**GUIDANCE NUMBER 24**

**GUIDANCE ON PREPARATORY RESEARCH**

In accordance with the HIPAA Privacy Rule, Rowan University School of Osteopathic Medicine (RowanSOM) may use or disclose Protected Health Information (PHI) for the purpose of ‘Reviews Preparatory to Research’ (RPR), wherein a researcher uses/reviews PHI for the purpose of developing a research protocol; formulating a research hypothesis; or to screen for study eligibility.

Under the ‘Reviews Preparatory to Research’ (RPR) mechanism, the RowanSOM may release PHI to a Researcher without an individual’s HIPAA Authorization or a Waiver of HIPAA Authorization granted by the Privacy Board. However, the law requires that the RowanSOM obtain from the Researcher the attached RPR Form to ensure privacy and confidentiality of the PHI being released.

**Procedures**

1. Researchers who are members of the RowanSOM may utilize PHI of the RowanSOM obtained through the RPR to contact patients for recruitment activities.

2. At no time during the review will the information be removed from the RowanSOM premises.

3. Special Note on Reviewing PHI for Recruitment Purposes. Researchers may use PHI obtained pursuant to this Review Preparatory to Research procedure to contact potential study subjects subsequent to receiving the RowanSOM-IRB approval for the study protocol. At no time you nor your staff will contact patients about the proposed study or conduct any research until you submit and receive the approval for the human subject protocol from RowanSOM, but only after IRB approval of the study has been obtained.

4. Researchers who are not members of the RowanSOM may utilize the PHI of the RowanSOM obtained through the RPR for recruitment only upon obtaining IRB approval of the study and obtaining a HIPAA Partial Waiver of Authorization from the IRB/ Privacy Board.

5. At Rowan SOM, the IRB serves as both HIPAA Privacy Board and the IRB.

6. The HIPAA Privacy Officer at RowanSOM verifies that the completed RPR Form is in compliance with the Standard Operating Procedure. If changes are required, the HIPAA Privacy Officer advises the Researcher of the changes needed. If no changes are required, the HIPAA Privacy Officer signs and dates concurrence and returns the RPR Form to the Researcher and retains a copy in the office. Signed RPRs will be reported to the Privacy Board.

7. The review of PHI will commence on the date of approval of the RPR Form and will expire on the date specified in the Certification Form. After the expiration date, you will no longer access the PHI for research preparation and will retain the PHI in accordance with the policies on human subject research, only if needed as part of an approved research protocol from the RowanSOM IRB.

8. At the time of IRB submission, the PHI in the research protocol submitted to the IRB should match the RPR. If additional PHI or data elements are added to an IRB without first going through the RPR process, the number of subjects may not be available. Any change or addition of PHI in an existing, verified RPR requires a revised RPR to be submitted to and verified by the HIPAA Privacy Officer at RowanSOM before submitting to the IRB in a research protocol.

**Note:** In the case where the PHI is being derived from another Covered Entity (CE) and the Rowan IRB is establishing a protocol for such study, the RPR must be completed. Note that the information is being obtained from another site and all documents from the site necessary to conduct research must be made available and part of the RPR process.

For additional Information, please contact the HIPAA Privacy Office at:

Ray Braeunig, CHC, CHPC, CHRC

Chief Compliance & Privacy Officer

Office of Compliance & Corporate Integrity

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**856-566-6136**

Reference: 45CFR 164.512(i)(1)(ii)