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University of
Wisconsin-Madison
HS IRB Application

Study # : IRB00001371

Principal Investigator:
Uwurb Pi1View: SF: Shared: PBA Basic Study
Information

BASIC STUDY INFORMATION

- * 1. Provide a short, lay-terms study title.

Clinical Trial: Drug

- * 2. Provide the full, formal study title. NOTE: This is the title that will appear in correspondence.

Clinical Trial: Drug

3. Is this study being transferred from another institution?

Answer Yes to this question only if:

- a) the principal investigator (PI) for this application is coming to UW-Madison, UW Health, or the Madison VA from another institution and
- b) they plan to open a study here that is already IRB-approved at their previous institution.

- * Yes No

- * 4. Identify the Principal Investigator.

Uwurb Pi1

View: SF: Shared: PI Information

PI INFORMATION

Principal Investigator: Uwurb Pi1

- * 1. Is the PI's primary appointment through the University of Wisconsin – Madison?

Yes No

- 1.1 Identify the appointment under which the PI will conduct this research.



The appointment is not listed above.

*
N/A

- * 2. Is this an investigator-initiated study?

- o For the purposes of this question, an investigator-initiated study is defined as one developed or authored by an individual (not a sponsor or group).

Yes No

View: SF: Shared: New Study Team

STUDY TEAM

1. Identify the points of contact for this study (limit of four).

*

Name	Email
Uwirb Pi1	andrew.drinkwater@wisc.edu
Uwirb Poc1	andrew.drinkwater@wisc.edu

2. List all the other members of the study team (not including the PI or points of contact).

Name	Email
Uwirb Poc2	andrew.drinkwater@wisc.edu
Uwirb Study Team Member 1	andrew.drinkwater@wisc.edu

View: SF: HSMR: Study Team New UI Roles

STUDY TEAM: ROLES

* 1. Identify the primary point of contact for this study.

Note: If the PI is serving as the primary point of contact, indicate that here.

Uwirb Poc1

* 2. Does this study involve recruiting, consenting, or interacting with human subjects?

Yes No

2.1 Tell us which study team members will: identify or recruit human subjects; obtain informed consent from human subjects; interact with human subjects; or perform cognitive assessments on human subjects.

Study Team Member	Identify or Recruit Subjects	Obtain Informed Consent	Interact with Subjects
Uwirb Pi1	yes	yes	yes
Uwirb Poc1	yes	yes	yes
Uwirb Poc2		yes	yes
Uwirb Study Team Member 1	yes		

View: SF: Shared: Updated Funding

FUNDING INFORMATION

* 1. Do you have pending or approved funding administered through Research and Sponsored Programs (RSP) or Business Services to support this project?

- Answer no to this question if this study will only be supported by VA funding; you will have the opportunity to add VA funding later in the application.

Yes No

* 2. Do you have pending or approved funding NOT listed on this page?

Yes No

View: SF: Shared: New COI

CONFLICT OF INTEREST (COI)

1. Please review the study team member Outside Activities Report (OAR) and

managed entities data below:

The following study team members have not completed their OAR for the year:

Uwirb Pi1, Uwirb Poc1, Uwirb Poc2, Uwirb Study Team Member 1

NOTE: Per campus policy all study team members must submit an OAR every year and keep it up to date.

No study team members have any managed entities at this time.

* 2. Do any study team members involved in the design or conduct of the research (including their spouses and dependent children) own intellectual property that will be used in the study or project?

Yes **No**

* 3. Besides the sponsor(s) of this project or entities listed above, do any study team members have a fiduciary or financial relationship with entities that will be involved in this study or that may be significantly affected by it?

Yes **No**

* 4. Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

Yes **No**

View: SF: HSMR: VA Status

DETERMINATION OF VA STATUS

NOTE: All studies that fall under Madison VA purview must be reviewed by the VA Research and Development (R&D) Committee in addition to being reviewed by the Health Sciences or Minimal Risk IRB. For information about the VA R&D Committee review process, please call 608-280-7007.

* 1. Indicate if any of the following apply to this study or project:

None of the above

NOTE: If the study or project rents or uses Madison VA (Wm. S. Middleton VA Hospital) facilities, contact the Madison VA Research Office to ensure the appropriate permissions are in place.

View: SF: HSMR: PRMC CRU

SCIENTIFIC REVIEW: UW CARBONE CANCER CENTER (UWCCC) PROTOCOL REVIEW MONITORING COMMITTEE (PRMC) AND CLINICAL RESEARCH UNIT (CRU)

* 1. Is the scientific question of the protocol cancer related?

Yes **No**

* 2. Are you specifically targeting cancer patients for enrollment in this study?

Yes **No**

* 3. Does this study involve the review and/or use of biological specimens/data /images/records from cancer patients?

Yes **No**

* 4. Will this study use the Clinical Research Unit (CRU)?

NOTE: If the answer to this question is Yes, you must upload a copy of the CRU application to the Submit activity form. You will see the Submit activity form when you click on the Submit link to

submit the completed IRB application.

Yes No

View: SF: HSMR: Scientific Review Updated

SCIENTIFIC REVIEW: OTHER

You are seeing this page because your application may require review by the ICTR Scientific Review Committee (SRC).

To determine whether SRC review is required for your application, please indicate whether any of the following apply to your study. If none apply, please select None:

*

Funding proposal or application has already undergone peer review

If none of the above apply, your application requires ICTR SRC review and will be automatically routed to the ICTR SRC when you submit it.

View: SF: HSMR: Clinicaltrials.gov

CLINICALTRIALS.GOV REGISTRATION

Registration at Clinicaltrials.gov may be required for Federal Drug Administration (FDA), International Committee of Medical Journal Editors (ICMJE) publication purposes, or as a condition of receiving federal funding as described below. Click on the help link above for additional information on these requirements.

* 1. Does this study need to be registered at Clinicaltrials.gov to meet the FDA's registration requirements? Note: The FDA requires study registration along with results and adverse event reporting for:

- a) all phase II - IV interventional drug or biologic trials, and
- b) trials of devices that are either
 - i. controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, or
 - ii. pediatric postmarket surveillance required by FDA

Yes No

* 1.1 Does this study need to be registered at Clinicaltrials.gov to meet the ICMJE or NIH requirements? Note: The ICMJE and NIH require the registration of all health-related interventional studies investigating relationships between the health-related intervention and any health outcomes (interventions include: drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, and process-of-care changes).

Yes No

View: SF: Shared New: Study Location General

EXTERNAL COLLABORATIONS

* 1. Will any UW/UW Health or Madison VA personnel conduct any of the following study activities at locations outside the UW/UW Health or Madison VA?

- Subject recruitment
- Obtaining informed consent
- Interacting or intervening with subjects

Yes No

* 2. Are you requesting that UW-Madison serve as the reviewing IRB for any external sites or individuals?

Yes No

3. Do you confirm the study team has reviewed and will meet the responsibilities described in Study Team Responsibilities When UW-Madison is Serving as the Reviewing IRB?

* Yes No

View: SF: Shared: Sharing Data Outside UW

SHARING OF DATA, IMAGES, OR SPECIMENS OUTSIDE UW-MADISON

* 1. Will subject data, images, or specimens be shared outside the UW-Madison?

Yes No

View: SF: Shared: PBA Study Summary

STUDY PROTOCOL AND PROCEDURES

* 1. Upload the stand-alone scientific protocol document associated with this application.

File
Protocol

* 2. Select the activities and procedures that apply to your study.

*Please note that these options may ask you for additional information in this application.

*If none of these options applies to your study, select "Not applicable".

*The study protocol must describe all study activities, including those not specifically listed below.

<input type="checkbox"/> Devices
<input checked="" type="checkbox"/> Drugs, biological agents, or nutritional supplements
<input type="checkbox"/> Fetal tissue, embryonic or induced pluripotent stem cell research
<input type="checkbox"/> Interviews, focus groups, surveys, questionnaires, assessments (e.g., QOL, SCID, BDI, etc.)
<input type="checkbox"/> International Research
<input type="checkbox"/> Not Applicable

* 3. Provide the number of subjects that will be recruited at sites for which UW-Madison is serving as the reviewing IRB. NOTE: You must provide an integer. If you are enrolling a range of subjects (e.g., 50 to 100 subjects), enter the larger number.

100

View: SF: Shared: PBA Consent and Authorization Upload

CONSENT AND AUTHORIZATION FORMS

* 1. Will you be using any consent or assent documents for this study?

Yes No

* 1.1 Upload all the consent and assent documents to be used for this study.

File
Consent

* 2. Will be using a separate HIPAA authorization form(s) for this study?

Yes No

View: SF: Shared: PBA Recruitment and Screening Upload

RECRUITMENT AND SCREENING DOCUMENTS

- * 1. Will any recruitment materials be used for this study?

*This includes flyers, emails, web/social media postings, radio or television ads, mailed letters or any other materials used for recruitment.

Yes No

- * 1.1 Upload all recruitment materials that will be used for this study.

File
Ad

- * 2. Will any materials be used to screen study participants?

*This includes phone screening scripts, questionnaires, or any other screening materials.

Yes No

- * 2.1 Upload all materials that will be used to screen potential participants.

File
Phone screen

View: SF: Shared: PBA Drug and Device Document Upload

DRUG AND DEVICE DOCUMENTS

- * 1. If drugs or biological products will be used in this study, upload the following documents as described below:

*For investigational (i.e., unapproved) drugs or biological products, upload the Investigator's Brochure(s) below.

*If an IB is unavailable, upload a summary document detailing the agent's pharmacological and toxicological effects, safety and effectiveness in humans, and potential risks and side effects, if any.

*For approved drugs or biological products, upload package inserts below.

File
IDB

- * 2. If devices will be used in this study, upload the following documents as described below if required:

*For studies assessing the safety or efficacy of an unapproved device(s), for each device upload a document containing the name of the device and intended use, a description of the device, and a brief summary of prior uses of the device (clinical and non-clinical) relevant to the assessment of device safety and efficacy.

*For studies assessing the safety or efficacy of an approved device(s), for each device upload a copy of the device instruction manual or package insert.

*For device(s) being used as tools to achieve study aims and that are not being assess for safety or efficacy, no uploads are needed. Describe the use of this device(s) in the protocol.

File
There are no items to display

- * 3. If applicable or requested by the IRB, upload any FDA correspondence.

File
There are no items to display

- * 4. If an IND and/or IDE will be required for this study, will the IND and/or IDE be held by the UW investigator?

Yes No

View: SF: Shared: PBA HIPAA General

HIPAA: GENERAL

* 1. Will the research involve identifiable information for any reason?

Yes No

2. Are you or any member of the study team conducting the study under an appointment that is within the UW-Madison Health Care Component (HCC) or the Madison VA?

* Yes No

View: SF: Shared: PBA HIPAA Authorization and Waivers

HIPAA: AUTHORIZATION AND WAIVERS

* 1. Will HIPAA authorization for access to the PHI be obtained for all or some subjects?

Yes, always: HIPAA authorization will be obtained from all subjects. Note: To be valid, HIPAA authorization for research must be obtained in writing and must be project-specific. Standard clinical consent and authorization does not cover research use.

* 2. Select which of the following identifiers will be associated with the health information you propose to collect for study purposes. Check all that apply to your study. If none of these identifiers will be collected for your study, select 'None of the Above'.

None of the Above

View: SF: Shared: Supplemental Documents

SUPPLEMENTAL INFORMATION

1. Provide any additional relevant documents (e.g., supplemental statistical justification information), if applicable.

File

There are no items to display

2. Describe what additional documents were added in 1.

View: SF: Shared: Final Page

FINAL PAGE

1. Do you certify that:

- The information presented in this application is accurate;
- If the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement; and
- The specific aims and description of research (including subject population, subject interventions, collaborators, performance sites, and general scope of work) in this IRB application are consistent with those described in the sources of support listed as providing financial and/or material resources to conduct this study.

* Yes No

To complete and submit this application to the IRB office, please follow the steps below:

Select Ready to Submit or Exit on this page to be directed to the application workspace.

In the application workspace, click the Submit activity to send the application to the IRB office.

NOTE: The Submit activity is only available to certain study team members.