Social, Behavioral, Education Research (SBER) Changes To Common Rule; Effective Date 7/19/2018

Category	Changes	Comments
Definitions		
• **Clinical Trial**	Prospective assignment of subjects to evaluate biomedical or **behavioral** health-related outcomes.	
• **Human Subject**	Individual about whom investigator obtains, **uses, studies, analyzes, or generates** identifiable private data	"identifiable" to be re-examined every 4 years by Feds; retains 'readily identifiable' standard
• **Not Research**	1. Scholarly/Journalistic activities, e.g., **oral history** 2. Public Health Surveillance 3. Criminal Justice agency research 4. Intelligence Agency / Homeland Security research	Confirmation of current practice
• **Limited IRB Review**	Required for some Exemptions. IRB must review: privacy; confidentiality of data; broad consent	More like Expedited review, not Exempt
Exempt Research		
• **Educational Research**	May not adversely impact students' opportunity to learn	Normal educational practices
• **Interactions** via educational tests, surveys, interviews	If: 1. not identifiable; 2. no risk; OR 3. identifiable with potential risk and limited IRB review required	Not with children; pregnant women okay; incidental inclusion of prisoners okay.
• **Benign behavioral interventions:** Brief, harmless, painless, not invasive, offensive/embarrassing	Same as above	With prospective agreement of adult subjects only; No deception unless prospective subject agreement;
• **Secondary research** with identifiable data for which **no consent required**	If: 1. publically available; 2. recorded w/o identifiers, OR 3. Federal research	
• **Storage of identifiable data** for Secondary research	Must use Broad Consent and get Limited IRB Review	Only applies to identifiable data to be saved for future unspecified research
• **Use of identifiable data** for Secondary research	Must use Broad Consent and get Limited IRB Review	

Category	Changes	Comments
Streamlining		
• Continuing review	**No longer required** for Minimal Risk or when in data analysis	Includes analysis of identifiable data
• (Federal) Grant Review	**IRB No longer required** to review	
Single IRB		
• Cooperative Research **(sIRB)**	Mandated for (federally funded) multisite research	Effective 1/20/2020
Informed Consent		
• "Regular" Consent	Focused presentation of key elements first – reason to participate or not. Requirement to post federally sponsored clinical trial **(includes behavioral health-related)** consent form on public website 60 days after study close.	New element for collecting/using identifiable data. Either: identifiers will be removed and data used for future research, OR data will not be used for future research, even if identifiers removed.
• Broad Consent	12 Specified elements cannot be changed or altered, but waiver of documentation okay	Optional alternative to study-specific consent
• Waiver of Documentation (signature)	**New** allowable criteria: signing is not a cultural norm and research is minimal risk	