

**Initial Study Review Form**

**Instructions:** *Submit this completed form for all research involving human subjects to the WMed IRB office. This application must be accompanied by a protocol detailing the background and rationale for the study, objectives, sample size description and justification, inclusion and exclusion criteria, research procedures, risks, data & safety monitoring plan, analytic plan, regulatory considerations, provisions for the protection of human subjects, etc.*

|  |
| --- |
| **Protocol Title:** |

1. **PRINCIPAL INVESTIGATOR & RESEARCH TEAM**
2. **Principal Investigator** *(At WMed, only individuals with a faculty appointment at the rank of assistant, associate or full professor may serve as the PI. Students, residents, fellows, and other trainees may not serve as PIs.)*

|  |  |
| --- | --- |
| **PI Name:** | **Date:** Click here to enter a date. |
| Credentials (e.g., licenses, certifications): | |

|  |  |
| --- | --- |
| Department/Division/Unit: | |
| Address: | |
| Email: | Phone Number: |
| Please provide CITI and Human Subjects Training Certificates: | |

1. **Additional Personnel** (insert additional rows if needed)  NA

**NOTE:** *Other study personnel include all individuals responsible for the design, conduct, or reporting of the study, including Sub-Investigators. All personnel must have current human subjects training certification.*

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Study Role | Department/Division/Unit  (if applicable) | Human Subjects Training Certificate Date |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **How many studies is the PI currently responsible for?**
2. **Does the PI have protected or dedicated time available to conduct this research?**

Yes No

If no, explain how the PI will have adequate availability to conduct and/or supervise the research:

1. **Are any members of the research team under the jurisdiction of another IRB?**

Yes  No

If yes, please explain:

1. **Has any member of the research team ever received a FDA 483, “Warning Letter”, Notice of Disqualification, or other warning or disciplinary action from an agency or licensing authority?**

Yes No

If yes, include a copy of the notice or report and related correspondence with your submission.

1. **Has this study been disapproved or terminated by another IRB?**

Yes No

If yes, provide the basis for the disapproval or termination:

1. **Please provide information concerning the funding sources for this research.**

NA (unfunded)  Industry Sponsor

Federal Government\*  Other Gov. (State, Local)

Foundation  Departmental/Unit Funds

Other:

Grantor/Sponsor Name:

Award/Contract Status:

Grant Title (if different from IRB submission title):

\*If WMed is the prime awardee of a federal grant that supports this research, a copy of the grant must be included with your submission

1. **ADDITIONAL REVIEWS/APPROVALS**
2. **Is COI review required**?

Yes  No

Supplement Form N COI Disclosure Form must be submitted at initial review whenever the PI or a member of the study team (or person with whom the PI or member of the study team has a personal relationship) has a known or potential conflict of interest.

A Personal Relationship includes the spouse, domestic partner, dependent children, individuals living in the same household, and other individuals with a consensual romantic, intimate, or sexual relationship.

1. **Is Institutional Biosafety Committee (IBC) committee review required?**

Yes  No

IBC has responsibility for Radiation Safety, Radioactive Drug Research, and Institutional Biosafety. If yes, include documentation of the review and any requirements or recommendations with your submission.

1. **Is Dual Use Research of Concern (DURC) review required?**

Yes  No

If yes, include documentation of the review and any requirements or recommendations with your submission.

1. **Is Medicare Billing Analysis required?**

Yes  No

If yes, include documentation of the review with your submission.

1. **APPLICABLE REGULATIONS**

Select the regulations or oversight agencies that you believe are applicable to this study. Regulatory oversight may be triggered by funding support, participation of agency employees in research activities as investigators or subjects, by the study of regulated products, by the subject population, by the use of protected information, etc. This list is not all-inclusive (e.g., OSHA and IATA aren’t included), but is intended to capture regulations or requirements relevant to the protection of human subjects that the IRB may have to consider. Select all that apply.

HHS ([Department of Health and Human Services](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html))

FDA ([Food and Drug Administration](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm))

HIPAA ([Health Insurance Portability and Accountability Act](http://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html))

CDC ([Centers for Disease Control](http://www.cdc.gov/od/science/integrity/hrpo/))

DOD ([Department of Defense](http://www.dtic.mil/biosys/hardte.html)); Branch:

DOE ([Department of Energy](http://humansubjects.energy.gov/regulations/))

DOJ ([Department of Justice](https://www.gpo.gov/fdsys/pkg/CFR-2003-title28-vol2/xml/CFR-2003-title28-vol2-part46.xml))

ED ([Department of Education](http://www2.ed.gov/about/offices/list/ocfo/humansub.html))

EPA ([Environmental Protection Agency](https://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml))

FERPA ([Family Educational Rights and Privacy Act](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html))

ICH-GCP E6 ([International Conference on Harmonization – Good Clinical Practice E6](http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf))

NSF ([National Science Foundation](http://www.nsf.gov/bfa/dias/policy/human.jsp))

PPRA ([Protection of Pupil Rights Amendment](http://familypolicy.ed.gov/ppra?src=ferpa))

VA ([Department of Veterans Affairs](http://www1.va.gov/ORO/index.asp))

Other:

1. **RESEARCH DESCRIPTION**
2. **Summary.** Briefly describe the proposed research **in language that can be understood by a non-scientist**. The abstract should summarize the objectives of the research and the procedures to be used, with an emphasis on what will happen to the subjects. **(Maximum 250 words)**

1. **Multicenter Studies.** Will the protocol be followed as written or are there components or aspects of the research that this site will not participate in or that will be modified? (e.g., local site will not recruit into one of the cohorts or into a sub-study; the age range will be narrowed, a specific procedure or test isn’t available locally so another will be performed; etc.)

NA, this is not a multicenter study

Yes, the protocol will be followed as written

No, the protocol will be modified as follows locally:

1. **RESEARCH SETTING/PERFORMANCE SITES**
2. **Describe the settings where research activities involving human subjects will take place (e.g., home, lab, hospital, clinic).**

1. **Indicate all sites where the research procedures will be carried out:**

Hospitals:

Clinics:

Research Institutes:

University:

Other, Specify:

1. **List all sites where research activities under the oversight of the local PI will be carried out.** For each site, indicate: (1) whether the site or personnel are under the jurisdiction of another IRB, (2) whether the site has granted permission for the research to be conducted, and (3) the contact information for the site point of contact.

1. **Is this a collaborative research study being conducted at multiple sites?**

Yes  No

If Yes:

Is this investigator the LEAD INVESTIGATOR?  Yes  No

Is this site the LEAD SITE or Coordinating Center?  Yes  No

If either of the above is Yes, *complete Supplement L.*

1. **Is this research being conducted outside of the United States?**

Yes  No

If Yes,*complete Supplement M.*

1. **SUBJECT POPULATION**
2. **The research population includes the following (check all that apply):**

Normal Adults/Healthy Volunteers

In-Patient Population

Out-Patient Population

Employees/Staff

Students *(describe whose students i.e. WMU, WMed etc.)*

Residents/Fellows

Children – *complete Supplement A*

Children who are wards of the state – *complete Supplement A*

Prisoners – *complete Supplement B*

Pregnant Women, Fetuses, or Neonates – *complete Supplement C*

Persons with Impaired Decision-Making Capacity – *complete Supplement D*

Persons with Limited-English fluency, specify anticipated primary language(s):

1. **Please indicate the total number of subjects anticipated to be enrolled at this site/by this investigator.** For the purposes of the IRB, a subject is enrolled once they have provided consent to participate, or for studies under waivers, once data has been collected on the subject. 
   1. If the study includes screening procedures after consent, how many subjects do you expect will meet inclusion/exclusion criteria and participate?
   2. If the research involves multiple subject groups or cohorts, provide the anticipated number of subjects in each of group or cohort (e.g., control/experimental, adults/children, etc.).

1. **Provide the age range for the proposed subject population (e.g., 0-5 years old):**
2. **Specify the inclusion criteria for each of the subject groups to be included in the research or indicate the page(s) of the protocol where this information can be located.**

1. **Specify the exclusion criteria for each of the subject groups to be included in the research or indicate the page(s) of the protocol where** **this information can be located?**

1. **If potential subjects will be excluded based on age, gender, race, ethnicity, primary language, pregnancy or childbearing potential, explain (a) the nature of the exclusion(s), and (b) the scientific basis or other justification for the exclusion(s) or indicate the page(s) of the protocol where this information can be located.**

NA

Nature of the exclusion(s):

Scientific basis or other justification:

1. **Secondary Subjects. Is information being obtained about individuals other than the “target subjects?”**

Yes  No

If yes, please explain:

1. **IDENTIFICATION/RECRUITMENT OF SUBJECTS**
2. **Describe how subjects will be identified for recruitment into or inclusion in this study.**

1. **Who will be responsible for determining whether or not potential subjects satisfy eligibility criteria and how will they do so? If the analysis of health information is necessary to determine eligibility, a medically-qualified person must be involved in the determination.**

1. **Will information from medical records, databases, or other data sources be used to identify and/or screen potential subjects prior to obtaining consent and authorization.**

No, records will not be accessed prior to consent and authorization

No, records will not be utilized to identify potential subjects

Yes, records will be accessed prior to consent and authorization, complete *Supplement E*

If Yes, indicate whether screening information will be retained on persons who do not ultimately participate in the study, and if so, what specific information will be retained and what identifiers, if any, it will include:

1. **Will potential subjects be screened by asking questions of them prior to obtaining consent for study participation (e.g., phone interview, on-line questionnaire, etc.)?**

Yes  No

If yes, answer the following and include a copy of the screening questions with your submission:

* 1. Describe the method of screening (e.g., phone interview, on-line questionnaire):

* 1. Indicate whether screening information will be retained on persons who do not ultimately participate in the study, and if so, what specific information will be retained and what identifiers, if any, it will include:

1. **If applicable, describe how, where, and by whom subjects will be recruited for participation in this study**.

1. **If applicable, describe any steps that will be taken to protect the potential subjects’ privacy during recruitment.**

Include copies of any proposed recruitment materials (e.g., brochures, posters, advertisements, social media, etc.) or scripts with your submission. All recruitment material must be approved by the IRB prior to use.

1. **INFORMED CONSENT**

Unless waived by the IRB, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR) or, for minors, parental permission.

Similarly, unless waived by the IRB, consent must be documented by the use of an IRB-approved written consent form signed by the subject or the subject's LAR. A copy of the consent form must be given to the person signing the form.

Assent may be required when subjects are unable to personally provide consent for reasons of age, mental state, legal status or other such reason.

1. **Which of the following apply to this research? *(check all that apply):***

Informed consent will not be obtained. *Complete Supplement E* to request a waiver of consent.

Informed consent will be obtained and documented with a signed, written consent form.

Informed consent will be obtained, but won’t be documented by signature on a consent form. *Complete Supplement E* to request a waiver of documentation of consent. Include a copy of the oral script and/or information sheet with your submission.

Informed consent will be obtained, but the consent form (or script or information sheet) does not include all required elements of consent. (Please see the Informed Consent Checklist for the elements of consent.) *Complete Supplement E* to request an alteration of consent.

Consent will be obtained, but some information will be purposely manipulated or withheld (deception). *Complete Supplement E* to request an alteration of consent.

Surrogate consent will be obtained from Legally Authorized Representatives (LARs) for some or all adult subjects. *Complete Supplement D* for subjects with impaired decision-making capacity.

If the research includes more than one subject group, and the answers to the above differ based on the cohort, explain your plan for each group here:

1. **Consent Process**
   1. Describe the circumstances under which consent will be obtained including where/how the process will take place (e.g., in the research office, in a private conference room, in the doctor’s office, in a group setting, over the phone, etc.).

* 1. Describe any steps that will be taken to ensure the potential participants’ privacy during the consent process.

* 1. Who will obtain consent? Describe their qualifications and experience in obtaining research consent. If any of the persons obtaining consent are inexperienced, a plan to train and supervise them must be included. A person qualified to fully explain and respond to questions regarding the research interventions or procedures, risks, and alternatives must participate in the consent process.

* 1. How will you ensure that subjects or LARs have sufficient opportunity to consider whether or not to participate? (Check all that apply)

Subjects will be provided the consent form to take home for consideration prior to signing.

Subjects will be allowed a waiting period of at least  to consider their decision.

Other (describe):

* 1. How will the subjects’ or LARs understanding of the information presented be assessed? (Check all that apply)

Subjects will be asked to “[Teach-Back](http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool5.html)”

Subjects will be asked open-ended questions about the research (purpose, procedures, risks, alternatives, voluntary nature)

A tool or post-test, such as ICEFT, DICCT, QuIC, or AHRQ Certification will be used. Specify:

Other, describe:

* 1. If recruitment of persons who aren’t fluent in English is anticipated, describe how you will ensure that they receive information in a language they are fluent in and are able to ask questions and have them answered (e.g., use of certified interpreters, translated materials):

1. **Documentation of Consent:** *Signed, written consent forms are required unless waived by the IRB. Include copies of all proposed consent forms and materials to facilitate the consent process (handouts, videotapes, electronic tools, etc.) with your submission.*
   1. How will the subjects’ informed consent be documented? (check all that apply)

Traditional signed written consent form

Written note in medical and/or research record

By completion of a research survey or questionnaire

Consent will be administered via an electronic or web-based form

The consent process will be audio or video recorded

Use of the short form consent process (The short form consent process should not be used when inclusion of subjects who aren’t fluent in English can be anticipated.)

Other, describe:

* 1. Is recruitment/inclusion of subjects who aren’t fluent in English anticipated?

Yes  No

* + 1. If yes, what languages do you expect the subjects will be fluent in?

* + 1. Will consent forms and other subject materials be translated? *(Note: Cost alone is insufficient justification for not translating materials)*

Yes

Some but not all, explain:

No, explain:

*Once the English-version of the consent form is approved, translated consent forms must be submitted to the IRB consistent with SOP 11.7.1.*

* 1. If the enrollment of subjects who cannot read the consent form, due to visual impairment, literacy, or other issues, is anticipated, how will consent be documented? Refer to [45 CFR 46.117(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117) or [21 CFR 50.27(b)(2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27) for information regarding the use of a short form.

NA

Short form

Other mechanism, describe:

1. **ONGOING CONSENT**

For studies with more than one interaction with subjects, informed consent should be an ongoing process that continues throughout their participation in the study. Efforts to ensure that subjects remain informed are important, particularly if changes are made to the study or new information becomes available that impacts risks, anticipated benefits, or alternatives to participation.

1. How will you ensure research participants remain informed about the study and continue to agree to participate in the research study after their initial informed consent has been obtained?

NA

1. **PROVISION OF RESULTS**
2. **Given the exams, tests, and procedures being done for the research, describe the likelihood and nature of** [**incidental or secondary findings**](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf)**, whether such findings will require verification (e.g., by a CLIA lab), and any plans for sharing such findings with subjects:**

1. **If the research includes genetic testing, indicate whether subjects will be informed of results and, if so, describe how and by whom.**

*Michigan law (MCL 333.17020 & 333.17520) indicate that if performed as component of biomedical research subject to FDA & OHPR oversight, Michigan rules do not apply. If performed as a pre-symptomatic or predicate genetic test only, specific informed consent is obtained from patient or LAR. The state of Michigan has a model consent document that it recommends for use in those cases.*

1. **If the research includes testing for communicable diseases, indicate whether the findings will require verification (e.g., by a CLIA lab), any plans for sharing findings with subjects, and whether findings must be reported to a state or federal agency:**

1. **If the research includes blinding, indicate whether subjects will be “unblinded” to study assignment and describe when and how this will be done:**

1. **Indicate whether subjects will be informed of the results of the study and, if currently known, when and how this will be done:**

1. **INTERVENTIONS/PROCEDURES**
2. **If the research includes an interventional component, such as a drug, device, therapy, or an intervention to change behavior or lifestyle; describe each intervention and its intended purpose or indicate the page(s) of the protocol where this information can be located:**

NA – No interventions

1. **Identify all exams, tests, or procedures that subjects will undergo for the research or indicate the page(s) of the protocol where this information can be located:**

NA

1. **Identify any protocol-required procedures that subjects would undergo regardless of their participation in the research and indicate whether the timing or other aspects of the procedures have been controlled or altered to facilitate the research:**

NA

1. **RISKS/RISK MITIGATION**
2. **List the possible risks, discomforts, or harms to subjects associated with the research.** If the risks differ based on group assignment, describe for each group. Estimate the (1) probability of occurrence, (2) the seriousness, and (3) the duration of each risk. If this information is captured in the protocol or investigators brochure (IB) or other materials, indicate the document and page numbers where the information can be located.

1. **What precautions have been taken to minimize these risks and what is their likely effectiveness?** Whenever possible, link the precaution(s) to the specific risk or risks. If this information is available in the study protocol indicate the page numbers where the information can be located.

1. **If this is investigator generated research, identify any alternative research methods or procedures considered in designing the research that might involve less risk and describe why they will not be used (e.g., a clinical trial as opposed to a records review, IV as opposed to oral formulation, etc.) or indicate the page(s) of the protocol where this information can be located:**

NA

1. **If applicable, describe access to/availability of emergency medical equipment and trained personnel at each setting where research interventions or procedures involving physical risk take place:**

NA – There are no physical risks to subjects anticipated in this study

1. **If the research imparts social, financial, psychological or other risks to subjects, describe the availability of and access to/availability services or support to mitigate these risks:**

NA

1. **Does the research include screening tools, questionnaires, or procedures that may indicate the presence of serious depression and/or suicidal ideation?**

Yes  No

If yes, describe the plan to refer or intervene in the event that potential serious depression and/or suicidal ideation are identified.

1. **If the research is greater than** [**minimal risk**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)**, describe the data safety monitoring plan or indicate the page(s) of the protocol where this information can be located:**

NA

1. **Are there any plans to do an interim analysis?**

Yes  No

If yes, describe the interim analysis plan or provide page number(s) in protocol where this information can be found:

1. **Have stopping rules been established for the study?**

Yes  No

If yes, describe the stopping rules or provide the page number(s) in protocol where this information can be found:

1. **Are there defined criteria for when study interventions should be discontinued?**

Yes  No

If yes, describe the criteria or provide the page number(s) in protocol where this information can be found:

1. **Are there exams or procedures that the subject will be asked to have done or follow to safely withdraw from the study?**

Yes  No

If yes, describe the procedures for safe withdrawal of subjects or provide the page number(s) in protocol where this information can be found (Note: Withdrawal procedures should also be described in the consent):

1. **Will subjects who withdraw from the interventional component of the study be asked for their permission to continue to gather information about them through follow up visits, phone calls, records review, or other methods?**

Yes

No

NA

If yes, describe what the subjects will be asked to permit or provide the page number(s) in protocol where this information can be found (Note: Such plans should also be described in the consent.):

1. **BENEFITS**
2. Describe the potential benefits to science and/or society which may accrue as a result of this research.

1. Are there any benefits which may accrue to the individual subjects in this research? Compensation is not considered a benefit.

Yes No

If yes, please explain:

1. **COSTS**

NA –No costs to subjects

1. **Describe the costs/potential costs that subjects may incur as a result of their participation (include travel, parking, medication, device, procedures, etc.).**

1. **Will the subject, or the subject’s insurance, be responsible for any costs incurred as a result of participation in the research?**

Yes  No

*If yes, describe each item that the subject, or the subject’s insurance, will be responsible for and the approximate cost of each:*

1. **Will subjects be reimbursed for any expenses related to their research participation?**

Yes  No

*If yes, indicate:*

* 1. What subjects will or may be reimbursed for (e.g., travel, parking, public transportation, etc.) and explain any potential limitations or qualifiers:
  2. The type of reimbursement *(i.e., cash, check, cash card, etc.)*:
  3. The source(s) of funds to provide reimbursement:
  4. The timing of reimbursements

1. **COMPENSATION**

NA –No compensation

1. **If subjects will receive compensation for participating in this research study, please describe*:***
   1. The amount and method of payment:
   2. The basis used to determine the amount of the payment:
   3. The distribution plan for the payment (one payment, pro-rated payment, etc.):
   4. The plan for payments in the event a subject withdraws early from the study:
2. **If the research involves children or adults unable to consent to participation, explain who will receive the compensation:**

1. **NON-MONETARY GIFTS/TOKENS OF APPRECIATION**

NA –No compensation

1. **If subjects will receive non-monetary gifts, incentives, or tokens of appreciation for participating in this research study, please describe*:***
   1. The item(s)\* that will be provided:
   2. The approximate retail value of the item(s):
   3. The distribution plan (i.e., when subjects will receive the items):
   4. Any conditions or requirements that must be fulfilled for subjects to receive the item(s):

\*Include a picture of the item(s) with your submission. The IRB may request a sample of the item(s) to review.

1. **If the research involves children or adults unable to consent to participation, explain who will receive the item(s):**

1. **Potential alternative language: Please Note: Do not use lotteries or raffles for compensation. Lotteries and raffles are not allowed at WMed.**

1. **PRIVACY**

If the research involves interaction with or observation of subjects, describe the provisions to protect the privacy interests of subjects. Include a description of (1) the settings where subjects will be interviewed, examined, or observed for the purposes of the research; (2) the settings where interventional components of the research and research procedures will take place, (3) any provisions being taken to maximize privacy:

NA – No interaction or observation

1. **DATA COLLECTION/CONFIDENTIALITY**
2. **Data Methods/Sources/Access**
   1. Describe the methods to obtain information about or from subjects:

Include copies of all questionnaires, surveys, interview questions, diaries, etc. with the submission. If the research involves interviews or focus groups that could evolve as conversation progresses, include a list of discussion topics and any “starter” questions for each topic that can reasonably be expected to be covered. If a draft of an instrument is submitted, it should be clearly labeled as such and a final version must be submitted and approved by the IRB before data collection begins.

* 1. Describe all data sources for the research and the general purpose of each (e.g., medical records will be reviewed to pre-screen for eligibility and obtain pertinent medical history):

* 1. Are all of the data sources internal ( Borgess,  Bronson,  WMed held)?

Yes  No

If no, describe the external data sources, any needed permissions to access the data and the status of these permissions, and how the data will be securely transferred, transported, or shared:

* 1. Will study personnel other than ( Borgess,  Bronson,  WMed) employees and sponsor representatives (such as monitors) require access to ( Borgess,  Bronson,  WMed) facilities, systems, or privately held information for the purposes of the research?

Yes  No

If yes:

* + 1. Identify (1) who (by class or name), (2) their home institution or organization, (3) what facilities, systems, or information they will require access to, and (4) why:

* + 1. Who will be responsible for supervision of non- ( Borgess,  Bronson,  WMed) personnel?

*Please note if study personnel are involved for places other than Borgess, Bronson or WMed additional confidentiality requirements may be necessary.*

* 1. Will Protected Health Information (PHI) be accessed, used, or disclosed for the research?

Yes  No

The Privacy Rule defines PHI as [individually identifiable](https://privacyruleandresearch.nih.gov/pr_08.asp#8a) health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered health information.

Indicate which of the following apply (more than one may be selected):

A partial waiver of the requirement for HIPAA Authorization is requested (e.g., for screening or for some subjects (e.g., retrospective cohort)) – *Complete Supplement F*

A full waiver of the requirement for HIPAA Authorization is requested – *Complete Supplement F*

The PHI accessed or used for this research is a [Limited Data Set](https://privacyruleandresearch.nih.gov/pr_08.asp#8d) (LDS) and a Data Use Agreement (DUA) is or will be in place prior to accessing or obtaining the LDS

HIPAA Authorization will be obtained:

The organization’s stand-alone HIPAA Authorization template will be used (select)

Borgess,  Bronson,  WMed

The HIPAA Authorization is embedded in the research consent document

* 1. Will educational records protected under [FERPA](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html) be accessed or used for the research?

Yes  No

If yes, describe how the research complies with FERPA:

* 1. Does the research involve the administration or use of surveys, interviews, or other evaluations or examinations protected under [PPRA](http://familypolicy.ed.gov/ppra?src=ferpa)? Yes  No

If yes, describe how the research complies with PPRA. (If the department or institution officer signs off on studies prior to submission this should cover FERPA concerns.)

1. **Research Records**
   1. Describe the types of research records that will be created or maintained for the research (linking key, paper worksheets, electronic files, direct electronic data capture, audio recordings, video recordings, etc.):

* 1. Will direct identifiers (e.g., name, medical record number) be replaced with a subject code on research records other than the linking key, consent form, and HIPAA authorization?

Yes  No

If Yes, describe the structure of the code (e.g., randomly generated number, sequential number plus initials, etc.) and indicate whether a linking file (key) will be created and, if so, how it will be protected:

If No, explain which direct identifiers will be included, on what records, and why they are needed:

* 1. Will research records include PHI?

Yes  No

* 1. Will research records include information that subjects or others might consider to be sensitive in nature (e.g., social security numbers, communicable disease status, substance abuse, mental health information, illegal behaviors, etc.)?

Yes  No

If yes, explain what sensitive information is included, why it is needed, and any additional safeguards that will be taken to protect it (beyond those described in “e”)”

* 1. Will a [Certificate of Confidentiality](https://grants.nih.gov/grants/policy/coc/index.htm) (CoC) be obtained for this research or is one already in place that covers this site and any recipient site or organization?

Yes  No

* 1. Describe how each of the research records described in “a” will be safeguarded from breach or unintended/accidental access or disclosure:

1. **Data Sharing**
   1. Will data be transferred, transmitted, or shared transmitted outside of:

Borgess,  Bronson,  WMed

If yes:

* + 1. What information will be transferred, transmitted, or shared?

* + 1. Who will data be sent to or shared with?

* + 1. For what purpose?

* + 1. Will the transferred, transmitted, or shared data include direct identifiers?

Yes  No

If yes, explain:

* + 1. Will the transferred, transmitted, or shared data be coded?

Yes  No

If yes, will the recipient have or be provided with access to the code or other means to re-identify subjects?

Yes, explain:

No

* + 1. Will the transferred, transmitted, or shared data include PHI?

Yes  No

If yes, explain:

* + 1. Will the transferred, transmitted, or shared data include sensitive information?

Yes  No

If yes, explain:

* + 1. How will the data be transferred, transmitted, or shared and how will it be protected?

* 1. Will research data or specimens be submitted to or retained in a database (such as [dbGap](http://www.ncbi.nlm.nih.gov/gap) or [NIDA](https://datashare.nida.nih.gov/)) or repository (such as [NIDDK Central Repository](https://www.niddkrepository.org/home/)) for possible future research after this study is complete?

Yes  No

If yes:

* + 1. Name of database, registry, or repository (or Sponsor name if sponsor-held):

* + 1. Describe what will be submitted or retained:

* + 1. Indicate if the information or specimens are identifiable, coded, or de-identified. If coded, describe access to the key enabling re-identification:

* + 1. Describe plans to obtain subject consent, and authorization, if applicable, for data and/or specimen storage and possible future research:

* + 1. Describe whether, and how, subjects can request withdrawal or destruction of their information or specimens:

1. **Record Retention**

**NOTE: Record retention may be dictated by regulations, grant or contract terms, or policy. Please consider each of these carefully before answering the below questions. At a minimum, signed research consent forms must be retained for 3 years after the completion of the research (for non-FDA studies) and HIPAA authorizations (or waivers) for 6 years after they were last relied upon.**

* 1. How long will research records and data be retained following completion of the study?

* 1. Will retained research records contain identifiable information, coded information, or fully de-identified information?

* 1. Where will records and data be stored and how will they be protected?

* 1. How will records or data be disposed of or destroyed (e.g., shredding)?

1. **CLINICAL TRIAL**
2. **Is this study a** [**Clinical Trial**](https://auth.osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf)**?**  **Yes**  **No**

If yes, answer the following:

* 1. What [phase of clinical trial](https://www.nlm.nih.gov/services/ctphases.html) best describes this research?

Phase I  Phase I/II  Phase II  Phase II/III  Phase III  Phase IV

Feasibility  Pivotal ([Feasibility vs Pivotal device studies](http://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM378265.pdf))

* 1. Is the trial “first-in-human”?

Yes  No

If yes, the protocol must describe the pre-clinical research or other data that supports the performance of the study.

* 1. Does the trial evaluate one or more [FDA-regulated products](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm)?

Yes  No

Product Type(s):

Product Name(s):

*Complete Supplement H for studies of drugs and biologics. Complete Supplement I for medical device studies.*

* 1. Will the trial enroll pregnant women or women of child-bearing potential?

Yes  No

If yes, the protocol and consent must describe any known or anticipatable risks to pregnant women and fetuses and any measures to mitigate those risks. Birth control requirements, if applicable, must also be described.

* 1. Will the trial collect data on “pregnant partners” (sexual partners of clinical trial subjects who become pregnant while the subject is on-study)?

Yes  No

If yes, describe the recruitment and consent process for the pregnant partner:

A description of any measures to monitor and mitigate risks and what data will be collected regarding the pregnancy and outcome must be provided in the protocol or other documentation. A consent form and HIPAA authorization (if PHI will be used) for the pregnant partner must be included with your submission.

* 1. Is the trial registered in [ClinicalTrials.gov](https://clinicaltrials.gov/)?

NA, registration is not required for this trial. Explain:

No, but trial will be registered prior to enrolling any subjects

Yes, ClinicalTrials.gov #:

**Note:** The following statement must be included verbatim in the consent form for FDA-regulated clinical trials that are or will be registered in ClinicalTrials.gov:

*"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*

**SUPPLEMENTS**

The Initial Submission Form is designed to obtain the information required for IRB review of all human subjects research. Additional information is required when research involves specific populations or procedures. This information is submitted using supplements to the initial submission form.

Please complete and upload any supplements relevant to this research:

CHILDREN – *Complete IRB Supplement A*

PRISONERS – *Complete IRB Supplement B*

PREGNANT WOMEN, FETUSES OR NEONATES – *Complete IRB Supplement C*

SUBJECTS WITH IMPAIRED DECISION MAKING CAPACITY – *Complete IRB Supplement D*

REQUEST FOR WAIVER OR ALTERATION OF CONSENT OR WAIVER OF DOCUMENTATION OF CONSENT – *Complete IRB Supplement E*

REQUEST FOR WAIVER OR ALTERATION OF HIPAA AUTHORIZATION – *Complete IRB Supplement F*

RESEARCH INVOLVING EXERCISE INTERVENTIONS, TESTING OR TRAINING –

*Complete IRB Supplement G*

RESEARCH INVOLVING DRUGS OR BIOLOGICS – *Complete IRB Supplement H*

RESEARCH INVOLVING MEDICAL DEVICES – *Complete IRB Supplement I*

STORED DATA/SPECIMENS FOR FUTURE USE – *Complete IRB Supplement J*

USE OF THE INTERNET – *Complete IRB Supplement K*

COLLABORATIVE RESEARCH – *Complete IRB Supplement L*

TRANSNATIONAL RESEARCH – *Complete IRB Supplement M*

CONFLICT OF INTEREST DISCLOSURE – *Complete IRB Supplement N*

**NOTE**: *The IRB will not review research that does not include the appropriate supplements.*

1. **SIGNATURES**

I will conduct the study identified above in the manner described in the protocol, this application, and any associated materials. If I decide to make any changes in the research or if any problems occur which involve risk or injury or the possibility of risk or injury to subjects or others, I will immediately report such occurrences or contemplated changes to the Institutional Review Board.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator Signature Date