HIPAA Form C

Request for Recruitment Waiver of Authorization

Protocol Number: IRB-_____
Name of Study: _____
Principal Investigator: _____

1. **Describe the nature and scope of the patient information to which access is sought:**

   This request for recruitment waiver of authorization is submitted in accordance with guidelines set forth by the Columbia clinical trials office and consistent with requirements of the Columbia privacy boards for HIPAA compliance.

   Describe how participants will be recruited:
   Potential participants who have consented to be contacted for research (CCR) in the electronic health record, Epic, through the Connect Patient Portal will be contacted based on the eligibility criteria of the protocol. The CCR consent form does not include HIPAA authorization for use of the patient's health information. This recruitment waiver is for that purpose. A TRAC request will be made to provide a cohort of potential participants in Epic through the Reporting Workbench.

   The IRB approved study description will be sent once to each patient via MyChart (Connect), who can indicate in Connect if they are interested in receiving more information or decline the invitation. Potential participants who do not respond in Connect may also be sent the information by Qualtrics or Redcap. Such reminders will be sent a maximum of 2 times. Patients who provide consent to participate in a study will also provide HIPAA authorization for use of their health information for study purposes, at which point this waiver will no longer apply.

2. **Please answer the following questions.**
   a) **Why would it be impractical to rely on Columbia University, or on a Columbia University-affiliated clinician with whom the potential participants have a treatment relationship, to contact the potential participants on your behalf?**

      This waiver applies only to patients who have already provided consent to be contacted for research. The CCR consent form does not include HIPAA authorization for use of the patient's health information. This recruitment waiver is for that purpose.

   b) **Describe your plan to safeguard the patient information from improper use and disclosure while it is in your possession.**

All patient data will remain encrypted throughout the study and all research team members are trained on HIPAA regulations. Access to PHI will be limited to study members using secure endpoints or certified systems. Where feasible, patient data will be coded with a linking study ID to PHI. In addition, effort will be made to interact with patients from a private location.

Throughout the conduct of the study and during retention of data after the study has concluded, security measures should include, but not be limited to, the following guidelines:

- Using Qualtrics or Redcap and not individual email outreach
- Using unique study IDs instead of direct identifiers where possible, storing the key that links identifiers with the IDs separately from the data
- Reporting to the IRB all concerns or comments voiced about the recruitment method by those patients who are contacted.

c) Describe your plan to destroy or return the patient information at the conclusion of the record review/recruitment activity.

All patient information will be securely stored at the conclusion of the research activity as long as required in accordance with IRB guidelines.

To track the utility of use of the CCR registry for recruitment, investigators are requested to:

- Keep records and report to the IRB: Number of emails sent, number that were opened, number who asked for more information, number successfully contacted, number enrolled.