Clinical IS **Update**

Topic:	**Research Recruitment Opt-Out**
Facility:	**Indiana University and IU Health**
Audience:	**Researchers and Staff**

Overview: *This document explains the process used to notify Clinical Research Systems when a patient tells a provider that they do not wish to participate in clinical research studies conducted at IU Health. In addition, this document demonstrates the changes seen by providers in PowerChart when the Clinical Research Systems team has implemented the request.*

Request Research "Opt-Out"

Per Clinical Research Recruitment Policy ADM 2.19, "Indiana University Health supports clinical research and the participation of IU Health patients ….and promotes a culture that enables the identification of potential subjects through electronic medical records and provides opportunities for patients to be contacted regarding participating in clinical research". On occasion, a patient may choose to decline being contacted for participation in clinical research opportunities as outlined in this policy.

Anyone receiving this request from a patient should take the following steps:

Step	Action
1	Acknowledge that the patient may choose to opt out of being contacted for clinical research opportunities with IU Health.
2	Send the following information via *secure* email to the **Clinical Research Systems** team at ClinicalResearchSystems@iuhealth.org : • Patients first name, middle initial, and last name • Medical record number • Date of birth • Phone number (if available)

Clinical Research Systems Team Member

Step	Action
3	Verify the information once the request is received.
4	Select **Not Interested** from the **Patient Interest in Prescreening** drop-down list of options in the **Clinical Research** band in PowerChart. *See the results of marking a patient as Not Interested on the next page.*

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Request Research "Opt-Out", (continued)

Marking a patient as **Not Interested** results in the following outcomes:

- Patient is automatically excluded from all PowerTrials prescreening recruitment rules.
- Patient's opt-out status will be pulled into the EDW so the patient can be excluded from any recruitment activities originating from the data warehouse.
- Researchers looking for potential study subjects will be expected to make sure that the subject has not opted out of participating in research at IU Health by reviewing the Clinical Research band prior to contacting them as permitted by Clinical Research Recruitment Policy ADM 2.19.

Cancel Research "Opt-Out" Request

Any provider who receives information from a patient indicating that the patient no longer wants to be on the "Opt-Out" list can send the following information via *secure* email to the Clinical Research Systems team at ClinicalResearchSystems@iuhealth.org-

- Patients first name, middle initial, and last name
- Medical record number

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