



DON Human Research Protection Program

The Revised Common Rule

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Overview

DON Human Research Protection Program

- Brief background on the revised rule
- Implementation dates
- Proposals that were not adopted
- Summary of key changes
- Informed consent Changes
- Exemptions
- Expedited review
- Continuing review
- Single IRB review
- Other changes that create flexibility



Why the changes?

DON Human Research Protection Program

- Enhance human subject protection
- Reduce administrative burden
- Align regulations with the current research climate
- Allow regulatory flexibilities for certain types of research commonly conducted by investigators





Timeline

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- Advanced Notice of Proposed Rule-Making (ANPRM) - July 2011
- Notice of Proposed Rule-Making (NPRM) – September 2015
- Final Rule – January 19, 2017
- Implementation...



Implementation Dates

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- Before January 19, 2018, all activities must comply with the pre-2018 rule
- Certain provisions that do not conflict with the pre-2017 rule can be implemented now...**but check with your IRB first**
- Studies that begin on or after January 19, 2018 shall comply with the New Common Rule
- Single IRB review in multi-institutional studies is effective on January 20, 2020





Implementation Dates, cont.

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- **Studies initially “approved” before January 19, 2018:**
 - Pre-2018 Rule applies
 - If the institution decides to apply the New Rule to previous research, this must be documented in writing.
- **Studies initially “approved” on or after January 19, 2018:** The New Rule applies





NPRM Proposals not Adopted

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- Non-identified biospecimens: extension of Common Rule to cover them. Would almost always require consent.
- Exemption Decision Tool
- Development of standardized privacy safeguards
- Clinical Trials: extension of Common Rule those that are not federally funded
- Broad consent template



How Human Subject is Defined in New Rule



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Under the New Rule: Human subject - a living individual about whom an investigator conducting **research**:

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

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable **biospecimens**



How Human Subject is Defined in Current Rule



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Under the Current Rule:

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

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

...no mention of biospecimens



Biospecimens

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- Federal agencies are committed to collaborating at least every 4 years to:
 - Reexamine the meaning of identifiability
 - Identify analytic techniques capable of generating identifiable private information or biospecimens





Activities deemed “Not Research”



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- Scholarly and journalistic activities: Focus on the specific individual about whom the information is collected
- Government functions with separately mandated protections outside of the New Rule:
 1. Public health surveillance e.g., Zika and Influenza
 2. Collection of information for criminal justice purposes
 3. Operational activities for national security purposes



Public Health Surveillance

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- Limited to:
 - conducted, supported, requested, ordered, required or authorized by a “public health authority.”
 - Activities 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 of diseases, or increases in injuries from using consumer products.





Informed Consent Changes

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1. Enhancements/Improvements to Informed Consent
2. Broad Consent
3. Posting of Consent Form for Clinical Trials
4. Waiver and Alteration of Informed Consent





Informed Consent

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- New Common Rule explicitly establishes a new standard: to provide the information that a **reasonable person** would want to have in order to make an **informed decision** about whether to participate
- Information presented in sufficient detail, and organized and presented in a way that facilitates subject's understanding of reasons why one might or might not want to participate. It must not be a mere list of facts.
- Key information must be provided first
- The first section must provide a concise and focused presentation of key information regarding why one might or might not want to participate



Informed Consent

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New element (§_116(b)(9)): Notice about possible future research use of information or biospecimens stripped of identifiers:

- Notifying prospective subject that subjects' information or biospecimens could be used for future research without additional consent; or
- Notifying prospective subject that subjects' information or biospecimens will not be used for future research.





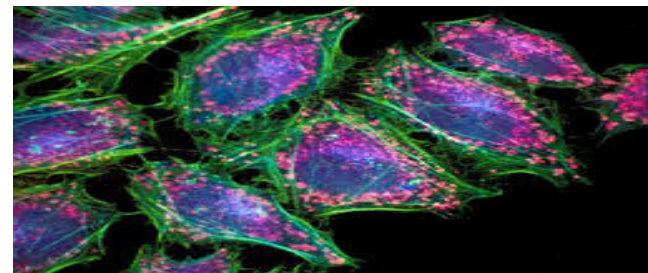
Additional Elements of Informed Consent



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Three new additional elements:

- Notice about whether clinically relevant research results, including individual research results will be given to subjects, and if so, under what conditions
- Notice about possible commercial profit, and whether subject will share in this profit (for research involving biospecimens)
- Notice about whether research might include whole genome sequencing (for research involving biospecimens) §.116(c)(7)-(9) 21





Secondary Research Defined



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Research use of information or biospecimens collected for either research studies other than the proposed research, or for non-research purposes (e.g., clinical care, public health, education)

Example: Retrospective Chart Review

...what else?



Broad Consent for Secondary Research



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- Broad Consent is an optional alternative to traditional informed consent or waiver of informed consent
 - It applies to:
 - The storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens
 - Collected for either a different research study, or for non-research purposes
- Creates future regulatory flexibilities



Current Rule and Secondary Research



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1. Using non-identified information or biospecimens
2. IRB grants a waiver of informed consent
3. Exemption 4 (has to be publicly available or recorded in a manner such that subjects cannot be identified)
4. IRB review and study-specific consent



New Rule and Secondary Research



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Additional Options are:

- Obtaining broad consent
- Meeting expanded exemption 4 or new secondary use exemptions





Transparency and Posting Consent Forms



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- IRB-approved consent form used to enroll subjects must be posted on a publicly available Federal website (to be designated) (for clinical trials supported by federal funding)
- To be posted after recruitment closes, no later than 60 days after last study visit
- Federal department or agency may permit or require redactions



Waiver of Informed Consent

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- New waiver criterion for research with identifiable private information or identifiable biospecimens in the New Rule
- The IRB must determine that the research could not practicably be carried out without accessing or using identifiers
- Non-identified information should be used whenever possible in order to respect subject's autonomy



Case Study

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Dr. Rowe wants to use stored lung cancer tissue from a previous closed study conducted in 1982. Each tissue sample is labeled with the subject's initials and date of birth (month and year). Dr. Rowe would like to analyze these specimens and compare the patient's diagnosis against today's current standards. She will not record the subject's identifiable private information. She will complete her analysis, and then destroy the identifiers.

Does this study meet the new waiver criterion?



Case Study

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Maybe....if:

1. The IRB determines the research could not practicably be carried out without accessing or using identifiers
2. Non-identified information is used whenever possible in order to respect subject's autonomy



Broad Consent

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The IRB cannot waive consent if individuals were **asked**, and **refused**, to provide broad consent to the storage, maintenance and use of identifiable private information or identifiable biospecimens





Flexibility with Exempt Research

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- Subpart C prisoners research expanded: exemptions do not apply **except** for research aimed at involving a broader subject population that only **incidentally** includes prisoners
- Subpart D children research:
 - Same restrictions as above for exemption 2 **and** new provision §.104(d)(2)(iii) also not applicable
 - New exemption 3 does not apply to children
 - Discussed in more detail in the next slides





Flexibility with Exempt Research

DON Human Research Protection Program

Research under Subpart D:

1. Subpart D children research - Research involving children does not meet exemption 2 for research involving survey or interview procedures or observations of children by investigators who participate in the activity being observed
2. § 104(d)(2)(iii) which allows for obtaining and recording identifiable private information, may not be applied to research involving children
3. New exemption 3 (benign behavioral interventions) does not apply to children





Exemption 2

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Exemption 2: Educational tests, surveys, interviews, and observations of public behavior exemption when:

- Information recorded cannot be readily linked back to subjects,
- **or** any information disclosure would not place subjects at risk of harm,
- **or** Identifiable information recorded with **limited IRB review** for privacy and confidentiality protection under §_.111(a)(7)



Exemption 3

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- Removed in New Rule because this type of research could be covered under Exemption 2
- For research involving the use of educational tests, survey procedures, or observation of public behavior if:
 - The human subjects are elected or appointed public officials or candidates for public office, or
 - Federal statute protects confidentiality without exception.



New Exempt 3

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For research involving benign behavioral interventions with **adults** who prospectively agree when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:

- Information recorded cannot be readily linked back to subjects, **or**
- Any information disclosure would not place subjects at risk of harm, **or**
- Identifiable information recorded with **limited IRB review** for privacy and confidentiality protection under §.111(a)(7)



New Exempt 3

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“benign behavioral interventions” (§_104(d)(3)) are:

- brief in duration
- harmless
- painless
- not physically invasive
- not likely to have a significant adverse lasting impact on the subjects
- investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- includes authorized deception research



Case Study

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Dr. Griffin would like to survey about 50 nursing students to assess how caffeine affect cognition. Each subject will drink a cup of coffee, look at 5 slides about nursing school, and then complete a 5-minute survey about their perception on the slide presentation.

Does this study qualify for Exempt 3?





Case Study

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Depends...

Are they adults?

Information recorded cannot be readily linked back to subjects, **or**

Any information disclosure would not place subjects at risk of harm, **or**

Identifiable information recorded with **limited IRB review** for privacy and confidentiality protection?

Is the intervention harmless?

Not likely to have a significant adverse lasting impact on the subjects?

Does the Investigator think the subjects will find the interventions offensive or embarrassing?



Exempt 4

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Secondary research use of identifiable private information or identifiable biospecimens (no longer has to be “existing”) if:

1. Identifiable private information or identifiable biospecimens are **publicly available**,

or

2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects **cannot be readily ascertained** directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects, OR...



Exempt 4

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3. Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health" OR
4. Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards





Exempt 5

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Exemption 5 (§_104(d)(5)): Public benefit and service programs research and demonstration projects

- Expanded to apply to such federally-supported research; no longer limited to federally-conducted research
- Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research



Exemption 6

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- Taste and food quality evaluation and consumer acceptance studies
- No Change!





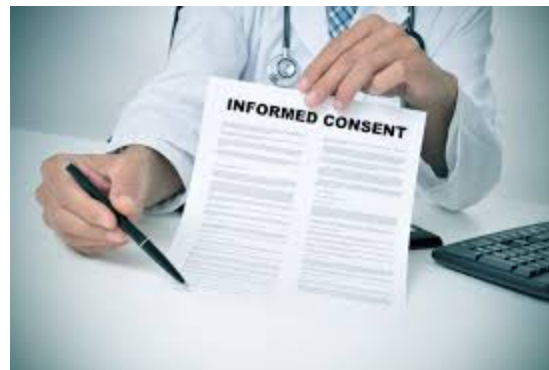
New Exemptions

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Exemption 7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

Exemption 8: Secondary research using identifiable private information or identifiable biospecimens

Both require Broad Consent!





Limited IRB Review

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- Required for exemptions 2(iii), 3(i)(C), 7, and 8 in the New Rule
- Exemptions 2(iii) and 3(i)(C) review:
 - For privacy and confidentiality protection under §_.111(a)(7)
- Exemptions 7 & 8 reviews:
 - For other safeguards related to privacy and confidentiality protection, and broad consent



Expedited Review

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- Categories in the Federal Register will be reviewed every 8 years and updated if Necessary
- Presumption that activities listed are minimal risk
 - Unless expedited reviewer determines otherwise, which would make the study not qualify for expedited review and would need to be documented
- Limited IRB review has been added to list of permissible use of expedited review mechanism §_.110, §_.109(f) and §_.115(a)(8)



Continuing Review

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No continuing review required for:

- Research approved by expedited review
- Exempt research requiring limited IRB review
- Research has completed interventions and only involves:
 - ❖ Analyzing data, including analyzing identifiable private information or identifiable biospecimens
 - ❖ Accessing follow-up clinical data from clinical care procedures. IRB can override this default and require continuing review, but this must be documented §_.109(f) and §_.115(a)(3).



Single IRB Review

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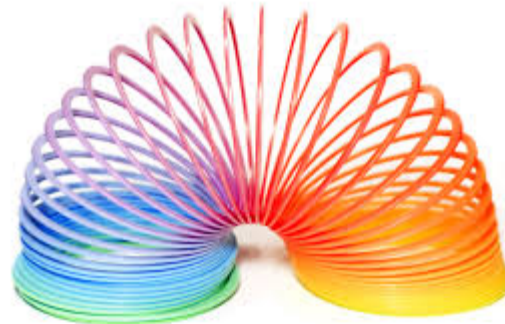
- Applies to U.S. institutions engaged in cooperative research for the portion of the research conducted in the U.S.
- Does not apply when:
 - ❖ When more than single IRB review is required by law (including tribal law)
 - ❖ Whenever any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context (§_.114(b))



Other Changes

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- No more IRB roster reporting to the Office of Human Research Protections
- No more “checking the box” on the Federalwide Assurance
- No more grant application reviews for IRBs





Summary

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- This is a summary of the major changes to the Common Rule
- The regulations are the foundation – institutions should implement by writing their own policies and procedure
- The revised rule is intended to grant more flexibility



Final Revisions

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Link to Final Revisions to the Common Rule:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>



**KEEP
CALM
&
FOLLOW
THE RULES**

A graphic of a "Keep Calm" sign. It features a crown at the top, followed by the text "KEEP CALM & FOLLOW THE RULES" in a bold, sans-serif font.



Questions

DON Human Research Protection Program

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