**ROWAN UNIVERSITY SCHOOL OF OSTEOPATHIC MEDICINE**

**Data Request for IRB Approved Projects and**

**Investigator Representation for Review of Protected Health Information Preparatory to Research**

1. **Project Information:** Click here to enter text.

 **PI:** Click or tap here to enter text.

 **Project Title:** Click here to enter text.

 **IRB Status:** [ ]  N/A, [ ] Pending

 [ ]  Approval, Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_

 [ ]  Rowan SOM, [ ] Other University IRB:

 **Data destruction date**: Click or tap here to enter text.

 If IRB approved, please attach IRB approval summary. If not IRB approved, briefly describe how this information is needed in preparation for your research study. Click or tap here to enter text.

2. **Regulatory Criteria for Review Preparatory to Research**

2.1 Describe the protected health information that you wish to use/disclose without specific patient authorization (e.g., type of data, X number of most recent surgical charts, all MRIs for patients with specific disease, etc.)

 Click or tap here to enter text.

2.2 a. Briefly describe how this information will be used and/or disclosed in the research project.

 Click or tap here to enter text.

 b. Will any information be shared with any person who is not an employee of the facility releasing the information?

 [ ] No [ ] Yes If yes, describe the circumstances:

 Click or tap here to enter text.

 c. Will any information be removed from the facility releasing the information where it is currently maintained?

 [ ] No [ ] Yes If yes, explain:

 d. Will patient-subject identifiers will be recorded?

[ ] No [ ] Yes If yes, explain how PHI will be separated from research data.

3. Identify the individuals who are authorized to review health information on behalf of the principal
 investigator:

 Click or tap here to enter text.

**Please include the list of study personnel who are authorized and have current research training to review health information.**

Click or tap here to enter text.

4. Investigator’s Representation. - I certify that:

* I will only review protected health information as necessary to prepare a research protocol or for similar preparatory to research purposes. [ ]
* Except as noted in section 2.2b and 2.2c I will not copy or remove PHI from the facility/space/location releasing information in the course of the review. [ ]
* The Protected Health Information I am requesting is the minimum necessary information for the preparation of this research. [ ]
* PHI identifiers will not be recorded if obtaining protected health information from another covered entity. [ ]
* Except as noted in Section 2.2b and 2.2c, I will only use the data on Rowan\_\_encrypted and password protected system only. [ ]
* I will keep all printed PHI and related data in a locked cabinet and locked office. [ ]
* I will store PHI data and study related dated in difference locked cabinets. [ ]
* I will ensure that the investigator has completed the current training and only perform all work on site. [ ]
* Prior to accessing any patient charts, I will verify the patient’s research opt-out statue prior to reviewing any clinical data containing PHI. [ ]
* I will strictly observe the data destruction date as stated in Section 1 of this form. [ ]
* Data handled by investigative team only with current training required, on-site only. [ ]
* Prior to accessing any patient charts, I will verify the patient’s Research Opt-out status prior to reviewing any clinical data. [ ]
* I will strictly observe the data destruction date in Section 1 of this form. [ ]

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Approved**- Compliance/Privacy Officer Signature

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Approved**- FPP Executive Director (when using Rowan patient data)

DO NOT RELEASE ANY RECORDS UNTIL RECEIPT OF IRB APPROVAL

**PLEASE ATTACH THIS FORM TO YOUR eIRB application.**