

Goodwyn Institutional Review Board, Ltd.

**APPLICATION FOR IRB WAIVER
OF HIPAA PRIVACY AUTHORIZATION**

Principal Investigator:

**Covered Entity where the
research activity will take
place:**
(Organization Name and
Address)

Sponsor:

Protocol Number:

*In order for the IRB to grant a waiver of the HIPAA Privacy Authorization requirement, the IRB must determine that your project involves no more than minimal risk to the privacy of individual participants. **Do not** submit this form if you are using de-identified data. **Do not** submit this form if you are using a limited data set. **NOTE:** Some responses require explanation that will need more room for text than available on these pages. In this case, please continue your explanation on an attached page.*

1a. State the purpose of the use or disclosure of individually identifiable health information (protected health information or "PHI") for this research activity/project:

1b. Describe what PHI will be used or disclosed for this activity/project. (List any item, collection, or grouping of information that includes PHI or attach the document that describes the PHI proposed, such as a screening questionnaire.):

1c. Indicate your sources of PHI:

- | | |
|--|--|
| <input type="checkbox"/> Physician/clinic records | <input type="checkbox"/> Hospital/medical records (in- and out-patient) |
| <input type="checkbox"/> Lab, pathology and/or radiology results | <input type="checkbox"/> Mental health records |
| <input type="checkbox"/> Biological samples obtained from the subjects | <input type="checkbox"/> Data previously collected for research purposes |
| <input type="checkbox"/> Interviews/Questionnaires | <input type="checkbox"/> Other (describe): |

1d. Explain why it is not practical to conduct this research without access to and use of the PHI:

2. Explain why it is not practical to get participants' authorization to use or disclose this information for your stated purpose:

3a. List persons who will have access to the PHI [identify each person by name or category. Examples include the investigator, the research staff, sub-investigators and their research staffs, statisticians, and all research monitors]:

3b. Will all of these persons be a part of the principal investigator's covered entity?

- Yes No

If no, please explain:

4. Have all personnel who will participate in this research activity/project been trained in all required policies and procedures relating to PHI (HIPAA)? Yes No
If no, please explain:

5a. Does the activity/project have an adequate plan to protect the PHI from improper use and disclosure? Yes No

5b. PHI must be securely maintained. Describe the elements that are in place to protect the PHI (check all that apply) and provide explanations as necessary:

Only authorized research personnel will be granted access to the PHI.
 Only authorized research personnel may record, view, and use the PHI.
 Physical security of computer workstations or paper files that will contain the records are maintained.
 Additional protections (describe):

5c. Will the PHI be entered into a computerized system? Yes No
If yes, describe security to control access (check all that apply):

Logon passwords will not be shared.
 Logon passwords must be periodically changed.
 Failed logon attempts result in automatic lockout.
 Additional protections (describe):

6a. Individual identifiers must be destroyed at the earliest opportunity consistent with the conduct of the research activity/project (unless retention is otherwise required). Describe how and when you will destroy the individual identifiers:

6b. If the individual identifiers will not be destroyed, explain why retention is required:

I assure Goodwyn Institutional Review Board, Ltd. (Goodwyn IRB) that the PHI for which I have requested this Waiver of Authorization will be used and disclosed only as described above and as required by law.

I assure Goodwyn IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research activity/project.

I also acknowledge and agree that: correspondence and notifications from Goodwyn IRB may be generated and signed in electronic form; I will receive hard copy (printouts) of such electronic documents; and any such printouts accurately reflect the electronic original. All such printouts shall be treated in all ways as originals.

Signature of Person Submitting the Application

_____ Date: _____

Title of Submitter: _____

Organization/Company Name of Submitter: _____

Phone #: _____ Beeper #: _____ Fax _____

Email: _____

Completed application forms should be sent to:
Goodwyn Institutional Review Board, Ltd.
9380 Main Street
Cincinnati, OH 45242
Fax: 513/793-2800 or 513/793-4800