Human Research Ethics Training Tips

Below is a table from the national association Public Responsibility in Medicine & Research (PRIM&R) of the Revised Common Rule changes and a column for UNC Implementation information.

PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

Here is PRIM&R's quick reference guide to the most significant changes in the final Common Rule published January 19, 2017. Although we have not included every change, nor every detail of the changes listed, we believe this list provides a clear overview of the revisions to the Rule that will affect researchers, institutions, and IRBs.

				UNC Implementation
IRB operations	Single IRBs for multisite research ("cooperative research")	Single IRBs generally required; however, some flexibility is provided in determining and documenting when a single IRB is not appropriate	46.114	**Effective January 25, 2018**
	External IRBs	Reliance arrangement with non-institutional IRB must be documented; *more stringent requirements proposed in the NPRM are not included*	46.103	**Current UNC practice**
	Checking the box	Option for FWA holders to check the box has been eliminated	46.101	UNC currently unchecks the box
	Continuing review	Continuing review of research is no longer required under various circumstances	46.109, 46.115	**Not allowed until July 19, 2018**
Informed consent	New language/clarity	Consent forms must be clearer and more focused; many changes added to emphasize that information provided must facilitate a potential subjects' understanding of why one would participate or not	46.116	**Can implement prior to July 19, 2018.**
	Basic and additional elements of informed consent	New basic element on collection of identifiable private information or identifiable biospecimens; three new additional elements on commercial profit, return of clinically relevant research results and whole genome sequencing	46.116	**Not allowed until July 19, 2018**
	Broad consent	Broad consent is an option for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens	46.111, 46.116	**UNC will not use Broad Consent**
	Recruitment/screening waivers	Allows waiver of informed consent for subject recruitment or screening, under certain conditions	46.116	**Not allowed until July 19, 2018**
	Clinical trials consent forms	Some clinical trials must post consent form online	46.116	**Not allowed until July 19, 2018**
	Electronic consent	Electronic consent is ok; must provide written copy	46.117	**Current UNC practice**

	Legally authorized representatives	If no law, institution can designate a representative	46.102	**NC State Law designates who can be a LAR**
Scope	Definition: Research	Defines what's NOT research: certain journalistic, public health surveillance, and criminal justice or intelligence activities	46.102	**Not allowed until July 19, 2018**
	Definition: Human subjects	Includes "information or biospecimens" obtained from through intervention and interaction OR "identifiable private information or identifiable biospecimens"	46.102	**Not allowed until July 19, 2018**
	Definition: Clinical trial	Clinical trials are now specifically defined	46.102	**Not allowed until July 19, 2018**
	Definition: Identifiable biospecimen/identifiable private information	Will be re-examined within one year and every four years after	46.102	**Not allowed until July 19, 2018**
	Definition: Vulnerable populations	Pregnant women and "handicapped" removed; replaces "mentally disabled" with "individuals with impaired decision-making capacity"	46.111	**Not allowed until July 19, 2018**
	Tribal law	Tribal law applies where applicable; added throughout	46.101, 46.114, 46.116	**Current UNC practice**
New guidelines for exemptions	Additional exemptions for low-risk studies	New exemptions added, including exemptions for secondary research on identifiable private information and identifiable biospecimens under various circumstances; various regulatory requirements, such as limited IRB review and broad consent, may apply	46.104 (see also 46.103, 46.109, 46.110, 46.111)	**Not allowed until July 19, 2018**
Compliance dates	1year (~~1~~7/19/18), 3 years for multisite (1/20/20)	Previous Rule applies to research approved prior to 1/19/17; new rule to approvals 1/19/17 or later	46.101	

Almost as important as the changes that are in the revised rule are the previously proposed changes that are NOT in the final regulations. Things that appeared in the NPRM but are **NOT included** in the final Rule include:

- the inclusion of research with non-identified biospecimens within the definition of human subjects research; the concept of "exclusions";
- reference to or reliance on any of the proposed tools, standards, or templates that had not been developed at the time of the NPRM (exemption determination tool, standardized privacy and data security safeguards, broad consent template, etc.);
- the clinical trials extension;
- the requirement to include non-required element of consent in an "appendix" to the form; and
- modifications to the definition of minimal risk.

Common Rule Departments & Agencies

1. **Department of Commerce 15 CFR 27**
2. **Department of Defense 32 CFR 219**
3. **Department of Energy 10 CFR 745**
4. **Department of Health & Human Services 45 CFR 46, subpart A Plus subparts B, C, D**
5. **Department of Housing & Urban Development 24 CFR 60**
6. **Department of Justice 28 CFR 46**
7. **Department of Transportation 49 CFR 11**
8. **Department of Veterans Affairs 38 CFR 16**
9. **Consumer Product & Safety Commission 16 CFR 1028**
10. **Environmental Protection Agency 40 CFR 26**
11. **Agency for International Development 22 CFR 225**
12. **National Aeronautics & Space Administration 14 CFR 1230**
13. **National Science Foundation 45 CFR 690**
14. **Department of Agriculture 7 CFR 1c**
15. **Central Intelligence Agency**
16. **Department of Education 34 CFR 97**
17. **Federal Policy for the Protection of Human Subjects (Common Rule 45 CFR 46, Subpart A)**
18. **Social Security Administration 20 CFR 431**

Not part of the Revised Common Rule Yet, plan to join later

19. ***Department of Homeland Security 6 CFR 46 NEW***
20. ***Food & Drug Administration NEW***
21. ***Department of Labor 29 CFR 21 NEW***
22. ***Office of the Director of National Intelligence NEW***

§II.102 Definitions for purposes of this policy.

(a) ***Certification*** means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) ***Clinical trial*** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral healthrelated outcomes.

(c) ***Department or agency*** *head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) ***Federal department or agency*** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.,* the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)

(1) ***Human subject*** *means a living individual about whom an investigator (whether professional or student) conducting research:*

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) ***Interaction*** includes communication or interpersonal contact between investigator and subject.

(4) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

(5) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of ''identifiable private information,'' as defined in paragraph (e)(5) of this section, and ''identifiable biospecimen,'' as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate ''identifiable private information,'' as defined in paragraph (e)(5) of this section, or an ''identifiable biospecimen,'' as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies

implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the **Federal Register** after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

(f) ***Institution*** means any public or private entity, or department or agency (including federal, state, and other agencies).

(g) ***IRB*** means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) ***IRB approval*** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) ***Legally authorized representative*** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this.

(j) ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(k) ***Public health authority*** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(l) Research *means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:*

(1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) *Written,* or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

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1. **Department of Commerce 15 CFR 27**
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