

**APPLICATION/CERTIFICATION FOR USE AND DISCLOSURE OF
PROTECTED HEALTH INFORMATION FOR RESEARCH
REQUESTING A WAIVER OF AUTHORIZATION**

1. Name(s) of Investigator(s)	Department(s) of Investigator(s)
_____	_____
_____	_____
_____	_____
_____	_____

2. Location and brief description of the Protected Health Information

- UNTHSC Clinic Records _____
- UNTHSC Research Records _____
- UNTHSC Other Records (specify) _____
- OMCT Medical Records (specify) _____
- OMCT Other Records (specify) _____
- Other (specify) _____

3. The investigator(s) seeks the use or disclosure of Protected Health Information (PHI) located at sites indicated in #2, (check one):

- Solely for Research on PHI of Decedents
(The investigator will be prepared to provide documentation of the individual's death)
- Solely to review PHI to prepare a research protocol or for similar purposes preparatory to research
(The investigator will not remove any PHI from UNTHSC or OMCT in the course of the review)
- To use or disclose existing PHI for other research purposes and is requesting a waiver of consent and authorization.

4. How many individual patient records will you access for this protocol?

5. State how you will identify protected health information in your research records?
(*i.e.: name of subjects, coded identifier, etc*)

6. Will you be sharing PHI with anyone outside of UNTHSC or OMCT? yes no
 If yes, what PHI will be shared and how will it be identified? (i.e: name of subjects, coded identifiers, etc.) _____

[NOTE: If the PHI is shared outside of UNTHSC or OMCT, additional documentation may be necessary to account for the disclosure(s). Furthermore, the sharing of PHI outside of UNTHSC or OMCT may require the outside party to comply with federal requirements (HIPAA).]

7. Will the PHI you access and record include any of the following elements (check all that apply)?

- | | |
|--|---|
| <input type="checkbox"/> Patient/Subject Name | <input type="checkbox"/> Device identifiers and serial numbers |
| <input type="checkbox"/> Postal address information, other than town or city, State & zip code | <input type="checkbox"/> Web Universal Resource Locators (URLs) |
| <input type="checkbox"/> Telephone numbers | <input type="checkbox"/> Biometric identifiers, including finger and voice prints |
| <input type="checkbox"/> Fax numbers | <input type="checkbox"/> Internet Protocol (IP) address numbers |
| <input type="checkbox"/> Electronic Mail addresses | <input type="checkbox"/> Full face photographic images and any comparable images |
| <input type="checkbox"/> Social Security Number | <input type="checkbox"/> Account numbers |
| <input type="checkbox"/> Medical record numbers | <input type="checkbox"/> None of the above |
| <input type="checkbox"/> Health plan beneficiary numbers | |
| <input type="checkbox"/> Certificate/license numbers | |
| <input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers | |

8. State how the PHI will be protected from improper use and disclosure:

9. When will you destroy the PHI? (Be specific; state a date or event, such as following data analysis, following publication, completion of protocol)

10. **To justify a waiver of the requirement to seek informed consent and/or HIPAA authorization from the subjects, you must be able to answer “YES” to items (a)-(f) below. Insert explanations that support your request for waiver.**

- a) **Will the research involve no greater than minimal risk to subjects or to their privacy?** yes no
(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

- b) **Is it true that the waiver will not adversely affect the rights and welfare of subjects?** yes no
(Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)
- c) **Is the risk to privacy reasonable in relation to benefits to be gained or the importance of the knowledge to be gained?** yes no
- d) **Would the research be impracticable without the waiver?** yes no
(If you checked "yes," explain how the requirement to obtain consent would make the research impracticable, e.g. are most of the subjects lost to follow-up or deceased?).
- e) **Would the research be impracticable if you could not record protected health information (PHI)?** yes no
*(If you checked "yes," explain how **not** recording PHI would make the research impracticable).*
- f) **When appropriate, do you have plans to provide subjects with pertinent information after their participation is over?** yes no
(e.g. Will you provide details withheld during consent, or tell them if you found information with direct clinical relevance for the subjects? This may be an uncommon scenario)

I certify that the above information is correct, that it will apply throughout the performance of the proposed research and that I will be responsible for safeguarding the confidentiality of the human subjects who are involved. I am aware of the confidential nature of the information obtained for the purposes of this research. No protected health information (PHI) from this research will be shared with or disclosed to others, for purposes other than conducting the research as described above.

Printed Name: _____

Signature: _____

Date: _____