

ANPRM Proposals and OHRP Table Comparison of Existing Rules with Some of the Changes Being

**Relevance to Risks & Harms in
Social, Behavioral and Educational
Sciences**

ANPRM: Minimal Risk

Questions Raised	SBR Risks	IRB SBR Risk Evaluation
Questions have been raised about the appropriateness of the review process for SBR	The nature of SBR risks is often significantly different from biomedical research; the difference is not adequately reflected in the current rules	Some IRBs overestimate the magnitude and probability of reasonably foreseeable SBR risks
Given paucity of data suggesting significant risks in certain types of research surveys and interviews the current system over regulates such research	Little evidence that IRB risk over-estimation effectively protect research subjects from psychological or informational risks	Over-regulating SBR may distract from attempts to identify those SBR studies that do pose and merit significant oversight

Expedited Review & “Data Security Protections”

Current Rule	Changes being Considered	Rationale for Change
<p>Issue 10: Research that poses minimal risk and includes only research activities in a list approved by the HHS Secretary is eligible to be reviewed in an “expedited” manner (e.g., with one reviewer, instead of a convened IRB).</p>	<p>This list would be updated now, and at regular intervals.</p>	<p>Determinations about risks should be based upon appropriate data.</p>
<p>Issue 1: There are no specific data security protections for IRB-reviewed research outside of broad requirements for protecting privacy and confidentiality.</p>	<p>Specified data security protections would apply to such research, calibrated to the level of identifiability of the information being collected.</p>	<p>Setting uniform specific standards will help to assure appropriate privacy and confidentiality protections to all subjects, without administrative burden of needing IRB review of each study.</p>

Exempt Review

Current Rule	Changes being Considered	Rationale for Change
<p>Issue 14: Six categories of studies qualify as “exempt” from the regulations, meaning that they do not have to comply with any of the requirements of the regulations.</p>	<p>These studies would no longer be fully exempt from the regulations</p>	<p>They would be subject to the new data security protections and for some studies (e.g., those using biospecimens) new consent requirements would apply.</p>
<p>Issue 15: The categories of studies that qualify as “exempt” are clearly defined. It is difficult to determine whether a study qualifies as exempt.</p>	<p>The criteria for determining whether a study is exempt would be more clear-cut and less open to interpretation</p>	<p>Clearer criteria will increase transparency of the system and reduce the time and effort spent in determining whether or not a study qualifies as exempt.</p>

SBR Specific Exempt Review

Current Rule	Changes being Considered	Rationale for Change
<p>Issue 17: Research involving educational tests, survey procedures, or observation of public behavior are exempt except if, both (i) information is recorded is identifiable, and (ii) disclosure could create significant informational risk.</p>	<p>This exempt category would be broadened by eliminating criteria (i) and (ii) for studies that involve competent adults.</p>	<p>The new data security protections obviate the need for (i) and (ii).</p>
<p>Issue 18: Currently, SBR that involve certain types of well-understood interactions with subjects (e.g., asking someone to watch a video and then conducting word association tests), are not exempt from IRB review.</p>	<p>The ANPRM seeks public comment on whether studies using common SBR methodologies can be identified that should be eligible for exemption.</p>	<p>To identify areas of research that do not warrant the current degree of regulatory oversight so that review requirements are better calibrated to the level of risk.</p>