**IRB Member CPR Reviewer Checklist**

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

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

1. Begin your review by stating the Project Number, the PI’s name, and the short title. Provide a brief summary of the project, including if any other sites are relying on the MCW IRB for review. Click or tap here to enter text.
2. Provide information about the current status of the project:
	1. Does the project remain open to enrollment *(refer to sections A1, B1, 6, and 14 in the CPR SmartForm)*? Yes [ ]  No [ ]
	2. Has IRB approval expired? Yes [ ]  No [ ]
3. Provide a description of the enrollment during this reporting period *(refer to sections 5, 7, and 14 in the CPR SmartForm)*.

|  |  |  |
| --- | --- | --- |
| **Number of subjects:** | **This reporting period** | **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| Withdrawn by PI after consent | Click or tap here to enter text.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. |

1. Enrollment goal *(refer to section 13 in the main project SmartForm)*:

Local Click or tap here to enter text. Global Click or tap here to enter text.

1. Additional comments: 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 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 [ ]  If yes, please provide a brief summary Click or tap here to enter text.
	2. 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 [ ]  Click or tap here to enter text.
	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 [ ]
7. Indicate all requirements that must be satisfied for IRB approval:

|  |  |  |
| --- | --- | --- |
| [ ]  | 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 |

|  |
| --- |
| **Comments/Concerns for Discussion** Discussion should be focused on the Risk/Benefit analysis.  |
| Click or tap here to enter text. |

|  |
| --- |
| **Required Modifications**Modifications must be made by the investigator before final approval can be granted.  |
| Click or tap here to enter text. |

**Criteria for Approval**

In accordance with 45 CFR 46.111 or 21 CFR 56.111, all of the following criteria must be satisfied and documented in the IRB minutes at the time of continuing review.

**If No, Please address in the comments section (above).**

i. Risks to subjects are minimized: (sound research design and acceptable procedures) Yes [ ]  No [ ]

ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. Yes [ ]  No [ ]

iii. Selection of subjects is equitable considering purpose and setting of research. and any special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Yes [ ]  No [ ]

iv. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.(*PRO SmartForm section 12, 12A, 12C, 12D*) Yes [ ]  No [ ]  N/A [ ]

v. Participants in the research project are identified as vulnerable populations, and the determinations made in the initial review are still applicable.

Yes [ ]  No [ ]  N/A [ ]

# [ ]  Pregnant women, fetuses and neonates (Subpart B)

This project involves the following (check as many as apply):

[ ]  [Section: Pregnant women or fetuses (45 CFR 46.204](#Pregnant_Women_204)):

[ ]  [Section: Neonates of Uncertain Viability (45 CFR 46.205 (a) and (b))](#Neonates_205a)

[ ]  [Section: Nonviable neonates (45 CFR 46.205 (c))](#Neonates_205c)

Reviewers must then complete the corresponding section(s) below, along with [final comments and recommendations.](#Final_Recommendations)

[ ]  **Section: Pregnant women or fetuses (45 CFR 46.204):**

1. Is this project receiving federal funding for the conduct of the research?

[ ]  Yes [ ]  No

If yes, pregnant women or fetuses may only be involved in the project if the following 10 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Does the application identify where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Any risk is the least possible for achieving the objectives of the research;

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with 45 CFR 46.116 and 117

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with 45 CFR 46.116 and 117, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under items 5 or 6 is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D; *See IRB Member Form: Research Involving Children (subpart D) Checklist*

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

[ ]  **Section: Neonates of Uncertain Viability (45 CFR 46.205 (a))**

1. Is this project receiving federal funding for the conduct of the research?

[ ]  Yes [ ]  No

If yes, neonates of uncertain viability and non-viable neonates may only be involved in the project if the following 4 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under paragraph [45 CFR 46.205(b)(2) or (c)(5)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The requirements of paragraph [45 CFR 46.205(b) or (c)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section have been met as applicable.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

[ ]  **Section: Neonates of uncertain viability (45 CFR 46.205 (b))**

1. Is this project receiving federal funding for the conduct of the research?

[ ]  Yes [ ]  No

If yes, until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional 2 conditions have been met.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of either parent of the neonate or, if neither parent can consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accordance with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

[ ]  **Section: Nonviable neonates (45 CFR 46.205 (c))**

1. Is this project receiving federal funding for the conduct of the research?

[ ]  Yes [ ]  No

If yes, nonviable neonates may only be involved in the project if the following 5 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Vital functions of the neonate will not be artificially maintained

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The research will not terminate the heartbeat or respiration of the neonate

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. There will be no added risk to the neonate resulting from the research.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of both parents of the neonate is obtained in accordance with 45 CFR 46 subpart A except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) do not apply.

[ ]  Yes [ ]  No [ ]  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

# [ ]  Prisoners (Subpart C) – *complete separate checklist*

# [ ]  Minors (Subpart D)

**Subpart D (children) Determinations (45 CFR 46 or 21 CFR 50)**

Check the allowable category below that best represents the degree of risk and benefit to which the children in this project will be exposed and explain your choice.

**Note: More than one category may be indicated. If multiple categories are indicated, please answer the additional question after each marked category.**

[ ]  Category 1 (404 or 50.51): The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

[ ]  Category 2 (405 or 50.52): The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.

[ ]  Category 3 (406 or 50.53): The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subjects’ conditions.

[ ]  Category 4 (407 50.54): The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. **Research which meets this category cannot be approved by the IRB and must go for review by Secretary of HHS or the Commissioner of Food and Drug to make a determination as outlined per 50.54.**

Explain your choice of category: Click or tap here to enter text.

1. **What permission will be obtained from the parents?**

[ ]  Permission from only one parent is being requested

[ ]  Permission will be obtained from both parents where possible.

Note: ***2 parent signatures are required for any project which meets category 3 (406 or 50.53).***

[ ]  A waiver of parental permission is being requested

[ ]  Informed Consent/Parental Permission has already been obtained

(i.e., previously IRB approved bank, incoming data from another institution, etc.)

[ ]  None of the Above – the project qualifies for exempt review. Select the level of contact

 [ ]  Project will not have direct contact with subjects, and an informed consent process or document is not required

 [ ]  Project will have direct contact with subjects, and an informational letter will be provided

1. **Please indicate whether the children in this project are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:**

 [ ]  All are capable

 [ ]  None are capable; explain: Click or tap here to enter text.

 [ ]  Some are capable; explain: Click or tap here to enter text.

1. **For subgroups of children capable of assent, how will assent be solicited?** Click or tap here to enter text.
	1. [ ]  A waiver of assent is being requested
	2. [ ]  Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
2. **For subgroups of children capable of assent, how will assent be documented?** Click or tap here to enter text.
	1. [ ]  A waiver of assent is being requested
	2. [ ]  Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
3. **Has the project team developed a plan to consent subjects who reach the age of majority?** [ ]  Yes [ ]  No [ ]  N/A
	1. **Describe the proposed plan:** Click or tap here to enter text.

vi. Informed consent, including the eight required elements, will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by regulations. Yes [ ]  No [ ]  N/A [ ]

vi. Informed consent will be appropriately documented, in accordance with, and to the extent required by regulations. Yes [ ]  No [ ]  N/A [ ]

vii. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Yes [ ]  No [ ]

viii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Yes [ ]  No [ ]

|  |
| --- |
| **Recommendation** |
| [ ]  Approve as submittedLength of approval period:[ ]  3 months, reason: Click or tap here to enter text.[ ]  6 months, reason: Click or tap here to enter text.[ ]  9 months, reason: Click or tap here to enter text.[ ]  12 months[ ]  Other, reason: 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, reason: Click or tap here to enter text.[ ]  6 months, reason: Click or tap here to enter text.[ ]  9 months, reason: Click or tap here to enter text.[ ]  12 months[ ]  Other, reason: Click or tap here to enter text. |
| [ ] TableReason tabling is recommended.        Click or tap here to enter text. | [ ]  Approval Denied Reason approval deniedClick or tap here to enter text. |

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