DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

ENGAGEMENT AND RECRUITMENT OF PATIENTS TO A RESEARCH PROTOCOL

6/18/2024

It is a standard practice for clinical and research teams within the Duke University Health System (DUHS) to engage patients through contacts including, but not limited to portal messages, mobile health devices, telephone, electronic surveys at clinic visits or hospital admissions, or directly via one or more clinicians. Any of these methods may be used to engage patients in research related to their health, if approved by the DUHS IRB. The DUHS IRB will, in its review, consider the appropriateness of the recruitment methods in regard to the target population and the research objectives.

Preferences must be considered for contacting patients about research related to their health. Investigators must consider the characteristics of the eligible population, and *where*, *when*, and *how* potential research participants will be recruited to ensure recruitment practices are ethical, equitable, and minimally intrusive. Investigators should consider the optimal population to target - those who are most likely interested in participation while minimizing the number of unsolicited contacts.

At any time, a Duke patient may opt out of receiving any more notifications of research opportunities from those other than the patient's clinician or care team. This preference can be changed at any time and ideally would be re-evaluated on a periodic basis. Researchers/study teams must check the opt out status for each patient who may be eligible for their study and exclude those not wishing to be contacted to prevent unwelcome emails, phone calls, or other contacts from those other than a patient's clinician. This status can be found in the patient's electronic medical record.

Best practices for engagement for patients who may be interested in research must be routinely practiced and include the following:

- Respect for participant autonomy;
- Protect individual rights to privacy;
- Free from coercion and influence;
- Provide maximum safety for both the prospective participant and the study team;
- Allow sufficient time for prospective participants to consider whether or not they are interested in proceeding to the consent process;
- Consider recruitment settings which are optimal to the routine encounter;
- Consider recruitment time frames and settings that reflect the degree of risk: For example, the greater the risk, the more time prospective participants may need to consider their decisions about participating and should be reflected in the contact method and setting;
- Protection from frequent contacts of patients for multiple studies (i.e., spam);

- Tailor contacts by setting and method most appropriate for a patient's diagnosis (i.e., special attention towards sensitive diagnoses);
- Inform patients of how they were identified;
- Key personnel who are involved in patient recruitment are required to review the patient's medical record for study eligibility and must confirm the patient is aware of the diagnosis prior to approaching a patient.

For patients who have opted out of research, the patient's clinician or care team may discuss research opportunities as part of the clinician-patient relationship. In cases where this occurs, the following best practices are recommended:

- Document this discussion in Maestro Care to appear as part of the After Visit Summary. Include how the patient will be contacted, i.e., a CRC will call the patient, or how the patient may contact the study team if interested in participation.
- Follow up contact by the study team, if indicated, should be timely to minimize patient confusion.

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