

## HIPAA and Subject Recruitment at Meriter

**You may contact a prospective subject if you have an IRB approved protocol for the following situations.**

- A Meriter employee asks a Meriter patient if they are interested in a specific study. The Meriter patient completes a study specific *Permission to Contact form*. The UW researcher may contact Meriter patients for whom they have a *Permission to Contact form*.
- A Meriter patient receives a study flier or brochure with contact information for the study. The Meriter patient uses the study contact information on the promotional material to reach out, indicating their interest in the study. The UW researcher may interact with the Meriter patient.
- You may send an Opt-In letter to a prospective subjects from Meriter's patient population that is signed by a collaborating Meriter Unit Manager or Director from the relevant clinical area.

### **When are Partial or Full Waivers of HIPAA Authorization Needed?**

- Record review study. The UW researcher needs a full waiver for all subjects whose records are used without the patients' permission (e.g., HIPAA Authorization).
- A study is comprised of two arms. One arm will be active participants who sign a HIPAA Authorization. The second arm is a different group of participants whose retrospective medical records will be used. The UW researcher will not interact with participants in the record review arm. The UW researcher needs a partial waiver for the record review arm to see these records without the patients' permission.
- The UW research team screens admission logs, procedure logs, and/or medical records for patients who meet study inclusion criterion. Patients who meet inclusion criterion are approached for study participation. The UW researcher is not part of the Meriter HIPAA Covered Entity so he/she needs a partial waiver for looking through health logs and records for potential subjects without permission from the patients.

Both the UW Arrow application and the Meriter Research Compliance application prompt users to request HIPAA waivers or authorization as appropriate.