Secondary Research Reviewer Checklist

☐ Initial Review ☐ Other: _____

Reviewer: _____ Submission ID: _____

Principal Investigator: _____ Protocol #: _____

If you have a conflict of interest with this study, ask the coordinator to assign the submission to another reviewer.

Protocol:

1. Are the data or specimens to be collected adequately described? ☐Yes ☐No
2. Is the study design appropriate? ☐Yes ☐No
3. Does the data access student academic records? ☐Yes ☐No
   If yes and records are from public K-12, complete Dept. of Education checklist
4. Does the research address a cancer-related question or population? ☐Yes ☐No
   If so, confirm PRMS approval is submitted ☐
5. Is the research FDA-regulated? e.g., does the study: ☐Yes ☐No
   If any of the 3 below, review must be expedited with annual continuing review.
   - ☐ Evaluates/develops a diagnostic assay
   - ☐ Evaluates/develops medical software/mobile medical app
   - ☐ Contributes data to FDA-required drug or device registry
6. Does the research involve fetal or embryonic tissue? ☐Yes ☐No
   If so, check with the COMIRB Director or Assistant Director for additional institutional approval

Protocol Comments (if needed):

Application Form:

1. Did the mentor sign the PI Attestation Form? ☐Yes ☐No ☐N/A

Funding: ☐ **N/A — No funding**

1. Is this a federally funded study? ☐ Yes ☐No
   a. If federally funded, are the grant submission and IRB application generally consistent? ☐Yes ☐No
   b. Is the Department of Defense funding the research? ☐ Yes ☐No
      If yes, complete Dept. of Defense checklist
   c. Is the Department of Education funding the research? ☐Yes ☐No
      If yes, complete Dept. of Education checklist

Sites:

1. Indicate the affiliated performance sites for this study:
   ☐ UCD-AMC ☐ UCD-DDC ☐ UCHealth (confirm HSR Portal clearance received ☐)

   ☐ CHCO (confirm CHCO letter received ☐) ☐ Denver Health (confirm SPARO letter received ☐)

   ☐ VA Eastern Colorado (confirm VA clearance letter received ☐) ☐ School of Mines

2. Is COMIRB being asked to serve as the IRB of record for any non-affiliated sites? ☐ Yes ☐ No

   If research is determined to be exempt, notify the PI that non-affiliated sites may not rely on COMIRB for IRB approval.

   IRB Authorization Agreement or SmartIRB letter:
   ☐ Finalized
   ☐ Not finalized

Sites Comments (if needed):

VA Requirements: ☐ **N/A — VA not a site**

☐ VA Purple Clearance has been received, or
☐ **if** VA investigators working off VA time: VA Yellow Clearance received

For Secondary Research under a waiver of consent, sites <u>are</u> engaged in research if:

a. The institution receives an award through a grant, contract, or cooperative agreement directly from HSS for non-exempt human subject research, even if all activities involving human subjects are carried out elsewhere.

b. Employees or agents from the institution obtain, for non-exempt research purposes, identifiable information from any source.

For Secondary Research under a waiver of consent, sites <u>are not</u> engaged in research if:

a. Employees or agents from the institution perform commercial or other services provided all of the following conditions also are met:
   The services performed do not merit professional recognition or publication privileges; the services performed are typically performed for non-research purposes; and the employees or agents of the institution do not administer any study intervention being tested or evaluated.

b. Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.

Vulnerable Subjects: ☐ **Yes** ☐ **N/A — None**

1. Are the researchers specifically studying (i.e., targeting) any of the following vulnerable populations? ☐ Yes ☐ No
   If so, refer to relevant vulnerable population checklist as needed. Do not check if data from vulnerable populations ***are only incidentally included***.
   ☐ Pregnant women/fetuses/neonates
   ☐ Economically and/or educationally disadvantaged
   ☐ Adults who cannot consent for themselves (must be expedited)
   ☐ Prisoners
   ☐ Children
   Child risk category: ☐ 45 CFR 46.404

VA Requirements: ☐ **N/A — VA not a site**

1. Prisoners: Has a CRADO waiver been obtained? ☐ Yes ☐ No ☐ N/A
2. Pregnant women: Has the Facility Director certification been obtained? ☐ Yes ☐ No ☐ N/A
3. Children: Has the Medical Center Director approval been obtained? ☐ Yes ☐ No ☐ N/A
4. Children: Does the protocol address relevance to the VA population? ☐ Yes ☐ No ☐ N/A

Data Collection:

1. If the source of the data and/or specimen is previously approved research, were the PI or investigators part of that research team? ☐ Yes ☐ No ☐ N/A
   If yes and NIH funded, complete an expedited review
2. Are the sources of the data and/or specimens adequately identified? ☐ Yes ☐ No
   a. Are any data and/or specimens collected in the UK or European Union/European Economic Area? ☐ Yes ☐ No
      If so, consult with the COMIRB Director or Brie about GDPR
3. Are access and collection of data and/or specimens adequately described? ☐ Yes ☐ No
4. Are identifiers accessed by the study team? ☐ Yes ☐ No
   If no, this is not human subjects research
5. Are identifiers recorded in research records?
   ☐ No
   ☐ Only for a reasonable period of time for data collection
   ☐ Yes
6. HIPAA: If study involves disclosure of protected health information (PHI), is the PHI disclosed limited to the amount reasonably necessary to achieve the purpose of the research? ☐ Yes ☐ No ☐ N/A
7. Are the data disclosed outside of the covered entity? ☐ Yes ☐ No

Data Collection Comments (if needed):

Data Management and Security:

1. Are the data securely stored? ☐ Yes ☐ No
2. Is the list of researchers who have access to the identifiable data set reasonably limited? ☐ Yes ☐ No ☐ N/A
3. Will identifiable data be reused or disclosed outside of the research team? ☐ Yes ☐ No ☐ N/A
   a. If yes, is the plan reasonable? ☐ Yes ☐ No ☐ N/A

VA Requirements: ☐ **N/A — VA not a site**

1. Are VA sensitive data appropriately stored at the VA (or waiver obtained?) ☐ Yes ☐ No
2. Will VA data be released outside of the VA? ☐ Yes ☐ No
3. Will VA data be retained per current VA policy? ☐ Yes ☐ No

Data Management and Security Comments (if needed):

Conflict of Interest: ☐ **N/A — No COI**

1. If applicable, has a COI Committee management plan (or determination that no plan is needed) been provided? ☐ Yes ☐ No
2. Is the COI management plan adequate? ☐ Yes ☐ No

Review Level

Indicate the appropriate review level:

☐ **Not Human Subjects Research (NHSR)**

☐ **Exempt, Category #4**

Research involving the collection or study of data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, and the investigator will not attempt to either re-identify or contact the subjects.

OR

Secondary research involving the use of identifiable health information when that use is regulated by HIPAA as "health care operations", "research", or "public health activities and purposes."

OR

Secondary research conducted on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes, and the information is subject to federal privacy standards.

☐ **Exempt, Category #5**

Research and demonstration projects which are conducted or supported by or subject to the approval of department or agency heads, and which are designed to study, evaluate, improve, 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.

*For VA studies: The determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

☐ **Expedited, Category #5** **Continue below.*

Research presents no more than minimal risk, and

Research involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for [research or] non-research purposes (such as medical treatment or diagnosis).

☐ **Privacy Board Review Required (for research involving *access* or use of PHI)** **Continue below.*

Expedited Review: ☐ **N/A**

1. Informational risks to subjects are minimized. The procedures to access, collect, and manage data are consistent with sound research design and do not unnecessarily expose subjects to informational risk. ☐ Yes ☐ No
2. 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. ☐ Yes ☐ No
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. ☐ Yes ☐ No
4. Informed consent — Waived, see below ☐ Yes ☐ No
5. Documentation of informed consent — Waived, see below ☐ Yes ☐ No
6. The research plan makes adequate provision for monitoring data security to ensure the safety of subjects. ☐ Yes ☐ No
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. ☐ Yes ☐ No

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Waiver of Consent and/or HIPAA Authorization ☐ **N/A**

Required with Expedited Reviews and when PHI is accessed or disclosed for Exempt Research

Complete Part A or Part B

Part A:

1. The research (including, if applicable, use and disclosure of PHI involves no more than minimal risk to the subjects ☐ Yes ☐ No
    a. There is an adequate plan to protect the identifiers from improper use and disclosure ☐ Yes ☐ No
    b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; **and** ☐ Yes ☐ No
    c. The application provides adequate written assurance that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart; ☐ Yes ☐ No

2. The waiver will not adversely affect the rights and welfare of the subjects ☐ Yes ☐ No

3. The research could not practicably be carried out without the waiver ☐ Yes ☐ No

4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format ☐ Yes ☐ No

5. Should subjects be provided with pertinent information after participation? ☐ Yes ☐ No ☐ Possibly, only in the case of a privacy breach

Part B:

1. The research or demonstration 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; **and** ☐ Yes ☐ No

   The research could not practicably be carried out without the waiver or alteration. ☐ Yes ☐ No

Waiver of Consent and/or HIPAA Authorization Comments (if needed):

Continuing Review Interval

☐ **Not Needed**

☐ **12 months**

☐ **Other: _____ months**

If continuing review is required, provide rationale:

The Secondary Research Review Recommendation is:

☐ Approved

☐ Approved with Administrative Changes

☐ Minor Modifications Required

☐ Deferred to Full Board

Additional comments (if needed): ☐ See Comments in InfoEd

_____ _____

Reviewer Signature Date