**General Instructions**

The secondary reviewer’s main responsibilities are to review the consent form(s) to ensure that the required elements of consent are present and that the document is understandable to lay participants.

**Before the Meeting**

1. **Refer to the agenda notes and other screening documents** (e.g. the convened checklist) uploaded in the HS-ERA comments. These materials will flag any special considerations that need to be made about the consent.
2. **Review the administrative stipulations, recommendations and notes** to save yourself time and effort.
3. Email your consent form revisions to your IRB Administrator **2-3 *business* days before the scheduled meeting date** to allow substantive concerns to be addressed prior to the meeting.
   1. Provide a tracked/ marked version of the consent form (preferred) or a word document with detailed notes.
   2. Please differentiate between stipulations (required changes) and recommended changes.
4. To ensure a thorough review, all sections of this form should be completed (as applicable)

**During the Meeting**

1. Have your notes and questions ready for the meeting discussion.
2. Discuss major (substantive) consent form issues during the meeting. Grammatical and other minor issues will be incorporated into the letter or tracked consent by the IRB staff.

**Study Information**

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| --- | --- |
| **IRB #:** |  |
| **Principal Investigator:** |  |
| **Protocol Title:** |  |
| **Your Name:** |  |

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| **ASSESS THE GENERAL CONSENT REQUIREMENTS (§46.116)**  *Review the consent document(s) and the plan to obtain consent in the protocol and/or HSERA application (Consent page) to assess the following.* |

**Recruitment / Consent Process**

1. The description of the consent process reflects that the prospective participant will have sufficient opportunity to consider whether or not to participate.

*In essence, is there sufficient time for the participant to decide whether or not they want to participate?*

**Yes  No  🡪 Comment:**

1. The description of the recruitment / consent process and description about the inclusion of vulnerable populations reflects that the possibility of coercion or undue influence is minimized. *Refer to* [*Penn IRB SOP 501*](https://irb.upenn.edu/documents/standard-operating-policies/) *for a list of vulnerable populations that may be susceptible to undue influence.*

* *Coercion: persuading someone through force or threats*
* *Undue influence: influencing one to act in a way other than their own free will or without adequate attention to the consequences*

*Has the team identified populations that may be vulnerable to undue influence (e.g., employees/students, those who may be economically disadvantaged, etc.) if applicable. Is so, is there are a plan to minimize undue influence?*

**Yes  No  🡪 Comment:**

1. Consent is documented, unless otherwise waived by the IRB.

**Yes  No  🡪 Comment:**

**Consent Form**

1. The prospective participant (or the legally authorized representative) is provided with information that one would want to make an informed decision about whether to participate, and an opportunity to discuss that information.

* *Does the information in the consent form provide all critical information so that the participant or the LAR can adequately understand the research and make informed choices?*
* *Does the consent process reflect that they are given the opportunity to ask questions?*

**Yes  No  🡪 Comment:**

1. The consent form is in language that is understandable to the prospective participant.

* *It is generally recommended that the consent form read at a 7th -8th grade reading level to be broadly understandable to individuals from various educational backgrounds. Please consider referring the team to the Health Literacy Guidance, if pervasive changes are needed:* [*https://irb.upenn.edu/sites/default/files/Health%20Literacy%20Guidance.pdf*](https://irb.upenn.edu/sites/default/files/Health%20Literacy%20Guidance.pdf)*. You may use the highlight feature in word to highlight words that require either definition or revision to lay terminology.*
* *Also consider the inclusion of limited English proficiency participants, when applicable*

**Yes  No  🡪 Comment:**

1. The consent document does not include any exculpatory language through which the participant is made to waive, or appear to waive, legal rights or the researchers from liability.

*For more information please see:* [*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html).

*Examples of Exculpatory Language:*

* *By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances.*
* *I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.*
* *By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.*
* *I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.*

**Yes  No  🡪 Comment:**

1. The informed consent presents information in sufficient detail and is organized and presented in a way that facilitates understanding of why one may or may not want to participate.

* *Information is not being withheld from participants.*
* *The document is organized and flows in a way that makes sense (e.g., use of headings/subheadings, tables/figures/pictures where necessary, etc.)*

**Yes  No  🡪 Comment:**

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| **ASSESS THE ELEMENTS OF CONSENT**  *Consider comparing the consent form to the Penn ICF Template:* [*https://irb.upenn.edu/forms*](https://irb.upenn.edu/forms)*.* |

**Required Elements**

1. **Does the main informed consent contain all elements required for informed consent?**

**Yes  No  🡪 Please check off the elements of consent that are MISSING / INSUFFICIENT. Include a stipulation below or add a comment in the tracked consent.**

A statement that the study involves **research;**

An explanation of the **purposes** of the research;

The expected **duration** of the participant's participation;

A description of the **procedures** to be followed;

Identification of any **procedures** **(or products)** **which are** **experimental;**

A description of the reasonably foreseeable **risks**/discomforts;

A description of the **benefits** to participants or others;

Disclosure of **alternative** **procedures** or courses of treatment;

A statement describing how **confidentiality** will be maintained;

An explanation of any **compensation** to be provided and description of injury coverage;

An explanation of **whom to contact** with questions/concerns;

A statement to indicate participation is **voluntary** and refusal will not involve loss of benefits;

A statement about whether or NOT data and/or biospecimens will be stored /retained for **future research** purposes?

1. If the data (i.e., information) and/or biospecimens will be retained by the study team in a coded or identifiable fashion, does the consent contain the following required elements of broad consent for their reuse?

**Yes**

**No** 🡪 **Please check off the elements of consent that are MISSING and include a stipulation to add these required elements.**

A statement about which identifiers will be retained and shared with data/specimens;

A description of the period of time that the data/ biospecimens may be stored, maintained, and used for research purposes;

A general description of the types of research that may be conducted;

The types of institutions or researchers that might conduct research with the data/specimens;

A statement whether participants will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research;

A statement regarding whether clinically relevant research and/or individual results will be disclosed to participants, and under what conditions;

Specifically related to the future use: A description of how confidentiality will be maintained during storage/sharing, reasonably foreseeable risks, benefits, who to contact about future use/storage and research related harms.

**Stipulations:**

**Recommendations:**

1. **Confirm that the consent form aligns with the protocol.**

*Does the description of the purpose, procedures, duration of participation, risks, benefits, alternatives, and compensation outlined in the consent form match the description in the protocol/HSERA?*

**Yes  No  🡪 Comment:**

**Additional Elements** *(included as applicable)*

1. **Does the main informed consent seem to require any additional elements?**

**No**

**Yes** 🡪 **Please check additional elements of consent that are needed. Include a stipulation below or add a comment in the tracked consent.**

A statement that there may be **unforeseeable** **risks** *(for early phase 1-2 research);*

The circumstances when participant **participation may be terminated** by the investigator;

Any additional **costs** to the participant;

The consequences of a participant's decision to **withdraw**, explanation of **how to withdraw,** and who to contact;

A statement that **significant new findings** which may affect willingness to continue participation will be provided to the participant;

A statement regarding whether clinically relevant research and/or individual results will be disclosed to participants, and under what conditions*NOTE: This may include, but is not limited to, diagnostic psychological or neurological testing, testing of specimens using assays or other in vitro diagnostic tests, diagnostic imaging, results other diagnostic devices, etc. If unsure, ask the research team if this is a possibility.*

***If the study includes the collection of biospecimens:***

*Note: Any collection of biospecimens should generally include these elements of consent. Exceptions may be appropriate such as situations where biospecimens are taken for the purposes of pregnancy screening and immediately discarded.*

A statement that biospecimens may be used for commercial profit, and whether or not the participant will share in this commercial profit;

A statement of whether the research will or might include whole genome sequencing

**Stipulations:**

**Recommendations:**

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| **Assess Other Participant Facing Materials**   * *If recruitment materials are drafted by the study team, compare them with the Penn Guidance:* [*https://irb.upenn.edu/homepage/biomedical-homepage/guidance/recruitment-and-consent/recruitment-of-human-participants/*](https://irb.upenn.edu/homepage/biomedical-homepage/guidance/recruitment-and-consent/recruitment-of-human-participants/) * *If the recruitment materials contain images of humans, do the images represent the targeted population, or are revisions needed? Non-representative materials (e.g., if images include only white people) may hinder enrollment of a diverse participant sample.* |

**Stipulations:**

**Recommendations:**

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| **Outline Non-Substantive Issues that should be Stipulated in the IRB Letter**  *If you have identified issues* ***not related to criteria for approval,*** *these should be outlined.*   * *Don’t re-iterate the administrative stipulations included in the agenda; if you feel any of those are wrong, point that out here* * *Summarize common issues (e.g. instead of pointing out every discrepancy between the online application and the full protocol, mention sections where there are inconsistencies and request reconciliation).* * *When identifying non-substantive issues, please be prepared with a potential solution to streamline the discussion.* |

**Stipulations:**

**Recommendations:**