Full Board Review  Expedited/Chair Review

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

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

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

Does this project meet the criteria for human subject research? Yes  No

If unsure please review the exempt/not human research checklist first

Does this project meet the criteria for exemption? Yes  No

**For Expedited reviews, all sections must be completed for documentation purposes.**

| **Protocol/Application Checklist** | **Yes** | **No** | **N/A or Comments** |
| --- | --- | --- | --- |
| **A. Funding** | | | **N/A – No funding** |
| Is funding by a federal grant or cooperative agreement? If yes, Grant #:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |
| ► If Yes, is the grant application consistent with the protocol?(NOTE: this only needs to be assessed if UCD/affiliate is primary awardee on federal grant) ► If Yes, and the study or grant involves multiple performance sites,  please make sure documents address Single IRB (sIRB) oversight. See  Section B, #4, below. |  |  | N/A – UCD/affiliate not primary awardee |
| Is NIH or CDC sponsoring/funding the research? (*in whole or in part*) |  |  |  |
| ► If yes, CoC language should be in the consent form. |  |  |  |
| Is the Department of Defense funding the research? |  |  | If yes, complete [DOD checklist](http://gcrc.ucdenver.edu/comirb/DOD-Checklist.doc) |
| Is the Department of Education funding the research? |  |  | If yes, complete [DoEd checklist](http://gcrc.ucdenver.edu/comirb/DOE-Checklist.doc) |
| Is there a source of funding that may indicate a conflict of interest with the conduct of the study? |  |  |  |
| **B. Performance Sites (**[**Engagement of Institutions in Research**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)**)** | | | |
| 1. Indicate affiliate sites engaged in this research:   UCD (AMC, DDC)  University Hospital (including CTRC)  CHCO (main)  CHCO (satellite):      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Denver Health (confirm DHHA approval received ) |  |  |  |
| 1. Indicate VA involvement:   VA-only study **(answer all VA requirement questions)**  Multi-site study involving VA **(answer all VA requirement questions)**  *VA Purple Clearance has been received*  Non-VA study **(VA requirement questions are N/A)**  ***if*** *VA investigators working off VA time:* VA Yellow Clearance received |  |  |  |
| 1. Is research performed in public schools w/subjects <18yo? (Attach T )   or  Is there access to **any** student academic records (including grad students)? |  |  | If yes, complete [DoEd checklist](http://gcrc.ucdenver.edu/comirb/DOE-Checklist.doc) |
| 1. What kind of IRB oversight is needed for **non-affiliated** sites? Note: Federally funded multisite studies must be reviewed by a single IRB (sIRB). If we approve research involving one or more non-affiliated sites and the study receives any funding from a federal department(s) or agency(ies), COMIRB must serve as the sIRB for all engaged sites.   (check all that apply) |  |  | **N/A – no non-affiliated sites**; remainder of this section is N/A |
| Alternate IRB will review non-affiliated sites (not applicable for federally funded multisite research)  (request IRB approvals if UCD/affiliate is central site)  COMIRB will be IRB of record for:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  IRB Authorization Agreement or SmartIRB letter:  Finalized  Not finalized  Single IRB oversight plan:  Finalized  Not finalized (if checked, request Minor Modifications. This must be in  place prior to approval.)  Sites are not ‘engaged in research’  [see engagement criteria [**Engagement of Institutions in Research**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html)**]**  **List non-engaged sites:**  **List any sites engaged in research not accounted for by PI:** |  |  | Needs clarification |
| 1. Is UCD the lead site for a multisite clinical trial?   ► If yes, the PI will need to develop an oversight plan and have it approved by the institution. We need a copy of the approval.  ► If the multisite study is **federally funded**, it must be under the oversight of a single IRB (sIRB). |  |  |  |
| **C. Subject Selection** | | | |
| 1. Is the selection of subjects reasonable and equitable? |  |  |  |
| 1. If any specific social/ethnic groups, such as minorities and women, are not included, is there adequate justification for their exclusion? |  |  | **N/A** |
| 1. Are the inclusion/exclusion criteria appropriate? |  |  |  |
| **D. Vulnerable Subjects/Special Population Requirements** | | | **N/A – No vulnerable pops** |
| 1. Pregnant women/fetuses |  |  | (Complete checklist) |
| 1. Fetal or Embryonic Tissue |  |  | (Requires review by Ethics Committee on Fetal Tissue prior to COMIRB approval) |
| 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:   Considerations: not disclosed in the consent, pediatric, 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. Other (describe): |  |  |  |
| 1. Have appropriate safeguards been included in the study to protect their rights and welfare? |  |  |  |
| **Comments:** |  |  |  |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| 1. Has the Facility Director certification been obtained for inclusion of Prisoners? |  |  |  |
| 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. |  |  |  |
| **E. Procedures** | | | |
| 1. Are the research procedures adequately described? |  |  |  |
| 1. Are the sources of the data and/or specimens adequately identified? |  |  |  |
| 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)? |  |  |  |
| 1. Does the protocol adequately distinguish how the research procedures differ from standard care/treatment? |  |  | N/A |
| 1. Are the procedures consistent with sound research design? |  |  | N/A |
| 1. Are all relevant materials submitted for review (data collection tools, questionnaires, educational materials, etc.)? *[initial review only]* |  |  | N/A |
| **VA Requirements**  7. Do you have any concerns with the procedures performed at the VA? |  |  | **N/A – VA not a site** |
| **F. FDA Drugs** | | | **N/A – no drugs dictated by protocol** |
| 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. Does the protocol dictate the use of specific drugs that are FDA-approved? |  |  |  |
| ► If yes, are all drugs being used within medical practice? (i.e., prescribed by treating physician)  **NOTE:** Attachment C not required unless specific drugs and/or doses are studied per the protocol.  ► For approved drugs being *studied* in a clinical trial without an IND, check any of the following that apply to this study:  Study seeks a new indication for use or other change in labeling  Study seeks a significant change in product advertising  Study uses a new route of drug administration, drug dose, or patient population that increases risks, or decreases the acceptability of risks, of the drug  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 no, must be reviewed by full board)  *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 used 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 **CRV** 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 recombinant DNA vaccine]  • If yes, conform IBC approval has been submitted  • If study is already under IBC oversight, include in feedback that **CRV** must also be submitted to IBC |  |  |  |
| **G. Devices** | | | **N/A – No devices described in protocol** |
| * 1. Does the research 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 the study test an FDA-approved device which has been modified, where there is testing to determine safety or effectiveness, or the modification puts subjects at risk? |  |  | If yes, complete separate Device Checklist |
| 3. Does this protocol involve an HUD? |  |  | If yes, complete separate Device checklist |
| 1. **Scientific Design** | | |  |
| Has the study received other scientific review (SARC, NIH, Other)?  ► If no, answer the following: |  |  | If yes, section is complete |
| * 1. Is the experimental treatment/manipulation justified? |  |  |  |
| * 1. Is the scientific design appropriate? |  |  |  |
| * 1. Is the data analysis plan adequate to achieve the study aims? |  |  |  |
| * 1. Is the Application consistent with the protocol? |  |  |  |
| **I. Risks** | | |  |
| 1. Is there a clear and accurate identification of risks? |  |  |  |
| 2. Are the risks of any experimental arm(s) clearly described? |  |  | N/A |
| 3. Are the risks of any control arm(s) clearly described? |  |  | N/A |
| 4. Are any risks from deviations from standard care, placebo use, medication switching, or wash-out periods clearly described? |  |  | N/A |
| 5. Is there adequate follow-up for subjects following participation? |  |  | N/A – no f/u needed |
| 6. Are all 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. |  |  | N/A – no discovery risk |
| **J. Recruitment** | | | **N/A – subjects not recruited** |
| 1. Do you have any concerns with recruitment methods/plan described in the Application/protocol?   Concerns: |  |  |  |
| 1. Do the investigators 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 advertisements used *(initial review only)*: |  |  | N/A – no ads used |
| Advertisements must: |  |  |  |
| Reference PI and COMIRB # |  |  |  |
| Advertisements must **not** (check boxes if not present in ads): |  |  |  |
| Imply a certainty of favorable outcome |  |  |  |
| Imply the study provides treatment (must state "research" not just "study") |  |  |  |
| Promise free medical care |  |  |  |
| Overemphasize payments |  |  |  |
| 1. Are subjects pre-screened in recruitment? (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 reasonable and does not unduly influence subjects? |  |  | N/A – no payments |
| 1. Are payments pro-rated (if appropriate)? |  |  | N/A – no payments |
| **VA Requirements**  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** |
| **K. Waiver or Alteration of Consent Process** | | | **N/A – Consent waiver not requested** |
| Category I or Category II criteria must be satisfied (except for FDA emergency waivers, see #2) | | |  |
| Category I | | | **N/A** |
| a) The procedures involve 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 (and [b] as well), 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** |
| The research could not practicably be carried out without the waiver **and** |  |  |  |
| The research project is to be conducted by, or subject to the approval of state or local government officials, **and** |  |  |  |
| 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 study aspects to avoid biasing results. | | |  |
| **L. Waiver of Documentation of Informed Consent** | | | **N/A – No waiver of documentation requested** |
| IRB may waive the requirement to obtain a signed form if (a **or** b): | | |  |
| 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 s/he wants documentation linking him/her 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. |  |  |  |
| 1. Does the information provided to participants include all required and appropriate additional elements of consent? |  |  |  |
| 1. Should the participant be provided with written information? |  |  |  |
| **M. Consent Process** | | | **N/A – Consent process waived** |
| 1. Are the 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 of influence/possible coercion 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?   * + - * 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)       * Please note: When non-English speaking subjects are enrolled with the Short Form, the study team must submit the English version of the standalone HIPAA authorization that will be translated and used with the Short Form. See HIPAA section below. |  |  |  |
| ► If no, is their exclusion appropriate? |  |  |  |
| 5. 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 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 appropriately documented, and a copy of the signed and dated consent form given to the person signing the form? |  |  | **N/A – documentation of consent waived** |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| 1. If any 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)? |  |  |  |
| **N. Privacy and Confidentiality** |  |  |  |
| 1. Do the procedures adequately respect privacy of the subjects? |  |  |  |
| 1. Are procedures 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 collecting any information such that the identification of the subjects or their responses could increase the risk to the subject?   Consider:   * information about personal use of alcohol, drugs, or other addictive products; * information about sexual attitudes, preferences, practices; * 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? |  |  |  |
| ► For non-NIH funded research: Are the study data so sensitive that a Certificate of Confidentiality should be required to protect against subpoena risk? |  |  | \*If yes, remember to look for appropriate disclosure in the consent. |
| ► 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) |  |  | If yes, discuss at meeting. |
| **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)? |  |  |  |
| **O. HIPAA** |  |  | **N/A – HIPAA regs do not apply to study** |
| 1. Have the appropriate HIPAA Authorization Forms been submitted: |  |  |  |
| 1. Waiver of Authorization |  |  | *Complete HIPAA waiver checklist* |
| 1. Authorization A form (recruitment, access) |  |  |  |
| 1. Authorization B (either built into consent form, or separate form) 2. Standalone HIPAA Authorization (required when study enrolls non-English speaker with the Short Form) |  |  |  |
| 1. Are all of the appropriate, specific outside disclosures made? |  |  | N/A |
| 2. Is expiration date of authorization listed (or 'has no time limit'/'will not expire')? |  |  | N/A |
| **VA Requirements**   1. Is a separate, VA-formatted HIPAA B form submitted? |  |  | **N/A – VA not a site** |
| 4. Will VA data be released outside of the VA? |  |  |  |
| 5. 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 and DUA submitted? |  |  |  |
| **P. Data Management and Security** |  |  |  |
| 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**  7. Is the storage plan appropriate for the data collected in the VA-regulated portion of the study? |  |  | **N/A – VA not a site** |
| 8. If data will be stored outside the VA, are the appropriate arrangements made to identify and disclose a data Coordinating Center? |  |  |  |
| 9. Will VA biological samples be stored on VA property (or appropriate waiver obtained)? |  |  |  |
| 10. Will VA data be retained per current VA policy? |  |  |  |
| **Q. Data Safety Monitoring Plan** |  |  |  |
| 1. Will the PI monitor for and report UAPs to COMIRB within 5 days? |  |  |  |
| 1. Is the data safety monitoring plan appropriate, given the scope and activities of the project? |  |  |  |
| 1. Has the investigator provided an adequate plan to monitor and ensure subject safety?   *Check all that apply to subject safety monitoring:*  AE monitoring/reporting  Periodic review of AEs/SAEs  Safety Officer  Internal DMC  Independent DSMB  Interim analysis  Other: |  |  | **Remainder of section N/A; no additional safety monitoring required** |
| 1. Are precautions taken to decrease the likelihood of harm (e.g. plans for referrals for new diagnoses relating to research procedures: hotlines, counseling, clinical evaluation)? |  |  |  |
| 1. Are contingencies taken to deal with harms if they occur? |  |  |  |
| 1. Are the study stopping rules and participant discontinuation criteria appropriate and adequate to protect subjects? |  |  |  |
| **R. Resources** |  |  |  |
| 1. Does the investigator 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 the PI is a student/trainee, have the signed Student/Trainee and Mentor responsibility agreements been submitted? *[initial review only]* |  |  | N/A |
| 1. If subjects might require additional medical or psychological resources as a result of the research, are these resources identified/available? |  |  | N/A |
| 1. If PI is the lead investigator in a multi-center study, is there an adequate plan to manage the study and monitor safety across sites? |  |  | N/A |
| **S. Conflict of Interest** |  |  | **N/A – No COI for study** |
| Is the COI Committee management plan (or determination that no plan is needed) submitted? |  |  | [if no, protocol must be deferred] |
| a) If yes, are there any additional human subject protections that should be considered given the management plan provided? |  |  |  |
| b) If any study personnel have a COI, does the consent form require a disclosure statement?  ► The following sample language can be added to the “Who is paying for this study?” Section.   * Financial Disclosure: [Name of investigator], a co-investigator, and the University of Colorado Denver have a financial interest with [name of company]. [Name of company] is the sponsor of this research study. Please feel free to ask any questions you may have about this matter. * Financial Disclosure: The study doctor, Dr. [name of investigator], has a financial interest with [name of company], as s/he is a consultant for the company. [Name of company] is the manufacturer of [name of device/drug]. Please feel free to ask any questions you may have about this matter. |  |  |  |
| b) 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] |
| **T. clinicaltrials.gov** |  |  |  |
| 1. Is this an applicable clinical trial that requires posting on clinicaltrials.gov (FDAAA)?  Please use this algorithm if this study is an intervention trial testing drugs or devices. Brief algorithm: <http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm> |  |  |  |
| 1. Is this a phase I drug study, w/ health outcomes, in very ill subjects (FDAMA)? |  |  |  |
| ► If yes to 1 or 2, is the ct.gov language (verbatim) in the consent form?  **See Consent Form Checklist section N for required language** |  |  |  |
| **U. Risk Assessment** |  |  |  |
| Minimal Risk Minimal Risk: A risk is minimal where 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 (requires full board review) |  |  |  |
| The following three criteria must be met for project to be approved (45 cfr 46.111, 21 cfr 56.111): | | | |
| Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk. | | |  |
| Risks to participants are minimized *whenever appropriate*, by using procedures already being performed on the participants for diagnostic or treatment purposes. | | |  |
| Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. | | |  |
| **If greater than minimal risk, what additional measures minimize risks?**  Qualified investigators  Appropriate inclusion/exclusion criteria  Close monitoring of subjects  Close follow-up of subjects  Appropriate safety monitoring plan  Appropriate withdrawal criteria  No unnecessary procedures | | | **N/A** |
| **V. Benefit Assessment** |  |  |  |
| The risks are reasonable in relation to the benefits. |  |  | (If no, the study cannot be approved.) |
| Generalizable knowledge  Improves treatment or system  Close monitoring  Potential therapeutic intent  Potential early diagnosis  Other (describe): | | |  |
| **Comments:** | | |  |
| **W. Continuing Review**  **Continuing Review is required at least annually for any research that:**   * + - * Requires ongoing Full Board review       * Is under FDA oversight (i.e., reviewed under 21 CFR 50 and 56)       * Is under DOJ oversight (i.e., reviewed under 28 CFR 46)       * Is reviewed under Pre-2018 Requirements, or       * (COMIRB Requirement) At least one other site is relying on COMIRB as IRB of record, and interactions with subjects will take place at that site.   **Continuing Review is not required by federal regulation for any research that:**   * + - * Is reviewed under the 2018 Requirements, and       * Is eligible for Expedited Review, or       * If greater than minimal risk, has progressed to the point that it involves only data analysis and/or collecting follow-up data from clinical (i.e., not research) procedures.       * Research that has progressed to the point that it involves only one or both of the following:       * Data analysis, including analysis of identifiable private information or identifiable biospecimens, or       * Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.   After reviewing the criteria above, please select a review interval:  **12 months**  If approved under the 2018 Requirements, the reviewer may still determine that annual review is necessary if they provide a specific rationale (select from the list below):  COMIRB requirement: At least one other site is relying on COMIRB as IRB of record, and interactions with subjects will take place at that site.  FDA oversight  DOJ oversight  PI is a mentee (e.g., student, resident, fellow, trainee)  Other (please specify):  **Less than 12 months:**       months  If less than 12 months, Provide a rationale for your recommended review cycle:  Significant risk to research subjects (e.g. death, permanent or long lasting disability or morbidity,severe toxicity) without the possibility of direct benefit to the subjects.  The probability and magnitude of anticipated risks to the subjects.  The nature and frequency of adverse events observed in similar research at this and other institutions.  The novelty of the research making unanticipated adverse events more likely.  The likely medical condition of the proposed subjects.  The involvement of especially vulnerable populations likely to be subject to coercion (e.g. institutionalized psychiatric patients, incarcerated minors).  A history or continuing non-compliance on the part of the PI  **No continuing review. Study reviewed under 2018 Requirements.** | | | |
| **Full Board** **Only**, can future reviews be Expedited? |  |  | (If no, skip section X) |
| ► The research must be minimal risk; is this the case? (Refer to Section U) |  |  |  |
| **X. Expedited Research Categories:** | | | **N/A – Full board review and study cannot be expedited** |
| **For Expedited review**, are **all** of the following true: |  |  |  |
| * The research (or the remaining research procedures) presents no more than minimal risk to subjects. (Not applicable for category (8) (b)) |  |  |  |
| * The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (Not applicable for category (8) (b)) |  |  |  |
| * The research is not classified. |  |  |  |
| * Study does **not** employ Major Deception |  |  |  |
| ► **If no was checked for any of the above, full board review is required** | | | **Full Board Review** |
| If the research does not fit any of the following categories or is more than minimal risk, it requires *initial* full board review*.* | | | **Full Board Review** |
| (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.  (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)  (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling | | | |
| (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;  (b) from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. | | | |
| (3) Prospective collection of biological specimens for research purposes by noninvasive means.  Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;(f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. | | | |
| (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. | | | |
| (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). | | | |
| (6) Collection of data from voice, video, digital, or image recordings made for research purposes. | | | |
| (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies | | | |
| (8) Does category (8) (a), (b) or (c) apply? | | | |
| * (8)(a) (i) the research is permanently closed to the enrollment of new subjects; | | | |
| (ii) all subjects have completed all research-related interventions; **and** | | | |
| (iii) the research remains active for long-term follow-up of subjects. | | | |
| * (8)(b) no subjects have been enrolled and no additional risks have been identified | | | |
| * (8)(c) remaining research activities are limited to data analysis | | | |
| (9) Continuing review of research, not conducted under an IND or IDE, where categories two (2) through eight (8) do not apply, but the full board IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.  **If previously determined to meet this category:**   1. The research continues to involve no more than minimal risk?   Yes  No  (If no, defer to full board)   1. There have been no additional risks identified since the initial review that would prevent an expedited review?   Yes  (If yes, defer to full board) No | | | |
| Comments/Concerns: | | | |

**N/A - No consent form or Info Sheet used in this study (skip to Reviewer Recommendation)**

| **Consent Form Checklist** | **YES** | **NO** | **COMMENTS or N/A** |
| --- | --- | --- | --- |
| *Note: 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. |  |  |  |
| 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…*” |  |  |  |
| 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.* “ |  |  |  |
| 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…*” |  |  |  |
| 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) |  |  |  |
| 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." |  |  |  |
| 1. **Are there alternative treatments?** (If not therapeutic, section not required)   Alternatives to the research's diagnostic/therapeutic method are listed.   * There may be other ways of treating your… * These other ways include… |  |  | N/A – non-therapeutic |
| 1. **Who is paying for this study?**   Sponsor/funding is listed. (If no sponsor, section not required)   * + - “*The research is being sponsored by <name>.*” |  |  |  |
| 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.”* |  |  |  |
| 1. **Will I have to pay for anything?**   Costs of participation are described.   * “*You will need to pay for…*” * “*It will not cost you anything to be in the study.*” |  |  |  |
| 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.*” |  |  |  |
| 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.*” |  |  |  |
| What Happens If I am injured or hurt during the study?  * *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>.”* * *“In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.” [for the majority of research] OR* * *“In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. The study site will provide or arrange for medical treatment or you may receive treatment at another health care facility of your choosing. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The investigator [and sponsor] will determine if your injury or illness is research-related. The term “research-related” illness or injury means physical injury caused by the study [drug(s)/device] or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the research.”*   *[for research which is initiated by industry and directly sponsored by industry – no deviations permitted without written permission from COMIRB Director]* |  |  | N/A |
| 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.* * *(if an applicable clinical trial [see checklist section T])*: A description of this clinical trial will be available on http://www.Clinical Trials.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. |  |  |  |
| 1. **What happens to data collected in this study?** *[For consent forms reviewed under 2018 Requirements.]*   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. |  |  | If this language is not present, it must be redlined into the consent form. |
| 1. **Who will see my research information?** *[Do NOT allow deletions to this language]*  * *“*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… * *(if applicable):* There are some things we cannot keep private… *(only required if mandatory reporting/disclosure risks – see checklist section I #6)* * **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… * **HIPAA Authorization for Optional procedures** *[if applicable]*   Any optional procedures in the study must have separate HIPAA authorization, which can be accomplished by:   * Describing optional procedures in the consent form (with opt-in/opt-out boxes), and one HIPAA section that includes a separate part for the optional procedures [*compound* HIPAA authorization]; **or** * After the signature block for the main study, having a new section for optional procedures, with its own HIPAA section and signature block [*separate* HIPAA authorization] |  |  | \*If study uses separate HIPAA B form, or HIPAA does not apply to study, see old standard language under 'VA Requirements,' section AA    N/A  N/A |
| 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*.” |  |  |  |
| 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? |  |  |  |
| 1. Does the consent release or appear to release the investigator, sponsor, the institution or its agents from liability or negligence? |  |  |  |
| 1. Reading level is in language understandable to the participant or representative? |  |  |  |
| 1. Should there be a signature line for the PI? (i.e., the PI should be required to obtain consent.) |  |  |  |
| 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.   ► Does the witness line indicate their role (consent process, signature, or both)? |  |  | **N/A** |
| 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… |  |  | **N/A** |
| 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… |  |  | **N/A** |
| 1. **Does the consent form need dbGaP language?**   The following dbGaP language is required for NIH-funded research involving genetic testing, as well as any research in which samples will be stored for future unspecified research:  *We may share data from our research with other researchers or data banks. One such data bank is called dbGaP, which collects genetic and other data and is sponsored by the National Institutes of Health. By broadly sharing data in data banks like this, we can make our discoveries more accessible to other researchers. Information which directly identifies you will not be sent to these data banks.* |  |  | If language is not present, direct coordinators to insert the paragraph as a redline change. |
| **VA Requirements** |  |  | **N/A – VA not a site** |
| **Y.** VA Form 10-1086 is used VA employee is named as the VA PI? |  |  |  |
| **Z.** Does the consent form state that all regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research? |  |  |  |
| **AA.** **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. **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.”* * *(if applicable):* There are some things we cannot keep private… *(only required if mandatory reporting/disclosure risks – see checklist section I #6)* * *“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.”* |  |  |  |
| **DD.** Research subjects rights statement is included |  |  |  |
| **EE.** Consent Form includes one of the following statements:  “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.”  OR  “Identifiers might be removed from the identifiable private information data or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.” |  |  | *If not included, this language must be redlined in the “How will my private information be protected?” section.* |

► Reviewer Recommendation

Approved

Approved with Administrative Changes

Minor Modifications Required

Deferred for Full Committee Review

Reclassify: Exempt or Not Human Subject Research

Comments (if needed):  See Electronic/Typed Comments

\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_     \_\_\_\_

Reviewer Date