Full Board Review  Expedited/Chair Review

|  |  |
| --- | --- |
| Reviewer: | Principal Investigator : |

|  |  |
| --- | --- |
| Protocol #: | Submission ID: |

Do you have a conflict of interest with this study? Yes  No

| **Protocol/Application Checklist** | **Yes** | **No** | **N/A or Comments** |
| --- | --- | --- | --- |
| Overview of Changes |  |  |  |
| Is the purpose for changes clear? |  |  |  |
| Have the study documents been appropriately updated?► If no, what additional changes are needed? |  |  |  |
| Is new funding being added?s)anges clear |  |  |  |
| If the new funding is federal, have we received a copy of the funding proposal? |  |  | **N/A** |
| ► If yes, is it consistent with the protocol? |  |  |  |
| ► If yes, does the consent form need CoC language? |  |  |  |
| Is a new site being added? ► If yes, please complete *Section C: Performance Sites* below. |  |  |  |
| **Level of Review:** |  |  |  |
| 1. Do all new procedures still fall into categories (1)-(7) of research that can be reviewed under expedited procedures? |  |  | **N/A**  (If no, defer to FB.) |
| For research previously approved as Expedited: |  |  | **N/A** |
| 1. Do the changes increase risk to more than minimal? |  |  | (If yes, defer to FB.) |
| For research previously approved by Full Board, only minor changes to the research may be approved under expedited procedures: |  |  | **N/A – Not FB** |
| 1. Do the changes increase risks to subjects more than minimally? |  |  | (If yes, defer to FB.) |
| 1. Do the changes substantively change the research design or methodology?  * *For example, adding a new study arm or subject population, or changing the drug or device being studied* |  |  | (If yes, defer to FB.) |
| 1. Do the changes reduce safety?  * *For example, cutting back on data and safety monitoring, testing performed for subject safety, or moving the study to a site with inadequate safety infrastructure*. |  |  | (If yes, defer to FB.) |
| 1. Are changes being made to inclusion or exclusion criteria that result in increased risks for future subjects? |  |  | (If yes, defer to FB.) |

**REMEMBER**: The Chair can only approve **minor** changes to **full board** studies via expedited review. If it is not a minor change, defer to full board for review.

If FB review and/or not a minor change, complete the rest of the checklist as applicable.

**Does the amendment change the risk level of the study?**

Yes  No

**Based on the changes made to the protocol and/or consent, is re-consent of subjects required?**

Yes (Currently enrolled subjects, if any, affected by the changes must sign the revised consent form.)

No (The changes are administrative in nature, and/or do not affect procedures or risks to subjects)

N/A (Consent form not revised in amendment)

► Reviewer Recommendation

Approved as a minor change (Expedited or Chair review ONLY)

Approved as a minor change with Administrative Changes (Expedited or Chair review ONLY)

Deferred to full board as more than a minor change

If minor modifications are required, complete the rest of the checklist, as applicable.

Summary of Changes/Comments (if needed):  See E-mailed Comments

|  |  |
| --- | --- |
|  |  |

Reviewer Date

| Protocol/Application Checklist | **Yes** | **No** | **N/A or Comments** |
| --- | --- | --- | --- |
| Funding |  |  | **Amendment does not affect section** |
| Is the project now funded by a federal grant or cooperative agreement? If yes, Grant #:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| ► If Yes, is the grant application consistent with the protocol? |  |  |  |
| Is NIH or CDC sponsoring/funding the research? (*in whole or in part*) |  |  |  |
| ► If Yes, does the consent form need CoC language? |  |  |  |
| Is there a new source of funding that may indicate a conflict of interest with the conduct of the study? |  |  |  |
| Is this study funded by the Department of Education or performed in public schools? |  |  | (See separate [DoEd checklist](http://gcrc.ucdenver.edu/comirb/DOE-Checklist.doc) to make sure changes do not affect DoEd requirements ) |
| Is this study funded by the Department of Defense? ► If yes, please complete *Section I, Scientific Review* below. |  |  | (See separate [DoD checklist](http://gcrc.ucdenver.edu/comirb/DOD-Checklist.doc) to make sure changes do not affect DoD requirements) |
| 1. **Performance Sites (**[**Engagement of Institutions in Research**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)**)** |  |  | **Amendment does not affect section** |
| 1. If adding DHHA, has SPARO approval been received? |  |  | N/A |
| 1. If adding CTRC, has adult/pediatric CTRC approval been received? |  |  | N/A |
| 1. Does the amendment **add** public schools/daycares with subjs <18yo, or any **new** access to student academic records (including grad students)? |  |  | (If yes, complete [DoEd checklist](http://gcrc.ucdenver.edu/comirb/DOE-Checklist.doc)) |
| 1. Indicate any **change** in VA involvement:   VA-only study **(answer all VA requirement questions)**  Multi-site study involving VA **(answer all VA requirement questions)**  *VA Purple Clearance been received*  Non-VA study/Yellow clearance **(VA requirement questions are N/A)**  *VA Yellow Clearance been received* |  |  | No change in VA involvement |
| 1. Are there any **new** non-affiliated sites added? |  |  |  |
| If yes:  Alternate IRB will review new non-affiliated sites(Request IRB approval(s)if UCD/affiliate is central site)  COMIRB will be IRB of record for new site:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ( IRB Authorization received or  IRB Contract in place)  **Study must have an expiration date for Single IRB requirement**    New Sites are not ‘engaged in research’  [see engagement criteria below; OHRP guidance, Oct 16, 2008]  List **new** non-engaged site(s):\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  | (If yes, complete [Relying Sites Checklist](https://research.cuanschutz.edu/docs/librariesprovider148/comirb_documents/forms/cf-143_relying-site-checklist.doc?sfvrsn=853485b9_2)) |
| 6. Is UCD being added as the lead-site?  ► If yes, an oversight plan signed-off by the institution is required prior to  COMIRB approval. |  |  |  |
| 1. **Subject Selection** |  |  | **Amendment does not affect section** |
| 1. Is the selection of subjects **still** reasonable and equitable? |  |  |  |
| 1. If any group such as minorities and women are now not included, is there adequate justification? |  |  |  |
| 1. Are the inclusion/exclusion criteria **still** appropriate? |  |  |  |
| 1. **Vulnerable Subjects/Special Populations Added** |  |  | **Amendment does not affect section** |
| 1. Pregnant women/fetuses |  |  | (Complete checklist) |
| 1. Children |  |  | (Complete checklist) |
| 1. Neonates |  |  | (Complete checklist) |
| 1. Prisoners |  |  | (Complete checklist) |
| 1. Adults who cannot consent for themselves (Decisionally Challenged) |  |  | (Complete checklist) |
| 1. Genetic testing with identifiers:   Considerations: commercialization, involves sensitive population, genome mapping or also includes substantial accompanying identifiable data  ► Should the study be reviewed at full board? |  |  |  |
| 1. Growth of perpetual cell lines not disclosed in the consent:   Considerations: Not disclosed in the consent, pediatric, includes identifiable data  ► Should the study be reviewed at full board? |  |  |  |
| 1. Classified research involving human subjects |  |  | (Requires full board review) |
| 1. Major Deception |  |  | (Requires full board review) |
| 1. Fetal or embryonic tissue (identifiable or not identifiable) |  |  | (Requires review by Ethics Committee on Fetal Tissue prior to COMIRB approval) |
| 1. Other (describe): |  |  |  |
| 1. Have appropriate safeguards been included in the study to protect their rights and welfare? |  |  |  |
| **Comments:** |  |  |  |
| **VA Requirements**   1. Has the Facility Director certification been obtained for inclusion of Prisoners? |  |  | **N/A – VA not a site** |
| 1. Has the Facility Director certification been obtained for inclusion of Pregnant Women? |  |  |  |
| 1. Has the Medical Center Director approval been obtained for inclusion of Children? |  |  |  |
| 1. If Children are being included in research, has the relevance to the VA population been described? |  |  |  |
| 1. Research involving neonates is limited to prospective observational and/or retrospective record review studies. |  |  |  |
| 1. **Procedures** |  |  | **Amendment does not affect section** |
| 1. Are the **new** research procedures adequately described? |  |  | N/A |
| 1. Are the **new** sources of the data and/or specimens adequately identified? |  |  | N/A |
| 1. Are any data or specimens collected in the European Union? If so, consult with COMIRB Director or Assistant Director. |  |  |  |
| 1. Is standard care/treatment adequately described (see Application p.4-5)? |  |  | N/A |
| 1. Does the protocol still adequately distinguish how the research procedures differ from standard care/treatment? |  |  | N/A |
| 1. Are the procedures **still** consistent with sound research design? |  |  | N/A |
| 1. Are any **added** subject materials submitted for review (data collection tools, questionnaires, educational materials, etc.)? |  |  | N/A |
| **VA Requirements**  7. Do you have any concerns with the procedures performed at the VA? |  |  | **N/A – VA not a site** |
| 1. **FDA Drugs** |  |  | **Amendment does not affect section** |
| 1. Are drugs that are **not** FDA-approved given to subjects? |  |  | (If yes, full board review is required) |
| ► If yes, the study has an IND documented by one of the following:  Sponsor protocol imprinted with IND#  Written communication from Sponsor documenting IND#  Written communication from FDA documenting IND# |  |  |  |
| 2. Are drugs that are FDA-approved given to subjects? |  |  |  |
| ► If yes, are all drugs being used according to FDA labeling? |  |  | (If no, full board review required) |
| ► If no, answer the following questions:  Study seeks a new indication for use or other change in labeling  Study seeks a significant change in the advertising of the product  Study uses a new route of drug administration, drug dose or patient population that increases risks or decreases the acceptability of risks  Study misrepresents the safety/effectiveness of the investigational drug use, or violates other requirements concerning the promotion and sale of drugs [21CFR 312.7]  Study requests a waiver of consent |  |  | *If any of these are checked, study requires an IND;* (discuss at meeting).  *If none of the boxes are checked then study is IND Exempt but FDA regulated.* |
| 3. Is the plan to dispense, store, and dispose of the drugs used in the study appropriate? |  |  |  |
| 4. Is a radioactive drug being added that is also under the jurisdiction of the Radioactive Drug Research Committee (RDRC)? [Does not include clinical trials or drugs under an IND]  • If yes, confirm RDRC approval has been submitted  • If study is already under RDRC oversight, include in feedback that PAM must also be submitted to RDRC |  |  |  |
| 5. Is a drug being used that is also under the jurisdiction of the Institutional Biosafety Committee (IBC)? [e.g., gene transfer or use of recombinant DNA]  • If yes, confirm IBC approval has been submitted  • If study is already under IBC oversight, include in feedback that PAM must also be submitted to IBC |  |  |  |
| **H. Devices** |  |  | **Amendment does not affect section** |
| * 1. Does the research now collect safety and/or efficacy data on medical device(s) in human subjects or on human specimens? |  |  | (If yes, complete separate Device Checklist; request from study coordinator) |
| Check yes if:  • Study collects data to determine device’s ability to (or safety in its use to) diagnose, predict, prevent, treat, cure or mitigate a disease process.  • Study collects data to determine device’s ability to (or safety in its use to) affect the structure or function of the body.  *Examples:*  *- Device’s ability to decrease symptoms in patients with X*  *- Device studied for its safety in identifying patients with X,Y,Z symptoms*  *- Device used to predict future occurrence of disease X*  *- Device’s ability to improve X function (e.g., intestinal motility, attention span, grip strength).*  Check no if:  • The device is being used as a tool to collect physiology data that does not directly relate to diagnosing or altering a disease process.  • The device is being used as a tool to alter body physiology or function in order to study a physiologic principle.  *Examples:*  *- Device used to measure liver size in patients with X vs. controls*  *- Device used to cool skin to see if erector pili muscle function differs in people with condition X vs. controls*  *- Device measures X function (e.g., intestinal motility, attention span, grip strength) to see how symptomatic patients differ from asymptomatic ones* |  |  |  |
| 2. Does PAM add an FDA-approved device that has been modified, where there is testing to determine safety or effectiveness, or the testing puts subjects at risk? |  |  | (If yes, complete separate Device Checklist) |
| 3. Does this amendment add use of an HUD? |  |  | (If yes, complete separate Device Checklist) |
| 1. **Scientific Design** |  |  | **Amendment does not affect section (complete if substantive changes to study design)** |
| * 1. Have the design **changes** had other scientific review (SARC, NIH, Other)?   If no, answer the following: |  |  |  |
| 1. Is the experimental treatment/manipulation **still** justified? |  |  |  |
| 1. Is the scientific design **still** appropriate? |  |  |  |
| 1. Is data analysis **still** adequate to achieve the study aims? |  |  |  |
| 1. Is the Application consistent with the protocol? |  |  |  |
| 1. **Risks** |  |  | **Amendment does not affect section** |
| 1. Is there **still** a clear and accurate identification of risks? |  |  |  |
| 2. Are the risks of any experimental arm(s) **still** clearly described? |  |  | N/A |
| 3. Are the risks of any control arm(s) **still** clearly described? |  |  | N/A |
| 4. Are any risks from deviations from standard care, placebo use, medication switching, or wash-out periods still clearly described? |  |  | N/A |
| 5. Is there **still** adequate follow-up for subjects following participation? |  |  | N/A |
| 6. Are any new risks of legal reporting requirements to external agencies (e.g. child abuse, HIV status, etc.) acknowledged by PI?  ► If yes, remember to look for appropriate disclosure in the consent, '*Who Will See My Research Information?'* section.  7. Are the risks still minimized? |  |  | N/A  N/A |
| 1. **Recruitment** |  |  | **Amendment does not affect section** |
| 1. Do you have any concerns with recruitment methods/plan described in the Application/protocol?   Concerns: |  |  |  |
| 1. Do the investigators still have the appropriate relationship with subjects for direct contact of potential subjects? |  |  | N/A |
| 1. Is the number of attempted direct contacts (per subject) excessive? |  |  | N/A |
| 1. Assess the following for any new advertisements added: |  |  | N/A |
| Advertisements must: |  |  |  |
| Reference PI and COMIRB # |  |  |  |
| Advertisements must **not**: |  |  |  |
| Imply a certainty of favorable outcome |  |  |  |
| Imply study provides treatment (must state "research" not just "study") |  |  |  |
| Promise free medical care |  |  |  |
| Overemphasize payments |  |  |  |
| 1. Is subject pre-screening added? (see [COMIRB pre-screen guidance](http://gcrc.ucdenver.edu/comirb/Guidance-Pre-screening.doc)) |  |  |  |
| ►If yes: Are waivers of consent or documentation of consent needed? |  |  |  |
| Are pre-screening data handled appropriately? |  |  |  |
| 1. Compensation is still reasonable and does not unduly influence subjects? |  |  | N/A – no payments |
| 1. Are payments pro-rated (if appropriate)? |  |  | N/A – no payments |
| **VA Requirements**   1. Non-veterans can only be enrolled if there are insufficient veterans available to complete the study. Is an appropriate plan outlined? |  |  | **N/A – VA not a site** |
| 1. **Waiver of Process of Consent** |  |  | **Amendment does not affect section** |
| 1. Category I or Category II criteria must be satisfied (except for FDA emergency waivers, see #2) | | |  |
| Category I |  |  | **N/A** |
| a) The procedures involves no more than minimal risk; **and** |  |  |  |
| b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;  For this criterion, be especially careful to consider the following:  ● If the study proposes re-use of data/samples previously collected for research purposes, was consent to bank and re-use these samples in the future given by subjects?  ● Are the aims of the current study consistent with the possible uses of banked data/samples previously consented subjects were informed of?  ● For both subjects who consented and did not provide consent for the proposed activities, will the current study produce results about the subject, or a specific group represented by the him/her, that are sensitive or otherwise stigmatizing?  **and** |  |  |  |
| c) The research could not practicably be carried out without the waiver(i.e., the project could not meet its aims if consent were required)  **and** |  |  |  |
| d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation |  |  |  |
| Category II |  |  | **N/A** |
| a) The research is **not** subject to FDA regulations; **and** |  |  |  |
| b) The research could not practicably be carried out without the waiver; **and** |  |  |  |
| c) The research project is to be conducted by, or subject to the approval of state or local government officials; **and** |  |  |  |
| d) Is designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. |  |  |  |
| 1. Is an emergency research waiver of consent being requested?   ►**ONLY** for FDA research (21 cfr 50.24) |  |  | ***If yes, the project is not eligible for expedited review****.* |
| 1. Will the researchers mislead or deceive subjects? |  |  |  |
| ► If Yes,  Major: mislead subjects about their health status, the researchers, or research purpose.  *If checked, full board review is required*  Minor: incompletely disclose some purpose of the study to avoid biasing results | | |  |
| 1. **Waiver of Documentation of Informed Consent** |  |  | **Amendment does not affect section** |
| 1. The IRB may waive the requirement to obtain a signed form if: |  |  |  |
| 1. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. |  |  |  |
| **-OR-** |  |  |  |
| 1. The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context. |  |  |  |
| 2. Does the information provided to participants include all required and appropriate additional elements of consent? |  |  |  |
| 3. Should the participant be provided with written information? |  |  |  |
| 1. **Consent Process** |  |  | **Amendment does not affect section** |
| 1. Are the **revised** procedures adequate to inform and negotiate consent? |  |  |  |
| 1. Is sufficient opportunity given to the prospective participant or representative to read and consider whether or not to participate? |  |  |  |
| 1. Are there elements ofinfluence or possible coercion that exist to entice consent (e.g. excessive compensation, unequal relationship provider-patient, employer-employee, and instructor-student) |  |  |  |
| ► If yes, are there procedures in place to minimize coercion? |  |  |  |
| 1. Will non-English speaking subjects be enrolled? |  |  |  |
| ► If yes, is an appropriate plan outlined?  **and**   * Are there appropriate resources/witness available? (short form will be used, consent will be translated into other language, waiver of documentation of consent has been requested) |  |  |  |
| ► If no, is their exclusion appropriate? |  |  |  |
| 1. If excluding non-English speaking subjects, provide rationale:   Respect to the health of the subjects,  The scientific purpose of the research, or  The scientific design of the research. | **N/A**  **Comments:** | | |
| 1. Will non-reading individuals be enrolled? |  |  |  |
| ► If yes, is there a plan to read the consent form and have an independent witness present? |  |  |  |
| 1. Is any of the research now under the purview of COMIRB, to be conducted outside Colorado?   ► If yes, is a verifiable definition of “legally authorized representative,” “children,” “guardian,” and any other relevant state law needed? |  |  |  |
| 1. Is consent **still** appropriately documented, and a copy of the signed and dated consent form given to the person signing the form? |  |  | **N/A – consent documentation waived** |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| 1. If pre-screening of subjects occurs at the VA, are waivers of consent and HIPAA requested? |  |  |  |
| 1. If recruiting from a recruitment database, are waivers of consent and HIPAA requested? |  |  |  |
| 1. For VHA regulated research, will consent be documented through the use of VA Consent Form (Form 10-1086)? |  |  |  |
| 1. Will the study maintain a master list of subjects (or is adequate justification provided to not maintain this list)? |  |  |  |
| 1. **Privacy and Confidentiality** |  |  | **Amendment does not affect section** |
| 1. Do the **revised** procedures adequately maintain privacy of the subjects? |  |  |  |
| 1. Are procedures **still** adequate to protect data confidentiality and anonymity? |  |  |  |
| 1. Does the researcher collect the minimal amount of identifying information necessary to achieve the aims of the study? |  |  |  |
| 1. Is the investigator now collecting any information such that the identification of the subjects or their responses could increase the risk to the subject?   Consider:   * information about sexual attitudes, preferences, practices; * information about personal use of alcohol, drugs, or other addictive products; * information about illegal activities; * information that could damage an individual's financial standing, employability, or reputation within the community; * information in a subject's medical record that could lead to social stigmatization or discrimination; or * information about psychological well-being/mental health |  |  |  |
| ► If YES, are there reasonable and appropriate safeguards to ensure the risks related to invasion of privacy and breach of confidentiality is no greater than minimal? |  |  |  |
| 1. For non-NIH funded research: Are the study data so sensitive that a Certificate of Confidentiality is required to protect against subpoena risk? |  |  | **N/A**       If yes, remember to look for appropriate disclosure in the consent. |
| 1. If a Certificate of Confidentiality is involved, and the study takes place at UCHealth, is the subject matter of the study so sensitive that the consent form be excluded from the medical record? (i.e., the study is about sensitive information and subjects’ require additional confidentiality protections) |  |  | **N/A**       If yes, this should be noted in the feedback letter. |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| 1. Is VA sensitive data appropriately stored at the VA (or waiver obtained)? |  |  |  |
| 1. Are there appropriate protections for Social Security #s (whole partial, or scrambled) collected? |  |  |  |
| 1. Will the study maintain a master list of subjects (or is adequate justification provided to not maintain this list)? |  |  |  |
| 1. **HIPAA** |  |  | **Amendment does not affect section** |
| 1. Are the HIPAA Authorization Forms **still** appropriate: |  |  |  |
| 1. Waiver of Authorization |  |  | *(Complete separate checklist)* |
| 1. Authorization A form (recruitment) |  |  |  |
| 1. Authorization B (either built-in or separate form) |  |  |  |
| 1. Are all of the appropriate, specific outside disclosures still made? |  |  | N/A |
| 1. Is the expiration date of authorization listed (or 'has no time limit'/'will not expire')? |  |  | N/A |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| 1. Will VA data be released outside of the VA? |  |  |  |
| 1. Are all disclosures of PHI outside of the VA, even if to another UCD-affiliate, made in both the HIPAA B form and the consent form? |  |  |  |
| ► If no, are the appropriate waivers submitted? |  |  |  |
| 1. **Data Management and Security** |  |  | **Amendment does not affect section** |
| 1. Will computer data be held in a secure manner? |  |  | N/A |
| 1. Will audio/visual data be held in a secure manner? |  |  | N/A |
| 1. Is there a plan to disguise or destroy unintentional identifying information collected during the recordings? |  |  | N/A |
| 1. Will paper records be held in a secure manner? |  |  | N/A |
| 1. Will biological samples be stored securely? |  |  | N/A |
| 1. Is the data destruction plan acceptable? |  |  | N/A |
| **VA Requirements**   1. Is the storage plan appropriate for the data collected in the VA-regulated portion of the study? |  |  | **N/A – VA not a site** |
| 1. If data will be stored outside the VA, are the appropriate arrangements made to identify and disclose a data Coordinating Center? |  |  |  |
| 1. Will VA biological samples be stored on VA property (or appropriate waiver obtained)? |  |  |  |
| 1. Will VA data be retained per current VA policy? |  |  |  |
| 1. **Data Safety Monitoring Plan** |  |  | **Amendment does not affect section** |
| 1. Will the investigator **still** monitor for and report unanticipated problems to COMIRB within 5 days? |  |  |  |
| 1. Is the data safety monitoring plan **still** appropriate, given the scope and activities of the project? |  |  |  |
| 1. Is the plan to monitor and ensure subject safety **still** adequate?   ► List any concerns: |  |  |  |
| 1. Are precautions **still** adequate to decrease the likelihood of harm (e.g. plans for referrals for new diagnoses relating to research procedures: hotlines, counseling, clinical evaluation)? |  |  |  |
| 1. Are there **still** adequate contingencies to deal with harms if they occur? |  |  |  |
| 1. Are the study stopping rules and participant discontinuation criteria **still** reasonable and appropriate? |  |  |  |
| 1. **Resources** |  |  | **Amendment does not affect section** |
| 1. Does the investigator **still** have access to a population that will allow recruitment of the necessary number of subjects? |  |  |  |
| 1. Does the investigator have adequate resources to conduct the research (e.g. time, staff, facilities)? |  |  |  |
| 1. If student/trainee PI, or mentor, is **being changed**, have new signed Student/Trainee and Mentor responsibility agreements been submitted? |  |  | N/A |
| 1. If subjects might now require medical/psychological resources as a result of the research, are these resources identified/available? |  |  | N/A |
| 1. If PI is now the lead investigator in a multi-center study, is there an adequate plan to manage the study and monitor safety across sites? |  |  | N/A |
| 1. **Conflict of Interest** |  |  | **Amendment does not affect section** |
| 1. Is the COI Committee management plan (or determination that no plan is needed) submitted? |  |  | **If no, defer to FB** |
| ► If yes, consider the following questions:   1. Does the COI management plan indicate an institutional conflict of interest (e.g., Institution holds patent or intellectual property)?    * + - If yes and the COI management plan recommends it, is the institutional COI adequately disclosed in the consent form? 2. Does the COI management plan indicate an investigator COI (PI and/or co-investigators)?  * If yes and the COI management plan recommends it, is the investigators' COI adequately disclosed in the consent form?  1. Level of DSMP oversight described in the Application (Section P of the Application form)/Protocol  * Is the level of oversight adequate for the safety of subjects or integrity of study data? * Is the level of independence in the DSMP appropriate (e.g., PI, DMC, DSMB)? * Is additional oversight needed? If yes, what do you recommend? |  |  | N/A  [If no, request the COI disclosure be added to the consent form.]  [If no, request the COI disclosure be added to the consent form.] |
| 1. Do you expect the impact of COI would change over the course of development of the device or drug?   ► If yes, are there any additional human subject protections that should be considered given the management plan provided |  |  |  |
| 1. Are there any **non-financial** COIs that should be considered (e.g., supervisory roles or other positions of power relative to subjects, and results to address)? |  |  | **[if yes, detail]** |
| 1. **clinicaltrials.gov** |  |  | **Amendment does not affect section** |
| 1. Does the amendment change this study to an applicable clinical trial?  * Please use this algorithm if the study **newly** tests drugs/device interventions.   Brief algorithm: <http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm> |  |  |  |
| 1. If study has been changed to become an applicable clinical trial, is the required language now in the consent form (see Consent Checklist, section N)? |  |  |  |
| 1. **Risk/Benefit Assessment** |  |  | **Amendment does not affect section** |
| 1. Has the amendment changed the risk/benefit ratio of the study?   ► If yes, why? |  |  |  |
| 1. Are the risks still reasonable in relation to the benefits?   ► If no, why not? |  |  |  |

**N/A – Amendment does not affect consent documentation (skip to Reviewer Recommendation)**

| **Consent Form Checklist** | **YES** | **NO** | **COMMENTS or N/A** |
| --- | --- | --- | --- |
| **The standard language examples below are not required as long as the required elements of informed consent are met.** |  |  |  |
| 1. **Key Information**   Informed consent begins with a concise and focused presentation of the key information. Applicability:   * + - Consent is longer than 6 pages (not including optional procedures or HIPAA), and     - The study is being approved under the 2018 requirements. |  |  | **No change** |
| 1. **Why is this study being done?**   Research purposes (i.e. protocol’s objectives) are clearly stated.   * + - “*This study plans to learn more about…*”     - “*You are being asked to be in this research study because…*” |  |  | **No change** |
| Other people in this study Number of participants is consistent with protocol.   * + - “*Up to <x> people from your area will participate in the study.*”     - “*Up to <x> people around the country will be in the study.* “ |  |  | **No change** |
| 1. **What happens if I join this study?**   All procedures or treatments to be done are described.  Which procedure(s) or treatment(s) are experimental is clearly stated.\*  Expected duration of subject participation.   * + - “*If you join the study, you will…*” |  |  | **No change** |
| 1. **What are the possible discomforts or risks?**   Reasonably foreseeable discomforts are described.  Risks are consistent with protocol.  Risks of all research-related treatments/procedures (**if they are directed by the protocol, they should not be considered standard care**…they are research-related) are described.   * + - “*Discomforts you may experience while in this study include…*”     - “*Other possible risks include…*”     - *If applicable:* “*The study may include risks that are unknown at this time*” (if risks well known- not required) |  |  | **No change** |
| 1. **What are the possible benefits of the study?**   Expected benefits are reasonably described.  Compensation is not listed as a benefit   * + - *Non-therapeutic study*: "This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks."     - *Therapeutic study*:"This study is designed for the researcher to learn more about \_\_\_\_\_\_\_\_. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks." |  |  | **No change** |
| 1. **Are there alternative treatments?**   Alternatives to the research’s diagnostic method or treatment. (If not therapeutic, section not required.) |  |  | **No change** |
| 1. **Who is paying for this study?**   Sponsor/funding is listed. (If no sponsor, section not required)   * + - “*The research is being paid for by <name>.*” |  |  | **No change** |
| 1. **Will I be paid for being in the study?**   Subject payment is consistent with protocol.   * + - “*You will not be paid to be in the study*.”     - “*You will be paid $XX.XX for each visit in this study. This will add up to a total of $XXX.XX if you complete all of the visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed*.”     - “*It is important to know that payments for participation in a study is taxable income.”* |  |  | **No change** |
| 1. **Will I have to pay for anything?**   Costs of participation are described, using one of the standard statements below.   * *“You will not be charged for [the study device/drug or] any of the study procedures or office visits for the study.”* * “*You and your insurance will have to pay for all of the visits, procedures and care described in this consent form. You will be responsible for co-payments and deductibles that are standard for your insurance coverage.” for…*” * “*You and your insurance will have to pay for the visits, procedures and care that are routine care for your medical condition. You will be responsible for co-payments and deductibles that are standard for your insurance coverage. The study will pay for visits, procedures and care done only for the research; these include, though may not be limited to, [insert high level list of study-funded procedures].”* |  |  | **No change** |
| Is my participation voluntary?  * “*Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.”* * *If applicable: “If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.”* * If applicable: “*If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.*” |  |  | **No change** |
| Can I be removed from this study?  * “*The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.*” * *If applicable*, “*Also, the sponsor may stop the study at any time.*” |  |  | **No change** |
| What Happens If I am Hurt?  * *If applicable, state: “If you have an injury while you are in this study, you should call <insert name> immediately. [His/her] phone number is <insert phone number>.”* * *“We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.” OR* * *“If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.” [for most industry-sponsored research – no deviations permitted without written permission from COMIRB Director]* |  |  | **No change** |
| Who do I call if I have questions?  * *The researcher carrying out this study is <investigator name>. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call <investigator name> at <investigator phone number>. You will be given a copy of this form to keep.* * *You may have questions about your rights as someone in this study. You can call <investigator name> with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB) for questions, concerns, or complaints. You can call them at 303-724-1055.* |  |  | **No change** |
| 1. **What happens to data collected in this study?** *[For consent forms reviewed under 2018 Requirements if the consent form does not need HIPAA language below.]*   The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data. |  |  | **No change** |
| 1. **Who will see my research information?**  * *“*The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.   The institutions involved in this study include:   * We cannot do this study without your permission to see, use… * We will see, use and disclose your information only as described… * We will do everything we can to keep your records a secret. It cannot be guaranteed. * The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information…   *PI Name and Mailing Address*   * Both the research records that identify you and the consent form signed by you may be looked at by others…. * We might talk about this research study at meetings… . * You have the right to request access to your personal health… * **The investigator (or staff acting on behalf of the investigator) will also make** *all or some* **of the following health information…**   *List Recipients*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     * Information about me that will be seen, collected, used… * **What happens to Data, Tissue, Blood and Specimens that are collected in this study?**   Scientists at the University of Colorado Denver and the hospitals….   * The data, or the tissue, blood, or other specimens is given by you to the investigators for this research and so no longer belongs to you. * Both the investigators and any sponsor of this research may study your data and tissue, blood, or other specimens collected from you. * If data, tissue, blood, or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval. * Any product or idea created by the researchers working on this study will not belong to you. * There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea. |  |  | **No change**  (if study uses separate HIPAA B form, or HIPAA does not apply to study, see old standard language under VA Requirements section) |
| 1. **Agreement to be in this study**   “*I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form*.” |  |  | **No change** |
| 1. Does the consent form contain any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights? |  |  | **No change** |
| 1. Does the consent release or appear to release the investigator, sponsor, the institution or its agents from liability or negligence? |  |  | **No change** |
| 1. Reading level is in language understandable to the participant or representative? |  |  | **No change** |
| 1. Should there be a signature line for the PI? (i.e., the PI should be required to obtain consent.) |  |  | **No change** |
| 1. When appropriate, there is a line for a witness to the subject’s signature or the subject’s legally authorized representative’s signature to sign and date the consent document.   a. Does witness line indicate their role (consent process, signature, both)? |  |  | **No change** |
| 1. **For studies involving genetic testing, when appropriate (e.g., when results are returned to participants**):  * **Genetic Information Nondiscrimination Act (GINA)**   A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways… |  |  | **No change** |
| 1. **If the study is funded or sponsored by the NIH or CDC, it has been issued or will obtain a Certificate of Confidentiality:**  * **Certificate of Confidentiality**   This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings… |  |  | **No change** |
| **VA Requirements** |  |  | **No change to VA Requirements or N/A** |
| 1. VA Form 10-1086 is used and a VA employee is named as the VA PI? |  |  |  |
| 1. Does the consent state all regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertain to non-veterans enrolled in VA-approved research? |  |  |  |
| 1. **Injury and Compensation**: There is a statement that in the event of a research-related injury the VA has to provide necessary medical treatment to the subject injured by participation. |  |  |  |
| 1. **Cost to Subjects**: A statement that a veteran-subject does not have to pay for care received as a subject in a VA research study except in accordance with federal law and that certain veterans have to pay co-payments for medical care and services provided by VA. |  |  |  |
| 1. **Invitation for questions** includes the VA research office contact information |  |  |  |
| 1. **Who will see my research information (VA HIPAA language)?**  * *“We will do everything we can to keep your records a secret. It cannot be guaranteed. Both the records that identify you and the consent form signed by you may be looked at by others. They are <list all that apply>:*   **If HIPAA is N/A to the study, this portion only may be used**   * + *Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.*   + *People at the Colorado Multiple Institutional Review Board (COMIRB)*   + *The study doctor and his/her team of researchers.*   + *<insert sponsor name>, who is the company paying for this research study.*   + *Officials at <the institution> who are in charge of making sure that we follow all of the rules for research*   + *<other groups as applicable>* * *“We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.”* * *“We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA form. It will mention* *companies and universities who will see your research records.* “ * *“You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed – if applicable].* * *“This authorization does not expire. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw this authorization, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.”* |  |  |  |
| EE. Research subjects rights statement is included |  |  |  |

**Does the amendment change the risk level of the study?**

Yes  No

**Based on the changes made to the protocol and/or consent, is re-consent of subjects required?**

Yes (Currently enrolled subjects, if any, affected by the changes must sign the revised consent form.)

No (The changes are administrative in nature, and/or do not affect procedures or risks to subjects)

N/A (Consent form not revised in amendment)

► Reviewer Recommendation

Approved

Approved with Administrative Changes

Minor Modifications Required

Deferred

Comments (if needed):  See Electronic/Typed Comments

|  |  |
| --- | --- |
|  |  |

Reviewer Date