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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

   If yes, 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 European Union/European Economic Area? ☐ Yes ☐ No
      If so, consult with the COMIRB Director or Assistant Director 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 or 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.

☐ **Expedited, Category #5***

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 (Complete Part A or Part B)
Required with Expedited Reviews, and when PHI is accessed or disclose for Exempt Research

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 (including, if applicable, access to and use of identifiable data and specimens or PHI) could not practicably be carried out without the waiver ☐ Yes ☐ No
4. Should subjects be provided with pertinent information after participants? ☐ 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 ☐ Yes ☐ No

alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**

The research could not practicably be carried out without the waiver or alteration.

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