

New Common Rule

What Researchers Need to Know

Office for the Protection of Research Subjects

Highlight of Common Rule Changes

- Definitions added for familiar concepts (intervention, clinical trial, vulnerable subject)
- Continuing review eliminated for expedited projects
- Consent has new required elements and required “key info” up front
- Single IRB review required for multisite projects
- HHS will not exercise oversight of research not funded by HHS
- Exemption categories heavily revised

What's not Changing?

- HIPAA requirements
- Ancillary approvals
- FDA-regulated research (Drugs/biologics/medical devices)
- Research with prisoners
- Existing options for biospecimen collection



Implementation Dates

- **Studies in the queue or under review on Jan 2 must be approved according to the New Rule**
- Submissions on or after Jan 21 must comply with the New Rule and iStar will be compliant with the New Rule
- At Continuing Review the reviewer will have an option to apply the New Rule or continue the study under the old rule
- Single IRB requirement begins Jan 2020



IRB Obligations Lifted

No longer required:

- IRB review of grant
- Reporting IRB membership to OHRP
- Reporting unanticipated problems to OHRP for non-HHS funded research
- Statement of ethical principles



Terms Defined/Changed

New Definitions in Common Rule

- **Benign behavioral intervention:** brief harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing
- **Intervention:** physical procedures/environmental manipulations by which information or biospecimens are gathered

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New Definitions in Common Rule

- **Vulnerable Subjects:** participants vulnerable to coercion/undue influence
- **Clinical trial:** study in which human subjects are prospectively assigned to interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- **Legally Authorized Representative:** individual/judicial/body authorized under applicable law to consent on behalf of prospective subject

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“Identifiability” – Evolving Concept

- **Federal agencies every 4 years will:**
 - Reexamine the meaning of identifiability
 - Identify analytic techniques capable of generating identifiable private information or biospecimens



Activities Deemed Not To Be Research

- **Scholarly and journalistic activities**
- **Government functions with separately mandated protections**
 - Public health surveillance activities
 - Collection of information for criminal justice purposes
 - Operational activities for national security purposes



Changes to Exemptions

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Reminder: IRB Levels of Review



Full Board

- greater than minimal risk; e.g. drug study/domestic violence study
- Reviewed by convened IRB committee



Expedited

- minimal risk; e.g. blood draw / alcoholism
- Reviewed by IRB Chair/designee



Exempt

- not greater than minimal risk; e.g. blood pressure / educational tests
- Reviewed by IRB Chair /designee/staff

Coded Data / Specimens

- e.g. analyzing discarded tissue
- Reviewed by IRB Staff

Not Human Subjects Research

- doesn't meet federal definition or is coded data
- Reviewed by IRB Staff

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

Overview of Exempt Categories

Category		Change
Exempt 1	Research on normal education practices	Restrictions added
Exempt 2	Surveys/interviews/education tests/observations	Criteria loosened
Exempt 3	Benign behavioral interventions	New (Replaced)
Exempt 4	Secondary research with Identifiable private info	New (Replaced)
Exempt 5	Federal research or demonstration projects	Expanded applicability
Exempt 6	Taste and food evaluation	No change
Exempt 7	Storage/maintenance of identifiable data/specimens for secondary research	New , requires "limited IRB review"
Exempt 8	Secondary research with identifiable data/specimens	New , requires "limited IRB review"

Exemption 1 – Education Research

- **Normal educational practices in established or commonly accepted educational settings**
- **What's new?**
 - IRB must consider "adverse affects" on student learning or on assessment of educators



Exemption 2 – Surveys/Interviews/ Educational Tests/Observation of Public Behavior

Research that only includes educational tests, surveys, interviews, or observation of public behavior (including visual or auditory recording) if one of the following:

- (i) Subjects identity cannot readily be ascertained directly or through linked identifiers;
- (ii) Any disclosure of subjects' responses would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

What's new?

- Exemption does not apply to projects involving:
 - Interventions
 - Collection of biospecimens
 - Linking to additional personally-identifiable data
 - Children (except for educational tests or some public observations)

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Exemption 3 – Benign Behavioral Interventions*

*Benign behavioral intervention --

- Must obtain the subjects' prospective agreement to the intervention and information collection
- No deception, except where the subject prospectively agrees (Debriefing still encouraged)
- No data collection via physical procedures (e.g. blood pressure, blood draw or saliva collection)

What's new?

- Exemption is completely new
- Limited to verbal or written data collection
- Limited to research with adults

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Examples of Benign Behavioral interventions

- Solving puzzles under various noise conditions
- Playing an economic game
- Being exposed to stimuli such as color, light or sound (at safe levels)
- Performing cognitive tasks

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Exemption 4 – Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

Secondary research with identifiable Information/specimens collected for some other initial activity, if ONE of following:

- Biospecimens or information is publically available
- Information recorded so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects
- Collection and analysis involving Investigators Use of identifiable health information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”
- Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities
- **What’s new?**
 - No longer limited to retrospective data review
 - Permits secondary use of identifiable protected health information (PHI) with HIPAA authorization or waiver

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Exemption 5: Federal research or demonstration projects

Research designed to study, evaluate, improve, or otherwise examine public benefit or service programs

What's new?

- Expanded to apply to such federally-supported research (no longer limited to federally-conducted research)
- Federal agencies must publish a list of projects covered by this exemption prior to research commencing

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Exemption 6: Taste and food quality evaluation and consumer acceptance studies

- Exemption permitted if wholesome foods without additives are consumed, or
- Food contains food ingredient at or below the level and for a use are generally regarded as safe (GRAS)

What's new? ***NO CHANGE!***

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New Exempt 7 – Storage and maintenance of identifiable material for which broad consent is required

IRB may exempt storage and maintenance of identifiable material for potential secondary research if...

- Consent was obtained for the primary research
- Broad consent was obtained
- IRB conducts a limited IRB review
- Investigators do not plan to return individual results to subjects

What's New?

- Exemption is completely new

**NOT USED
AT USC**

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Exempt 8 – Use of identifiable data/specimens for which broad consent is required

IRB may exempt secondary research with identifiable info/specimens if:

- Consent was obtained for the primary research
- Broad consent was obtained
- IRB conducts a limited IRB review
- Investigators do not plan to return individual results to subjects

**NOT USED
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Broad Consent for Future Research using Identified Data or Bio specimens (*Exempt 7 & 8*)

- Broad consent is not necessary nor permitted by FDA regs
- Gives subjects more control over research that might be done with their identifiable data
- Enables exemption of secondary research
- Necessitates an IT system to track individual biospecimens/data (refused/agreed or no response) to validate their inclusion in the study
- If subject declined to grant broad consent IRB cannot waive consent for secondary research
- IRB may apply expedited 5 with waiver of consent in order to approve secondary research with identifiable data/specimens

**NOT USED
AT USC**

What's New?

- Exemption is completely new

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Limited IRB Review

- Mandatory for granting exemptions 7& 8 (secondary storage or use of research w/identifiable private info/specimens)
- Conducted by convened IRB (but IRB may use expedited review procedure)
- Continuing review not required after limited IRB review has been performed



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Changes to Expedited Review

Changes to Expedited Review

- No CR unless the IRB has a reason to require it and can justify that reason
- No CR for projects conducting data analysis only
- OHRP will review the expedited categories annually



Continuing Review No Longer Required

No Continuing Review*:

- Research approved by expedited review that is non-FDA regulated
- Non-FDA research interventions completed and only involving:
 - Data analysis, including identifiable private information or identifiable biospecimens
 - Accessing follow-up clinical data from clinical care procedures

*IRB can override this default and conduct CR, but must justify and document

Full Board:
NO CHANGE...
...except new ICF requirements

Informed Consent Changes

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Changes to Informed Consent

1. “Key Information” presented first
2. New Elements of Consent (Basic & Additional)
3. Broad Consent
4. Public posting one consent form per clinical trial
5. Waiver and Alteration of Informed Consent



“Key Information” in Informed Consent

- Must provide a “concise and focused presentation of key information” up front why one might or might not want to participate:
 - Voluntary participation
 - Summary of research procedures
 - Risks
 - Benefits
- Short consent (e.g. 4 pages) may not require key information section
- New USC consent templates provided
opr.usc.edu/hsirb/forms



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New Elements of Consent

- New element of consent (required as applicable)
 - De-identified data or biospecimens may be shared for future research (or not)
- Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
- Clinically relevant results will be returned (or not)
- Research will involve whole genome sequencing

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Public Posting of Consent Forms for Clinical Trials

- One IRB-approved consent form used to enroll participants must be posted on publicly available website for clinical trials supported by federal funding
- Post after recruitment closes, no later than 60 days after last study visit
- Federal department or agency may permit or require redactions
- Federal website: clinicaltrials.gov and regulations.gov (see Docket ID: HS-OPHS-2018-0021)



Waiver of Consent: New Criteria

- New waiver criterion for research with identifiable private information or identifiable biospecimens
 - The IRB must determine the research could not practicably be carried out without accessing or using identifiers
- Non-identifiable information should be used whenever possible



Consent Not Required for Screening

- No consent for screening, recruiting, or determining eligibility of prospective subjects **if**:
 - information is obtained through oral or written communication OR;
 - investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

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Single IRB & Other Changes

*Single IRB (sIRB) Review for Multi-site Studies

*One IRB reviews for all participating sites in U.S.

- Applies to all federally funded multi-site research studies effective January 2020. (NIH funded sIRB requirement effective Jan 25, 2018)
- FDA permits sIRB review
- Reviewing IRB is identified by funding department or agency or proposed by the fund recipient
- sIRB exceptions:
 - If local IRB review is required by law (e.g., tribal law)
 - If sponsor determines single IRB not appropriate



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USC Flex Policy: bypass New Rule

Flex policy establishes approval category not subject to federal regulations that applies to minimal risk research (otherwise known as expedited and exempt).

Research Eligible for Flexibility Policy* if all of the following:

- Not federally funded/federally regulated
- Research involves “minimal risk”
- Equivalent protections to Common Rule

*Flex exclusions: clinical trials, clinical interventions, research requiring ancillary reviews (rad safety, biosafety, conflict of interest, etc.)

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GDPR: European Data Protection Regulation

- GDPR regulates use, access, collection, and processing of all personal data from the [European Economic Area \(EEA\)](#), regardless of the citizenship of the individual to whom the data pertains.
- USC investigators conducting research with data from [EEA](#) must comply with GDPR obligations and consent requirements

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Changes to iStar:

- **Grant/Contract applications**
- **Type of Review**
 - Expedited Categories and Exempt Categories
 - Other sites for exempt (GDPR compliance)
 - Retrospective Studies
- **Special Subject Populations**
- **Informed Consent Page**
 - New checkbox at 24.10 for consent process
 - New option for waiver of signed informed consent
- **Automatic Certificates of Confidentiality**
- **Continuing Review for Expedited studies**

NIH Changes

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New NIH Policy for Certificate of Confidentiality

- **Cert of Confidentiality automatic condition of NIH award**
- **Applies to all NIH-funded research beginning December 13, 2016**
- **Limits disclosure “identifiable, sensitive” information**
 - Includes all identifiable human subjects data, biospecimens, individual level human genomic data, or other research data
 - Information/biospecimens are also considered to be identifiable if there is a very small risk of deductive disclosure
- **NIH will continue to issue CoCs for other non-NIH research falling under its mission**
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

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NIH Policy- NIH Funded Clinical Trials

- Registration of research and reporting of results on ClinicalTrials.gov (effective 1/18/2017)
- Good Clinical Practice training requirement (effective 1/1/2017)
- Single IRB-of-Record requirement for multisite studies (effective 1/25/2018)

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Common Rule Resources from USC

- **Check the OPRS website for updates**
 - <https://oprs.usc.edu>
 - Important dates
 - Changes to institutional policies and procedures
 - New informed consent templates
 - Updated guidance materials

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Common Rule Resources from Feds

- **Federal Policy for the Protection of Human Subjects, Text of New Rule**
 - <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>
- **Secretary's Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachments, including:**
 - Attachment B, Recommendations on Benign Behavioral Intervention
 - Attachment C, Recommendations for Broad Consent Guidance
 - <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html>

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Questions



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