**WSU Institutional Review Board - Study Completeness Checklist**

**OFFICE USE ONLY:**

PI:       IRB #:       Date Submitted:

[ ]  Exempt: \_\_\_\_ [ ]  Expedited: \_\_\_\_ [ ]  Full Board

**Required Findings for Approval Letter (check all that apply):**

[ ]  HIPAA – Recruitment Partial Waiver [ ]  HIPAA – Full Waiver [ ]  Consent – Full Waiver

[ ]  Consent – Waiver of Signature/Oral Consent [ ]  Use of LAR [ ]  Non-Significant Risk Device

[ ]  Pregnant Women/Fetus/Neonate [ ]  Children

| **REQUIREMENT** | **COMMENTS** |
| --- | --- |
| TRAINING – IRB Office Only |
| [ ]  All required human research training completed |  |
| [ ]  All required training not completed, emailed PI to notify him/her of necessary training. Training must be completed prior to final approval. |  |
| [ ]  N/A |  |
| STUDY APPLICATION |
| [ ]  Key Personnel Section Completed |  |
| [ ]  Study Funding Completed  [ ]  Federally funded  |  |
| [ ]  Project-Specific Disclosure Form completed and attached [ ]  IRB Review of Management Plan [ ]  N/A |  |
| [ ]  Ancillary Reviews Completed  [ ]  All supporting documents attached [ ]  N/A IBC Review [ ]  Pending [ ]  Complete [ ]  N/A   |  |
| [ ]  Key Study Information Included [ ]  N/A |  |
| [ ]  Study Procedures Questions Complete and Accurate[ ]  Full Protocol Attached [ ]  N/A [ ]  Investigator-Initiated Study [ ]  Non-Significant Risk Device determination (document finding in approval letter [ ]  IND/IDE is held by PI or member of study team |  |
| [ ]  Risks |  |
| [ ]  Benefits and Alternatives |  |
| [ ]  Privacy questions completed and provide adequate protections. |  |
| [ ]  Confidentiality and Data Security plan is appropriate and mirrors protocol:* Specific description of how data will be collected (e.g., paper or electronic CRFs) and access within study team.
* Specific description of how and where study data will be maintained locally.
* Specific description of how and what study data will be disclosed to sponsor and/or external collaborators (e.g., electronic submission) including what security measures are in place (e.g., encryption).
* Specific description of how long data will be maintained locally, including what identifiers will be maintained long term.
 |  |
| [ ]  Cost and Compensation |  |
| VULNERABLE POPULATIONS/SUBPARTS |
| [ ]  N/A No Subparts Apply |  |
| [ ]  PI Completed Pregnant Women, Pregnant Women, Neonates, and/or Human Placenta or Fetal Material Form (document findings in approval letter) |  |
| [ ]  Children [ ]  Written/Oral Assent [ ]  Parental Permission (document findings in approval letter)  |  |
| [ ]  Other |  |
| HIPAA |
| [ ]  N/A Does not involve PHI |  |
| [ ]  PI provided a list of PHI that will be recorded prior to authorization? [ ]  N/A |  |
| [ ]  PI provide adequate description of how this PHI will be managed and destroyed for subjects who do not provide authorization? [ ]  N/A |  |
| [ ]  WSU Authorization Template Language in Consent Form |  |
| [ ]  Non-template Authorization language used, all of the following in highlighted version:* Element #1 - A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
* Element #2 - The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure (e.g., PI Name and his/her research staff members at WSU/Premier).
* Element #3 - The names of individuals, organizations, companies, and/or class of individuals to whom WSU/Premier officials and researchers (the covered entity) may disclose (share) or who may use the subject’s PHI in relation to the research study.
* Element #4 - A description of the purpose(s) of the requested use or disclosure.
* Element #5 - The authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
* Element #6 - Signature of the individual and date. If the subject's legally authorized representative signs the authorization, a description of the representative's authority to act for the individual must also be provided.
* Statement #1 - A statement of the subject's right to revoke authorization and how to do so, and, if applicable, the exceptions to the right to revoke authorization.
* Statement #2 – A statement explaining whether non-research treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization. In addition, whether a subject can still participate in research study if they don’t provide authorization.
* Statement #3 - A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.
 |  |
| [ ]  Partial or Full Waiver (document finding in approval letter)[ ]  Recruiting and Eligibility Screening of Ident. Info.* The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
* The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
 |  |
| INFORMED CONSENT |
| [ ]  N/A Exempt Study |  |
| [ ]  Waiver requested under 46.116(d): Waiver or Alteration of Required Elements of Consent with Justification to Support Finding (document finding in approval letter) |  |
| [ ]  Waiver requested under 46.117(c): Waiver of Written Documentation Consent with Justification to Support Finding (document finding in approval letter) |  |
| [ ]  Single ICF [ ]  Multiple ICFs [ ]  N/A |  |
| [ ]  ICFs contain all required elements: * Statement that the study involves research.
* Explanation of the purposes of the research.
* Expected duration of the subject’s participation.
* Description of the procedures to be followed.
* Identification of any procedures that are experimental.
* Description of any reasonably foreseeable risks or discomforts to the subject.
* Description of any benefits to the subject or to others which may be reasonably expected from the research.
* Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
* Statement describing the extent to which confidentiality of records identifying the subject will be maintained and should identify entities, such as health care providers, clinical investigators, sponsors, contract research organizations, study monitors, and regulatory agencies who may gain access to the subject’s electronic health record relating to the clinical investigation.
* For research involving more than minimal risk, and explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they include and how to access them.
* Explanation of whom to contact for answers to questions or for complaints about the research.
* Explanation of whom to contact for answers to questions about injury.
* Explanation of whom to contact concerning rights as a research subject.
* Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the subject may withdraw without penalty at any time.
* For research that involves the collection of identifiable private information or identifiable biospecimens, include one of the following statements: (1) Identifiers might be removed from your identifiable private information (or/and identifiable biospecimens). After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your (or your legally authorized representative’s) consent; or (2) Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
* For federally-funded studies approved on or after January 21, 2019, consent includes 1-page key information summary.
 |  |
| [ ]  Additional Elements (only required when appropriate) 46.116(b) √ if present* A statement that the FDA may inspect subject’s records that should not imply that the FDA needs permission from subject to do so.
* For Applicable Clinical Trials includes the following statement: *“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.”*

**An Applicable Clinical trial is a trial in which the:*** Study type is interventional
* Primary purpose is NOT device feasibility
* Studies an FDA-regulated device product, and
* One or more of the following:
	+ At least one U.S. facility location
	+ Product manufactured in and exported from the United States
	+ Conducted under an FDA IDE

**OR*** Study type is interventional
* Primary purpose is NOT phase 1
* Studies an FDA-regulated drug product (including biological product), and
* One or more of the following:
	+ At least one U.S. facility location
	+ Product manufactured in and exported from the United States
	+ Conducted under an FDA IND
* If women are enrolled who are capable of becoming pregnant a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
* Anticipated circumstances under which the subject's participation may be terminated by the Principal Investigator without regard to the subject's consent
* Any additional cost to the subject that may be a result from participation in the research
* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
* A statement that 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
* The approximate number of subjects involved in the study. If the research involves a multi-site study, the total number of subjects at all sites should also be provided.
* 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).
* For all research involving a Test Article regulated by the FDA, informed consent documents must include, as applicable:
* A statement that the purpose of the study includes an evaluation of the safety of the Test Article.
* The regulatory status of the agent using terms that can be easily understood by the targeted subject population. For example, “the use of drug [insert name] in this study is considered investigational, meaning it has not been approved by the FDA for marketing in the US for the use being tested in this research.”
* For related clinical testing, the amount of blood or other fluids to be obtained
* If funded, the name of the sponsor or funding agency and a statement that the sponsor is providing funds for the conduct of the research. If the study is sponsored by an internal department, this should also be listed in the consent document
* Any conflict of interest disclosure language required by WSU
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| [ ]  Research uses IRB-reviewed screening consent/telephone script for recruitment [ ]  N/A |  |
| [ ]  Consent process detailed and appropriate |  |
| [ ]  LAR use justified and appropriate process in place[ ]  N/A |  |
| DATA AND SAFETY MONITORING |
| [ ]  No plan needed – not a clinical intervention or more than minimal risk |  |
| [ ]  Data and Safety monitoring plan detailed and appropriate |  |
| SUPPORTING DOCUMENTS |
| [ ]  Questionnaires, surveys, diaries, personality tests, quality of life assessments or other surveys, data collection forms, interview and focus group scripts, etc.…. attached[ ]  N/A |  |
| [ ]  All recruitment materials, including advertisements, brochures, letters to physicians, etc.… [ ]  N/A |  |
| Continuing Review/Administrative Update Determination |
| [ ]  FDA Regulated – 1 Year CR required[ ]  Meet Expedited Criteria for Renewal – 2 Year Adm. Renewal[ ]  Full Board Review – 1 Year CR required |  |
| REVIEWED BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name |