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Funded clinical trials or observational outcomes studies must be registered on [ClinicalTrials.gov](#).

Funded evidence synthesis studies must be registered on [PROSPERO](#).<sup>20</sup> Funded patient registries must be registered on <https://patientregistry.ahrq.gov/>.

### Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, the Department of HHS issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information; it is administered and enforced by the Department of HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The [Office for Civil Rights](#)<sup>21</sup> provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools for AMI a cover identity information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available at the [NIH website](#).<sup>22</sup>

### Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees that fail to meet the mutually agreed-on milestones. Applicants proposed milestones will be finalized in contract negotiations and prior to execution. Please see PCORI's [Standard Contract Template](#) for more information.

### Co-Funding

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a PCORI-funded project and would like to seek PCORI funding to add a new award to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a program officer in advance.

**Note:** PCORI will not fund a project that is already funded through another funding entity. By submitting the application to PCORI, the AO is certifying that no overlap in funding exists at the time of submission. Prior to receiving a PCORI contract, awardees must disclose all current and pending support.

<sup>19</sup> Available at <https://www.clinicaltrials.gov/>

<sup>20</sup> Available at <http://www.crd.york.ac.uk/PROSPERO/>

<sup>21</sup> Available at <http://www.hhs.gov/ocr/office/index.html>

<sup>22</sup> Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html/>











