

Transition to the Revised Common Rule

(Federal Policy For the Protection of Human Subjects)



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Belinda Smith, MS, RD, CCRC & ORI Staff

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Objectives

- Outline transition from the current ("old rule") to the Revised Common Rule ("new rule")
- Provide overview of new rule provisions relevant to research investigators

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Revised Common Rule



- Published in Federal Register 1/19/17
- Implementation delayed 2 times

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Current Implementation Date

- January 21, 2019



- More time for OHRP to provide guidance on interpretation & implementation of rule


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Existing Studies
New Studies
Submitted Studies


Existing Studies –
Studies Approved Prior to
Implementation Date

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Existing Approved Studies




Institution must determine whether it will transition existing studies to the revised rule & if so, document when transition occurs



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Implications of Transitioning Existing Approved Studies?



If an institution elected to transition ALL Existing Approved Studies to the Revised Rule on or after the Compliance Date....

The Protocols Would be Required to Comply with the Entirety of the Rule's Provisions
(*can't pick and choose*)


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- No current plans to transition existing studies
- **Existing Studies Approved under the Current Common Rule** may continue to operate under that rule through completion
- Should an investigator wish to transition an existing study, contact ORI. PI would need to create and submit a new protocol after the Compliance Date

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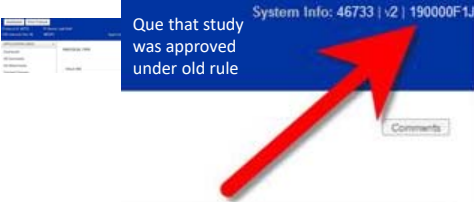
Existing Studies Still on Paper

- Import Application at Continuing Review – don't select "create application"
- Video tutorial "[Import a Full or Expedited Application](#)".



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Imported protocols initially approved on paper will have the OLD PROTOCOL NUMBER in the upper right-hand corner of the E-IRB banner.
Contact ORI if you don't see the number



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New Studies—
Studies Approved After the Implementation Date

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Studies Approved after 1/21/19 will be Subject to the Revised Common Rule



A Year ago, ORI put consent templates into production which incorporate the revised rule requirements

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Submitted Studies –
Studies Submitted Prior to Implementation Date (not yet approved)

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Implementation date = Compliance date
Regulation Provides no Grace Period

Institutions not permitted to implement the new rule

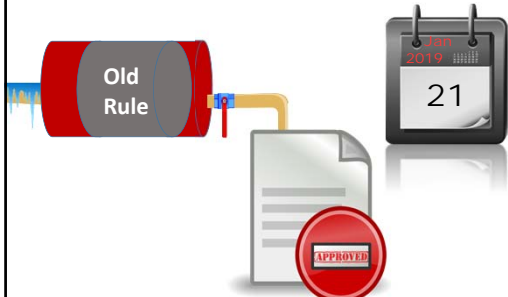


Institutions not permitted to review new research according to the old rule

Based on Approval Date

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Approve what is in the Pipeline



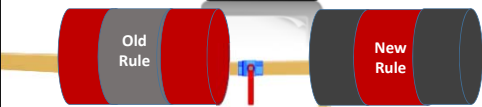
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The Residual Submitted Protocols

Full Review that was "Approved Pending Minor Revisions" prior to 1/21/19 = Approved & Remain Under Old Rule




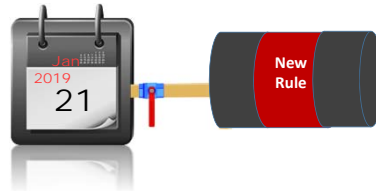
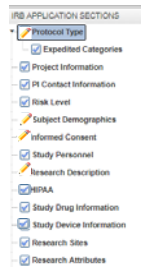
Any other Initial Submission Not Approved prior to 1/21/19 = Under New Rule



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The Residual Submitted Protocols Not Approved Before 1/21/19

Application will convert to New Rule and ☒ will revert to  icon

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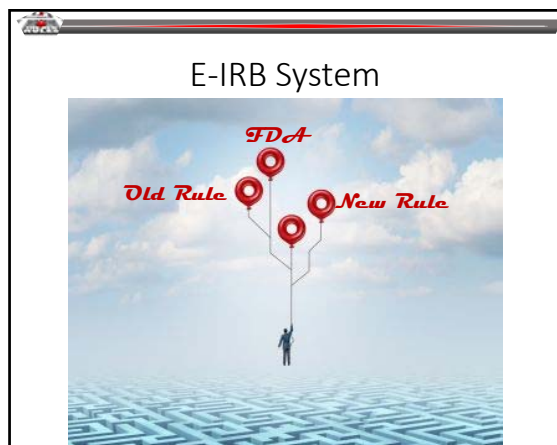


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Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations (October 2018)

- ➔ FDA intends to harmonize to the extent applicable (just started so not there yet)
- ➔ Like always, FDA-regulated protocols will have to follow/comply with both
- ➔ While the regulations differ, those that offer the greater protection to human subjects should be followed

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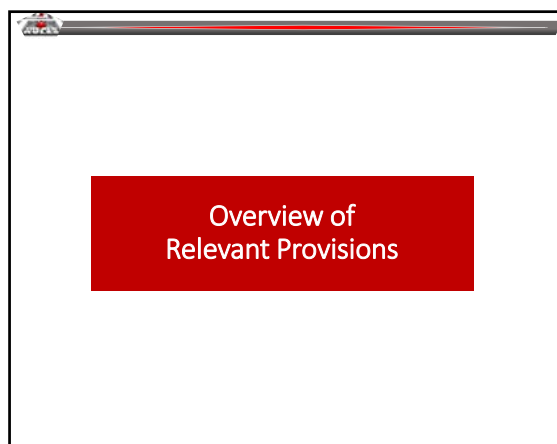


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Summarize

OLD RULE	NEW RULE
<ul style="list-style-type: none"> Existing Studies Approved prior to 1/21/19 Submitted Full Review Studies "Approved Pending Minor Revisions" prior to 1/21/19 	<ul style="list-style-type: none"> New Studies Approved After 1/21/19 Submitted Full Review studies with Major revisions placed on meeting after 1/21/19 Unapproved Expedited or Exempt Submission

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What needs IRB review? **REVIEW**

- ➔ Still based on Common Rule Definition of Research & Human Subject
 - Human Subject – clarifications
- ➔ No change in process
- ➔ What needs IRB Review?
 - www.research.uky.edu/office-research-integrity/what-needs-irb-review
 - Guidance
 - Forms
 - Definitions

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What needs IRB review?



- Revised rule deems select activities as “not human research” requiring IRB review, when not done to develop generalizable knowledge; but done purely as...

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What needs IRB review?



- Scholarly or journalistic activities
 - oral history or biography, where focus is on the specific individual, or literary criticism of an author or piece of literature;
- Public health surveillance
 - required by a public health authority (outbreaks, monitor disease patterns, vaccine campaigns);
- Criminal justice activities authorized by law; or
- National homeland security activities

– www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html
– www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-to-be-research-public-health-surveillance/index.html

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Elimination of Grant Proposal Review

- Eliminate requirement for IRB review of grant applications & proposals



- The IRB must review and approve such research (e.g., a research protocol) for certification; however, the IRB no longer is required to review and approve the research grant application or proposal

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EXEMPT REVIEW

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Exempt Review



- Exempt further regulations – still apply ethical principles
- New categories will appear in E-IRB
- Certain research that required Expedited Review will be eligible for Exempt review
- Review categories before submitting & contact ORI with any questions
- Select categories (2&3) will require a “limited IRB review” (does not require an IRB to consider all of the IRB approval criteria; just privacy & confidentiality)

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Limited IRB Review Considerations



- Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- Use of the information;
- Extent to which the information will be shared or transferred or otherwise disclosed or released;
- Likely retention period or life of the information;
- Security controls that are in place to protect the confidentiality and integrity of the information; and
- Potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Revised Common Rule Preamble

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Exemptions – New Categories

1. Normal Education Setting
2. Educational Tests, Surveys, Interviews, Public Observation
3. Benign Behavioral Intervention
4. Secondary Research of Identifiable Information or Specimens Collected for Other Purpose for which Consent Not Required

RESTRICTED
EXPANDED
New
EXPANDED

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Exemptions

5. Research conducted supported by Federal Agency	EXPANDED
6. Taste & Food Quality	No Change
7. Storage or Maintenance for Which Broad Consent Is Required	<i>Requires institution wide tracking system</i>
8. Secondary research for which Broad Consent Required	

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University of Kentucky Office of Research Integrity Exemption Categories Tool

- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except “for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners”
- Subpart B: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1	104(d)(1)	Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices	N/A	Not Likely to Adversely Impact Students' Opportunity to Learn or Assessment of Educators Providing Instruction
2	104(d)(2)	Research only includes interactions involving Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:	N/A	Data Collection Only; May include visual or auditory recording; May NOT include Intervention Only includes interactions
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked)	N/A	Surveys & Interviews: No Children ; Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	N/A	Surveys & Interviews: No Children ; Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	NO Children
3	104(d)(3)(i)	Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:	N/A	NO Children ; May Not include Medical Interventions; Subject prospectively agrees;
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked)	N/A	(ii)BBI must be: <ul style="list-style-type: none"> • Brief in Duration • Painless/Harmless • Not Physically Invasive • Not Likely to Have a Significant Adverse Lasting Impact on Subjects • Unlikely that Subjects Will Find Interventions Offensive or Embarrassing (iii)No deception unless participant prospectively agrees
		B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
4	104(d)(4)	Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria met:		No Primary Collection from subjects for the research; Allows Both <u>Retrospective and Prospective Secondary Use</u>
		(i) Biospecimens or Information is Publically Available	N/A	Must be publically available
		(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects	N/A	PI does not contact; Will not re-identify
		(iii) 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"	N/A	HIPAA regulations still apply; HIPAA protections include authorization or waiver of authorization; Does not include Biospecimens (only PHI); Only covers "investigator's use"; does not indicate that sharing is permitted under this exemption.
		(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	N/A	If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)
5	104(d)(5)	Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study...improve... public benefit or service programs.	N/A	Must be posted on a Federal Web Site
6	104(d)(6)	Taste and Food Quality – no change	N/A	Wholesome food without additives; ingredient level and use found to be safe (see ii)
7*	104(d)(7)	Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required *UK NOT USING	-Broad consent is obtained --Documented or documentation waived - If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review	All requirements for Broad Consent Met; MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses
8*	104(d)(8)	Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required *UK NOT USING	-Privacy and confidentiality review & -research is within the scope of the broad consent & -PI does not plan to return research results	Privacy and Confidentiality protections adequate; Broad consent was obtained; Documented or documentation waived No plan to return research results; MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses

What's New with Expedited Review?

- ➔ Non-FDA Regulated Expedited research will undergo an Annual Administrative Review (AAR) instead of a continuing review (CR)



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Four Annual Administrative Review Questions

1. Status of the research
2. If subjects enrolled in last year, attached consent for last 2 subjects
3. If enrolling, submit clean consent(s) for stamp
4. Did Unanticipated Problem/Adverse Event occur in last 12 months (*IRB expectation any meeting prompt criteria have been reported*) & provide summary UP/AE since last review with assessment whether events warrant changes to protocol, consent process, or alter risk/benefit ratio

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What's New with Expedited Review?

- ➔ Streamline while maintaining open lines of communication
- ➔ Non-response is still considered non-compliance and will eventually result in protocol being inactivated
- ➔ FDA-Regulated Expedited must undergo CR



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Screening Exception

- ➔ An IRB may approve a research proposal in which an investigator will review information or results from previously collected biospecimens for the purpose of screening or determining the eligibility of prospective subjects without obtaining informed consent under certain conditions.

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Screening Exception

Condition 1:

- ➔ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative
- ➔ IRB policy prohibits "cold calls or contact"



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Screening Exception

Condition 2:

- ➔ The investigator will use identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens
- ➔ Must have legitimate authorization and access to records or specimens
- ➔ If screening falls within covered entity, HIPAA rules apply



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Key Informed Consent Revisions

1. New Process – Concise Summary of Key Information Presented Before “Body” of Consent
2. New Basic and Additional Elements
3. Changes to Waiver Criteria for Informed Consent
4. Waiver of Documentation
5. E-signature on Consent allowed
6. Consent Exception Allowing Investigators to Obtain Information to Determine Eligibility
7. New Requirement for Clinical Trials

Ada Sue Selwitz

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Tool – Informed Consent Requirements

Checklist including:

- General requirements
- 9 Basic Elements
- 9 Additional Elements
- FDA Statements
- Other

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Consent \ Assent Checklist
Federally Required Elements of Informed Consent
DHHS 45 CFR 46 & FDA 21 CFR 50

Yes	No	N/A	General Informed Consent Requirements:
			(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
			(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
			(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
			★ (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
			★ (5) (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
			★ (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
			(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Yes	No	N/A	Basic elements of informed consent - unless the IRB has approved a waiver or alteration of informed consent, the following information must be provided to each subject or the legally authorized representative:
			(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
			(2) A description of any reasonably foreseeable risks or discomforts to the subject;
			(3) A description of any benefits to the subject/others that may reasonably be expected from the research;
			(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
			(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
			(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
			(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

Consent \ Assent Checklist
Federally Required Elements of Informed Consent
DHHS 45 CFR 46 & FDA 21 CFR 50

Yes	No	N/A	Basic elements of informed consent - unless the IRB has approved a waiver or alteration of informed consent, the following information must be provided to each subject or the legally authorized representative:
			(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
			<p>★(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:</p> <p>(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or</p> <p>(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.</p>

Yes	No	N/A	Additional elements of informed consent - the following elements of information, when appropriate, must also be provided to each subject or the legally authorized representative (if applicable):
			(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
			(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
			(3) Any additional costs to the subject that may result from participation in the research;
			(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
			(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
			(6) The approximate number of subjects involved in the study;
			★ (7) A statement that the subject's 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;
			★ (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
			★ (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Yes	No	N/A	Additional FDA Related Statements (include in addition to the above, if applicable):
			Purpose should indicate if study will test or collect data on an FDA regulated product. (e.g., test safety and effectiveness). Proof of concept or early feasibility research may test "how something works" instead of "how well it works". Indicate if results will be shared with FDA;
			Description includes reference to FDA approval status or specific use in study (i.e., FDA has approved ____ for some uses but not for your specific disease). Listing approval status is more meaningful than ambiguous terms like "investigational";

Consent \ Assent Checklist
Federally Required Elements of Informed Consent
 DHHS 45 CFR 46 & FDA 21 CFR 50

Yes	No	N/A	Additional FDA Related Statements (include in addition to the above, if applicable):
			Sections discussing confidentiality should indicate that FDA may look at or copy pertinent portions of records;
			Applicable FDA regulated clinical trials statement regarding registration and results posting on Clinicaltrials.gov- Exact statement from 21 CFR 50.25(c); and 3/7/2012
			For FDA studies, (if not covered in HIPAA Authorization section of consent), indicate that if subject withdraws from study early, the data collected until that point remains in the study database and may not be removed.
			Other Statements Required by UK IRB (if applicable)
			Information concerning payment including but not limited to amount and schedule of payment.

Yes	No	N/A	Assent (if applicable)
			For studies involving children capable of assent, propose a process that takes into account, oral and written communication; illustrates respect for the child; conveys voluntary nature of decision; and includes information the child requires, in a manner he/she can understand, in order to make a decision about participating in the research.
			For children at an age, maturity, and degree of literacy, develop a simplified Assent Form using format and language appropriate for the study population.
			If young children are involved who are yet unable to read, develop an assent script, which provides young children with information in a format that facilitates a voluntary decision whether or not to assent. Documentation should take a form that is appropriate for the purpose of recording that assent took place.

Yes	No	N/A	Sample Statements Required by Sponsors
			For studies with a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH), FDA or other agency – include language informing research participants of the protections and the limits to protections provided by the CoC. 12/13/2016
			Studies subject to the NIH Genomic Data Sharing (GDS) Policy (i.e., NIH-funded projects that generate large-scale genomic data) NIH expects investigators to obtain consent to share participants' genomic and phenotypic data broadly through databases. Include language to specify if the data will be shared via unrestricted- or controlled-access databases, or both. 1/25/2015
			NIH Funded Clinical Trials clinical trials statement regarding registration and results posting on Clinicaltrials.gov 1/18/2017

★ = Not enforceable until the new Common Rule goes into effect 2019

General Informed Consent Requirements

- Provide information a reasonable person would want to have to make a decision & provide opportunity to discuss.
- Present concise & focused Key Information to assist subject in understanding reasons why might or might not want to participate; organized & presented to facilitate comprehension.
- As a whole, presents sufficient detail & does not merely provide lists of isolated facts, but facilitates understanding of reasons why one might or might not participate.

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Concise Summary of Key Information



- Is Not a summary of full protocol (like an abstract)
- Does not need to include all required elements
- Doesn't have to look identical to our template
- typically does not include exclusions unless the exclusion involves restrictions that would affect someone's decision to participate
- ✓ Is presented first vs. being dispersed in the document
- ✓ Should include the information that is most crucial to a participant's decision whether or not to participate
- ✓ May or may not be risks & benefits; could be other pros and cons that a prospective participant would weigh

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How do you figure out what is "Key"?

- Varies with context of the study
- Investigator's Experience with study population
- Empirical Research
- Systematic Participant Feedback
- Potential Participants Input
- Associations
- Support Groups



Examples of Key Information pages for Simulated Studies
www.research.ukv.edu/ori/human/SampleIRBapplication.html

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New Required Elements

- 1 Basic
- 3 Additional



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If study collects Identifiable Private Information or Identifiable Biospecimens, then Consent Must Include a statement that:

- (i) identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent;

OR

- (ii) the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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Additional Elements-

- Specimens or Information used for or could result in Commercial Profit, and if so, whether participant will share in profit
- Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- Whether the research will (if known) or might include whole genome sequencing

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UK Informed Consent Template

- ➔ Templates put into production 12/17 included the key information & new elements
- ➔ FDA has indicated that inclusion of these elements, content, organization, presentation is “not inconsistent” with their regulations, therefore should be no need for separate consent forms

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Informed Consent Waiver vs. Waiver of Documentation


- ➔ Under very select circumstances, regulations permit IRB to:
 1. waive/alter the informed consent (alter would involve omitting any one of required elements of informed consent); or
 2. waive documentation of informed consent.



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Consent Waiver Criteria:

- (i) The Research No More than Minimal Risk;
- (ii) Research Could Not Practicably be Conducted without the Requested Waiver or Alteration;
- (iii) If Using Identifiable Private Information or Identifiable Biospecimens, Research Could Not Practicably be Carried Out without Using Such Information or Biospecimens in an Identifiable Format;
- (iv) Waiver or Alteration Will Not Adversely Affect Rights & Welfare of Subjects;
- (v) Whenever Appropriate, the Subjects or Legally Authorized Representatives Will be Provided with Additional Pertinent Information After Participation.




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FDA Harmonization Proposed Rule: IRB Waiver/Alteration of Informed Consent for Minimal Risk Clinical Investigations (November 15, 2018)



- ➔ If finalized, would permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent for FDA-regulated minimal risk clinical investigations
- ➔ FDA guidance (July 2017) – stated until regulation revised, FDA does not intend to object to an IRB using common rule criteria to waive or alter informed consent

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Waiver of Consent Documentation



- (i) Option 1- Consent ONLY linked record and Principle Risk is Breach of Confidentiality
- (ii) Option 2- <Minimal Risk & procedure where written consent not norm outside of research
- (iii) Option 3- <Minimal Risk & Distinct Cultural Group Community in Which Signing Form is Not the Norm & appropriate alternative mechanism for documenting that informed consent will be obtained.

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Requirement Specific for Select Clinical Trials

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Posting Federally Funded Clinical Trial Consent Form

- ♦ *As a means of increasing transparency and facilitating the development of more informative consent forms*
- ♦ *The primary purpose is to improve the quality of consent forms in federally funded research by assuring that—contrary to current practices, under which it is often very difficult to ever obtain a copy of these documents—they eventually would become subject to public scrutiny and that they will provide useful models for others*

Common Rule Preamble

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Posting Federally Funded Clinical Trial Consent Form

Clinical trials conducted or supported by a Common Rule department or agency (e.g., NIH) must post the consent form on a publicly available federal website.

The consent form must:

- have been used in enrolling participants;
- be posted on the Federal website after the clinical trial is closed to recruitment; and
- be posted no later than 60 days after the last study visit by any subject, as required by the protocol.

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Posting Clinical Trial Consent Form

- ♦ 2 publicly available federal websites will satisfy the posting requirement:
 - ClinicalTrials.gov; and
 - a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).
- ♦ HHS and other Common Rule agencies are developing guidance about this.

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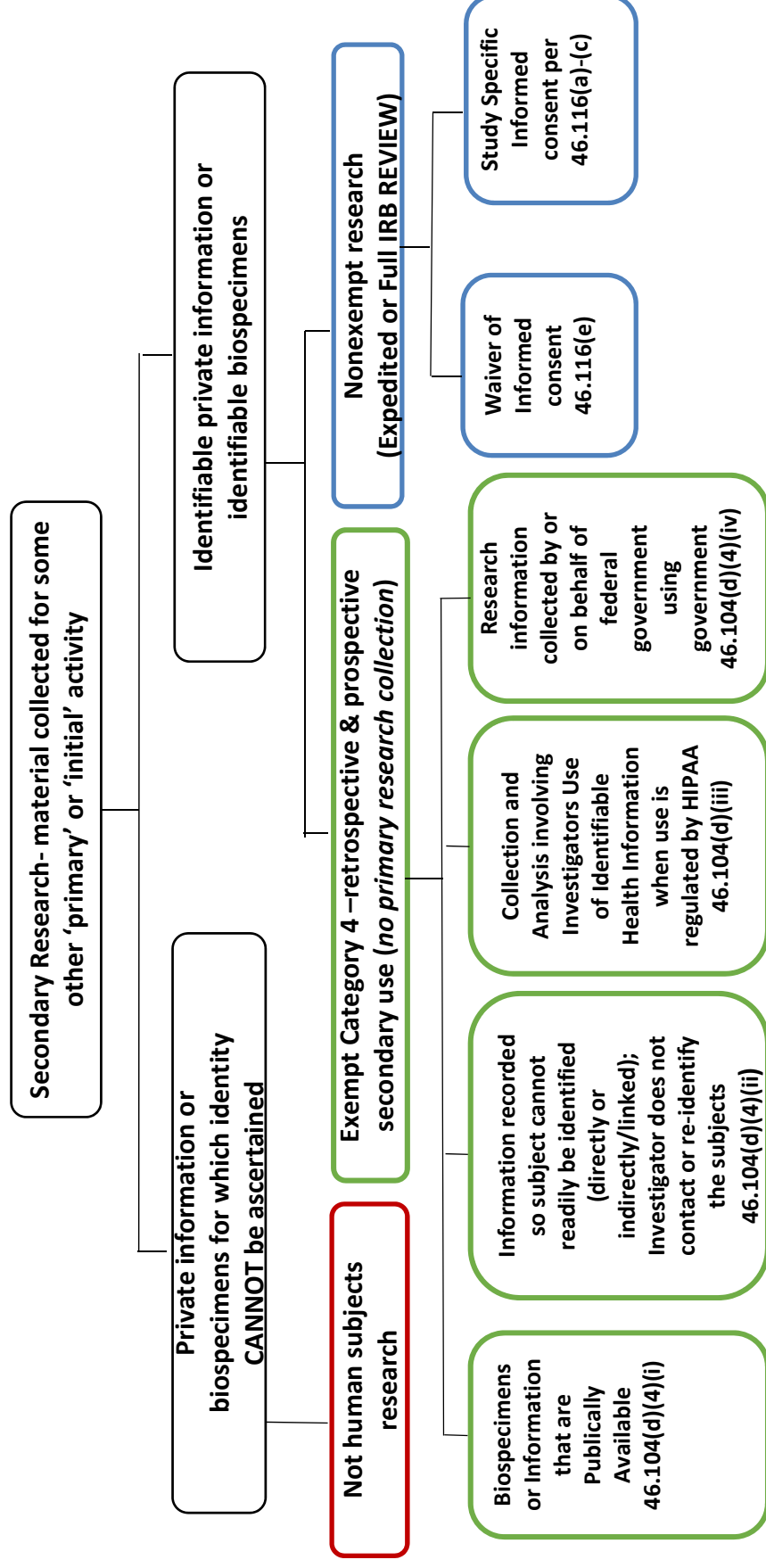
Secondary Research



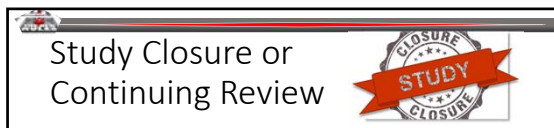
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Revised Common Rule

UK Secondary Research Options



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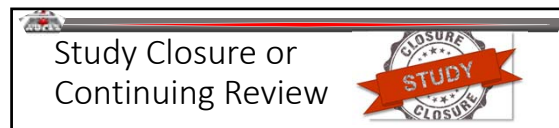


Study Closure or Continuing Review

No further Continuing Review required when study has progressed to point of data analysis and

- old rule – data are de-identified
- new rule – data may have identifiers

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Study Closure or Continuing Review

- ➔ Data collection is complete AND the only activity is data analysis AND:
 - Data are de-identified; or
 - Data for studies approved after January 21, 2019 with identifiers, is encrypted; or
 - For FDA-regulated studies, there are no outstanding data queries or other investigator/site responsibilities in the trial (remember to confirm with external study sponsor before answering "yes" to prevent inactivating the protocol prematurely).

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E-IRB System Shutdown Dates

- ➔ E-IRB will be offline from noon, Friday, January 18, 2019, through 8:00 am, Tuesday, January 22, 2019.
- ➔ The shutdown is required for RIS to implement programming changes to the E-IRB system based on the Revised Rule.

Urgent reporting—
contact ORI or submit to
IRBsubmission@uky.edu
if after hours [include IRB #]



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Human Subject Protection Education

- ➔ CITI Program website will be taken offline 1/19 for updating of existing modules affected by the revised Common Rule. Should be available 1/20
- ➔ ORI counts the Optional New Common Rule Course as refresher HSP
- ➔ Non-UK personnel – several HSP options
www.research.uky.edu/office-research-integrity/non-uk-or-community-based-study-personnel-faqs

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Looking Ahead

- ➔ 2019 – AAHRPP Accreditation Application
- ➔ 2020 – AAHRPP Site Visit
- ➔ 2020 – Common Rule Single IRB Mandate



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Staying Informed




- ➔ ORI Home and What's New Webpage
www.research.uky.edu/office-research-integrity
- ➔ Join ORI Listserv www.research.uky.edu/office-research-integrity/ori-listserv
- ➔ Policies & Guidance
www.research.uky.edu/office-research-integrity/policies-guidance
 - IRB Survival Handbook
 - IRB SOPs




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Education Opportunities 

- ➔ Repeat date 1/17/19 “What Research Will Qualify as Exempt at UK?”
- ➔ Repeat “Transition to the Revised Common Rule” TBD




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- ➔ OHRP Videos & Resources
www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html
- ➔ OHRP FAQs
www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html

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Questions or Support 

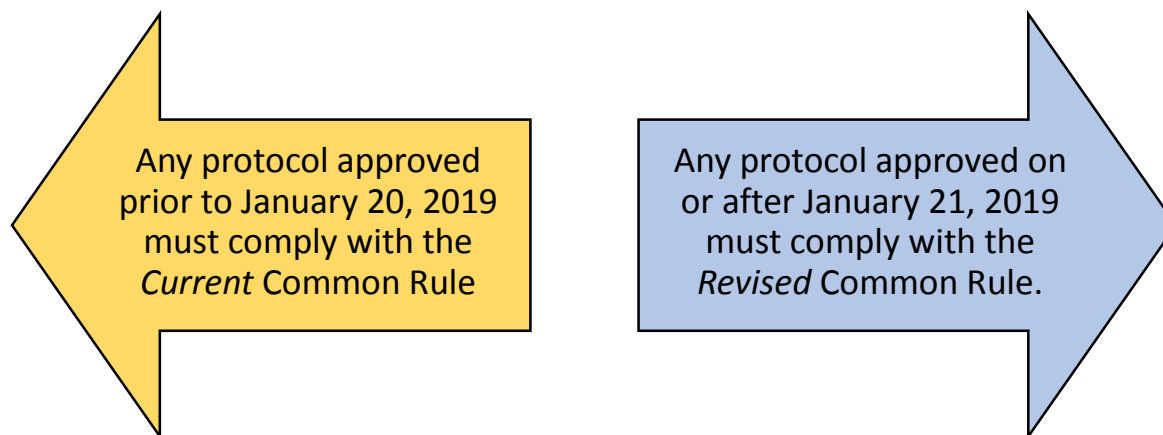
- ➔ Email general questions to IRBsubmission@uky.edu or contact the ORI main line at 859-257-9428.
- ➔ For protocol specific questions, contact the ORI main line at 859-257-9428, with the protocol number to connect with the ORI Professional Associate managing your protocol

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University of Kentucky Office of Research Integrity (ORI) Revised Common Rule Changes Summary

The Federal Policy for the Protection of Human Subjects (commonly referred to as “*the Common Rule*”), provides ethically based regulations for the review and conduct of human research studies. The Department of Health and Human Services (HHS) Office for Human Research protections (OHRP) issued changes to modernize, strengthen, and streamline the rule in January 2017. However, the rule was amended to delay the effective and compliance dates. Most changes will go into effect on January 21, 2019.

This document provides plans for transitioning to the revised rule, as well as an overview of the 2019 primary changes. We will update this document with additional information and answers to frequently asked questions (FAQ) as OHRP provides federal guidance on interpretation and practical application of the new rule.



Existing Studies Approved under the Current Common Rule

Existing IRB approved studies may continue through completion under the Current Common Rule. Studies approved by the IRB prior to January 21, 2019 will continue to operate under the current rule, and as such, will not be expected to comply with all of the changes generated by the Revised Rule.

However, if a research investigator wishes to transition an existing study to the Revised Common Rule, contact ORI to discuss options. Note: The new application must comply with all applicable revised common rule requirements.

Studies Approved Under the Revised Common Rule

While much of the revised regulations apply to IRB review and management, investigators will see a number of changes. This document provides an overview of key changes. The University of Kentucky E-IRB system, standard operating procedures, policies, guidance, and website are undergoing provisional changes based on the revised regulations. However, there are pending lists and guidance documents that HHS has yet to issue. Should OHRP release guidance that alters the interpretation and application of the Revised Rule, we will update materials accordingly.

Studies Subject to Food and Drug Administration (FDA) Regulations

The revised rule has created differences between HHS and FDA human subject regulations. The FDA has not yet revised their regulations. They issued guidance in October 2018 indicating intent to harmonize, to the extent possible, with the Revised Common Rule. Until that time, ORI and Research Information Services (RIS) have included instructions or programming logic to apply provisions that do not conflict with FDA regulations.

KEY REGULATORY CHANGES UNDER THE REVISED COMMON RULE

Activities Deemed not to be research that do not require IRB review:

There has been no change in the process for determining what activities meet the federal of research and human subject and require IRB review. Investigators are encouraged to consult [ORI guidance and contact ORI for questions or a “Not Human Subject Determination”](#). The revised rule has provided determinations on select activities that are considered “not human research and do not require IRB review” if done purely as described below. These include:

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

See the “What Research Activities Need Institutional Review Board (IRB) Review?” Fast Pass Video [[YouTube Video](#)] or [What Needs IRB Review](#) website for additional information.

Informed Consent Documentation & Process:

The revised rule shifts the focus of informed consent to the potential subject with:

- Information that a “Reasonable Person” would want in order to make an informed decision;
- Changes to facilitate subject’s understanding of the key reasons he/she would or would not choose to participate in research; and
- Requirements that Key Information essential to that decision be presented first in the document and discussion.

In preparation for the change, the UK ORI implemented revised informed consent templates a year in advance of the Revised Rule compliance date. The changes focus on a reasonable person standard and encourages creating consent documents that facilitate understanding. This involves formatting to fit the context of the study and the study population’s needs, rather than prescriptive reliance on template language. The [UK Consent Form Template FAQ](#) provides guidelines for improving the consent documents and process.

The rule includes a new required element for studies that collect identifiable information or identifiable specimens. The element informs subjects regarding intent to conduct future research with the identifiable information or specimens collected as part of the initial research. Specifically, whether or not identifiers will be removed and material used or shared with others for future research, without the subject's additional consent. There are also three additional elements, which the investigator must include when applicable. The three elements inform subjects regarding potential commercial profit, whole genome sequencing, and return of research results. To ensure your consent documents include all required elements, use the [UK Federally Required Elements of Informed Consent](#) Checklist.

FDA clarified in the [2018 Guidance](#), that the Revised Common Rule provisions related to content, organization, and presentation of the consent form and process are not inconsistent with FDA's current policies. The clarification is in effort to avoid the need for sponsors or investigators to develop, and IRBs to review, two separate informed consent forms.

General Waiver of Informed Consent:

The IRB may waive the requirement or approve alteration of elements of informed consent if it finds and documents that the research meets certain conditions. In addition to the current criteria for waiving or altering consent, the rule adds consideration of a fifth condition. This new requirement is that the research could not practicably be carried out without accessing or using information or biospecimens in an identifiable format. See the Waiver of Informed Consent/Assent Process and Documentation Video for additional information. [\[YouTube Video\]](#)

Waiver of Documentation of Informed Consent:

The IRB may waive the requirement to obtain a signed consent document for some or all of the subjects if certain conditions are met. In addition to the current conditions for waiving documentation, a waiver may be granted for international research where the signature on the informed consent form is not culturally appropriate. See the Waiver of Informed Consent/Assent Process and Documentation Video for additional information. [\[YouTube Video\]](#)

Screening or Determining Eligibility:

An IRB may approve a research proposal in which an investigator will review information or results from previously collected biospecimens for the purpose of screening or determining the eligibility of prospective subjects without obtaining informed consent if either of the following conditions are met:

- 1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or,
- 2) The investigator will use identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The UK IRB is awaiting federal guidance on specific application of this exception in terms of recruitment. The UK IRB policies and guidance on recruitment have not

changed (see [A Principal Investigator's Guide to Identification and Recruitment of Human Subjects for Research](#)).

Exempt Review (Non-FDA-Regulated New Exemption Categories):

The Final Rule establishes new exempt categories of research. The new categories will appear in E-IRB after the revised rule effective date.

Certain research that required Expedited IRB review, will be eligible for Exempt IRB review under the revised rule. For instance, a record review qualifying for the new Exemption Category 4, will allow both prospective and retrospective review of records, whereas in the past, only retrospective reviews qualified for Exempt review. See the [UK ORI Exemption Categories Tool](#) for the six categories available at UK, and associated conditions, allowances and limitations.

In addition to making the exempt certification determination, the IRB reviewers are required to conduct a limited review for select exempt categories, in order to ensure there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

Investigators are encouraged to review [the exempt review categories](#) before submitting an application in E-IRB. Since the E-IRB system does not allow switching review types (i.e., expedited to exempt) once the application is created, changing review type would require creating a new application.

Expedited Review (Non-FDA-Regulated):

- The expedited categories have not been updated by OHRP as of yet.
- Select Social Behavioral Education research that required initial Expedited Review will be eligible for Exempt review (see above) under the revised rule.
- Non-FDA Regulated Expedited research will undergo an abbreviated administrative review (consisting of four questions), instead of a continuing review.

Continuing Review:

Continuing review provides the IRB with an opportunity to determine whether there is new information that represents a significant new finding and whether the finding warrants communicating to subjects who have already enrolled in the research.

Comprehensive Continuing Review is no longer required in select minimal risk research (see Expedited Review section above).

Investigators with Full review or FDA-regulated protocols will complete a continuing review application to allow for substantive IRB review.

Non-FDA regulated, Expedited review protocols will undergo with an abbreviated annual review. The abbreviated review maintains open lines of communication between the investigator and the IRB, while streamlining reporting appropriate to minimal risk research.

Clinical Trials Definition:

In order to harmonize with other agencies' definition of a clinical trial, the revised rule definition is, "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 health-related outcomes".

Principal Investigator Posting of Clinical Trial Consent Form:

There is a new requirement for clinical trials conducted or supported by a Common Rule department or agency (e.g., National Institutes of Health) for posting the consent form on a publicly available federal website. The consent form must:

- have been used in enrolling participants;
- be posted on the Federal website after the clinical trial is closed to recruitment; and
- be posted no later than 60 days after the last study visit by any subject, as required by the protocol.

At this time, two publicly available federal websites will satisfy the consent form posting requirement:

- ClinicalTrials.gov; and
- a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

HHS and other Common Rule agencies are developing guidance about [this posting requirement](#) that will shape the University of Kentucky's Policies and Procedures.

Staying Informed:

Information contained in this document will be updated as additional information is available, and if/when OHRP issues guidance or announcements regarding the revised Common Rule. Information will be posted on the [ORI website](#), [ORI News & Announcements webpage](#), and via the [IRB listserv](#) and [education sessions/materials](#).

Email general questions to IRBsubmission@uky.edu or contact the ORI main line at 859-257-9428.

For protocol specific questions, contact the ORI main line at 859-257-9428, with the protocol number to connect with the ORI Professional Associate managing your protocol.

The Office of Research Integrity will strive to facilitate the conduct of ethical human subject research during this transition. We appreciate the service of the Institutional Review Board members and the cooperation of the research community.