### WORKSHEET: Criteria for Approval

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The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = subject’s legally authorized representative)

#### 1 General Considerations (Check if “Yes” or “N/A”. All must be checked)

- The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.
- For initial review the principal investigator is not Restricted. (“N/A” if not initial review)
- Materials are complete.

#### 2 Criteria for Approval of Research: (Check if “Yes” or “N/A”. All must be checked) (Applies to initial, continuing, modifications)

- Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- Risks to subjects are minimized by using procedures already being performed on the subjects for other purposes. (“N/A” if none)
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)
- The research plan makes adequate provision for monitoring the data collected regarding both harms and benefits to determine whether participants remain safe. (“N/A” if no vulnerable subjects)
- The informed consent process meets one of these sections or checklists

**Section 5: Consent Process**
- Waiver or alteration of consent process (HRP-410) **Permanently closed to enrollment**

**Section 6: Long Form**
- Waiver of documentation (HRP-411) **Permanently closed to enrollment**

**Short Form (HRP-317)**
- Waiver or alteration of consent process (HRP-415) **Permanently closed to enrollment**

- Additional applicable criteria are met (“N/A” if none)

#### 3 Additional Considerations (Check all that apply.)

- Does the research involve no more than Minimal Risk to subjects?
- Should review take place more often than annually? If so, specify period.
- Is verification needed from sources other than the investigator that no material changes have occurred since prior review? (“N/A” if initial)
- Does information need to be provided to subjects because it may affect their willingness to continue participation? (“N/A” if initial)

#### 4 Primary Reviewer Criteria for Initial review (Check if “Yes” or “N/A”. All must be checked; May be determined by a primary reviewer)

- The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)
- There are no inconsistencies between the DHHS grant and protocol. (“N/A” if there is no DHHS grant.)
- The plan for communication among sites is adequate to protect subjects. (“N/A” if not a multicenter trial where PI is the lead or not initial)

**Complete remaining items when applicable**

#### 5 Consent Process (Check if “Yes”. All must be checked)

- The investigator will obtain the legally effective informed consent of the subject or LAR.
- The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
- The circumstances of consent minimize the possibility of coercion or undue influence.
- Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
- There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
- Consent will disclose the elements in **Section 7: Elements of Consent Disclosure**

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1 When research involves more than Minimal Risk to participants, consider the following issues where appropriate, as described in the investigator protocol: 1. The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. 2. What data are reviewed, including safety data, untoward events, and efficacy data. 3. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants). 3. The frequency of data collection, including when safety data collection starts. 4. Who will review the data. 5. The frequency or periodicity of review of cumulative data. 6. The statistical tests for analyzing the safety data to determine whether harm is occurring. 7. Any conditions that trigger an immediate suspension of the research. 8. Plans to establish data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. 9. Conditions that trigger an immediate suspension of the research, if applicable.

2 Advertisements (HRP-315); Payments (HRP-316); Additional Federal Agency Criteria (HRP-318): Pregnant Women (HRP-412 -); Prisoners (HRP-415); Children (HRP-416); Cognitively Impaired Adults (HRP-417); Non-Significant Risk Device (HRP-418)

3 Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

4 Implement when the veracity of the information provided is questioned.
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#### 6 Long Form of Consent Documentation (Check if “Yes” or “N/A”. All must be checked)

- The written consent document is accurate, complete, and consistent with the protocol.
- The written consent document embodies the elements in Section 7: Elements of Consent Disclosure.
- The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
- The subject or LAR will sign and date the consent document.
- The person obtaining consent will sign and date the consent document.
- A copy of the signed and dated consent document will be given to the person signing the document.
- If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. (*N/A* if no signature line)
- When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. (*N/A* if all subjects are able to read)

#### 7 Elements of Consent Disclosure (Check if “Yes” or “N/A”. All must be checked)

**Required:** (*Can be omitted if there are none.)*

- The study involves research.
- The purposes of the research.
- The expected duration of the subject’s participation.
- The procedures to be followed.
- Identification of any procedures, which are experimental.*
- Any reasonably foreseeable risks or discomforts to the subject.*
- Any benefits to the subject or to others, which may reasonably be expected from the research.*
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
- The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
- How to contact the research team for questions, concerns, or complaints about the research.
- How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects’ rights; to obtain information; or to offer input.
- Whom to contact in the event of a research-related injury to the subject.
- Participation is voluntary.
- Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**Required for More than Minimal Risk Research**

- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
- Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**Required for Clinical Trials**

- The approval of the IRB.
- The probability for random assignment to each treatment.
- The subject’s responsibilities.
- When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
- The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
- When there is no intended clinical benefit to the subject, a statement to this effect.
- The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
- If the results of the trial are published, the subject’s identity will remain confidential.

**Required for FDA-Regulated Research**

- The possibility that the Food and Drug Administration may inspect the records.
- The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
- The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
- For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "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."

**Additional:** (Include when appropriate.)

- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
- If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject’s decision to withdraw from the research.
- Procedures for orderly termination of participation by the subject.
- 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.
- Approximate number of subjects involved in the study.
- Amount and schedule of all payments.