**IRB Member Expanded Access Use Reviewer Checklist**

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| 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. |

This checklist should be used in lieu of the *New Protocol Reviewer Checklist* for projects which request to use an investigational test article for treatment purposes. IRB Committee Members should review *IRB Member SOP: Expanded Access Use- Drugs or Biologics or IRB Member SOP: Expanded Access Use - Devices* for more information.

1. Please identify the type of expanded access mechanism being proposed:

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| **DRUGS/BIOLOGICS** | **DEVICE** |
| [ ]  Individual patient expanded access IND  | [ ]  Compassionate Use (devices only) |
| [ ]  Intermediate-Size Patient Population Expanded Access | [ ]  Humanitarian Use Devices |
| [ ]  Treatment IND or Treatment Protocol | [ ]  Treatment Investigational Device Exemption (IDE)  |

1. Begin your review by stating the PRO Number and the PI’s name (in e-Bridge the project number, short title and PI name will suffice). Provide a summary of the project/treatment use and describe the clinical procedures involved: Click or tap here to enter text.
2. Do the investigator(s) and project 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, specialty, access to facilities, resources needed to conduct the project as indicated in the eBridge SmartForm.)*

[ ]  Yes [ ]  No CommentsClick or tap here to enter text.

1. Is the proposed subject population appropriate? [ ]  Yes [ ]  No. Comments Click or tap here to enter text.
2. Are procedures to maintain confidentiality appropriate? [ ]  Yes [ ]  No. Comments: Click or tap here to enter text.
3. Does this project involve the use of a test article (i.e., drug, device, biologic, botanical or dietary supplement or other)? [ ]  Yes [ ]  No, if no please explain: Click or tap here to enter text.
4. Identify the test article or HDE device: Click or tap here to enter text.
Select the applicable review treatment use pathway
5. Individual patient expanded access IND: IND number Click or tap here to enter text.
6. Intermediate-Size Patient Population Expanded Access: IND number Click or tap here to enter text.
7. Treatment IND or Treatment Protocol: IND number Click or tap here to enter text.
8. Compassionate Use: FDA Assigned U# Click or tap here to enter text.
9. Treatment IDE: IDE # Click or tap here to enter text.
10. Humanitarian Use Device (HDE): HDE# Click or tap here to enter text.
11. The test article is intended to treat a serious or immediately life-threatening disease: [ ]  Yes [ ]  No [ ]  N/A (HDE-only)
	1. If No, please explain Click or tap here to enter text.
12. There is no comparable or satisfactory alternative drug/device or other therapy available to treat that stage of the disease in the intended patient population; [ ]  Yes [ ]  No [ ]  N/A If No, please explainClick or tap here to enter text.
13. The test article is under investigation in a controlled clinical trial under an IND or IDE in effect for the trial, or all clinical trials have been completed [ ]  Yes [ ]  No [ ]  N/A If No, please explain Click or tap here to enter text.
14. The sponsor of the controlled clinical trial is actively pursuing marketing approval of the test article with due diligence [ ]  Yes [ ]  No [ ]  N/A If No, please explain Click or tap here to enter text.
15. Will Informed consent be sought and documented? [ ]  Yes [ ]  No [ ]  N/A Comments:Click or tap here to enter text. Click or tap here to enter text.

Identify the Consent template Proposed:

[ ]  MCW Treatment Use Consent Template

[ ]  MCW HRPP HUD (HDE-cleared) Template

[ ]  Clinical Consent. If the clinical consent form is being proposed to be used, confirm the consent form include the following elements?

1. A clear statement that the device has not been proven safe or effective in the way most devices are approved. [ ]  Yes [ ]  No [ ]  N/A
2. Did the Investigator submit the patient information packet from the Sponsor?
[ ]  Yes [ ]  No If no- does the consent include:
3. A simple description of what the device is and mechanism of action
[ ]  Yes [ ]  No
4. Describe any reasonably foreseeable risks or discomforts associated with use of the HUD [ ]  Yes [ ]  No

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| **Comments/Concerns for Discussion** |
| Click or tap here to enter text. |

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| **Recommended Modifications** |
| Click or tap here to enter text. |

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| **Recommendations**  |
| [ ]  Approve as submittedLength of approval period:[ ]  3 months[ ]  6 months[ ]  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[ ]  6 months[ ]  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. |

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