**IRB Member New Project (Convened Committee) Review Checklist**

IRB Meeting Date:Click or tap here to enter text. eBridge #:Click or tap here to enter text.

Principal Investigator:Click or tap here to enter text. Reviewer:Click or tap here to enter text.

[ ]  Other site(s) is relying on the MCW IRB for review (see IRB C2 checklist for more info)

**The items below should be used as a guide to direct your oral presentation of this new project at the IRB meeting. This checklist does not need to be read word for word. Please begin your review by giving the title of the project and PI name.**

**Please use the comments box to provide additional information regarding the “Yes/No” responses.**

1. Provide a brief summary of the project (including: Title, PI, Dept/Div). What is the research question? What are the research methods/procedures involved? What is the scientific rationale? *(Refer to SmartForm sections 28, 29 & 30)*  Click or tap here to enter text.
2. Do the investigator(s) and research staff have sufficient expertise for this project, i.e. does this project require additional training or specialized techniques which the PI or team must be proficient in? *(Consider background, medical training, speciality, access to facilities, resources needed to conduct the project as indiciated in the PRO SmartForm. For MCW investigators, the Departmental Review process attests that the PI has the skills and abilities to conduct the research and that the Department supports the time, effort and financial commitment required to conduct the research.* Yes [ ]  No [ ]  Comments: Click or tap here to enter text.
	1. In the following circumstances, a CV for the lead investigator from each relying site should be uploaded in section 52.1. Resources available to the lead investigator should be described in the protocol or in an addendum to the protocol.

[ ]  MCW IRB is the Reviewing IRB for another site

[ ]  The multi-site project is investigator-initiated and the MCW investigator is the lead PI for the entire project

[ ]  The MCW investigator is lead PI for the entire project, and the project is FDA regulated and/or federally funded

* 1. Do the investigators from relying sites have sufficient expertise and adequate resources to conduct this project?

 Yes [ ]  No [ ]  N/A [ ]  Comments: Click or tap here to enter text.

1. Does this project involve the use of a test article (i.e. drug, device, biologic, botanical or dietary supplement or other)? *(Refer to Question 10.2)*

Yes [ ]  No [ ]  Comments: Click or tap here to enter text.

1. For drugs and biologics, what is their status? *(Refer to Section 10 IND & 10A Drugs/Biologics – Part I,10A.4 )*

[ ]  There is an IND, IND# Click or tap here to enter text.

[ ]  Qualifies as IND-exempt

[ ]  On-label use (under approved indication) (Google the FDA label indication, use FH web based resources such as “Lexi Comp” & “Up to Date”, consult the Pharmacist on your Committee)

1. For devices(including in-vitro diagnostics or software), what is their status? *(Refer to Section 10 IDE & 10B Devices/In Vitro Diagnostics – Part II, 10B.7 & 10B.7.1)*

[ ]  There is an IDE, IDE# Click or tap here to enter text.

[ ]  Determined to meet NSR criteria

[ ]  Qualifies as IDE-exempt

[ ]  On-label use (under approved indication)(review the uploaded FDA approval or 510(k) indication letter in section 52)

1. For botanicals, dietary supplements or other, what is their status? *(Refer to Section 10, 10A Drugs/Biologics – Parts I & II*

[ ]  There is an IND, IND# Click or tap here to enter text.

[ ]  Determined to be IND-exempt, by FDA

[ ]  On-label use (under approved indication) (Use FH web based resources such as “Natural Medicines Database”, consult the Pharmacist on your Committee)

1. Does this project include any of the following activities: Use of a placebo, washout periods, or significant deviations from standard of care? *(Refer to question 10.A.7 & 31.0*) Yes [ ]  No [ ]
	1. How does the project propose to minimize risk associated with these activities for potential subjects? *(Refer to question 32.2)* Click or tap here to enter text.
2. **Additional Federal Agencies Requirements:** Does the project receive funding from one of the following federal agency (DoD, EPA, DoJ, BoP). *(Refer to section 11)* Yes [ ]  No [ ]  N/A [ ]

If yes – please complete and upload the [Additional Federal Agencies Requirements Checklist](https://www.mcw.edu/departments/human-research-protection-program/irb-committees-and-members/checklists) with your review.

1. **Federal Subparts:** Does the project involve any of the identified populations Pregnant Women &/or fetuses, Children/Minors, Prisonerswhich may trigger additional review criteria to be considered *(Refer to question 12.2)* Yes [ ]  No [ ]  N/A [ ]

If yes – please complete the appropriate checklist and upload the with your review.

* Subpart B – Pregnant women &/or fetuses
* Subpart C – Prisoners
* Subpart D – Children/Minors
1. Will the project likely to involve other vulnerable populations (individuals with impaired decision-making capacity, elderly, or economically or educationally disadvantaged persons, non-English speaking individuals)? *(Refer to section 12.2)* Yes [ ]  No [ ]  N/A [ ]
* Have additional safeguards been included to protect the rights and welfare of these subjects?

Yes [ ]  No [ ]

* If the project is enrolling non-English speaking subjects, is there a plan or procedures to ensure ongoing consent, data collection & subject communication including translated documents and/or interpreter services? *(Refer to section 12.2, section 52.1 for uploaded documents)*

Yes [ ]  No [ ]  N/A [ ]

1. Is the proposed subject population appropriate? *(Refer to section 15)* Yes [ ]  No [ ]  Click or tap here to enter text.
2. Are the recruitment procedures appropriate? *(Refer to question 17.1 and 17.2)* Yes [ ]  No [ ]

a. Have advertisement or recruitment materials been submitted for IRB review?

Yes [ ]  No [ ]  N/A [ ]  (*See section 52.1 for uploaded documents*)

If yes, please complete the [*Advertisement and Recruitment Material Checklist*](https://www.mcw.edu/departments/human-research-protection-program/irb-committees-and-members/checklists) and attach to your review.

1. Will participants be compensated with gifts, payments, travel reimbursement, etc? *(Refer to question 18.1)* Yes [ ]  No [ ]
	1. If yes, is the compensation provided appropriate given the population, time commitment and in line with MCW IRB SOP: *Recruitment Methods and Compensation* ? Yes [ ]  No [ ]  Click or tap here to enter text.
2. Does the project propose to use procedures consistent with sound research design to yield the expected knowledge? *(Refer to Sections 28, 29 & 30 in the PRO SmartForm)* Yes [ ]  No [ ]  Click or tap here to enter text.
3. Does the project focus or involve the treatment of one of the following conditions: Alcohol abuse, drug abuse,a psychiatric diagnosis? *(Refer to section 28, 29 & 30)* Yes [ ]  No [ ]  N/A [ ]

If yes, does the team have a plan to reconsent subjects every 15 months in accordance with WI state law? *(Refer to section 39)* Yes [ ]  No [ ]

1. Are procedures to maintain confidentiality appropriate? *(Refer to section 34)* Yes [ ]  No [ ]
* Will the team collect sensitive data for the project? Yes [ ]  No [ ]
	+ If yes, is the justification or rationale acceptable? Yes [ ]  No [ ]
* Has the project been issued a Certificate of Confidentality? Yes [ ]  No [ ]
* While the project is being conducted, will the research data be (Select all that apply) :
	+ [ ]  Identifiable, or
	+ [ ]  Coded, or
	+ [ ]  De-identified
* When will the project data be de-identified?
	+ [ ]  During data analysis
	+ [ ]  At end of project
	+ [ ]  Never
* Where will project records and/or specimens be stored locally?
	+ During the conduct of the project: Click or tap here to enter text.
	+ Once the project is complete: Click or tap here to enter text.
* How long will project records be stored locally?
	+ [ ]  10 years per MCW policies
	+ [ ]  Indefinitely
	+ [ ]  Other: Click or tap here to enter text.
1. For Federally Funded Projects only, has the team uploaded their Data sharing and Management Plan (DMP)? Yes [ ]  No [ ]  N/A [ ]
	1. Is the data sharing language in the proposed ICF consistent with the NIH Data sharing and Management Plan provided: Yes [ ]  No [ ]  Click or tap here to enter text.
2. Will the project team access or screen medical records for potential subjects for the project? *(Refer to question 42.1)* Yes [ ]  No [ ]
	1. If yes, please determine if a HIPAA waiver of authorization for recruitment is required, and include in proposed motion.
3. Please indicate all regulations this project should be approved under:

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|[ ]  **Department of Health and Human Services (DHHS)** 45 CFR 46.111 | All greater than minimal risk research submitted for review by the MCW IRB and/or receiving federal funding  |
|[ ]  **Food and Drug Administration (FDA)** 21 CFR 56.111 | Research that involves a drug, device, biologic, in-vitro diagnostic, botanical medical food or dietary supplement that is part of the research intervention. |

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| **Comments/Concerns for Discussion**Discussion should be focused on the Criteria of IRB Approval (see below) . |
| Click or tap here to enter text. |

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| **Required Modifications**Modifications must be made by the investigator before final approval can be granted. In eBridge, modifications to the eBridge SmartForm must be entered as Reviewer Notes. |
| Click or tap here to enter text. |

**CRITERIA FOR APPROVAL:**

**After reviewing the entire PRO SmartForm, protocol, proposed consent formand other supporting documents (such as IB), please indicate if the project meets the identified criteria.**

*In accordance with* ***45 CFR 46.111*** *or* ***21 CFR 56.111****,* ***all*** *of the following requirements (i-vii) must be satisfied and documented in the IRB minutes in order to approve research covered by these regulations.*

**If the project does not meet all the criteria noted below, the reviewer should make a motion to table the project. To document this, please provide a brief explanation (1-3 sentences) if any of these criteria are not met in the comments box provided.**

* + 1. Risks to subjects are minimized (sound research design & acceptable procedures).

Yes [ ]  No [ ]  Comments: Click or tap here to enter text.

* + 1. Risks to subjects are reasonable in relation to anticipated benefits.

Yes [ ]  No [ ]  Comments: Click or tap here to enter text.

* + 1. Selection of subjects is equitable considering purpose and setting of research.

Yes [ ]  No [ ]  Comments: Click or tap here to enter text.

* + 1. Informed consent, including the criteria below, will be sought. Yes [ ]  No [ ]  N/A [ ]  Comments: Click or tap here to enter text.
1. Informed consent begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not participate in the research. Yes [ ]  No [ ]  N/A [ ]  Comments: Click or tap here to enter text.

*Required elements of Informed Consent: In order to satisfy criterion iv, the following required elements must be present in the informed consent document :*

* + A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ A description of any reasonably foreseeable risks or discomforts to the subject. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ A description of any benefits to the subject or to others which may reasonably be expected from the research. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
	+ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
	+ An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Yes [ ]  No [ ]  Click or tap here to enter text.
	+ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
		1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, If this might be a possibility. Yes [ ]  No [ ]  Click or tap here to enter text.

**OR**

* + 1. A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. Yes [ ]  No [ ]  Click or tap here to enter text.

*Additional elements of informed consent. When appropriate one or more of the following elements of information should be included in the informed consent document:*

* A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* Any additional costs to the subject that may result from participation in the research. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. . Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* The approximate number of subjects involved in the study. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. . Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
* A statement indicating whether clinically relevant results, including individual research results, will be disclosed to subjects, and if disclosed under what conditions. Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.

**For federally funded studies only – Does the consent form include:**

* NIH’s Certificate of Confidentiality language or equivalent language

Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.

If No, has a justification been provided from the Sponsor Yes [ ]  No [ ]

* NIH’s Data Sharing Language or equivalent language

Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.

If No, has a justification been provided from the Investigator Yes [ ]  No [ ]

1. Informed consent will be appropriately documented. Yes [ ]  No [ ]

 Comments: Click or tap here to enter text.

1. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Yes [ ]  No [ ]  Comments: Click or tap here to enter text.
2. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Yes [ ]  No [ ]  Comments Click or tap here to enter text.:
3. The project has the resources necessary to protect subjects including but not limited to:
	* Adequate time for the researchers to conduct and complete the research.
	* Adequate number of qualified staff.
	* Adequate facilities.
	* Access to a population that will allow recruitment of the necessary number of subjects.
	* Availability of medical or psychosocial resources that subjects may need as a consequence of the research.

Yes [ ]  No [ ]  Comments: Click or tap here to enter text.

Are all criteria under 45 CFR 46 or 21 CFR 56.111 satisfied?

Yes [ ]  No [ ]  *(Project must be tabled)* Comments: Click or tap here to enter text.

Do any of your modifications include requests for information not currently available in any of the documents included with this submission?  (e.g. Are your modifications written in the form of open ended questions, or with words such as "clarify", "justify", "describe", or "provide additional detail"?)

Yes [ ]  *(Project cannot be approved with modifications)*

No [ ]  Comments: Click or tap here to enter text.

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| --- |
| **Recommendation**  |
| [ ]  Approve as submittedLength of approval period:[ ]  3 months: indicate reason:Click or tap here to enter text. [ ]  6 months: indicate reason: Click or tap here to enter text.[ ]  9 months: indicate reason: Click or tap here to enter text.[ ]  12 months[ ]  Other (specify): Click or tap here to enter text. | [ ]  Conditionally approve pending minor modifications \*\**These modifications must qualify for expedited review. If not, the project should be tabled.*Length of approval period:[ ]  3 months, indicate reason: Click or tap here to enter text.[ ]  6 months, indicate reason: Click or tap here to enter text.[ ]  9 months: indicate reason: Click or tap here to enter text.[ ]  12 months[ ]  Other (specify): Click or tap here to enter text. |
| [ ]  Table *\*\* Reasons for tabling must be provided.*Reason(s): Click or tap here to enter text. | [ ]  Approval Denied*\*\* Reasons for denial must be provided.*Reason(s): Click or tap here to enter text. |
| Privacy Board Determination: HIPAA Waiver of AuthorizationApprove [ ] Disapprove [ ]  |

Reviewer Name:Click or tap here to enter text. Date: Click or tap to enter a date.