RUTGERS UNIVERSITY
Office for Research

WORKSHEET: Criteria for Approval

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4.202 (HRP-314)	04.24.2024	1 of 4

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) N/A:** ☐	
☐	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, that are consistent with sound research design and that do not unnecessarily expose subjects to risk.	
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐	
☐	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.[i]	
☐	Selection of subjects is equitable.[ii] (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 to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk, unless a clinical trial) N/A:** ☐ [iii]	
☐	There are adequate provisions to protect the privacy of subjects. [iv]	
☐	There are adequate provisions to maintain the confidentiality of data.[v]	
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐	
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **Waiver or alteration of consent process 6.208 (HRP-410)** ☐ **Permanently closed to enrollment**	
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **Waiver of documentation 6.207 (HRP-411)** ☐ **Permanently closed to enrollment** ☐ **Short Form 6.202 (HRP-317)** ☐ **Waiver or alteration of consent process 6.208 (HRP-410)**	
☐	Additional applicable criteria[vii] are met **("N/A" if none)**	
3	**Additional Considerations** (Check all that apply.)	
☐	Does the research involve no more than Minimal Risk to subjects?	
☐	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 4.201 (HRP-313) WORKSHEET: 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.	
☐	Should review take place more often than annually?[viii] If so, specify period: _____	
☐	Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[ix] **("N/A" if initial) N/A:** ☐	
☐	Does information need to be provided to subjects because it may affect their willingness to continue participation? **("N/A" if initial) N/A:** ☐	
☐	Check if all of the above were considered but do not apply.	
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, an IRB-approved subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)	
☐	The plan for communication among sites is adequate to protect subjects. **("N/A" if not a Multi-Site trial where PI is the lead or not initial) N/A:** ☐	
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.	
☐	The prospective subject or the LAR 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.	
☐	Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR 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.	

☐	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 LAR's understanding of the reasons why one might or might not want to participate.
☐	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**

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 a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("N/A" if no signature line) 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 LAR, and that consent was freely given. **("N/A" if all subjects are able to read) N/A:** ☐

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.
- ☐ One of the following statements about any research that involves the collection of

Required for Clinical Trials that Follow ICH-GCP

- ☐ 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 should 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.

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 LAR, 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

☐ 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.

☐ 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.

☐ 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.

☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

☐ 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).

☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects. [x]

8	**Additional Considerations for Electronic Consent (Check if "Yes" or "N/A". All must be checked)**
☐	Electronic consent document includes all elements in **Section 7-Elements of Consent Disclosure**
☐	The date of the electronic signature will be captured **(N/A if waiver of documentation of consent is requested and justified ☐)**
☐	Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
☐	Electronic consent process includes age appropriate materials to facilitate comprehension.
☐	Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
☐	Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
☐	Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.
☐	Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
☐	The informed consent process outlines in detail how any included documents will be utilized.
☐	Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.
☐	For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identity and assent when the child initially presents to the investigator. **(N/A if the research is not an FDA-Regulated Clinical Trial ☐)**

[i] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[ii] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[iii] When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the

specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5)

[iv] The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be "sensitive" or "private." The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects' potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c)

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[v] The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c)

[vi] When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

[vii] 9.202 (HRP-315) - WORKSHEET - Advertisements; 9.203 (HRP-316) - WORKSHEET - Payments; 4.203 (HRP-318) - WORKSHEET - Additional Federal Agency Criteria; 7.201 (HRP-412) - WORKSHEET - Pregnant Women; 7.202 (HRP-413) - WORKSHEET - Non-Viable Neonates; 7.203 (HRP-414) - WORKSHEET - Neonates of Uncertain Viability; 7.204 (HRP-415) - WORKSHEET - Prisoners; 7.205 (HRP-416) - WORKSHEET - Children; 7.101 (HRP-417) - CHECKLIST – Adults with Impaired Decision-Making Capacity; 8.201 (HRP-418) - WORKSHEET - Non-Significant Risk Device.

[viii] 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.

[ix] Implement when the veracity of the information provided is questioned.

[x] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.