GUTHRIE	INSTITUTIONAL REVIEW BOARD OF THE GUTHRIE CLINIC

FEBRUARY 2020

Application to Conduct Research Using Medical Records collected solely for nonresearch purposes

Send this form to:	***IRB Office Use Only:***
Lori Robinson, CIC, IRB Coordinator **Donald Guthrie Foundation** **570-887-4885** **LoriA.Robinson@guthrie.org**	**IRB Number _____**

This document is used to request a Waiver of Authorization to Use and Disclose Protected Health Information (PHI) and a Waiver of Consent to Participate in Research.

I. General Information

1) Title of study

2)Sponsor ☐ Investigator-initiated ☐ NIH/PHS ☐ Commercial *(specify)* ☐ Other *(specify)*

3) Investigators	Name; Contact Information	CITI Training
Principal Investigator		☐ Completed
Faculty Sponsor*		☐ Completed

If the Principal Investigator is a resident or trainee of The Guthrie Clinic, then this application must be:

- Sponsored by a Faculty Mentor who will be held to the same Assurances as the Principal Investigator.
- Accompanied by a brief protocol describing the aims, background, proposed analysis, and significance of the work.

4) List or Research Team Members including Investigators and those who will collect and use PHI

Name; Role on Study; Contact Information	CITI Training
	☐ Completed
	☐ Completed
	☐ Completed
	☐ Completed
	☐ Completed
	☐ Completed
	☐ Completed

5) Briefly describe the purpose of the research project

6) Approximately how many records do you expect to review?

7) Briefly describe the time frame and search criteria for the records you propose to review (eg, hospital-acquired pneumonia, 2005-pres)

8) Where will the review of PHI take place?

☐ **Guthrie - using Guthrie approved applications (with Guthrie username and password) for data storage**

Other. Explain:

9) Who or what institution is the legal custodian of this PHI?

☐ **The Guthrie Clinic**

Other. Explain:

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10) Who will collect the PHI and who will use it?

☐ **Research Team Members Only**

Other. Explain:

11) Beside the research team listed above, will PHI be disclosed to anyone else? ☐ **Yes** ☐ No

If Yes, to whom will PHI be disclosed?

12) Does the recorded data contain either 1) any protected health information (as listed in #17 below), **or** 2) a code to allow the re-identification of the individual?

☐ **Yes** ☐ No, recorded data is fully de-identified (all 18 elements of PHI are removed). If a code is used, the key to the code must not be disclosed to the researchers who are conducting research on de-identified information.

a) If "Yes" what is your plan to protect the identities from improper use and disclosure?

☐ **Any PHI will only be accessed and stored using Guthrie approved applications (with Guthrie username and password)**

☐ **Other. Explain:**

b) If "Yes", describe the plan to destroy identifiers at the earliest opportunity that is consistent with the goals of the study.

☐ **Before any results are shared, any information that could potentially identify a patient will be removed from the data**

☐ **Other. Explain:**

13) Can this research be *practicably* conducted without access to the PHI? ☐ **Yes** ☐ No

14) Can this research be *practicably* conducted without a waiver of consent? ☐ **Yes** ☐ No

15) Does this protocol present any unusual risks to the confidentiality of subjects' medical information while participating or afterwards? (For example, history of drug use; genetic testing.) If yes, Explain: ☐ **Yes** ☐ No

16) Will this protocol collect information about subjects that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation? If yes, Explain: ☐ **Yes** ☐ No

17) Describe the type of data to be collected and used and complete the table below

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Direct Identifiers		**Identifiable Information**	**Indirect Identifiers** (Limited Data Set)	
Used/ Collected (check if yes)	**Disclosed** (check if yes)		**Used/ Collected** (check if yes)	**Disclosed** (check if yes)
☐	☐	Names		
☐	☐	Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code		
		City/Town, State and Zip Code *To be considered de-identified, only the first three digits of the zip code may be used*	☐	☐
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)	☐	☐
☐	☐	Ages less than 90 and a single aggregated category for “90 or older”	☐	☐
☐	☐	Ages 90 or greater and data are not aggregated into a single category of “90 or older”		
☐	☐	Telephone numbers, including fax		
☐	☐	Electronic mail addresses		
☐	☐	Social security numbers		
☐	☐	Medical record numbers		
☐	☐	Health plan beneficiary numbers or any other account numbers		
☐	☐	Certificate/license numbers, & vehicle identifiers and serial numbers, including license plate numbers		
☐	☐	Implanted device identifiers and serial numbers		
☐	☐	Web Universal Resource Locators (URLs)		
☐	☐	Internet Protocol (IP) address numbers		
☐	☐	Biometric identifiers, including finger and voice prints or audio recordings		
☐	☐	Full face photographic images and any comparable image, including video recordings		
☐ None of the Direct Identifiers noted above will be collected			☐ None of the Indirect Identifiers noted above will be collected	

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Waiver of HIPAA: Can this research be *practicably* conducted without a waiver of HIPAA authorization? ☐ Yes ☐ No

If you are using a limited data set with no direct identifiers, a waiver of HIPAA may not be required.

Disclosures:
Do you intend to disclose information? ☐ Yes ☐ No
If Yes, to whom?

If yes, and the data includes only indirect identifiers as a limited data set, then a data use agreement must be signed with the recipient of the limited data set.

If yes, and the data used includes direct identifiers then the risk to privacy may be greater than minimal and full IRB review is required. Please provide rationale as to why the disclosure of the protected health information with these direct identifiers is thought to involve no more than minimal risk to the rights, welfare and/or privacy of the individuals.

Fully describe any additional privacy protections that will be put in place in order to protect the privacy of the individuals.

II. Assurances of Principal Investigator

As Principal Investigator of this study, I assure the IRB that the following statements are true:
The information provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines.
The PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule. I will only store PHI on Guthrie Servers. I will not email or store PHI on portable electronic media. If these conditions are not met, I understand that approval of this research could be suspended or terminated.

Signature of Principal Investigator	**Date**
Signature of Faculty Sponsor	**Date**

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FOLLOWING SECTION IS TO BE COMPLETED BY IRB CHAIR OR DESIGNATED REVIEWER

III. Assessment and Determination

WAIVER OF INFORMED CONSENT	
1) Does the research involve more than minimal risk to the subjects?	☐ **Yes** ☐ No
2) Can the research be *practicably* carried out without the waiver	☐ **Yes** ☐ No
3) Can the research be *practicably* carried out without using the identifiable private information in an identifiable format?	☐ **Yes** ☐ No
4) Will a waiver of the requirement to obtain informed consent adversely affect the rights and welfare of the subjects?	☐ **Yes** ☐ No
5) Is it appropriate to provide subjects with additional pertinent information after participation?	☐ **Yes** ☐ No

Waiver of Consent: The requirements for waiver of consent have been reviewed and documented as above. If all criteria are answered "No" waiver of consent is determined as acceptable by the IRB.

CRITERIA FOR EXPEDITED REVIEW	
(1) Does the research involve more than minimal risk to the subjects?	☐ **Yes** ☐ No
(2) Does identification of the participants and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, If yes, will reasonable and appropriate protections be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.	☐ **Yes** ☐ No Answer only if Yes to (2) ☐ **Yes** ☐ No
☐ **Approved after expedited review - Category 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). per [45CFR46.110(b)(1), 116(d), 117(c), 45CFR164.512(i)(1)] Continuing Review is not required unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects Reviewer justification for why continuing review would enhance protection of research subjects. Explain only as applicable:	☐ Referred for Review at Convened Meeting

Determination of FLEXIBILITY per policy GF-IRB-322-002

☐ **The research is determined by the IRB to be no more than minimal risk**

☐ **The research is not federally funded**

☐ **The research is not conducted in New York State**

All of the above are met and the research is eligible for flexibility ☐

OR If not all of the above are met: The research is not eligible for flexibility ☐

The requirements for waiver of consent, expedited review and flexibility have been reviewed and documented as above.

***Conflict of Interest Statement:* I do not have a personal, scientific or financial interest in this project.**

IRB Chair/Designated Reviewer — Date