Medical Human Subjects Research – Some of the Changes
To Common Rule; Effective Date 1/19/2018, IF Implemented

Category	Changes	Comments
Definitions		
• **Human Subject**	Individual about whom investigator obtains, **uses, studies, analyzes, or generates** identifiable private data	• Retains "readily identifiable" standard, NOT HIPAA standard; • does NOT include DE-identified data or specimens; • "identifiable" to be re-examined every 4 years by Feds
• **Clinical Trial**	Prospective assignment of subjects to evaluate biomedical or **behavioral** health-related outcomes.	
• **Not Research**	1. Scholarly/Journalistic activities 2. Public Health Surveillance 3. Criminal Justice agency research 4. Intelligence Agency / Homeland Security research	Confirmation of <u>current practice</u>
• **Limited IRB Review**	Required for some Exemptions. IRB must review: privacy; confidentiality of data; broad consent	More like Expedited review, not Exempt
• **Broad Consent**	12 Elements required: • Risks • Benefits • Confidentiality of Data • Voluntary • Commercial Profit • Whole Genome Sequencing • Types of Future Research • Description of identifiable data/specimens, what identifiers, will sharing occur and with whom	• Optional alternative to study-specific consent; • for secondary use of identifiable private data and specimens for <u>unspecified</u> future research • Elements of Broad Consent may not be waived or altered.

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	• Duration of storage/use (can be indefinite) • Statement that subjects will not be informed of specific future research • Results may not be disclosed • Whom to contact for questions	
Exempt Research		
• **Interactions** via surveys, interview	If: 1. not identifiable; 2. no risk; OR 3. identifiable <u>with</u> potential risk <u>and</u> limited IRB review required	<u>Not</u> with children; pregnant women okay; <u>incidental</u> 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, 3. covered by HIPAA, OR 4. Research by or on behalf of federal agencies or departments	HIPAA Waivers may still be necessary
• **<u>Storage</u> of identifiable data** for Secondary research	Must use Broad Consent and get Limited IRB Review	Only applies to <u>identifiable</u> data to be saved for future <u>unspecified</u> research
• **<u>Use</u> of identifiable data** for Secondary research	Must use Broad Consent and get Limited IRB Review	IRB review that research to be conducted is consistent with broad consent

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• "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.	1 New regular element: removal of identifiers to use data/specimens for future use, OR no future use even if de-identified. 3 New 'additional' elements for collecting/using identifiable data/specimens, as appropriate: ▪Commercial profit ▪Return of results ▪Whole genome sequencing
• Broad Consent	12 Specified elements cannot be changed or altered, but waiver of documentation (signature) okay	
• Waiver of Documentation (signature)	**New** allowable criteria: signing is not a cultural norm and research is minimal risk	
• Waiver of Regular Consent for use of Identifiable Data/specimens	IRB must find that it is not practicable to use nonidentifiable data/specimens	
• Screening exception	No informed consent required for recruiting, screening, determining eligibility if part of a study, not a stand-alone procedure	FDA not (yet) in sync; Waiver of HIPAA Authorization for recruitment may still be required
Streamlining		
• Continuing review	**No longer required** for Minimal Risk or regular study 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 > than 1 site for (federally funded) research	Effective 1/20/2020