



**POLICY STATEMENT REGARDING
RECRUITMENT OF “OTHER PEOPLE’S PATIENTS”
TO A RESEARCH PROTOCOL**

10/22/2007

It is a standard practice of the Duke University Health System (DUHS) Human Research Protection Program to disapprove investigators making a "cold contact" with potential research subjects who receive medical care within DUHS. A "cold contact" in this setting is defined as a planned contact (such as a face-to-face contact, telephone call, letter, or email) with a potential research subject by the investigator or a member of the investigator's key personnel when neither the investigator nor the contacting person is known to the potential subject as having a reason to know his/her medical diagnosis or other identifiable private information such as protected health information (PHI). Conversely, if a caregiver known to the patient as having reason to know his/her medical diagnosis or other PHI agrees to make contact with the patient seeking his/her research participation, or seeking an expression of his/her interest in learning more about possible research participation, this would not be regarded as a "cold contact".

In the setting where an investigator proposes to recruit other people's patients, the DUHS IRB provides guidance to the investigator to complete the following steps:

- Obtain permission of the patient's DUHS physician to contact the potential subject. If the patient is not currently receiving care within DUHS, the permission would be requested from the person's primary care provider.
- Provide IRB-approved study information (brief) to the patient's physician or primary care provider or other caregiver who is known to the patient.
- The physician, primary care provider or other caregiver then provides the patient with an introduction to the study and the name of the investigator (staff member) who will contact the patient. This introduction may be made in person during a hospital or clinic visit or via a letter to the patient from the physician or other appropriate caregiver. If a letter is to be used, it should contain the telephone number the patient may call to receive more information about the study if he/she needs this to decide whether to permit initial contact by the study team, or to express a lack of interest in study participation and request that no further research contact occur.
- In the absence of patient objection, the caregiver notifies the investigator/staff person to proceed with contacting the patient. In the case of patient objection, the caregiver notifies the investigator/staff person not to proceed with contacting the patient. If initial patient contact is by letter, the investigator must wait at least 10 days after sending the letter so a patient not interested in the study may express that preference.

- Once the above events have occurred, and the patient has not objected to learning more about the study, the investigator (staff member) is free to contact the patient about participating in the study.