Community Medical Center | RWJBarnabas HEALTH

Application for Waiver Approval for Use or Disclosure of Protected Health Information (PHI) for Research Purposes

Date Request Submitted: 4-8-2020

Date Records Required: 4-17-2020

Department from which records are Requested:

Principal Investigator (Please Print):

Name: Andrew Vassallo, PharmD, BCPS, BCCCP

Address: 99 W Rt 37 Toms River, NJ 08755

Phone #: 732-557-8000 Ext: 18070 Fax #:

Email: Andrew.vassallo@rwjbh.org

Co-Investigator Contact Information:

Name: Jose Iglesias, DO Phone #: 732-691-3668 Email: jiglesias23@gmail.com

Name: Vishal Patel, PharmD, BCPS Phone #: 732-974-1007 Email: vishal.patel@rwjbh.org

Name: Phone #: Email:

In order for the Institutional Review Board (IRB) to grant a waiver approval of the use or disclosure of PHI, the IRB must be satisfied that your project involves no more than minimal risk to the privacy of individual participants and meets all the criteria listed below.

A. The project has an adequate plan to protect subject identifiers from improper use and disclosure as described below. Examples of elements that should be included in an adequate plan are noted below (Put an "X" by all that apply and add any other protections in your plan):

- X Only authorized persons will be granted access.
- X Only authorized persons may enter and view study data.
- X Passwords and system identifications will not be shared.
- X Physical security of the workstations/files will be maintained.
- X Adequate backup plan is in effect.
- X Staff are trained on the data entry system and importance of security procedures.
- X Workstations with the database will not be left unattended.
- _____ Additional protections: _____

B. Investigators are required to only obtain the minimum necessary data in order to achieve the goals of the research. Briefly describe the PHI for which use or access is requested and justify why the data you are obtaining is the minimum necessary to achieve the goals of the research.

Necessary information for this study includes patient's FIN, MRN, age, sex, medical/social history, medications administered, vital signs, lab values, diagnosis, and disposition.

This will be used to evaluate the treatment protocols given to COVID-19 patients in the ICU.

C. The project has an adequate plan to destroy the participant identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law. Please explain when/if the participants identifiers will be stored or retained.

Patient information will be stored in a password protected excel file kept on a password protected folder only accessible on hospital computers. Everything used in the medication use evaluation will have personal identifiers removed to protect patient's PHI.

D. Explain why the research could not practically be conducted without the waiver (in other words, why you cannot obtain patient authorization).

This is a retrospective review which does not include testing new therapy on subjects in a prospective manner. There is minimal harm to patients and it would be difficult to contact previous patients for consent.

E. Explain why the research could not practicably be conducted without access to and use of the individual identifiable health information.

This is a retrospective review which does not include testing new therapy on subjects in a prospective manner. There is minimal harm to patients and it would be difficult to contact previous patients for consent.

F. Information about data/specimens will not be used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for use in future IRB approved research. Please affirm your acceptance below with your signature.

By signing below you will also provide assurance that you and your research team will comply with the use and disclosure restrictions described above, and 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 Community Medical Center's policies concerning Uses and Disclosures of Protected Health Information Created for Research that includes treatment.

Signature of Principal Investigator — Date: 4-8-2020

IRB Office Use Only

This waiver of authorization was reviewed under (please select one):

☐ Full Board Review ☑ Expedited Review

Approved by: _____ (Signature) Approval Date: 4/9/2020

☑ Chair, Institutional Review Board ☐ Designee of Chair, Institutional Review Board

Community Medical Center IRB #1
Name of Institutional Review Board

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Waiver of Informed Consent

If you are requesting (a) a waiver of informed consent or (b) waiver of the consent procedure requirements to include all or alter some or all of the elements of informed consent [45 CFR 46.116(d)], you must document the responses to each of the following four statements:

		Circle One	
1.	The research in its entirety involves no greater than minimal risk.	(Yes)	No
2.	The waiver of informed consent will not adversely affect the rights and welfare of the subjects.	(Yes)	No
3.	It is not practicable to conduct the research without the waiver/ alteration.	(Yes)	No
4.	Whenever appropriate, subjects will be provided with additional pertinent information after their participation.	(Yes)	No

If you have circled the **"Yes"** response to each of the four previous statements, in order to receive the waiver, you must (a) describe the reason(s) the waiver is necessary and (b) explain whether entire informed consent is being waived or only certain required elements are being waived (if so, list which ones).

There will be no active treatment or test subject – patients will be retrospectively reviewed for their treatment of COVID-19 in the intensive care unit. All PHI will be protected observing HIPAA laws.

Principal Investigator: _____ (Signature) Date: 4-8-2020

If a waiver is granted under the previously mentioned conditions, documentation of informed consent (i.e., signed consent form) is also waived. Even if the waiver is granted, the Institutional Review Board (IRB) may require other conditions. The IRB may require the researcher to provide subjects with an information sheet (written summary) about the research.

IRB Office Use Only

This waiver of authorization was reviewed under (please select one):

☐ Full Board Review ☑ Expedited Review

Approved by: _____ (Signature) Approval Date: 4/9/2020

☑ Chair, Institutional Review Board

☐ Designee of Chair, Institutional Review Board

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