

Office of Research

TTUHSC EI PASO

Regulatory Lite



A hint of research compliance tips for your everyday life

Pre-screening Subjects

Did you know that there is a way you pre-screen a principal investigator's (PI) clinical list of incoming patients to see if they pre-qualify for a study?

It's true! Study research personnel can pre-screen a PI or coinvestigator's (CO-I) clinical patient schedule before patients come in for their clinic visit, but there are certain rules that need to be followed.

First, a HIPAA waiver must be submitted and approved through iRIS for that portion of the study, and the study application should indicate that prospective subjects, who are patients of the PI and/or CO-I, will be pre-screened in this manner.

Second, the PI and other CO-I's working on the study must agree to having their patient lists pre-screened.

Third, only study-pertinent patient records should be accessed for review purposes, and no PHI may be collected during the pre-screening.

Fourth, remember that only those with a direct patient care relationship may approach a potential subject to inform them about a study opportunity.

If you have any additional questions, feel free to reach out to your Research Compliance Unit.

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