Use of Electronic Health Records (EHRs) as a Recruitment Tool: Methods to Protect Privacy
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Background: Widespread implementation of electronic medical records or EHRs may lead to opportunities for introducing efficiencies into the clinical research process. While such systems are often touted as a rich resource, concerns are also raised about ownership of medical record data, use of protected health information, and individual privacy rights.

Methods: Our healthcare system, in concert with our academic medical practices, recently underwent a full conversion to a nationally recognized EHR, with implementation of the EHR in our four affiliated hospitals, all hospital outpatient clinics, all medical school outpatient clinics, a regional affiliated medical group, and a number of local private practices.

Findings: Now that the implementation phase of the EHR is complete, researchers are beginning to request research use of the rich database. In particular, our IRB was asked to consider whether the EHR could be used as a recruitment tool. We developed a model that can be used for recruitment for clinical trials through the EHR at our institution. The model involves written approval from clinic or practice directors to allow access to the EHR for identification of potential subjects, written contact with each Primary Care Provider (PCP), an opt-out mechanism by which the PCP can tell the researchers not to contact particular patients, a written letter of recruitment to potentially eligible patients after these approvals, and subsequent information to the PCP once an eligible patient becomes an actual research subject. The model has multiple steps and safeguards built into each step. Our goal in developing this model was to facilitate patient recruitment into an important federally funded clinical trial, while maintaining patient privacy and respecting the critical doctor-patient relationships that have developed over many years. While some may view this model as cumbersome for researchers, or too indirect with PCPs, the IRB evaluated the model as sufficiently protective while enabling use of a resource for recruitment.

Conclusions: We believe use of the model will be valuable to other institutions working to develop methods to enhance clinical trial recruitment. As other institutions implement the model, consideration of scope of persons allowed to access records and necessary permissions should be considered. Also, there should be consideration of the potential for inundating patients with recruitment requests, and parameters that may minimize that risk. Possible solutions include, perhaps, only allowing this avenue for federally funded research and/or only for large trials.