Research Study Subject Recruitment and Screening –HIPAA Waiver Procedure

Purpose: This standard operating procedure ("SOP") establishes the general rules and processes for accessing Protected Health Information or PHI, including in Epic, for any and all study recruitment and/or study screening activities (preparatory to research), through the use of a full or partial HIPAA Waiver. Requests for full HIPAA waivers in other situations (e.g., retrospective chart reviews) are outside scope of this SOP.

General Rules:

1. All requirements of this SOP must be consistent with the research procedures set forth in Rutgers eIRB+, Rutgers Office for Research, and the RWJBarnabas Health ("RWJBH") Research Office ("RRO") requirements, as applicable. If there is a conflict between the requirements, then the terms of this SOP shall control.

2. It is permissible for clinical staff members of a patient's Clinical Care Team (as defined in Appendix A), who are also researchers in good standing with the Rutgers IRB and RWJBH, as applicable, to review that patient's medical records, to determine the patient's eligibility for research studies. This "eligibility review" can be completed in advance of a patient visit and/or before the research study is introduced to the patient.

3. Researchers who are NOT members of a patient's Clinical Care Team are not permitted to review patient medical records to determine eligibility for research studies except as set forth below with IRB-approved partial waivers to the HIPAA authorization requirements.

4. EPIC access for clinical care purposes does not authorize automatic access to EPIC for research, including recruitment and/or screening.

IRB-approved Waivers to the HIPAA Authorization Requirements:

5. To allow a Study Team and its members (as defined in Appendix A), who are in good standing with Rutgers and/or RWJBH as applicable, to solicit or access PHI for the purposes of screening and/or recruitment ***before*** a study subject has given informed consent and HIPAA authorization, the Rutgers IRB (or other designated IRB) must approve a full waiver or as and when applicable, a partial waiver of the HIPAA authorization requirement for these purposes. **Important Note:** the term "partial" HIPAA waiver implies that the identified patient to be enrolled as a study participant will later sign the IRB approved study consent form and HIPAA authorization.

For the avoidance of doubt, the Rutgers IRB procedures require that an investigator who is not part of the clinical care team request a HIPAA waiver for access to PHI in Epic for screening and recruitment. An assigned HIPAA committee member will review the request and make and document a determination through the eIRB+ system.

Hypothetical clinical research scenarios illustrating when a partial HIPAA waiver is required (versus when it is not) are provided as Appendix B to this SOP.

6. As part of the request for a waiver of HIPAA authorization for screening and recruitment, the investigator must submit the following information to the Rutgers eIRB+ or other designated IRB:

a. A description of the planned recruitment processes, including screening activities.
b. A justification as to why the PHI sought is necessary for recruitment and screening purposes (i.e., why the research cannot be carried out without access to the PHI during the recruitment and screening stage)
c. An attestation that use/disclosure of PHI for the purposes of screening for the research involves no more than minimal risk to the privacy of the potential study participant/patient
d. A brief description of the PHI required to determine eligibility.
e. A plan to protect the PHI from improper use and disclosure.
f. A plan to destroy the identifiers at the earliest opportunity if the potential study participant/patient does not ultimately sign the study consent form and HIPAA authorization (or provide a legal, health or research justification for requesting to retain identifiers)
g. Written assurances that the PHI will not be reused or disclosed except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the Privacy Rule.
h. Any other information that the reviewing IRB requires.

7. The request for a waiver of HIPAA authorization shall be submitted to the Rutgers IRB or designated IRB (except, in RWJBH's sole discretion, if RWJBH has another IRB as the IRB of record) for review. All IRB decisions including approvals or denials of HIPAA waivers shall be stored and maintained in the IRB eIRB+ or other designated IRB for review and approval.

Note: This SOP applies only to recruitment and screening.

Appendix A: Definitions

1. **Clinical Care Team:**

   Two or more health care professionals who work collaboratively with patients and their caregivers to accomplish shared clinical goals. This may include a physician and his or her clinical support staff (such as advanced practice nurses, RNs, patient care technicians) or members of a multi-disciplinary team such as clinical pharmacists, social workers, nutritionists, nurses, attending physicians, residents and medical students or other trainees). Physicians within the same practice who might reasonably be expected to cover for one another may also be considered part of the practice patient's care team. For the purposes of the Partial HIPAA waiver SOP, however, a member of the clinical care team is a health care professional who would reasonably be expected to require access to a patient's medical record in order to perform their job duties as a clinician.

2. **Protected Health Information or PHI:**

   Shall have the same meaning in this document as the term "protected health information" in 45 CFR §160.103.

3. **Study Team:**

   A team of one or more individuals who conduct and implement a study at a study performance site, including RWJBH. Study team members work on the study under the supervision of the principal investigator, and may include co-investigators, research nurses, study coordinators, regulatory managers, data managers, pharmacists, research assistants and data entry clerks, among other roles as documented in eIRB.

Appendix B: Partial HIPAA waiver scenarios

Hypothetical clinical research scenario	**Potential HIPAA implications/partial HIPAA waiver requirements**
1. An RU clinician investigator is the Principal Investigator ("PI") for a clinical trial of a new therapeutic for patients with heart failure. The study enrolls outpatients from the RWJUH clinic. The Rutgers University ("RU") employed study team (who are not members of the clinical care team) plans to access clinic appointment schedules and review patient records to screen for potential eligibility. They may use Deep6 AI Cohort Builder and/or SlicerDicer to aid in the process.	Partial HIPAA waiver required as RU study team are not members of the clinical care team.
2. An RU clinician investigator is developing a new biomarker in her research lab to aid in the diagnosis of Crohn's disease. She seeks to recruit her own patients and patients of her colleagues within the same Rutgers Health practice for a one-time blood draw study. She must confirm that the patient has a diagnosis of Crohn's disease and was never treated previously with monoclonal antibody therapy.	Partial HIPAA waiver not required. The investigator has a treating relationship with the prospective participants by virtue of being their treating physician, or a potentially covering treating physician within the same practice.
3. The recruitment plan for a Rutgers study to collect microbiome samples from pregnant women in their second trimester entails the use of SlicerDicer and to message potential participants (who appear to meet the study inclusion/exclusion criteria) via MyChart. The MyChart message directs patients who are interested in learning more about the study to click the green "yes" button, so that the RU employed study team (who are not members of the clinical care team) may communicate directly with the potential participant about joining the study.	Partial HIPAA waiver required as the RU study team are not members of the clinical care team, and they will view PHI through SlicerDicer in generating the list of potentially eligible participants. (Note that patients are able to set a preference to NOT be contacted within MyChart.)

	Hypothetical clinical research scenario	Potential HIPAA implications/partial HIPAA waiver requirements
4.	A Cooperman Barnabas Medical Center (CBMC)transplant surgeon is the PI for a clinical trial of a new anti-rejection drug. The CBMC employed study team (which includes a nurse with clinical responsibilities as well as a research assistant ***without*** clinical responsibilities) will review the records of patients who have just been admitted to CBMC for renal transplant to see if they qualify for the study.	Partial HIPAA waiver required since one of the members of the study team is not part of the clinical care team.
5.	A Rutgers University ("RU") clinical psychologist investigator is interested in understanding more about the emotional burden of full-time, live-in caregivers of adults with dementia. The main recruitment strategy entails placement of flyers with a QR code in the waiting room of a Geriatrician's practice. The QR code leads to a study landing page where the caregiver is asked preliminary questions as to whether they qualify for the study, i.e. whether they live with the person they care for or not; whether the person they care for (who is not a study participant) has been diagnosed with dementia, etc.	No partial HIPAA waiver needed. The study participants are not patients. (Note: hospital policies with respect to distributing or posting study recruitment flyers need to be followed.)
6.	A clinician investigator is studying a novel treatment for a rare metabolic condition. ALL participants for this study will be recruited from outside of the health system. A potential participant with this condition finds out about the study by searching on Clinicaltrials.gov or other external search and contacts the study team, for example, by phone or email or by responding to a matching program such as ResearchMatch, to find out more information on the study. Since the potential participant lives several states away and is not a patient of the health system, she sends copies of her medical records to the study team and asks that the coordinator go through the eligibility checklist and review relevant sections of her medical record before scheduling an appointment to come in for a screening visit to assure that she is likely to qualify for the study.	Partial HIPAA waiver would not be needed because ALL potential participants are self-identified. In this scenario, the potential participant is voluntarily sending her records to the study team. In this scenario, no RU or RWJBH records will be accessed before the consent/HIPAA authorization is signed.

Hypothetical clinical research scenario	**Potential HIPAA implications/partial HIPAA waiver requirements**
7. An RU clinician investigator is a site PI for a multi-center trial looking at digital cognitive behavioral therapy for young adults with Sickle Cell Disease (SCD). He plans to engage his colleagues across the health system who treat patients with SCD. The study recruitment plan entails **asking the clinicians to provide their potentially eligible patients with a flyer for the trial. The flyer provides a brief description of the trial as well as directions for the prospective participant to contact the RU study coordinator for more information.**	Partial HIPAA waiver NOT required since the prospective participant will be contacting the study team. The RU study coordinator will elicit information from the potential participant over the phone in order to determine whether the participant is likely eligible for the study prior to scheduling a screening visit and will NOT view PHI in advance of the potential participant signing the consent/HIPAA authorization.
8. An RU clinician investigator is a site PI for a multi-center trial looking at digital cognitive behavioral therapy for young adults with Sickle Cell Disease (SCD). He plans to engage his colleagues across the health system who treat patients with SCD. **The study recruitment plan entails asking the referring clinicians to identify potentially eligible patients and to provide those patients with a flyer for the trial. The clinicians will then ask the patient whether he/she gives permission for the study team to contact them.** If the patient agrees, the referring clinician will message the RU study coordinator (who is not a member of the patient care team) through Epic so that they may contact the prospective participant. Upon receiving the message, the study coordinator briefly reviews the potential participant's chart for eligibility and then contacts them to describe the study in more detail. If the potential participant is in agreement, a screening visit is scheduled.	Partial HIPAA waiver required. The RU study team will view PHI prior to the potential participant signing the consent/HIPAA authorization.
9. An RU clinician investigator conducting a trial for Parkinson's Disease plans to screen and enroll only her own patients. She is assisted by a research nurse who has patient care responsibilities as well as research duties. No other research staff will be involved in participant recruitment.	No partial HIPAA waiver required. All members of the study team who view PHI in advance of the potential participant signing the consent/HIPAA authorization have a treatment relationship with the potential participant.