Revised Common Rule at Emory University [1]

Definitions	Rule change
Research	The new rule explicitly removes four categories of activities from the Common Rule's 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 **Emory Impact:** The Emory IRB *already* recognized that these activities were not within the IRB's scope, and did not review them. Thus there will be no change locally as a result of this clarification in the rule.
Clinical Trial Definition	The pre-2018 Rule provided no definition of a clinical trial. The 2018 Rule defines a clinical trial as: "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 aligns with the NIH definition. **Emory Impact:** The Emory IRB has been using this definition for NIH-regulated trials already. The definition in the 2018 Rule relates to the new requirement to publicly post a copy of the informed consent form after enrollment is closed. Study teams must remember to comply with this requirement.
Benign Behavioral Intervention	The pre-2018 Rule provided no definition of "benign behavioral interventions." The 2018 Rule uses this term in one of the Exempt research categories, and defines a benign behavioral intervention as: 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. Examples 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. **Emory Impact:** Studies meeting the definition above will now be exempt instead of needing IRB oversight and expedited review (unless FDA-regulated or funded by Dept. of Justice).

[1] Adapted from University of Arizona new common rule implementation guide

Exempt studies	Rule change
Exempt project determination	Exemption categories have been extensively changed. **Emory Impact:** Some more studies will now be exempt. Emory will not be implementing the new categories related to "broad consent" at this time.
Exempt categories	The exempt categories have been revised as noted below. The (*) signifies the specific change from the pre-2018 Rule. **REVISED** Exempt category 1 – research in educational settings *Revised to specify that the research must not adversely affect students' opportunity to learn required educational content or harm chances for educational advancement, or adversely affect the assessment of educators who provide instruction. **REVISED** Exempt category 2 – research involving educational tests, survey procedures, interview procedures, or observations of public behavior *Revised to allow collection of *identifiable sensitive* data, if the study undergoes "limited IRB review" for privacy and security of data. **NEW** Exempt category 3 – research involving benign behavioral interventions (as defined in the regulations) *This research cannot involve deception unless the deception is authorized by the participant **REVISED** Exempt category 4 – secondary research involving identifiable private information or identifiable biospecimens for which consent is not required *Revised to remove word 'existing' to describe data used * *Identifiable* private data can now be used if the research data is covered by HIPAA * Other minor clarifications **REVISED** Exempt category 5 – research and demonstration projects conducted or supported by a federal department or agency *Revised to allow for easier applicability **UNCHANGED** Exempt category 6 – taste and food evaluations **NEW** Exempt category 7 and category 8 for storage and maintenance for secondary research for which broad consent is required- will not be implemented since Emory is not implementing Broad Consent at this time.

Exempt research and vulnerable populations	**Pregnant Women** – All exemptions may apply if the condition of the exemption is met. **Prisoners** – None of the exemptions apply, except for research aimed at involving a broader subject population and only incidentally includes prisoners. **Children** – Exemptions (d)(1) and (d)(4-8) may involve children. Exempt (d)(2) (research on educational tests, surveys, interviews or observations) may include children, but: *Exempt (2)(i) and (ii) only apply to educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed; and *Exempt (2)(iii) is not applicable to research with children. This exemption is where the investigator can readily ascertain the identity of the child. **Emory Impact:** Easier to do certain research involving prisoner data, and research with pregnant women
Limited IRB review	The pre-2018 Rule did not contain the concept of limited IRB review for exempt research. The new rule outlines several exempt categories that require an increased level of review by the IRB; either for data security and privacy protections, or for confirmation of broad consent elements and return of research results. We will detail only the ones required for data security and privacy protections. The exempt category requiring limited IRB review, and which will be relevant at Emory, are: • Exempt (d)(3) research involving benign interventions that are identifiable (directly or through links) and the responses may be damaging to the subject's reputation, financial standing, employability, educational advancement, criminal or civil liability. • Exempt category (d)(2) – research involving educational tests, survey procedures, interview procedures, or observations of public behavior when the data collected is identifiable and potentially damaging/sensitive (Exemption category (d)(4) – secondary use of identifiable private information that is covered by HIPAA – will not be useful at Emory. Secondary research use of such data is intentionally excluded from Emory's "covered entity" and thus is not protected by HIPAA.) **Emory Impact:** Submissions requiring limited IRB review will need to provide information related to these considerations:

	• The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified; • How the information will be used; • The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released; • The likely retention period of the information; • The security controls that are in place to protect the confidentiality and integrity of the information; and • The 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.

Expedited Studies	**Rule change**
Expedited review categories	There is no change to the expedited categories under the 2018 Rule, but the new Rule removes the requirement to determine that a project is "minimal risk" – it can be expedited as long as it falls within one (or more) of the expedited categories. The one exception is category F9, that requires continuing review. The FDA and the Department of Justice have not harmonized with this change (so category F1 cannot be expedited)
Continuing review elimination	Studies approved after January 21, 2019 will no longer be subject to continuing review, unless the IRB finds and documents the need to require a continuing review to enhance the protections of research subjects. EXCEPTIONS: FDA-regulated studies, and studies funded by the Department of Justice, must still undergo annual continuing review. The Emory RB ***may*** **require continuing review** for minimal risk research when the research involves: • Principal Investigator (PI) or co-PIs who have received a determination of continuing or serious non-compliance in the past two years; • As determined by the IRB because of a change in risk, protection or inclusion of subjects, or other concerns that require increased oversight; • Projects that involve deception that is not prospectively authorized; or • A conflict of interest management plan exists • Studies involving an international site or other non-local sites Existing projects will be assessed at the next continuing review to determine if they should transition to the new rule. Moving a project to the new rule 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.
Single IRB (sIRB) review for multi-site studies	Effective in 2020, the 2018 Rule requires that all multi-site (meaning more than one site) conduct sIRB review. The sIRB is determined by the prime awardee and the federal agency supporting the study. Note that the NIH single IRB policy was effective as of January 25, 2018.

Informed Consent	Rule change
Informed Consent requirements	The informed consent requirements have been highly modified. A brief explanation of the changes is noted: • Significant changes to the content, organization, and presentation of information and process to facilitate a subject's decision about whether to participate; • Changes to the basic and additional elements of consent; • Creation of the concept of broad consent; • Changes in the criteria for the waiver or alteration of consent; • New provisions that allow IRBs to approve research for which investigators obtain information or biospecimens without consent for the purposes of screening, recruiting, or determining the eligibility of prospective subjects provided certain conditions are met; and • Requirement to post* to a federal website a copy of the IRB approved version of the consent form after closure of enrollment (but within 60 days of last patient visit). *Only one posting is required per multi-site study, which can be done by the sponsor. This only applies to clinical trials that are conducted or supported by a federal department or agency.
Informed consent elements	**NEW** required element of informed consent for studies involving collection of identifiable private information or identifiable biospecimens. One of the following statements must be in the informed consent: • A statement that the identifiers might be removed from the information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research without additional informed consent; **OR** • A statement that the subject's information or specimens, even if identifiers are removed, will not be used or distributed for future research. **NEW** additional elements of informed consent will be required of applicable research studies. These additional elements are: • 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; • A statement regarding whether clinically relevant research results; including individual research results, will be disclosed to subjects, and if so, under what conditions; and • For research involving biospecimens, whether the research (if known) or might include whole genome sequencing. • New provisions that allow IRBs to approve research for which investigators obtain information or biospecimens without consent for the purposes of screening, recruiting, or determining the eligibility of prospective subjects provided certain conditions are met; and Review our new templates for informed consent/HIPAA in our website.
Broad Consent	Currently, broad consent will not be applied at Emory.

Other items of interest

Topic	Rule change
Screening, recruiting, or determining eligibility of prospective subjects	The new rule states that an IRB can approve access to identifiable information or identifiable specimens without the prospective informed consent of the subject 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. However, a waiver of PHI authorization **will still be required** as the HIPAA rule does not allow such access without prior written authorization or a waiver of authorization. Reminder: You still need IRB approval of the study before recruiting or screening of subjects. The IRB may require consent depending on the study.
Other federal agencies	**FDA** – Cannot implement part of the rules that conflict with FDA regulations. See FDA guidance. **Department of Justice (DOJ)** – Cannot implement part of the rules that conflict with DOJ regulations.
Newborn Screening Act	With the implementation of the new rule, the New Screening Saves Lives Reauthorization Act of 2014 will no longer be effective. Secondary research with nonidentified newborn blood spots will be treated in the same way as secondary research with any other type of nonidentifiable biospecimen.