Transitioning Currently Approved Studies to the Final Rule

Background:

Effective January 21, 2019, the federal government revised the regulations for the conduct of human research protections ([45 CFR 46](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)). Studies that were reviewed and/or approved prior to this date will be grandfathered and continue to receive review under the [Pre-2018 Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html). VHRPP will allow for and can assist you with transitioning your currently approved study to comply with the Final Rule, however, these studies must comply with all components of the Final Rule.

**Studies that may qualify for transition and therefore do not need ongoing continuing review:**

For studies that fall into the **Pre-2018 Requirements** (meaning the study received a formal IRB review prior to January 21, 2019):

* + Chart Reviews
  + Grant Reviews
  + Non-FDA regulated studies that have progressed to the point of either:
    - Study is no longer enrolling and participants have completed research-related interventions. The study remains active only for long term follow-up.
    - Study enrollment is permanently closed, participants have completed all research-related interventions, and long-term follow-up has been completed. The remaining research activities are limited only to data analysis.
    - If your study includes consent forms (and you would like your study considered under the revised regulations), you will be required to transition those documents to the updated ICD template on our website in order to comply with the 2018 requirements. If consent forms are no longer in use (e.g. enrollment is closed and research procedures are complete), it is not necessary to submit revised consent forms in order to transition to the Final Rule.
  + Minimal risk (expedited studies) with a consent form(s), as long as, the consents are modified to comply with the revised Common Rule (see below\*).
  + Note: ***The IRB may still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision.*** Final approval letters (FAL)s will communicate the outcome as it relates to ongoing continuing review ([IRB Policy III.k](https://vanderbilt.policytech.com/dotNet/documents/?docid=14990&public=true))
  + ***Special Note:*** You are still required to report enrollment numbers for studies to the IRB for institutional tracking as well as submit amendments, Adverse Events, or Non-Compliance with the Protocol reports as long as the study remains active. A submission to close the study with the IRB is also required when the study is complete.

**What Changes will I need to make?**

* For **chart reviews that were approved under a waiver**, you will be required to provide additional justification in the event you are retaining identifiers.
  + - You can elect to submit an amendment and update the information in your PHI/Consent section and this information will be considered at the time of your next continuing review or
    - If your study is due for continuing review, a member of our staff will request this information as part of your pre-review for consideration by the Committee.
* For **minimal risk (expedited) studies that include a consent form**, you will be required to:
  + - Submit an amendment **prior** to your next continuing review to transfer your currently approved consent form(s) to our [revised consent template](https://www.vumc.org/irb/applications-and-consents) (**Note:** both the Health Sciences and the Social and Behavioral Sciences consents have been revised\*\*) to comply with the revised Common Rule.
    - Remember, you are not required to transfer your study. If you do not, your study will continue to receive a Continuing Review.
    - Please note that at least one more continuing review will be required for all currently approved studies over the next year after you submit the amendment to transfer as the IRB Committees assess each study to ensure it qualifies under the revised regulations.
    - Final approval letters will communicate the outcome as it relates to ongoing continuing review.
    - ***Special Note:*** You are still required to report enrollment numbers for studies to the IRB for institutional tracking as well as submit Amendments, Adverse Events, or Non-Compliance with the Protocol reports as long as the study remains active. A submission to close the study with the IRB is also required when the study is complete.

**Other Requirements under the Final Rule:**

* If the project meets the definition of a clinical trial and is supported by a federal department or agency, an IRB approved informed consent document used to enroll subjects must be posted on clinicaltrials.gov, no later than 60 days after the last study visit of any subject. Note: The term “clinical trial” refers to research studies in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes.
* There are new required elements of consent including [(IRB Policy IV.A.2)](https://vanderbilt.policytech.com/dotNet/documents/?docid=15494&public=true)
  + A statement about whether a study involves the collection of identifiable private information or identifiable biospecimens
  + If the study involves the use of biospecimens, the ICD must indicate if biospecimens may be used for commercial profit, and if the participant will share in that profit
  + A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions
  + For research involving biospecimens, a statement about whether the research may include whole genome sequencing.

Special Notes:

* The DISCOVR-e application has been updated to provide more detailed information regarding the access, use, and disclosure of PHI, as well as, a new question for waiver of consent under the Final Rule. Note that any amendment to currently approved studies will require completion of these updated fields on the PHI/Consent tab in order to update this information which may require additional review/revisions.
* FDA regulated research does not qualify for transition to the Final Rule at this time so continuing review for those studies will be required.
* You are still required to report enrollment numbers for studies to the IRB for institutional tracking as well as submit amendments, Adverse Events, or Non-Compliance with the Protocol reports as long as the study remains active. A submission to close the study with the IRB is also required when the study is complete.
* Remember, ongoing continuing review continues to be at the discretion of the IRB Committees so some studies may not be eligible for transition.
* If you believe your study may now meet one of the Exempt research categories, contact our office for assistance.