

Children's Hospital Institutional Review Board

Information Sheet

Access to Children's Populations for Research Studies by Non-Staff Investigators

This information sheet discusses the relationship between outside investigators who wish to obtain access to a Children's population, and the Children's clinician who is willing to provide the access without participating as an investigator for the project. In general, the board requires that the Children's clinician serve as an active liaison and subject advocate. The Children's clinician is responsible for the following:

- Screening of outside inquiries to determine which, in the opinion of the clinician, hold the greatest promise for Children's patients and families, and complement the research goals of the division. This precludes "overstudy" of limited or vulnerable populations, which might benefit the group as a whole but impose significant risk or hardship on individuals.
- Determining which potential participants should and should not be contacted about the study, based on the clinician's knowledge of them.
- Approaching potential participants on behalf of the outside research team. The purpose of this approach is to obtain the individual's or family's permission to be contacted about the project. It is intended to protect the privacy of patients and families. Potential participants must agree to the release of their names, not merely fail to object to the release.
- Providing information and support to participants during the study. Families may choose to approach study investigators directly with questions and concerns. However, many will prefer to ask the clinician with whom they have an ongoing relationship, particularly when the research team is from another institution or geographic region.
- Where appropriate, providing follow-up care or referral services to participants. This will be affected by the clinician's ongoing relationship with the family, and is particularly important when the research team is not based locally.