The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used.

1	**General Considerations** (All must be **"Yes"**)	
1.1	☐ **Yes** ☐ **No**	The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.
1.2	☐ **Yes** ☐ **No** ☐ **N/A**	For initial review none of the investigators or research staff are Restricted. **("N/A" if not initial review)**
1.3	☐ **Yes** ☐ **No**	Materials are complete.
2	**Criteria for Approval of Research:** (All must be **"Yes"** or **"N/A"**) (Applies to initial, continuing, modifications, convened, and expedited)	
2.1	☐ **Yes** ☐ **No**	Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
2.2	☐ **Yes** ☐ **No** ☐ **N/A**	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if no such procedures)**
2.3	☐ **Yes** ☐ **No**	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.
2.4	☐ **Yes** ☐ **No**	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.)
2.5	☐ **Yes** ☐ **No** ☐ **N/A**	When the research involves more than minimal risk[1] to subjects, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if no more than minimal risk)**
2.6	☐ **Yes** ☐ **No**	There are adequate provisions to protect the privacy of subjects.
2.7	☐ **Yes** ☐ **No**	There are adequate provisions to maintain the confidentiality of data.
2.8	☐ **Yes** ☐ **No** ☐ **N/A**	When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
2.9	☐ **Yes** ☐ **No** ☐ **N/A**	Informed consent will be sought from each prospective subject or LAR, in accordance with, and to the extent required by: ☐ **SECTION 5: CONSENT PROCESS** ☐ **WAIVER OR ALTERATION OF THE CONSENT PROCESS (CHECKLIST:Expedited Review)**
2.10	☐ **Yes** ☐ **No** ☐ **N/A**	Informed consent will be appropriately documented, in accordance with, and to the extent required by: ☐ **Long Form** ☐ **Short Form** ☐ **Waiver of documentation (CHECKLIST: Expedite Review)** ☐ **Waiver or alteration of consent process (CHECKLIST: Expedite Review)** ☐ **Permanently closed to enrollment**
2.11	☐ **Yes** ☐ **No** ☐ **N/A**	The criteria in the corresponding CHECKLISTS are met when the research involves: **("N/A" if none involved)** ☐**CHILDREN** ☐**NEONATES** ☐**PREGNANT WOMEN** ☐**COGNITIVELY IMPAIRED ADULTS** ☐**PRISONERS**
2.12	☐ Yes ☐ No ☐ N/A	**Additional applicable criteria are met ("N/A" if none)** ☐ **Recruitment Materials and Payments (CHECKLIST: Recruitment Materials and Payments)**
3	**Additional Considerations** (May be **"Yes"** or **"No"**)	
3.1	☐ **Yes** ☐ **No**	Does the research involve no more than minimal risk to subjects?
3.2	☐ **Yes** ☐ **No** ☐ **N/A**	Does the research require Continuing review? **(Note that for FDA or DOJ overseen research, there is no option not to require Continuing review.)** The research does not require Continuing review if one of the following apply: ☐ The research is eligible for expedited review. **(See CHECKLIST: Expedited Review)** ☐ The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
3.3	☐ **Yes** ☐ **No** ☐ **N/A**	Should review take place more often than annually? If so, specify period. **("N/A" if a modification)**
3.4	☐ **Yes** ☐ **No** ☐ **N/A**	Is verification needed from sources other than the investigator that no material changes have occurred since prior IRB review? (Implement when the veracity of the information provided is questioned.) **("N/A" if initial review)**
3.5	☐ **Yes** ☐ **No** ☐ **N/A**	Is there information that needs to be provided to current or former subjects because it may affect their willingness to continue participation? **("N/A" if initial review)**

4	**Primary Reviewer Criteria** (All must be **"Yes"** or **"N/A";** These items may be determined by a primary reviewer)	
4.1	☐ **Yes** ☐ **No** ☐ **N/A**	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.)
4.2	☐ **Yes** ☐ **No** ☐ **N/A**	The plan for communication of information among sites is adequate to protect subjects. **("N/A" if this is not a multicenter trial or the investigator is not the lead)**
	Complete remaining items when applicable	
5	**Consent Process** (All must be **"Yes"**) ☐ **N/A (if closed to accrual or waiver of consent granted)**	
5.1	☐ **Yes** ☐ **No**	The investigator will obtain the legally effective informed consent of the subject or LAR.
5.2	☐ **Yes** ☐ **No**	Consent will be obtained only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
5.3	☐ **Yes** ☐ **No**	Consent will be obtained only under circumstances that minimize the possibility of coercion or undue influence.
5.4	☐ **Yes** ☐ **No**	Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
5.5	☐ **Yes** ☐ **No**	The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5.6	☐ **Yes** ☐ **No**	Informed consent must begin 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 want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
5.7	☐ **Yes** ☐ **No**	Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
5.8	☐ **Yes** ☐ **No**	The information to be given to the subject or LAR does not include any exculpatory language through, which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
5.9	☐ **Yes** ☐ **No**	Consent will disclose the elements in **Section 7: Elements of Consent Disclosure**
6	**Long Form of Consent Documentation** (All must be "Yes") ☐ **N/A (if closed to accrual or waiver of consent granted)**	
6.1	☐ **Yes** ☐ **No**	The written consent document is accurate, complete, and consistent with the protocol
6.2	☐ **Yes** ☐ **No**	The written consent document embodies the elements in **Section 7: Elements of Consent Disclosure**
6.3	☐ **Yes** ☐ **No**	The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
6.4	☐ **Yes** ☐ **No**	The subject or LAR will sign and date the consent document.
6.5	☐ **Yes** ☐ **No**	The person obtaining consent will sign and date the consent document.
6.6	☐ **Yes** ☐ **No**	A copy of the signed and dated consent document will be given to the person signing the document.
6.7	☐ **Yes** ☐ **No** ☐**N/A**	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)**
6.8	☐ **Yes** ☐ **No** ☐ **N/A**	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 the subject's LAR, and that consent was freely given. **("N/A" if all subjects are able to read)**

7 **Elements of Consent Disclosure** (All required and all appropriate additional elements must be disclosed and documented) ☐ **N/A (if closed to accrual or waiver of consent granted)**

HHS Definition of Minimal risk *(46.102i): Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test.*

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

☐7.1 The study involves research.
☐7.2 The purposes of the research.
☐7.3 The expected duration of the subject's participation.
☐7.4 The procedures to be followed.
☐ 7.5 Identification of any procedures, which are experimental.*
☐ 7.6 Any reasonably foreseeable risks or discomforts to the subject.*
☐ 7.7 Any benefits to the subject or to others, which may reasonably be expected from the research.*
☐ 7.8 Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
☐ 7.9 The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
☐7.10 How to contact the research team for questions, concerns, or complaints about the research.
☐7. 11 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.
☐7.12 Whom to contact in the event of a research-related injury to the subject.
☐7.13 Participation is voluntary.
☐7.14 Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
☐7.15 The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
☐7.16 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
- ☐ 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; or
- ☐ 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.

Required for More than Minimal Risk Research

☐7.17 Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
☐7.18 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 that Follow ICH-GCP

☐7.19 The approval of the IRB.
☐7.20 The probability for random assignment to each treatment.
☐7.21 The subject's responsibilities.
☐7.22 When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
☐7.23 The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
☐7.24 When there is no intended clinical benefit to the subject, a statement to this effect.
☐7.25 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.
☐7.26 If the results of the trial are published, the subject's identity will remain confidential.

Required for FDA-Regulated Research

☐7.27 The possibility that the Food and Drug Administration may inspect the records.
☐7.28 The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
☐7.29 The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
☐7.30 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.)

☐7.31 The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
☐7.32 If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
☐7.33 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
☐7.34 Any additional costs to the subject that may result from participation in the research.
☐7.35 The consequences of a subject's decision to withdraw from the research.
☐7.36 Procedures for orderly termination of participation by the subject.
☐7.37 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.
☐7.38 Approximate number of subjects involved in the study.
☐7.39 Amount and schedule of all payments.
☐7.40 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.
☐7.41 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
☐7.42 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).

If additional information or changes are necessary, explain below:

Proposed Modification(s) and/or Stipulation(s) for Approval:	