training (available online through CITI) prior to IRB approval.

I2. Does your study meet any of the following criteria for registration at clinicaltrials.gov?

d. None of the above

Y: Attachments

Y1. Attach IRBManager Protocol Form.

IRBManager Protocol Form.pdf	Protocol Form	*Download and save the IRBManager Protocol Form. Complete and attach in Section Y1.*

Y2. Recruitment Materials - Including flyers, advertisements, recruitment scripts, emails, etc.

No answer provided.

Y3. Complete and attach Consent/Assent form(s) and/or Waiver to Obtain/Document/Alter Informed Consent.

Consent Form.pdf	Consent Form #1	*Download and save Consent/Assent Forms. Complete and attach in Y3.*
Waiver to Obtain Document.pdf	Consent Form #1	

Y4. Data Collection Instruments - Survey/Interview questions, chart review data collection forms, etc.

design.pdf	Survey #1

Y5. Grant Application if Federally funded

No answer provided.

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).

No answer provided.

Y7. Other Documents that may be important for IRB review.

No answer provided.

Z. Assurances

Z.1 As Principal Investigator or Student Principal Investigator, I certify the following:

a. I have reviewed this protocol submission and acknowledge my responsibilities as Principal Investigator or Student PI. 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 Human Subjects Research Training within the last 3 years or will complete it prior to IRB approval. 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 polices relative to the protection of the rights and welfare of the subjects enrolled in this study. j. I understand that this study may be subject to continuing review and approval by the IRB. k. If this study is approved under Exempt review, I will provide status updates to the IRB upon request to keep the study in an active/approved state.	*All must be checked.*

IMPORTANT Information about submitting this form:

● If you are the author of this form and would like to share it with co-investigators for editing/reviewing BEFORE submitting, please use the "Collaborators" option at the top of this page. The "collaborators" will receive an email with a link to this form and will then have the ability to review and/or edit the submission.

● To submit the form, select the "Sign" box below. You will then be requested to enter your user name and/or password to indicate that you have read and understood the above assurances. After you enter your password, you will need to select the "Submit" box on the next page to complete your part of the submission process. When you receive a message that the form has been submitted, you have properly submitted the form.

● If you receive an error message when signing this form, please try changing your web browser. If you still receive an error message, contact the IRB Office (irbinfo@uwm.edu or 414-229-3182 / 414-229-7455 / 414-229-3173) and provide us with the date/time of the error, the browser you are using, your name, and the study title.

● If you are not the PI of this study, after you submit the form the PI will receive an email notification requiring him/her to review the submission. The PI has the ability to either approve and submit the form to the IRB or reject the form back to you for revisions. The PI will receive weekly reminders about this form, until the PI submits or rejects the form. The IRB recommends you also communicate the PI's role in the submission process to ensure the process is completed.

Signed Wednesday, August 28, 2019 8:29:35 AM ET by Kraft, Patrick