Research – Documenting a Patient’s Interest to Participate

Introduction
With Connect Care, research and clinical staff will be able to flag when a patient is interested in participating in a specific research study. This flagging is done by linking the patient to the specific research study and updating the patient’s association status. It is important to understand the difference between consent to be approached for research and interest to participate in a research study, and how these two workflows are represented in Connect Care. The following sections briefly explain these two processes.

Consent to approach
The Health Information Act (HIA) states in sections 54 and 55 that whenever a researcher has access to personal medical information (e.g. a study has a waiver of consent from a Research Ethics Board and the researcher has pre-screened the chart), the custodian (AHS Intermediary) must obtain consent from the patient to be approached by the researcher. Once the patient consents, the research team may approach the patient and discuss the research study. This is called consent to approach.

Currently, consent to approach is not documented anywhere in the system, and with Connect Care this process will stay the same. The consent or decline to approach will not be documented in the CIS.

Interest to participate in a research study
Once the patient has been approached, the research team will explain and discuss the information regarding the specific research study in order to assess if the patient is interested in participating. Please note: this is not the Informed Consent Process, this is referring to the initial contact to verify patient interest.

If a patient’s clinical care team, through conversation with the patient, identifies that the patient would like to speak to a member of the study team regarding a specific study, they may link the patient to the specific research study and update the patient recruitment status to “interested” or “declined” (should the patient express that they are not interested in that specific study). Please note this is only possible in the cases where the member of the clinical care team is listed in the ethics application and the research study record in Connect Care.

After explaining the research study, if the patient expresses interest in participating and consents to the study, the research team should link that patient to the specific research study and update the patient’s recruitment status accordingly. If the patient expresses that they are not interested in participating in that specific study, no further action is required from the study team. Study teams members must only link the patient to the respective study once the participant signs the informed consent form specific to that research study.