**WORKSHEET Primary Reviewer, Initial Application**

**INSTRUCTIONS:**

1. **Purpose:** This worksheet is for use by Designated Reviewers (expedited reviews) and the Primary and Secondary Reviewers (convened IRB reviews) when preparing for the review of initial applications for a study and for non-UW sites that are reviewed by the UW IRB per a reliance or cooperative agreement, including deferral responses and conditional approval responses. It is not used for the Limited IRB Review process. The Primary and Secondary Reviewers use this worksheet, **together with the Pre-review Note prepared by HSD Staff**, to review the application, identify and write down issues for discussion by the IRB. The Pre-review Note can be found in the Reviews tab of the ZIPLINE application. Filling out this form is not a requirement, but reviewers may wish to take notes on it to use as a guide during the IRB meeting.
2. **Review strategy:** Review to the applicable regulations and HSD/UW policy requirements as described in this worksheet and in the HSD Staff Pre-review Note, as follows:
3. Evaluate the materials against the criteria to determine which ones are met; which are not met and why; and what is needed to determine whether the criteria are met. Identify potential solutions when possible.
4. Ask for additional information or clarification only when there is a regulatory or policy basis for the question.
5. Calibrate the level of review to the level of risk. Lower risk research does not require the same level of protections to meet the criteria for approval.
6. Do not impose changes or restrictions on the research if it qualifies for approval without the changes or restrictions.
7. Embrace flexibility in study design when the flexibility is allowable under the criteria for approval.
8. Be sure you understand the study design before requesting changes or placing restrictions.
9. Assess each application independent of other reviews.
10. HSD uses the acronym **P.A.U.S.E** as a framework to interrupt self- identified bias while reviewing applications. Don’t forget to- **P**: Pay attention to your reactions **A**: Acknowledge your assumptions **U**: Understand your perspective **S**: Seek different perspectives **E**: Examine your options and make a decision.
11. **Presentation to the convened committee:** 
    1. Provide a short descriptive summary of the purpose and procedures of the study. For example, rather than listing all surveys simply state that the subject will complete 5 surveys or that the subject will have 12 blood draws over the first 24hrs with a total of 120ml, instead of listing each time point and volume.
    2. Present issues identified in your review to the other IRB members. Discuss one criterion of approval at a time and try to come to a resolution before moving on to the next.
    3. Discuss issues identified in pre-review note. When possible, avoid re-stating the issue and indicate agreement or disagreement.
    4. Make a motion by proposing an IRB action, research risk level, and approval period.

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| **1. Study Information** | | | | |
| **Study Number:** | |  | **Principal Investigator:** |  |
| **Study Title:** | |  | | |
| **2. Reviewer Conflict of Interest** | | | | |
| **Met** | **Criteria** | | | |
|  | **2.1 No conflict of interest.** The Primary Reviewer has no conflict of interest with respect to the item in review. | | | |
|  | Review the [SOP Reviewer Conflict of Interest](https://www.washington.edu/research/policies/sop-reviewer-conflict-of-interest/) for discussion and definition of conflict of interest. If you have a conflict, **STOP** and consult with your Team Lead about the need to re-assign the item to another IRB member. | | | |
| **3. Criteria for Approval** | | | | |
| **Met** | **Criteria** | | | |
|  | **3.1 Risks to subjects are minimized.** | | | |
|  | Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.  **Review:**  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 1. Overview, 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 5. Procedures, 9. Privacy and Confidentiality, 10. Risk/Benefit Assessment, 11. Economic Burden, 12. Resources)  ZIPLINE SmartForm: Funding and Grant Proposal (if any)  ZIPLINE SmartForms: Study Scope  ZIPLINE SmartForm: Drugs and SUPPLEMENT Drugs, Biologicals and Botanicals  ZIPLINE SmartForm: Devices and SUPPLEMENT Devices  ZIPLINE SmartForm: Study Protocol, Measures, Instruments, Supplements, Investigator Brochures, Drug Package Inserts, and/or Device Manuals  **Points to consider:**   * Does the research design allow the proposed research to address the study objectives and result in scientifically and statistically valid results? * Are risks and anticipated benefits accurately identified, evaluated, described and managed? * Has the research design taken into account any special vulnerabilities among prospective subjects that might be relevant to minimizing the risk of participation? * Are there appropriate methods for screening participants before enrollment? * Is the research team appropriately qualified to perform the study procedures and is the research site adequate ([**SOP Research Team**](https://www.washington.edu/research/policies/sop-research-team-2/))? * If appropriate, are there adequate plans to inform subjects about specific research results that might affect the subject’s health and/or decision to participate? | | | |
| **Discussion items:** | | | |
|  | **3.2 Risks to subjects are reasonable.** | | | |
|  | Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.  In evaluating risks and benefits, consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research. (Review, *When to describe risks for studies evaluating medically recognized standards of care* in the [GUIDANCE Consent](https://www.washington.edu/research/hsd/guidance/consent/#r) for more information.)  Do not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) among those research risks that fall within the purview of its responsibility.  **Review:**  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 1. Overview, 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 5. Procedures, 9. Privacy and Confidentiality, 10. Risk/Benefit Assessment, 11. Economic Burden, 12. Resources)  ZIPLINE SmartForm: Funding and Grant Proposal (if any)  ZIPLINE SmartForms: Study Scope  ZIPLINE SmartForm: Drugs and SUPPLEMENT Drugs, Biologicals and Botanicals  ZIPLINE SmartForm: Devices and SUPPLEMENT Devices  ZIPLINE SmartForm: Study Protocol, Measures, Instruments, Supplements, Investigator Brochures, Drug Package Insert, and/or Device Manuals  **Points to consider:**   * Are the study aims/objectives clearly specified? * Is the importance of the aims clear? * Are there adequate preliminary data to justify the research? * Are drug or device safety and efficacy data sufficient to warrant the proposed phase of testing? * Are there direct potential benefits to the participants? * If the research involves the evaluation of a therapeutic procedure, have the risks and benefits of the research interventions been evaluated separately from those procedures that are taking place as part of patient clinical care? | | | |
| **Discussion items:** | | | |
|  | **3.3 Selection of subjects is equitable.** | | | |
|  | In making this assessment, take into account the purposes of the research and the setting in which the research will be conducted and be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, people with physical or developmental disabilities, or economically or educationally disadvantaged persons.  **Review:**  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 1. Overview, 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 10. Risk/Benefit Assessment, 11. Economic Burden)  ZIPLINE SmartForm: Funding and Grant Proposal (if any)  ZIPLINE SmartForm: Supporting Documents and Study Protocol, Supplements  **Points to consider:**   * Will the burdens of participating in the research fall on those most likely to benefit from the research? * Are inclusion and exclusion criteria clearly stated and reasonable? * Will any special physiological, psychological, or social characteristics of the subject group pose special risks for them? Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate? * To the extent that participation in the study is burdensome, are these burdens distributed fairly? Will subject selection avoid placing a disproportionate share of the research burdens on any single group? Is the proposed subject population already so burdened that it would be unfair to ask them to accept an extra burden? * Does the nature of the research require or justify using the proposed subject population? * To the extent that benefits to the subjects are anticipated, are they distributed fairly? Do other groups of potential subjects have a greater need to receive any of the anticipated benefits? | | | |
| **Discussion items:** | | | |
|  | **3.4 Informed consent will be obtained or waived.** | | | |
|  | One of the two options below is true.  **Option 1:** Legally effective informed consent will be obtained from the subject or the subject's legally authorized representative. Consent will include all required elements and will be obtained under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative is in language understandable to the subject or the representative. The consent does not include any exculpatory language through which the subject or the representative 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. Review the [GUIDANCE Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design) for more detailed information about requirements for the consent process and forms. The [WORKSHEET Consent](https://www.washington.edu/research/forms-and-templates/worksheet-consent/) provides a brief checklist of general consent requirements and elements.  **Option 2:** The research qualifies for a waiver or alteration of some or all elements of consent, or a waiver of the requirement to obtain consent. Review the [Designing Consent guidance](https://www.washington.edu/research/hsd/guidance/consent/design/#4) for waiver requirements.  **Review:**  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 8. Consent, 11. Economic Burden)  ZIPLINE SmartForm: all consent documents and recruitment materials  **Points to consider:**   * Are the methods for recruiting subjects well defined? * Is the individual performing the recruitment appropriate for the process? * Does the consent form present the Key Information that a reasonable person from this subject population would want to know before deciding whether to participate? * Do the proposed explanations of the research provide an accurate assessment of its reasonably foreseeable risks ([Guidance Consent](https://www.washington.edu/research/hsd/guidance/consent/#r)) and anticipated benefits, including relevant risk information as described in the IRB application and any supplemental information (e.g., investigator brochure, drug package insert, device manual)? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described? * Is the language and presentation of the information to be conveyed appropriate to the subject population? (Consider the level of complexity and the need for translation into a language other than English.) * Are the timing of and setting for the explanation of the research conducive to good decision making? Should anything more be done to enhance the prospective subjects' comprehension of the information and their ability to make a choice? * Who will explain the research to potential subjects? Should someone in addition to or other than the researcher be present? * Should subjects be re-educated and their consent required periodically? * If the consent plan excludes some or all of the consent requirements, does the research meet the waiver criteria? Is more than minimal risk involved? Do subjects need to be given more information after completing their participation? * If the subjects are susceptible to pressures, are there mechanisms that might be used to reduce the pressures or minimize their impact? | | | |
| **Discussion items:** | | | |
|  | **3.5 Documentation of consent will be obtained or waived.** | | | |
|  | One of the two options below is true.  **Option 1:** informed consent will be documented by the use of a written consent form and signed by the subject or the subject's legally authorized representative. A copy will be given to the person signing the form.  The documentation of consent can be accomplished using a consent document that embodies the elements of informed consent. An alternate method involving the oral presentation of information to the subject or representative can be used for unexpected encounters with potential subjects who are not English speakers. Review the [GUIDANCE Consent](https://www.washington.edu/research/hsd/guidance/consent/#10) for more detailed information about the requirements for documented consent.  **Option 2:** The research qualifies for a waiver of the documentation requirement. Review the guidance on [Designing the Consent Process](https://www.washington.edu/research/hsd/guidance/consent/design/#waivedoc) for waiver requirements.  **Review:**  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 8. Consent, 11. Economic Burden)  ZIPLINE SmartForm: all consent documents and recruitment materials  **Points to consider:**   * Does the research include a plan to document consent by the use of a written consent form signed by the subject? * Are there any barriers to obtaining documented consent? Have these barriers been adequately addressed? * If the research does not include a plan to documented consent, does the research meet the criteria for a waiver of documented consent? Is more than minimal risk involved? Does the research involve procedures that usually require documented consent? Is the principal risk of the research a loss of confidentiality? * Are there any screening procedures for which a waiver of documented consent is needed? | | | |
| **Discussion items:** | | | |
|  | **3.6 Data and safety monitoring is adequate** | | | |
|  | The research plan must have adequate provision for monitoring the data collected to ensure the safety of subjects, when appropriate. It is UW IRB policy to require a data safety monitoring plan for all clinical trials, independently of whether the research funding source requires it. The monitoring plan should be commensurate with the risks as well as the size and complexity of the research. Review the UW Institute of Translational Health Sciences [guidance on data safety monitoring plans](https://www.iths.org/investigators/services/dsm/data-and-safety-monitoring-plans/).  ***Review:***  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 5. Study Procedures, 10. Risk/Benefit Assessment)  ZIPLINE SmartForm: Supporting Documents and Study Protocol, Data Safety Monitoring Plan, DSMB Charter  ***Points to consider:***   * How will the research data be recorded and maintained? * Are the plans for data and statistical analysis defined and justified, including the use of stopping rules and endpoints? * Is the plan for monitoring the progress and safety of the research adequate in terms of timeliness and thoroughness? * Is the monitoring plan commensurate with the risk and complexity of the research? * If the PI is other than full-time on the project, is the oversight and monitoring time sufficient? * Should the IRB request or recommend that a data and safety monitoring board (DSMB) be appointed? | | | |
| **Discussion items:** | | | |
|  | **3.7 Privacy and Confidentiality are adequately protected.** | | | |
|  | The research must include adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, when appropriate.  *Privacy* refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.  *Confidentiality* refers to how identifiable information about the subject will be protected.  ***Review:***  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 5. Procedures, 9. Privacy and Confidentiality,)  ZIPLINE SmartForm: Supporting Documents and Study Protocol, Measures, Instruments, Supplements  ***Points to consider:***   * Does the research involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? Would reasonable people be offended by such an intrusion? Should the research be revised to avoid the intrusion? * If privacy is to be invaded, does the importance of the research objective justify the intrusion? What, if anything, will the subject be told later? * Do the privacy protections take into account the local context, such as cultural issues, customs and beliefs? * Has the risk level of the data been appropriately classified? Are the data security protections commensurate with the risk level of the data? * Will the research collect sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data through coding, limiting access to the data, or whatever methods that may be appropriate to the study? * If the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, what is the likelihood that research information will be subpoenaed? Should a Certificate of Confidentiality be sought from a federal agency (if the study is not funded by NIH) to protect the research data and the identity of the subjects from subpoena or other legal process? * Are the investigator's disclosures to subjects about confidentiality adequate? * Should documentation of consent be waived in order to protect confidentiality? | | | |
| **Discussion items:** | | | |
|  | **3.8 Any protected and vulnerable populations have adequate safeguards.** | | | |
|  | When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally or physically disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study and in the IRB review process to protect the rights and welfare of these subjects.  ***Review:***  ZIPLINE SmartForm: Basic Information and IRB Protocol (sections: 2. Participants, 3. Setting, 4. Recruiting and Screening Procedures, 6. Children (Minors) and Parent Permission, 7. Assent, 8. Consent, 11. Economic Burden)  ZIPLINE SmartForm: all consent documents, assent forms, and parental permission forms, and recruitment materials  ZIPLINE SmartForm: Supporting Documents and Study Protocol, Measures, Instruments, Supplements  ***Points to consider:***   * Are recruitment procedures designed to assure that informed consent is freely given? * What special safeguards are included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, persons with physical or mental illness, and persons who are economically or educationally disadvantaged)? * Does the nature of the disease or behavioral issue to be studied permit free consent? * Are participation incentives likely to unduly influence a prospective subject's decision to participate? | | | |
| **Discussion items:** | | | |
| 1. **Other requirements and determinations** | | | | |
| **Met** | **Criteria** | | | |
|  | **HIPAA.** When the research involves Protected Health Information under HIPAA, read the Core Education Handbook and review [GUIDANCE HIPAA](https://www.washington.edu/research/policies/guidance-hipaa-2/) for additional regulatory requirements. | | | |
| **Discussion items:** | | | |
|  | **Pregnant women.** When the research involves pregnant women, read the Core Education Handbook chapter for guidance and review [WORKSHEET Pregnant Women](https://www.washington.edu/research/forms-and-templates/worksheet-pregnant-women/) for additional regulatory requirements. | | | |
| **Discussion items:** | | | |
|  | **Prisoners.** When the research involves prisoners, read the Core Education Handbook for guidance and review [WORKSHEET Prisoners](https://www.washington.edu/research/forms-and-templates/worksheet-prisoners/) for additional regulatory requirements. | | | |
| **Discussion items:** | | | |
|  | **Children.** When the research involves children, read the Core Education Handbook for guidance and review [WORKSHEET Children](https://www.washington.edu/research/forms-and-templates/worksheet-children/) for additional regulatory requirements. | | | |
| **Discussion items:** | | | |
|  | **Other applicable requirements and determinations.** Check the Pre-review Note (or the Pre-review Worksheet if reviewing by the expedited process) for other requirements and determinations that apply to the research (e.g., FDA regulations for investigational drugs, devices and/or biologics, special funding agency requirements and so forth). Assess whether these additional requirements have been met using relevant worksheets and SOPs. | | | |
| **Discussion items:** | | | |
| 1. **Motion** | | | | |
|  | **5.1 IRB Action**. Choose one: | | | |
|  | **Approval:** The item is approved. The activity may be conducted within the constraints (if any) established by the IRB. All of the applicable criteria for IRB approval are met (or continue to be met) without any changes, requests for confirmation or additional information, or conditions that must first be fulfilled. | | | |
|  | **Conditional Approval:** The IRB has determined that the applicable criteria for IRB approval have been met, based on the assumption that specific conditions will be met by the investigator and subsequently verified.  The IRB requires as a condition of approval that the investigator: (1) make specified changes; (2) confirm specific assumptions or understandings on the part of the IRB; and/or (3) provide additional or revised information or documents such that, based on the assumption that the conditions are satisfied, the applicable criteria for approval would be met and required determinations would be made. | | | |
|  | **Deferral:** The IRB is unable to approve the research because the applicable criteria for IRB approval have not been met. The IRB defers the item for further review at a future date after modifications and/or additional information have been provided by the investigator.  Modifications, clarification, revised documents and/or additional information are required from the investigator in order to determine that the applicable criteria for IRB approval are met. | | | |
|  | **Disapproval**: The criteria for IRB approval are not met, and the IRB is not willing to re-consider the item.  An item is disapproved rather than deferred when the IRB believes that it is very unlikely that: (1) The applicable criteria for approval will be met even with substantial modifications and/or additional information; or (2) it is not possible to obtain (or the investigator is unwilling to provide) the substantial modifications or additional information that would be necessary to meet the applicable criteria for approval.  ***Note:*** *This action cannot be taken as part of the expedited review process. If the designated reviewer is concerned that the criteria for approval will not be met, the item in question must be taken to the full board for review.* | | | |
|  | **5.2 Risk level.** Choose one: | | | |
|  | [**Minimal risk**](https://www.washington.edu/research/glossary/minimal-risk/)**:**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 tests. | | | |
|  | **More than minimal risk:**The probability and magnitude of harm or discomfort anticipated in the research ARE GREATER in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. | | | |
|  | **5.3 Approval period.**  Choose one: | | | |
|  | Requirements for future continuing review will vary depending on whether a study has federal support as well as IRB consideration of: the nature, magnitude, and probability of the risks; subject vulnerabilities; adverse events; complaints or compliance issues; the investigator’s experience; and other factors.  Primary and Secondary Reviewers should refer to the **Pre-review Note** for information about continuing review regulatory requirements for a particular study. Designated Reviewers and HSD staff should refer to **SOP IRB Review** for guidelines about continuing review requirements. | | | |
|  | |  |  |  | | --- | --- | --- | | **Regulatory requirements for, and frequency of, continuing review** | | | | **Regulatory Authority** | **Continuing Review Required** | **Frequency** | | Revised Common Rule - RCR  (2018 Requirements) | YES, if:   * review by the convened IRB is required * eligible for expedited categories 8b or 9 * the research includes prisoner populations * the IRB or designated reviewer requires it and documents the reason, even if it meets the regulatory criteria for not requiring continuing review   NO\*\*, if:   * eligible for expedited categories 1-7, 8a, or 8c * remaining activities are limited to data/specimen analysis and/or follow-up of clinical care data * approved under Limited IRB Review | ≤ 1 year\*  n/a | | Original Common Rule – OCR  (pre-2018 Requirements)  Food and Drug Administration (FDA)  Department of Justice (DoJ) | YES | ≤ 1 year\* | | OCR + Flexibility Policy\*\*\* | YES | ≤ 3 years |   \* One year is the default for studies that must undergo continuing review but the IRB can grant approval periods of less than one  year if warranted by: the nature, magnitude, or probability of risks; subject vulnerabilities; adverse events; complaints or  compliance issues; the investigator’s experience; and other factors. Alternatively, the IRB may specify a specific enrollment  number as a threshold for when continuing review is to occur (e.g., after 5 subjects have experienced the study intervention or  after six months, whichever comes first).  \*\* The IRB has the option to require continuing review at any time so long as the justification is documented. Examples of what  might be an appropriate justification for requiring continuing review include: the research involves complex issues that may  rapidly evolve into problems; the researcher has a significant recent history of compliance issues; the IRB determines that a  Certificate of Confidentiality (CoC) is required in order for the study to qualify as no greater than minimal risk and an expiration  date will allow the IRB to track expiration of the CoC; the application creates a registry or repository that will give out large  amounts of data/specimens.  \*\*\* Studies approved prior to January 21, 2019 that are eligible for the UW Flexibility Policy (**GUIDANCE Authority and**  **Responsibilities of HSD and UW IRB**) may receive an approval period of up to three years. Review **SOP IRB Review** for details about eligibility criteria. | | | |

**Keywords:** IRB review