Subject: Contacting patients directly for research: Research Opportunities Direct to You (RODY) Program Overview

Research Opportunities Direct to You (RODY) Program Overview

Introduction
Meeting patient enrollment targets continues to be a challenge for many studies across Partners. The reasons for this are multi-factorial, but for many, involving the patient’s clinician in the review process, often adds to the effort, time and resources required. The Research Opportunities Direct to You (RODY) program allows a patient to agree to be contacted directly by researchers without involving their clinician. Utilizing this preference to contact patients directly may be appropriate for some studies and will be determined by the IRB. If you believe direct patient outreach is appropriate for your study, we ask that you review the information regarding appropriate use below.

Description of Program

The RODY program provides researchers with an alternative to the existing policy for contacting patients for research. The existing policy for research contact\(^1\) requires that a clinician known to the patient participate in the contact. Clinicians do not ‘give permission’ for their patients to be contacted, they review lists of patients generated by the researcher and indicate which of their patients are appropriate FOR contact, and AGREE to cosign the recruitment letter or be mentioned in the recruitment letter.

The RODY program allows a patient to agree to be contacted directly by researchers without involving their clinician.

\(^1\) Log in to the Partners Research Navigator with your Partners username and password is required. Direct link: [https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/PHRC-Policy-and-Guidance.aspx#12](https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/PHRC-Policy-and-Guidance.aspx#12) (Section 12: Recruitment and Remuneration)
Through the RODY patient outreach program, patients are asked by clinical front desk staff if they are willing to be contacted directly by researchers about research studies. The patient response is noted in the Epic registration screen. Possible responses include:

| Agree to direct contact (RODY YES) | Decline direct contact (RODY NO) |

A RODY YES response means that the patient is willing to be contacted directly by a researcher.

A RODY NO response means that the patient is not willing to be contacted directly by researchers. Of note, RODY NO patients may still be contacted about research studies in the usual way with a recruitment letter co-signed by one of his/her clinical care providers (e.g., PCP, specialist provider, other provider appropriate to the research, such as a physical therapist for a back pain study).

As of January 2017, RODY YES patients may be contacted directly by US mail. In the near future, we expect that RODY YES patients will also be able to be contacted electronically through Patient Gateway.

**Program Scope**

RODY preferences have been set for patients seen across 700+ practices at the Massachusetts General, Brigham and Women’s, and Newton Wellesley Hospitals. As of January 2017, there are approximately 30,000 patients who have set a RODY YES preference to direct contact by researchers. In the near future, we expect that patients will also be able to set their RODY preference through Patient Gateway.

**Frequently Asked Questions**

**How do I find out which patients have agreed to be contacted directly?**

The patient’s preference for contact about research studies (RODY status) is available as a patient attribute and can be used in RPDR queries. It is also available in the Contact table that is returned with patient identifiable RPDR datasets.

**Do I need to inform the IRB about using RODY YES patients?**

YES. You will need to request direct contact of RODY YES patients in the Recruitment section of the Insight/eIRB application and describe the plan in your IRB proposal. A [template for recruitment letters to RODY YES patients](#) is available on the IRB website.

**YOU MUST RECEIVE IRB APPROVAL TO CONTACT RODY YES PATIENTS.**

**What if I plan to recruit RODY YES as well as RODY NO patients?**

Your protocol submission must include all plans for recruitment. You would need at least TWO separate recruitment letters for these strategies, one for RODY YES and one or two for RODY NO patients. Which templates you use will depend on your recruitment approach-- you may want to submit all options to the IRB to give you the most flexibility. Letters should be short, simply written, include the PI’s name, and indicate whether or not the patient might receive a follow-up phone call.

[Sample Research Opportunities Direct to Patient Recruitment Letter from Researcher](#)

[Sample Recruitment Letter from Patient’s Physician with Enclosed Letter from Researcher](#)
Sample Recruitment Letter Co-Signed by Patient’s Physician and Researcher

What if there is no RODY designation in the RPDR?

This means that the patient has not been asked about direct contact by researchers. These patients must be recruited in the standard manner, in collaboration with the patient’s clinical care provider.

What if I have or my patient has questions about the RODY program? What if a patient wishes to change his/her mind?

You and your patients can learn more about the RODY program by calling 1-866-391-7030. Patients may also use this number to change their minds and decline further direct contact. In the near future, we expect that patients will also be able to set their RODY preference through Patient Gateway.