Actualización Sobre la Regla Común de los EEUU de América

II Curso Internacional Sobre Aspectos Éticos para la Investigación en Salud para los Comités de Ética en Investigación de EsSalud

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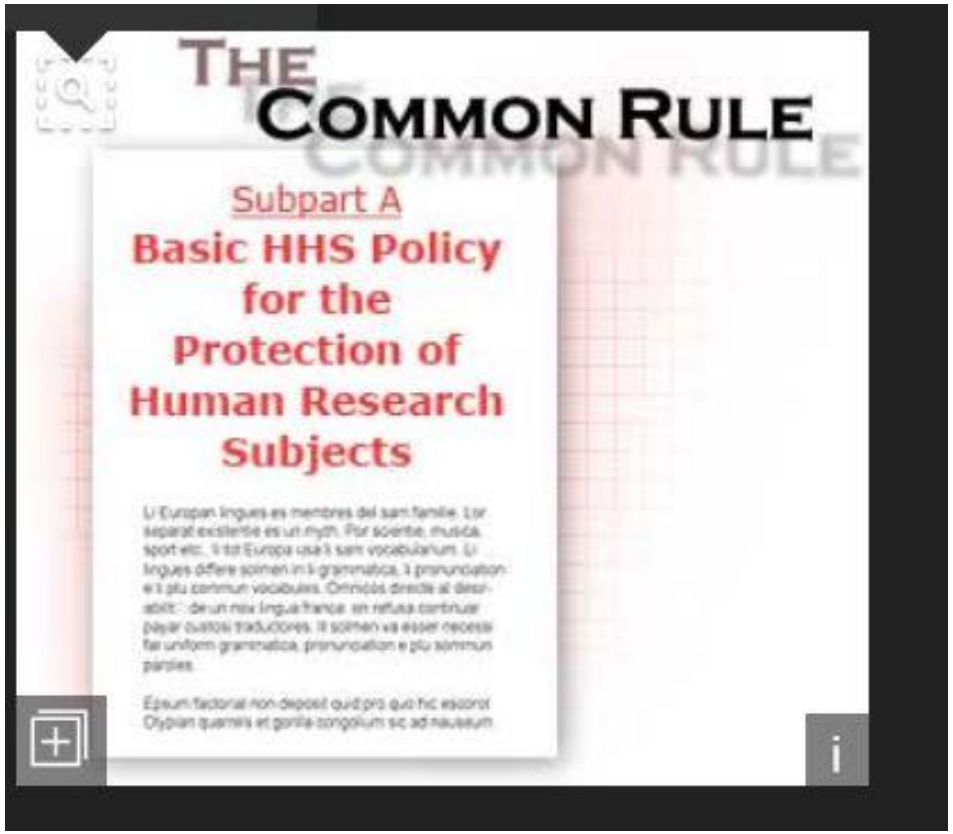


UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

Common Rule

- CFR 45 Parte 46. Código de Regulaciones Federales
- **Investigación:** Un estudio **sistemático**, incluyendo desarrollo, pruebas y evaluación diseñados para desarrollar o contribuir al **conocimiento generalizable**.
  - Sistemático: se refiere a metodología organizada y estructurada formalmente para obtener nuevos conocimientos. Por lo general, implica desarrollo de un protocolo con objetivos claramente señalados.
  - Generalizable: se refiere al conocimiento obtenido que está destinado a tener una aplicación amplia o general fuera del grupo que participó en la investigación.

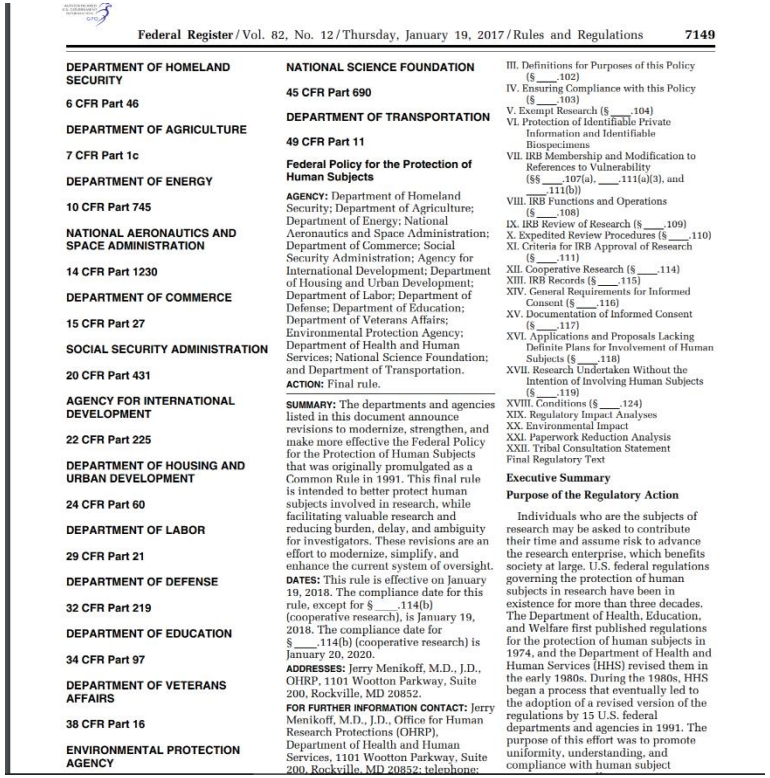
Regla Comun

- **Sujeto Humano:** Un individuo vivo sobre quien un investigador (profesional o estudiante) al conducir investigación obtiene datos a través de **intervención** o **interacción** con el individuo, o **información privada identificable.**
  - Intervención: procedimientos físicos y manipulaciones del ambiente del sujeto realizados con propósitos de investigación.
  - Interacción: incluye comunicación o contacto interpersonal entre investigador y sujeto.
  - Información privada identificable: información sobre la conducta que ocurre en un contexto en el cual un individuo puede esperar razonablemente que ninguna observación o registro está siendo tomado, así como información que ha sido dada para propósitos específicos por un individuo y que el individuo puede razonablemente esperar que no se hará pública.

Regla Común

- Sub parte A, Conocida como la “ regla común”
  - Provisiones básicas para los IRBs, consentimiento informado, y cumplimiento de normas.
  - Agencias federales: Su titular determina si una actividad particular esta comprendida en la regla común.
- Sub parte B: Protecciones adicionales para embarazadas, fetos humanos y neonatos
- Sub parte C: Protecciones adicionales para prisioneros
- Sub parte D; Protecciones para niños

Modificaciones “ Regla Común”



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DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 46

DEPARTMENT OF AGRICULTURE

7 CFR Part 1c

DEPARTMENT OF ENERGY

10 CFR Part 745

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1230

DEPARTMENT OF COMMERCE

15 CFR Part 27

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 431

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 225

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 60

DEPARTMENT OF LABOR

29 CFR Part 21

DEPARTMENT OF DEFENSE

32 CFR Part 219

DEPARTMENT OF EDUCATION

34 CFR Part 97

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 16

ENVIRONMENTAL PROTECTION AGENCY

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

Federal Policy for the Protection of Human Subjects

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule.

SUMMARY: The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

DATES: This rule is effective on January 19, 2018. The compliance date for this rule, except for § ___.114(b) (cooperative research), is January 19, 2018. The compliance date for § ___.114(b) (cooperative research) is January 20, 2020.

ADDRESSES: Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone:

III. Definitions for Purposes of this Policy (§ ___.102)
IV. Ensuring Compliance with this Policy (§ ___.103)
V. Exempt Research (§ ___.104)
VI. Protection of Identifiable Private Information and Identifiable Biospecimens
VII. IRB Membership and Modification to References to Vulnerability (§§ ___.107(a), ___.111(a)(3), and ___.111(b))
VIII. IRB Functions and Operations (§ ___.108)
IX. IRB Review of Research (§ ___.109)
X. Expedited Review Procedures (§ ___.110)
XI. Criteria for IRB Approval of Research (§ ___.111)
XII. Cooperative Research (§ ___.114)
XIII. IRB Records (§ ___.115)
XIV. General Requirements for Informed Consent (§ ___.116)
XV. Documentation of Informed Consent (§ ___.117)
XVI. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects (§ ___.118)
XVII. Research Undertaken Without the Intention of Involving Human Subjects (§ ___.119)
XVIII. Conditions (§ ___.124)
XIX. Regulatory Impact Analyses
XX. Environmental Impact
XXI. Paperwork Reduction Analysis
XXII. Tribal Consultation Statement
Final Regulatory Text

Executive Summary

Purpose of the Regulatory Action

Individuals who are the subjects of research may be asked to contribute their time and assume risk to advance the research enterprise, which benefits society at large. U.S. federal regulations governing the protection of human subjects in research have been in existence for more than three decades. The Department of Health, Education, and Welfare first published regulations for the protection of human subjects in 1974, and the Department of Health and Human Services (HHS) revised them in the early 1980s. During the 1980s, HHS began a process that eventually led to the adoption of a revised version of the regulations by 15 U.S. federal departments and agencies in 1991. The purpose of this effort was to promote uniformity, understanding, and compliance with human subject

- Aplican solo a las protecciones básicas establecidas en la Parte A.
- Salvaguardas especiales para embarazadas, fetos, prisioneros y niños no cambian
- Las previsiones de la FDA no se afectan

Modificaciones a la Regla Común

- En Enero 19 2017, 16 agencias federales de los Estados Unidos, incluyendo los Departamentos de Salud y Servicios Humanos y Departamento de Trabajo (Labor) publicaron la primera revision de las regulaciones federales para la protección de los sujetos humanos que participan en investigaciones científicas desde 2005 . La “Regla Común” ha estado vigente desde 1991 y aplica a toda la investigación que es conducida, patrocinada o regulada por el Gobierno federal de los EE UU. Estas modificaciones deben entrar en práctica en Enero 19 de 2018.
- Estudios colaborativos tienen 2 años mas para entrar en vigor

Cambios “Regla Común”

- Consentimiento informado:
  - Al inicio del mismo debe manifestarse que se busca la participación en investigaciones clínicas y que el consentimiento es voluntario
  - El propósito de la investigación, la duración y los procedimientos
  - Los riesgos previstos y los riesgos razonables y molestias al sujeto
  - Alternativas de tratamiento que puedan ser ventajosas para el sujeto
- El consentimiento debe publicarse en una pagina Web del Gobierno federal en 60 días desde que fue reclutado el sujeto, pero se deben excluir los datos personales y comerciales

Consentimiento “ Amplio "para Muestras Biológicas

- Se debe informar al sujeto que las muestras pueden ser usadas con fines comerciales y que el sujeto puede o no recibir beneficios económicos
- Si se hace secuencia genómica o si pudiera ser usado, se debe informar al sujeto
- Se debe notificar si las investigaciones con tejido humano que puedan ser identificables van a ser compartidas con otros investigadores o instituciones e informar quienes o cuales será
- Si el tejido es identificable, el consentimiento debe describir el tiempo de almacenaje previsto (o si es indefinido) y el periodo en que esas muestras podrian ser usadas para investigaciones (o si es indefinido)
- A menos que exista un acuerdo previo acerca de estudios específicos, debe informarse que el sujeto no será notificado sobre los resultados de estudios efectuados con tejido identificable, incluyendo los propósitos del estudio
- El consentimiento debe aclarar a quien contactar para preguntas acerca de los derechos del sujeto con respecto acerca de material almacenado y uso del mismo si existiera información identificable y a quien contactar en caso de daño

Estudios Exentos

- Investigaciones sobre métodos educacionales, a menos que el estudio afecte el rendimiento del estudiante o de la clase o:
  - La información sea re- identificada
  - La revelación de datos del estudio pongan al sujeto en riesgo de sufrir acciones criminales, financieras o daños en su reputación
- En bioespecímenes :
  - Los datos personales no son re- identificados
  - Cualquier investigación secundaria esta regulada por HIPAA
  - La investigación secundaria es conducida por, o de parte de una Agencia federal e involucra información originada fuera de una investigación científica, en tanto los datos personales del donante estén cubiertos por las leyes federales de los EE UU
  - Una investigación secundaria en la que el IRB o CEI determine que el estudio secundario esta dentro de las previsiones del consentimiento amplio
  - La definición de sujeto humano no incluye el uso de especímenes no identificables

Revisión Continua de Estudios

- Enero 2020 : Un solo CEI (IRB) para estudios multicentricos realizados dentro de los Estados Unidos de América
- En estudios de riesgo mínimo, los investigadores no tienen la obligación de informar anualmente al IRB (CEI) que la investigación esta en marcha, por lo que no se requiere la revisión constante del comité. Sin embargo las obligaciones de informar cambios o eventos adversos se mantiene
- Esto aplica a
  - (a) Investigaciones designadas como de revision expedita
  - (b) Investigación que ha progresado al punto que uno o ambos de los siguientes elementos que han sido parte de la revisión del IRB :
    - (i) Análisis de datos incluyendo aquellos que provienen de información privada o de bioespecímenes identificados
    - (ii) Acceso a información clínica de seguimiento de datos que provienen de un tratamiento clínica

Modificaciones

- Vulnerabilidad : Se retira a la embarazada como vulnerable y se reemplaza a “ personas mentalmente discapacitadas "con “ individuos con capacidad de decisión disminuida”
- Se elimina la revisión continua del CEI en algunos casos especiales
- Se revisaran las condiciones para que un protocolo sea considerado como revisión expedita cada 8 años
- Consentimiento amplio para muestras biológicas
  - Beneficios, uso posterior factible, posible uso comercial, tipo de investigaciones que harán, instituciones que podrían usar las muestras, riesgos, resultados comunicados o no a los sujetos
- Explicación de la información clave clara en el consentimiento de sujetos
- Los formularios de consentimiento (no los datos de los sujetos) deberán ser exhibidos en un sitio web público

Classification of Research Activities under Proposed Changes to the Common Rule.

Classification	Application of Common Rule Protections	Examples
Excluded	"Outside the scope of the regulations." The Common Rule regulatory requirements (e.g., IRB review) do not apply to these research activities.	Oral histories and interviews for biographies. Data collection for an institution's operational monitoring and quality-improvement activities. Operations-improvement activities to evaluate the effects of programs to change use of an accepted practice such as hand washing but not evaluate the practice itself. Research that carries no physical risks and is nonintrusive, such as surveys of adults and observations of public behavior, when information is recorded without linked identifiers and disclosure would not harm the finances or other interests of the person. Research involving collection or analysis of existing data, records, or specimens if the source is publicly available or if information cannot be linked to individuals (e.g., census data).
Exempt	Low-risk research or research involving information that needs privacy protections. Because they are unlikely "to result in harm to the subject and the subject must prospectively agree to intervention or data collection" these studies do not require IRB review or informed consent.	Social and behavioral research with adults involving brief, "harmless, painless, not physically invasive" interventions, such as reactions to watching a video, playing games, or solving puzzles. Secondary analysis of large databases including identifiable information when "prior notice has been given and privacy safeguards" (e.g., Health Insurance Portability and Accountability Act) exist. Research involving educational practices, public benefit programs, or taste and food quality.
Expedited	Research involving minimal-risk procedures ("risks are no greater than those of everyday life") according to an HHS-approved list. Existing procedures for review by one IRB member. Two changes: if the procedures are on the HHS list, they are to be expedited unless the reviewer explicitly states that they are greater than minimal risk; and the list of accepted procedures will be updated at least every 8 years.	Studies involving only blood draws (less than 500 ml per 8-week period) or biospecimens collected in a noninvasive manner (e.g., placenta, hair clippings, or cells from a mucosal swab).
Full panel	Research that involves greater-than-minimal-risk interventions. No changes in requiring review by full IRB panel and written informed consent.	Phase 1 study of experimental drug or vaccine.

Reform of Clinical Research Regulations, Finally

Ezekiel J. Emanuel, M.D., Ph.D.

N Engl J Med 2015; 373:2296-2299 | December 10, 2015 | DOI: 10.1056/NEJMp1512463

Interpretación FWA

- La regla común ahora se aplicará sólo a las actividades de investigación con sujetos humanos que no son exentas.
- De acuerdo al preámbulo de la disposición: "*tomamos nota de la preocupación expresada por comentaristas sobre investigaciones no financiadas por fondos Federales"*
- **Las organizaciones ahora pueden decidir entre:**

    - Aplicar los principios de la Regla Común a todas las investigaciones, independientemente de la Fuente de financiamiento
    - Aplicar la Regla Común solamente a investigaciones patrocinadas por las agencias que adhieren a esta o
    - Aplicar la Regla Común a la investigacion patrocinada por las agencias que adhieren y aplicar otras reglas a investigaciones no patrocinadas por éstas

Section	Summary of Change	Impact
Exempt research .104[i]	Section .104, has been assigned as "Exempt Research" Revisions to exemptions • New restrictions have been added to the old exemptions – only the taste and food quality study exemption remains the same. • New subsection (b) describes the use of and restrictions on exemptions for research subject to Subparts B, C, & D including an allowance for the exemptions to apply to research aimed at involving a broader subject population that only incidentally includes prisoners. • The following exemptions require a "limited IRB review": (d)(2)(iii), (d)(3)(i)(C), (d)(7), (d)(8) New exemptions • Research involving benign behavioral interventions in conjunction with the collection of information from adults (d)(3). • Secondary research uses of identifiable private information or identifiable biospecimens (d)(4). • Storage or maintenance for secondary research use of private information or identifiable biospecimens (d)(7). • Research involving the use of private information or identifiable biospecimens that have been stored or maintained for research use (d)(8).	Documents such as SOPs, submission forms, reviewer worksheets, and template letters may need to be updated. IRB electronic systems may require modification.
IRB functions and operations .108	The list of requirements for written procedures was modified and moved from .103 to .108 to be consistent with FDA regulations 21 CFR 56.108. • The requirement for meeting space and sufficient staff to support the IRB in old section 46.103(b)(2) is now found at .108(a)(1). • The IRB roster detail requirements formerly in old section 46.103(b)(3) is now found at .108(a)(2). • Requirements for written procedures described in the old section 46.103(b)(4) and 46.103(b)(5) have been included at .108(a)(3) and (4). • Revised (a)(3)(iii) to include "Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any	Citations in documents such as SOPs may need to be updated. Documents such as SOPs, guidelines, and letters that describe reporting obligations and modifications to research may need to be updated.

Section	Summary of Change	Impact
	proposed changes have been reviewed and approved by the IRB" (except when necessary to eliminate apparent immediate hazards to the subject).	
IRB review of research .109	Revision to describe the new "limited IRB Review" • An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)). New subsection (f)(1) eliminates continuing review in the following circumstances (unless an IRB determines otherwise) • Research eligible for expedited review in accordance with §46.110; • Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); • Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. Procedures that may currently be tied to continuing review (e.g., training verification, conflicts review) may need to be modified. IRB electronic systems may require modification. Consider whether organization would benefit from an annual report in lieu of IRB continuing review.
Expedited review procedures .110	Revised to permit "limited IRB review" to be conducted through expedited review. • Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). Revised to create a default position that the published categories of research that may be reviewed by expedited review are minimal risk, unless the reviewer determines otherwise for a study.	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. IRB electronic systems may require modification.

Section	Summary of Change	Impact
Criteria for IRB approval of research .111	A new subsection (8) has been added to essentially eliminate consideration of the "111 criteria" when conducting "limited IRB review" and describing the criteria the IRB must consider instead. • (8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. IRB electronic systems may require modification.
Cooperative research .114	*The compliance date for this part of the regulations (§46.114(b)) is January 2020.* Revised to add a requirement (b) for institutions located in the United States that are engaged in cooperative research to rely upon approval by a single IRB for that portion of the research that is conducted in the U.S. • The reviewing IRB will be specified by the federal department or agency supporting or conducting the research; the "lead institution" may propose the reviewing IRB, but final federal approval will be required. • Specifies circumstances when requirement for single IRB does not apply (reasons of law or as determined by the federal department or agency conducting or supporting the research)	Documents such as SOPs, guidelines, and forms and templates utilized for reliance may need to be updated.
IRB records .115	Revised to describe additional documentation requirements • Documentation of the rationale for conducting continuing review of research that otherwise would not require continuing review (3). • Documentation of the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk (8). • Documentation specifying the responsibilities that an institution and an	Documents such as SOPs, reviewer checklists, and forms and templates utilized for reliance may need to be updated.

Section	Summary of Change	Impact
	organization operating an IRB each will undertake to ensure compliance with the requirements of the final rule (9).	
General requirements for informed consent .116	Section .116 is one of more extensively modified sections, primarily due to added regulations for the use of biospecimens in research. • New subsection .116(a) has been added to describe the general requirements for informed consent, and stipulate that broad consent may be obtained in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. • The list of conditions previously embedded in a paragraph has been separated and the conditions numbered as .116(a) (1-3) and (6). • Subsection .116(b) now contains the basic elements of consent and .116(c) the additional elements. *General* .116(a) - Summary of new requirements • .116(a)(4) states that subjects must be provided with the information that a "reasonable person" would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information. • .116(a)(5)(i) states that the informed consent process must begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be "organized and presented in a way that facilitates comprehension." • .116(a)(5)(ii) states that informed consent as a whole must present information in sufficient detail and organized in such a way that does not "merely provide lists of isolated facts, but rather facilitates the prospective subject's … understanding of the reasons why one might or might not want to participate." *Basic elements of informed consent* .116(b) - Summary of new requirements • .116(b)(9) requires one of two statements when the research involves the	Documents such as SOPs, guidelines, submission forms, reviewer worksheets, and consent templates may need to be developed or updated. Systems to track refusals for future research may need to be developed. Procedures to support compliance with the requirement to post clinical trial consent forms may need to be developed.

Section	Summary of Change	Impact
	collection of identifiable private information or identifiable biospecimens: ○ Identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from the subject; or, ○ The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. *Additional elements of informed consent* .116(c) – Summary of new requirements (when appropriate) • .116(c)(7) requires a statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. • .116(c)(8) requires a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. • .116(c)(9) requires a statement about whether the research project will or might include whole genome sequencing. *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens* .116(d) – New This subsection addresses the use of broad consent, and specified elements, as a permitted alternative to the use of the standard elements for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. • .116(d)(1) specifies the basic elements from .116(b) and (c) that must still be included (risks, benefits, confidentiality, voluntary, commercial profit, and whole genome sequencing). • .116(d)(2) requires a general description of the types of research that may be conducted. • .116(d)(3) requires a description of the identifiable information or identifiable biospecimens that might be used in future research; whether sharing might occur; and, the types of institutions or researchers that might conduct research.	

Section	Summary of Change	Impact
	• .116(d)(4) requires a description of the length of time that the identifiable information or identifiable biospecimens may be stored, maintained and used. • .116(d)(5) unless subjects will be provided details about specific studies, this element requires a statement that subjects will not be informed of the purposes or details of any specific research studies that might be subsequently conducted, and, that they might have chosen not to consent to some studies. • .116(d)(6) unless it is known that clinically relevant research results will under all circumstances be disclosed to subjects, this element requires a statement that research results may not be disclosed to subjects. • .116(d)(7) requires contact information to be provided for questions about rights, questions about storage and use, and in the event of a research-related harm. *Waiver or alteration of consent in research involving public benefit and service programs conducted by/subject to the approval of state or local officials* .116(e) – New • Specifies that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual. • Specifies that IRB's may not omit or alter any of the requirements of consent (.116(a)). If a broad consent procedure is used, an IRB may not omit or alter any of the required elements at .116(d), i.e., alteration is not permitted. *General waiver or alteration of consent* .116(f) – Summary of new requirements • .116(f)(1) cautions that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual. • 116(f)(2) addresses alterations of informed consent. Two new	

Section	Summary of Change	Impact
	conditions/restrictions are included. An IRB may not omit or alter any of the .116(a) general requirements for informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements at .116(d), i.e., alteration is not permitted. • .116(f)(3) includes the four existing waiver conditions with the following addition: for research that involves using identifiable private information or identifiable biospecimens, it is a requirement that the research could not practicably be carried out without using such information or biospecimens in an identifiable format. *Screening, recruiting, or determining eligibility* .116(g) – New • Effectively eliminates need for an IRB to grant screening or recruitment waivers by stating that an IRB may approve research in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent, if either of the following conditions are met: ○ the information will be obtained through oral or written communication with the prospective subject, or ○ by accessing records or stored biospecimens. *Posting of clinical trial consent form* .116(h) – New • Addresses requirements for posting clinical trial consent forms on a publicly available federal website that will be established as a repository for consent forms. According to subsection .116(h)(3), one consent form for each clinical trial must be posted on the federal website after the trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. A federal department or agency may permit or require redactions.	
Documentation of informed consent .117	Revisions to documentation requirements • .117(a) now specifically allows electronic signatures for consent documentation and specifies that a written copy must be given to the person signing the consent form. • .117(b)(1) specifically allows consent forms to be read to the subject.	Documents such as SOPs, guidelines, submission forms, reviewer worksheets, and consent templates may need to be

Section	Summary of Change	Impact
	• .117(b)(2) requires that, when using the short form to document consent, the informed consent must begin with a concise and focused presentation of the key information to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection requires that this part of the informed consent must be organized and presented in a way that facilitates comprehension. • .117(c) still addresses waivers for the requirement to obtain a signed consent form and maintains the two pre-existing exceptions. Importantly a third category is added that allows waiver of documentation of consent if the subjects are members of a distinct cultural group or community in which signing forms is not the norm. This added category is restricted to minimal risk research and requires an appropriate alternative method for recording that informed consent was obtained.	developed or updated.