BAYLOR UNIVERSITY
OFFICE OF THE VICE PROVOST FOR RESEARCH

Summary of Changes to Human Subject Research (IRB) Regulations
Effective Date: January 21, 2019

This guide serves to assist researchers to understand the New Common Rule and how it will be implemented at Baylor University. This is not a comprehensive list of the changes in the new rule, but highlights the most important areas impacting researchers.

Implementation Date

Projects approved **before** January 21, 2019	All projects approved before the implementation date remain under the Pre-2018 Requirements. These projects will retain their existing level of review and all other IRB requirements, including continuing review requirements for Expedited and Full Board protocols.
Projects approved **on or after** January 21, 2019	All new IRB applications approved on or after January 21, 2019 will be approved under the 2018 (New Common Rule) Requirements. IRB forms will be updated to comply with the 2018 Requirements and will be available for download after January 20, 2019.
Transition of ongoing approved research	There is no regulatory requirement to transition research initiated prior to January 21, 2019 to the 2018 requirements. At the time of continuing review or the submission of an amendment, the Office of Research Compliance will review any research initiated prior to 01/21/19 to determine if a transition to the 2018 requirements would be appropriate. **Moving an existing study to the 2018 Requirements means the entire new rule applies.** This may require revisions to the informed consent, reconsent of subjects, and increased data security and privacy standards for these existing studies.

Revised Definitions

Topic	Revisions	BU Implementation
Human Subject	The new rule revises the definition of human subject to include a living individual about whom an investigator (whether professional or student) conducting research: • Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or • Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.	There is no effect on current IRB practices. The regulatory definition of human subject remains substantively the same but in the revised Common Rule "data" is replaced with "information or biospecimens" for clarity.

Research	The new rule explicitly removes four categories of activities from the rule jurisdiction: • Scholarly or journalistic activities, including oral history, journalism, biography, literary criticism, legal research, and historical scholarship; • National security missions; • Public health surveillance; • Criminal justice activities.	There is no effect on current IRB practices.
Clinical Trial	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.	This definition and the NIH definition of clinical trial are now identical. This will affect NIH-funded research that meets this definition.

Informed Consent

Topic	Revisions	BU Implementation
New General Requirements	Changes to the general requirements for informed consent to provide key information and promote autonomy by ensuring prospective subjects receive the information needed to make an informed decision. Changes to the informed consent general requirements include: • informed consent must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision • information must be presented in a way that facilitates an understanding of why one might, or might not, want to participate • the informed consent form should not simply list isolated facts, but instead should help people process complicated information • key information such as the study's purpose, risks, benefits, and alternatives, must be provided at the beginning of the consent form.	Consent templates have been updated. A new checklist is also available.

New Elements	Four requirements have been added to the elements of informed consent. The first is required for all studies, and is a statement about whether participants' information or biospecimens might (or will not) be stripped of identifiers and used for future research. The three new elements of informed consent, to be added as applicable, are: • information about possible commercial profit • information about whether clinically relevant research results will be returned to the subjects • information about whether research activities will or might include whole genome sequencing.	Consent templates have been updated. A new checklist is also available.
Changes to Waiver of Informed Consent	When identifiable biospecimens or private information are involved, the IRB must determine that the research could not practicably be conducted without the use of the identifiable information. If the research could be done using non-identifiable information, then that is what should be done.	The Request for Waiver/Alteration of Consent form has been updated.
Documentation Waiver Expanded	The IRB may waive the requirement for a signed informed consent form when the subjects are members of a distinct cultural group or community in which signing forms is not the norm, and the research involves no more than minimal risk, and there is an alternative method for documenting that consent was obtained.	The Request for Waiver of Documentation of Consent form has been updated.
Screening, recruiting, or determining eligibility of prospective subjects	The new rule allows the IRB to approve access to identifiable information or identifiable specimens without the prospective participant's informed consent for purposes of screening, recruiting, or determining eligibility if: • The investigator obtains information through oral or written communication with the prospective subject; OR • The investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.	A waiver of informed consent will no longer be required to access identifiable information for determining eligibility. Pre-screening consents (written or verbal) and waivers for documentation of consent for pre-screening will no longer be required.

Exempt Research

Topic	Revisions	BU Implementation
Category 1: Educational Practices	Exemption revised. A new restriction to the applicability of Exemption 1 requires that the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.	Exemption Application has been updated.
Category 2: Educational tests, surveys, interviews, observation of public behavior	Exemption revised. There are three primary changes: • Addition that this "only includes interactions" involving educational tests, surveys, interviews, and observation of public behavior. Exemption 2 is not applicable to research involving interventions. • Addition to second criterion requiring that the disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement." • Allows for the use of limited IRB review where identifiable information is recorded (even if sensitive).	Exemption Application has been updated.
Category 3: Benign behavioral interventions	New exemption. Research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. A benign behavioral intervention must be brief in duration (although data collection may take longer). Also, the intervention must be harmless, painless, and not physically invasive. Further, the intervention must not be likely to have a significant adverse lasting impact on subjects. The investigator must have no reason to believe that the intervention will be offensive or embarrassing to subjects, and should take into consideration the subjects' population, the context of the research, the topic, and other characteristics of the study.	Exemption Application has been updated.
Category 4: Research on existing data	Revised exemption. Secondary research use of identifiable private information or identifiable biospecimens. One change is that the private information and biospecimens no longer	Exemption Application has been updated.

	have to be in existence prior to the start of the research but must meet one of the applicability provisions.	
Category 5: Public benefit service	Revised exemption. Expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a new requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.	Exemption Application has been updated.
Category 6: Taste and Food Evaluations	No changes to this category that allows for the review or research involving taste and food quality evaluation and consumer acceptance studies.	Exemption Application has been updated.
Category 7: Storage and maintenance for secondary research collected under broad consent	New exemption. Due to administrative requirements, this exemption is not being implemented at Baylor.	Not implemented.
Category 8: Secondary research for which broad consent is required	New exemption. Due to administrative requirements, this exemption is not being implemented at Baylor.	Not implemented.

IRB Review

Topic	Revisions	BU Implementation
Continuing Review – Expedited Protocols	Continuing Review is not required for research approved under the expedited procedure unless the IRB finds and documents the need to require a continuing review to enhance the protections of research subjects.	Even though continuing review is no longer required, the research is still under the purview of the IRB. Therefore, a simplified progress report will be required prior to the approval anniversary.
Continuing Review – data analysis/follow-up only	Continuing Review is not required for 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: • Data analysis, including analysis of identifiable private information or identifiable biospecimens, or • Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.	Even though continuing review is no longer required, the research is still under the purview of the IRB. Therefore, a simplified progress report will be required prior to the approval anniversary.

Limited IRB Review	Limited IRB review is a process that is required only for certain exemptions. In limited IRB review, the IRB must determine that certain conditions, primarily that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data, are met. Continuing review of limited IRB approval is not required.	Procedures in the IRB office have been revised to accommodate this review process.
Single IRB	Effective 01/20/20, most federally-funded multi-site research is required to rely upon the approval of a single IRB.	Baylor already encourages the use of a single IRB for multi-site research. However, more formal processes and procedures for this requirement will be in place by 01/20/20.
Grant Review	IRB review of the federal grant for congruency between the grant and protocol is no longer required.	The grant document will no longer be requested by the IRB.