UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Final Rule – Significant Changes

As many of you already know, the Final Rule, which updates the regulations at 45 CFR 46, Subpart A, Federal Policy for the Protection of Human Subjects (Common Rule) will be effective on January 19, 2018. Many of the changes made in association with the Final Rule will require immediate updates to UC San Diego human subjects research policies, procedures, and forms. Some of the changes will not be implemented immediately as they will require additional information including further interpretation from federal agencies and will be implemented as that information is provided.

Some of the most significant changes are outlined in this document. Researchers should continue review the HRPP website to learn of "new" policies and procedures as they become operational.

At this time, the Final Rule changes will be ***effective only for studies that are federally supported/conducted that are initially approved on or after January 19, 2018.*** Federally supported/conducted studies initially approved before that date will continue to comply with regulations, policies and procedures that were in effect before that date. The IRB/HRPP will on a case-by-case basis determine whether a study approved before January 20, 2018 (pre-2018) will continue to apply pre-2018 rules. If the IRB/HRPP determines that Final Rule regulations, policies, and procedure will apply, the PI will be notified of this determination.

Studies that are not federally supported/conducted will not be affected by the Final Rule. However, the IRB/HRPP will continue to review changes associated with the Final Rule and will implement those changes on non-federally support/conducted studies, as appropriate. If you have any questions, please contact the HRPP Office at hrpp@ucsd.edu.

Category	Topic	Details	Impact on researchers
Overview	Who does the Final Rule affect?	Only studies that are federally conducted and/or supported. Studies that are not federally conducted/funded are not affected at this time.	Ensures IRB/HRPP is informed study is conducted/supported by DHHS
	When does the Final Rule go into effect?	January 19, 2018	Begin addressing changes with the Final Rule for projects that will not receive approval before January 19, 2018
	What about studies approved before January 19, 2018?	Studies that are federally conducted/supported will continue to comply with pre-2018 rules or the 2018 requirements. The IRB/HRPP will review at the time of continuing review to determine on a case-by-case basis to change the project to use the Final Rule.	At the time of continuing review a determination will be made and PIs informed

New definitions	Clinical Trial	Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.	The additional of "behavioral" health-related outcomes may affect some social and behavioral researchers
	Vulnerable populations	The final rule no longer includes pregnant women or ''handicapped'' or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. The final rule uses the term ''individuals with impaired decision-making ability'' to replace the term ''mentally disabled persons.''	Should be considered by researchers when completing Research Plan and consent documents
	Human subjects	Changes to the current definition of a human subject include the following: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (6) An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.	Should be considered by researchers when planning research design
	Research (defines what is not research)	The following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or	Most of this information is already in place (see Fact Sheet)

		authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.	
Exemptions	Categories (includes new and updated categories)	Updated category 1: Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Updated category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the	Some not in affect at UCSD. See Exemptions document here. Should be considered by researchers when planning research design and when completing Research Plan and other study documents

		subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7). New category 3: (3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7). (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount	

		of received cash between themselves and someone else. (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Updated category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501	

		et seq. Updated category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. Unchanged category 6: Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	

		New category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8). New category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__117; (iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.	
	Applicable subparts	*Subpart B (pregnant women, human fetuses, and neonate.* Each of the exemptions may be applied to research subject to subpart B if the conditions of the exemption are met. *Subpart C (prisoners).* The exemptions do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners. *Subpart D (children).* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do	Should be considered by researchers when planning research design and when completing Research Plan and other study documents

		not participate in the activities being observed. Paragraph (d)(2)(iii) may not be applied to research subject to subpart D. See also the Exemptions document here.	
IRB operations	Limited Review	See Exemptions document. a) 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 §__.104 for which limited IRB review is a condition of exemption (under §__.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).	Should be considered by researchers when planning research design and when completing Research Plan and other study documents
	Continuing review for expedited projects	Not required under various conditions including studies that undergo expedited review unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects; 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; and research reviewed in accordance with the limited IRB review procedure. The final rule does not require investigators to provide annual confirmation to the IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. Institutions that choose to require some accounting of ongoing research not subject to continuing review have significant flexibility in how they implement their own requirements. Note that under the final rule, investigators would still have the current obligations to report various developments (such as unanticipated problems or proposed changes to the study) to the IRB.	Should lessen burden on researchers once last continuing review completed. The IRB/HRPP will review a possible requirement of the researchers providing an account of ongoing research.
	Additions to criteria for approval	The final rule does, however, revise two of the existing criteria for approval of research: (1) Special considerations related to the involvement of vulnerable populations, and (2) privacy and confidentiality of data provisions. As discussed in more detail in Section VII, the language	Should be considered by researchers when planning research design and when completing Research Plan, consent, and other study documents

		regarding vulnerable populations at §__.111(a)(3) and (b) has been revised to reflect the current understanding of which populations should receive special consideration due to potential vulnerabilities specific to the purposes and context of human subjects studies and to parallel other references to vulnerable populations found at §__.107(a). Section __.111(a)(7) in the final rule retains the pre-2018 language, but also adds an additional requirement, thereby serving a dual function as both the primary regulatory provision requiring IRB review of the adequacy of protections for the privacy of subjects and confidentiality of identifiable private information (including that obtained from the analysis of biospecimens), and as the primary limited IRB review requirement needed to satisfy certain exemption determinations in §__.104(d).	
	Cooperative research	Mandated for more than one site for federally funded research beginning 120/2020	
	Reliance on non-institutional IRBs	For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to §ll.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.*, in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).	If researchers wish to rely on a non-commercial, non-UCSD IRB or if the researcher wishes other sites to rely on the UCSD IRB, the researchers must first contact the HRPP Director to provide sufficient information to make a determination whether relying on a non-UCSD IRB or having other sites rely on the UCSD IRB is appropriate.
	Records	Requires records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review and documentation specifying the responsibilities that an institution and an organization operating an IRB each will	Rationale will be provided to researcher by IRB/HRPP

		undertake to ensure compliance with the requirements of this policy, as described in §__.103(e).	
Informed consent	New "general" requirements for informed consent	(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) Except for broad consent obtained in accordance with paragraph (d) of this section: (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 releases or appears to release the investigator, the sponsor, the	Must be taken into account when describing the consenting/assenting procedures and creating consent/permission/assent documents (see federally funded consent/permission/assent sample documents coming soon)

		institution, or its agents from liability for negligence. Concise and focused presentation of the key information includes the following: The beginning of an informed consent would include a concise explanation of the following: (1) the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research.	
	Additions and updates 45 CFR 46.116 regarding informed consent	New subsection: (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. New subsection: (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. New subsection: (5)(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.	Broad consent will not be available because of current technology associated with electronic medical records. Other additions/updates should be considered by researchers when planning research design and when completing Research Plan, consent, and other study documents. Updated sample consent/permission/assent documents will be available soon.

		Added two elements to the 8 previous basic elements: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimen: (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 (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. Added three elements to the 6 previous additional elements of consent: (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). Added subsections regarding broad consent. New subsection: (h) *Posting of clinical trial consent form.* (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such	

		informed consent forms. (2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted. (3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.	
	45 CFR 46.117	(a) Except as provided in paragraph (c) [discusses waiver of documented consent] of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. (b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following: (1) A written informed consent form that meets the requirements of §__.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative. (2) A short form written informed consent form stating that the elements of informed consent required by §__.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §__.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in	Should be considered by researchers when planning research design and when completing Research Plan, consent, and other study documents

		addition to a copy of the short form. (c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following: (i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or (iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.	
	Waivers	General waiver or alteration of consent—(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens. (2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of	Should be considered by researchers when planning research design and when completing Research Plan, consent, and other study documents

		this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section. (3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that: (i) The research involves no more than minimal risk to the subjects; (ii) The research could not practicably be carried out without the requested waiver or alteration; (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.	
	Recruitment/screening waivers	An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, 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 obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.	Should be considered by researchers when planning research design and when completing Research Plan
Tribal Law		Provides definition of when Tribal law applies (noted throughout Final Rule)	Should be considered under appropriate circumstances by researchers when planning research design and when completing Research Plan, consent, and other study documents