RECRUITING AT OTHER INSTITUTIONS:

What can we do that doesn't require IRB approval for the recruitment site?

BACKGROUND

According to the **Office of Human Research Protections** (OHRP), any institution that is **Engaged in Human Subjects Research** needs IRB review. Tufts Health Sciences IRB only has oversight over Tufts University, Tufts Medical Center, MelroseWakefield, and Lowell General.

OHRP has posted guidance on <u>Engagement of Institutions in Human Subjects Research</u> that explains when an institution is or is not **Engaged.** (We also have posted this guidance in <u>worksheet</u> form.)

RECRUITMENT ACTIVITIES THAT DO NOT ENGAGE A SITE IN THE RESEARCH:

- Informing prospective subjects about the availability of the research
- Providing prospective subjects with IRB-approved information about the research (recruitment flyers, copies of the ICF)
- Informing prospective subjects how they can contact the investigators
- Getting the prospective subjects' permission for the investigators to contact them (including passing along the prospective subject's contact information, with their permission)

ACTIVITIES THAT DO ENGAGE A SITE IN THE RESEARCH:

- ★ Medical record review
- × Screening
- X Acting as representatives of the study team
- X Obtaining consent for the research / Enrolling subjects
- ✗ Collecting data for the research

BOTTOM LINE

If the recruitment site can identify prospective subjects *without* a medical record review, screening, or any other **X** activities that **Engage** the site in the research, then the site doesn't need IRB approval in order to conduct \checkmark activities that **don't Engage** it.

You may still need permission from the site to recruit there! Ask your collaborators at the recruitment site to touch base with their IRB office about what may be required. (Note that if you are being asked to recruit for an external study, you **must** submit to the IRB for a formal determination.)

For more guidance on IRB requirements for collaborative research, see <u>this slide deck</u> or <u>contact the IRB office</u>.