**IRB Member Checklist For 6-Year Renewals**

|  |  |
| --- | --- |
| IRB Meeting Date: Click or tap here to enter text.  | eBridge CPR#: Click or tap here to enter text. PRO#: Click or tap here to enter text. |
| Principal Investigator: Click or tap here to enter text. | Reviewer: Click or tap here to enter text. |

**What Constitutes Substantive and Meaningful Continuing Review?**

Continuing review of research must be substantive and meaningful. **Please address EACH of these points during your oral presentation of this 6-Year Renewal at the IRB meeting.**

1. Begin your review by stating the short title and indicate what progress report this is for the study. *Protocol SmartForm header and CPR tab.*  Briefly summarize the study, and include information regarding the overall project including whether MCW/FH site is the coordinating site. (*Refer to* *Protocol* *SmartForm* *sections 7, 29, 30, and any additional checklists uploaded in study history, and applicable sections of the consent form)*. Click or tap here to enter text.
2. Briefly discuss the following points:

a. List the number of participants for the current reporting period and the cumulative total that have been screened, enrolled, completed study, and are in follow-up (Include participants withdrawn from the research and progress made towards achieving accrual goal.) . (*Refer to* *CPR SmartForm sections 5, 7, and 14* *Protocol SmartForm section 13)*

|  |  |  |
| --- | --- | --- |
| # of participants | This reporting period | Cumulative total |
| Screened | Click or tap here to enter text. | Click or tap here to enter text. |
| Signed consent form | Click or tap here to enter text. | Click or tap here to enter text. |
| Currently active | Click or tap here to enter text. | Click or tap here to enter text. |
| Completed all project related procedures and visits | Click or tap here to enter text. | Click or tap here to enter text. |
| Currently in long term follow up | Click or tap here to enter text. | Click or tap here to enter text. |
| Withdrawn by PI after consent | Click or tap here to enter text. | Click or tap here to enter text. |
| Withdrew self after consent | Click or tap here to enter text. | Click or tap here to enter text. |
| Unable to complete due to death after consent | Click or tap here to enter text. | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Enrollment goal: | Local: Click or tap here to enter text. | study wide: Click or tap here to enter text. |

1. Provide information about multi-site status *(refer to sections 3 and 7 of the main eBridge SmartForm)*:
	1. Is this a multi-site project? Yes [ ]  No [ ]
		1. If yes, is the appropriate multi-site documentation provided?
			1. Report on multi-site progress Yes [ ]  No [ ]  Click or tap here to enter text.
			2. Have there been any external reportable events during this reporting period?
			Yes [ ]  No [ ]  Click or tap here to enter text.
		2. If yes, is the the PI at this site is serving as the coordinating PI or is MCW IRB serving as the IRB of record for another site(s)? Yes [ ]  No [ ]  Click or tap here to enter text.
			1. If yes, is the appropriate multi-site documentation provided?
				1. Breakdown of enrollment at other sites Yes [ ]  No [ ]  Click or tap here to enter text.
				2. Unanticipated problems at other sites Yes [ ]  No [ ]  Click or tap here to enter text.
				3. Deviations at other sites Yes [ ]  No [ ]  Click or tap here to enter text.
				4. Overall progress of project (e.g. sites that have been added, sites to be added, accrual status at sites, etc.): Yes [ ]  No [ ]  Click or tap here to enter text.
2. Describe any additional events that occurred locally during this reporting period *(refer to Protocol RE tab, CPR SmartForm sections 8, 9, and 18)*:
	1. Have any adverse events or unanticipated problems involving risks to subjects or other occurred in this reporting period? Yes [ ]  No [ ]
		1. If yes, please provide a brief summary Click or tap here to enter text.
	2. Have any deviations occurred in this reporting period? Yes [ ]  No [ ]
		1. If yes, please provide a brief summary Click or tap here to enter text.
	3. Have any complaints about the research occurred in this reporting period? Yes [ ]  No [ ]
		1. If yes, please provide a brief summary Click or tap here to enter text.
3. Describe any changes that were made to the project during this reporting period *(refer to Protocol AME tab and CPR SmartForm sections 15, 17, and 18)*:
	1. Were any amendments or modifications made to the research since the last IRB review? Yes [ ]  No [ ]
		1. If yes, provide summary of major changes Click or tap here to enter text.
	2. Are there any recent literature, publications, or interim findings related to the research during this reporting period? Yes [ ]  No [ ]
		1. If yes, provide summary of major changes Click or tap here to enter text.
4. Describe any additional reports that have been provided during this reporting period *(refer to* *CPR SmartForm sections 16 and 18; Protocol RE tab*; *Protocol SmartForm section 33; and QI Tab in eBridge)*:
	1. Does this project utilize a formal monitoring board (DSMB, DMC, SRC, etc.)? Yes [ ]  No [ ]
		1. If yes, was a report provided? Yes [ ]  No [ ]
	2. Did any monitoring visits and/or external reviews or audits occur during this reporting period? Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
	3. Did any routine reviews or requested reviews by the MCW HRPP QI Office occur during this reporting period? Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
5. Describe any relevant information that may affect the risk/benefit ratio and provide verification of the protocol (*refer to* *CPR SmartForm section 9, 14, 15, 16, and 18; Protocol AME and RE tab)*:
	1. Has there been any information about risks associated with the research during this reporting period? Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
	2. Does it appear that any unapproved changes have occurred since the previous review?
	Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
	3. Did you find any inconsistencies during your review that may warrant a for-cause audit or requested review by the MCW HRPP QI Office? Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
	4. Are there any significant new findings that arise from the review process and that may relate to subjects’ willingness to continue participation? Yes [ ]  No [ ]
		1. If yes, provide summary Click or tap here to enter text.
	5. Based upon the information provided for the above questions; do the benefits of the research still outweigh the risks? Yes [ ]  No [ ]
		1. If no, provide summary Click or tap here to enter text.
6. If the research project remains open to enrollment, is the current consent form still accurate and complete *(refer to uploaded consent form and consent /document tab for comparison of uploaded consent form to currently approved consent form)*? Yes [ ]  No [ ]  N/A [ ]

***Review of Modified SmartForm (6-Year Renewal)****:*

*The purpose of the 6-Year Renewal is to re-examine the scope and details of the entire study with fresh-eyes and confirm it still meets regulatory criteria for approval.*

1. Do the MCW investigator(s)and research staff **still** have sufficient expertise for this project, i.e. does this study 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 study as* indicated *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 [ ]  Click or tap here to enter text.
2. Is another site(s) relying on the MCW/FH IRB for review (see IRB C2 checklist for more info)
Yes [ ]  No [ ]  N/A [ ]
3. If Yes, please identify in what capacity MCW/FH IRB is serving:

[ ]  MCW/FH IRB is the Reviewing IRB for another site

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

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

1. If Yes, do the investigators from relying sites have sufficient expertise and adequate resources to conduct this study? *For the above options, 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.*
Yes [ ]  No [ ]  Click or tap here to enter text.
2. Has this project **added** a new drug, device, biologic, botanical or dietary supplement or other which has not been previously reviewed & approved by the IRB with this 6-Year Renewal?

Yes [ ]  No [ ]  N/A [ ]  *(Refer to Question 3.2 & Section 53)*

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. Did this project include **or add** any of the following activities with this 6-Year Renewal: Use of a placebo, washout periods, or significant deviations from standard of care? (Refer to question 10.A.7 & 30.2)
Yes [ ]  No [ ]
	1. How does the project propose to minimize risk associated with these activities for potential subjects? *(Refer to question 32.2 & Section 53)* Click or tap here to enter text.
2. **Additional Federal Agencies Requirements:** Does the study receive funding from one of the following federal agency (DoD, EPA, DoJ,or BoP). *(Refer to section 11)* Yes [ ]  No [ ]  N/A [ ]

If yes – please complete and upload the [Additional Federal Agencies Requirements Checklist](http://www.mcw.edu/hrpp/IRBCommittees/CommitteeMemberResources.htm) with your review.

1. **Federally regulated Vulnerable Populations:** Does the study involve any of the identified vulnerable populations (Pregnant Women &/or fetuses, Children/Minors, Prisoners) *(Refer to question 12.2)*Yes [ ]  No [ ]  N/A [ ]

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

* Subpart B – Pregnant women &/or fetuses
* Subpart C – Prisoners
* Subpart D – Children/Minors
* Decreased Decisional subjects
1. Did the project **add a new** other vulnerable populations (such as cognitively impaired persons, elderly, or economically or educationally disadvantaged persons)? *(Refer to section 12.2 & Section 53)*
Yes [ ]  No [ ]  N/A [ ]
	1. Have additional safeguards been included to protect the rights and welfare of these subjects?
	Yes [ ]  No [ ]
2. **If the project is still recruiting and enrolling,** is the proposed subject population still appropriate? *(Refer to section 15 & CPR)* Yes [ ]  No [ ]  N/A [ ]  - this project is no longer enrolling subjects
	1. Does the project team need to access or screen medical records for potential subjects for the study? *(Refer to question 42.1)* Yes [ ]  No [ ]
		1. If yes, please determine if HIPAA waiver of authorization for recruitment is required, and include in proposed motion.
	2. Are the recruitment procedures still appropriate? *(Refer to question 17.1)*
	Yes [ ]  No [ ]  N/A [ ]  Click or tap here to enter text.
3. Have **new** advertisement or recruitment materials been submitted for IRB review with this progress report? Yes [ ]  No [ ]  N/A [ ]
	1. If yes, please complete the [*IRB Member Form: Advertisement and Recruitment Material Checklist*](http://www.mcw.edu/hrpp/IRBCommittees/CommitteeMemberResources.htm) and attach to your review.
4. Has the project **added or modified** participants compensation (i.e. gifts, payments, travel reimbursement, etc)? *(Refer to question 18.1 & Section 53)* Yes [ ]  No [ ]
	1. If yes, is the compensation changes described appropriate given the population, time commitment and in line with *IRB SOP:* *Recruitment Methods and Compensation* ?
	Yes [ ]  No [ ]  Click or tap here to enter text.
5. Does the project proposes 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.
6. 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 [ ]
	1. 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 [ ]
7. Are procedures to maintain confidentiality still appropriate? *(Refer to section 34)* Yes [ ]  No [ ]  Click or tap here to enter text.
* Will the team collect sensitive data? Yes [ ]  No [ ]
* If yes, is the justification or rationale acceptable? Yes [ ]  No [ ]
* Has the project been issued a Certificate of Confidentality? Yes [ ]  No [ ]  N/A [ ]
* 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 Funding 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. Please indicate all regulations this study should be approved under:

|  |  |  |
| --- | --- | --- |
| [ ]  | **Department of Health and Human Services (DHHS)** 45 CFR 46.111 | All greater than minimal risk research submitted for review by the MCW/FH 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. |

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

|  |
| --- |
| **Required Modifications**Modifications must be made by the investigator before final approval can be granted. In eBridge, modifications to the new study 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 form and 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 study. 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.

*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:*

1. 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.
2. 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.

1. 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.
2. 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.

1. 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.
2. The approximate number of subjects involved in the study.

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

1. 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.
2. 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.
3. 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 projects only – Does the consent fom include:

* NIH’s Certificate of Confidentiality language or equivalent language has been included 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 Sponsor Yes [ ]  No [ ]
1. Informed consent will be appropriately documented. Yes [ ]  No [ ]  Comments: Click or tap here to enter text.
2. 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.
3. 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.
4. 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 [ ]  *(Study 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 [ ]  *(Study cannot be approved with modifications)*

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

|  |
| --- |
| **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 study 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.