This guidance/process is being provided for the Rowan Medicine Human Subject Offices and Human Subject Research.

- Reference: http://www.rowan.edu/som/hsp/guidance/index.html
- The CFR (Code of Federal Regulations) Parts 160 and 164 are to be followed always.
- Our Notice of Patient Privacy (NPP) identifies research {for Rowan Medicine patients} as the following:

"While most uses and disclosures related to research require your authorization, in some limited situations we may disclose your health information to researchers when their research has been approved by an Institutional Review Board or similar privacy board that has waived the individual authorization requirement in accordance with the regulations covering this area."

This helps in our efforts to contact the patient (s) for research purposes but in no way is the full authority for approval of a waiver of authority to contact patients. The approval must follow the guidelines below for this to be administered properly.

The following steps should be followed when identifying patients from Rowan Medicine:

1. All information must be populated in the Rowan Medicine eIRB.
2. Identification of possible subjects through preparation for research database search which is reviewed by study team members. This access to possible subjects and search may come from a variety of databases (applications). This must be spelled out when initial request is submitted to IRB/Privacy Board for access to patient information. Approval for this extraction of data must be approved by the IRB/Privacy Board.
3. If possible subject is a patient of Rowan Medicine; the study team will call patient/possible subject to gauge interest in participating in this clinical trial. If patient expresses interest, the study will be briefly explained. ***Please note that contacting the patient can be a problem as many patients do not understand this aspect of HIPAA, we should be cautious when contacting the patient via the telephone and must be approved by the IRB/Privacy Board.***
4. The patient/possible subject will be scheduled for screening visit where informed consent will be obtained and study will be explained in detail.
5. During the consent process, the subject will be informed there may be contact with his/her Primary Care Physician to obtain records/history or to just advise that subject is in a clinical trial. This information will be documented (added) as part of the consent process as well.
6. Primary Care Provider will be contacted by study team member if necessary for medical information or study inclusion criteria.

While submitting research the detailed process upon which is followed for accessing patient records must be part of the IRB Request. It will be the Privacy Officer's responsibility to review the established protocol at that time.