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Instructions for Rascal submission to use Epic's Consent to Contact for Research Registry

through the Connect Portal and Qualtrics / REDCAP

These instructions apply whether use of Epic's Consent to Contact for Research (CCR) registry is proposed during submission of a new Protocol, i.e., Rascal "Protocol" Event, or in a "Modification" Event to an approved protocol, or as a modification embedded within a "Renewal" Event for an approved protocol. In the case of Modifications and Renewals, the modification summary should clearly state that use of the CCR registry is being requested, and should indicate if the use of the registry is in addition to currently IRB approved recruitment methods or will be replacing any of them.

Requests to use the CCR registry should be approved promptly by the IRB if the instructions below are followed.

Important note: The CCR registry does not currently include minors, as the CCR consent form is only presented to patients who are at least 18 years old.

1. **Add HIPAA Form C to IRB submission.**

In the Rascal HIPAA module, the appropriate form to select is "Form C: Consent to Contact for Research". The HIPAA Form C is a request for waiver of HIPAA authorization and is required because the consent form that patients sign to provide consent to be contacted for research, based on information in their medical records, does not include HIPAA authorization language. Attach the completed form to the IRB protocol.

2. **In the Recruitment and Informed Consent section of the Rascal IRB application form, in response to the instruction "Select all methods by which participants will be recruited:", select the checkbox for "Epic Consent to Contact for Research (CCR) Registry".**

When the checkbox is selected, a text box will appear with the instruction, "Enter the text that will be sent to eligible patients, using this template language". The text that will be sent to eligible patients should be entered in the text box, using the following template language.

a. **The "Patient Facing Study Name" to be displayed in the Connect Portal:**
[Short title to be displayed in Connect to the patient]

and

b. **The "Patient Facing Study Description" that will be sent to potential participants, using the following template**:

You are receiving this message because you consented to be contacted for research in the electronic health record, Epic, through the Connect Patient Portal and you may be eligible to participate in this study. **[required]**

[Short description of the study for the patient]

If you want to learn more about this research study, a research team member will contact you. They will explain the study and answer any questions you may have.

Finding out more about a study does NOT commit you to participating in it. Select one of the following:

☐ *I am interested in learning more. Please contact me using my contact information in Epic.*
☐ *No, thank you; I am not interested in this research study.*

If you do not wish to be contacted in the future about any research studies, please contact the Columbia University Privacy Office at 212-305-7315 or by email: hipaa@cumc.columbia.edu. **[required]**

3. **In the Recruitment and Informed Consent section of the IRB application form, in response to the statement, "Describe how participants will be recruited:", describe use of the CCR registry.**

The following sample language is provided for this purpose:

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.

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 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** will be sent the information by **Qualtrics or Redcap**. Reminders will be sent a maximum of 2 times.*

When requesting to use the CCR Registry, **Researcher** agrees:

- to use Qualtrics or Redcap and not individual email outreach
- 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
- to report to the IRB all concerns or comments voiced about the recruitment method by those contacted

4. **In the Procedures page of the IRB application form, select "Analysis of Existing Data", and complete the Analysis of Existing Data page that will appear after the Procedures page is saved.**

   On the Analysis of Existing Data page, select "Columbia and/or NYP" and then "Data to be analyzed were or will be collected for clinical care" in response to the question, "Data will be obtained from (select all that apply)". In response to the prompt, "Provide the specific patient information that will be extracted or requested in a TRAC report, i.e., each data variable", enter the criteria for the data that will be extracted or requested in a TRAC report, which should be consistent with the IRB protocol. Inconsistencies between the TRAC request and the IRB-approved protocol will result in delay of approval of the TRAC request.

   Criteria to include:

   - Patients who have answered "YES" to consent to be contacted for Research **(required)**
   - *[list of variables, which must be consistent with the scope of the IRB-approved protocol (for modifications and renewals) or proposed study (for new protocols)]*

5. **Qualtrics/ Redcap Survey (template provided below), for maximum two (2) follow-up contacts to potentially eligible patients who received an initial contact through Epic:**

The following sample language is provided for this purpose:

Page 1 (email message):
Thank you for seeking healthcare at Columbia University Irving Medical Center – NewYork-Presbyterian Hospital.

Through the CONNECT link you agreed to be contacted to learn about participating in a research study.

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Dr. (PI Name) is conducting a research study to learn [e.g. whether an experimental drug may be helpful for people with certain medical conditions]. You may be eligible to take part in this research study.

- *Click here to learn about this research study.*
- *If you do not wish to be contacted in the future about any research studies, please contact the Columbia University Privacy Office at 212-305-7315 or by email: hipaa@cumc.columbia.edu.*

Page 2: If the patient clicked the link to open the survey, they should be provided with the same information that will be entered in the text box in Rascal, as described in section 2 above, with one revision: the response options will be limited as follows:

☐ *I am interested in learning more.*
☐ *No, thank you; I am not interested in this research study.*