SUBJECT: Conversion of an approved study to the 2018 Requirements (Revised Common Rule)

1. PURPOSE:

This SOP establishes the procedures for converting studies approved prior to the 2018 Requirements (Revised Common Rule) which are eligible for this transition.

2. DEFINITIONS:

2018 Requirements: 45 CFR 46: *Protection of Human Subjects*, effective 2019 (replaced the Common Rule). Also called the Revised Common Rule.

Common Rule: 45 CFR 46: *Protection of Human Subjects*, effective 1991

FDA: U.S. Food and Drug Administration

HRPP: Human Research Protection Program

IRB: Institutional Review Board

MVAHCS: Minneapolis VA Health Care System

PI: Principal Investigator

Revised Common Rule: Equivalent to the 2018 Requirements defined above.

RCO: Research Compliance Officer

3. OVERVIEW:

Conversion of studies to the regulations of the 2018 Requirements may be completed to remove administrative burden on studies approved under the 1991 Common Rule which are not greater than minimal risk and would not require IRB oversight under the new regulation. Studies which are categorized as clinical trials, are FDA-regulated, and are actively collecting data are not currently eligible for conversion to the 2018 Requirements at MVAHCS. Research which is eligible for, but not converted to the 2018 Requirements will have a documented reason for this decision. The IRB Administrator is authorized to make determinations of study eligibility to transition to 2018 Requirements using the tool in Appendix A and may train IRB staff to make these assessments.

4. PROCEDURES:

a) Upon submission of the continuing review materials for each study, the IRB Coordinator uses the Transition Checklist (Appendix A to this SOP):

   i) The IRB Coordinator opens the submitted continuing review materials and reviews the abstract/methods to determine whether the study falls under an IRB exempt category under the 2018 Requirements or does not meet the definition of research (including data/specimen repositories). If any of these apply, the IRB Coordinator labels the study as appropriate for transition to the 2018 Requirements. If none of the categories apply, the IRB Coordinator continues on to next bullet on the Transition Checklist.

   ii) The IRB Coordinator determines if the study matches the 2018 Requirements definition of a “Clinical Trial”. If this definition is met, the study will not be transitioned to the 2018 Requirements at this time. The IRB Coordinator proceeds with processing the continuing review submission according to normal procedures. If the study does

not qualify as a Clinical Trial, the IRB Coordinator continues on to next bullet on the Transition Checklist.

iii) The IRB Coordinator considers whether the study is regulated by the FDA. If yes, the study will not be transitioned to the 2018 Requirements at this time; and processing of the continuing review submission continues according to normal procedures. If it does not qualify as FDA-regulated research, the IRB Coordinator continues on to next bullet on the Transition Checklist.

iv) The IRB Coordinator considers whether the study is reported to be in data analysis. If yes, the study is labeled as transitioned to 2018 Requirements. If no, the IRB Coordinator continues on to next bullet.

v) Any studies appearing to qualify for transitioning to the 2018 Requirements are verified in discussion with the IRB Administrator.

vi) The PI and study contact for studies identified to be transitioned will be notified by receipt of a letter specifically noting this action, and reminding the PI of his/her responsibilities which remain despite the lack of continuing review by the IRB. The RCO will be copied on this notification.

b) Studies that do not meet the 2018 requirements of IRB exempt/non-research under the 2018 Requirements, do not meet the 2018 Requirements definition of a “clinical trial,” are not FDA-regulated, or are not in data analysis, will not be transitioned to the 2018 Requirements at this time. The continuing review submission will be processed per normal procedures.

c) Studies or investigators which have been noncompliant with VA policy and MVAHCS procedures may or may not be converted to the 2018 Requirements, based on the judgment of the IRB Administrator, in consultation with the ACOS/Research if needed. A decision to not convert, and the reason, will be documented in the study file. The decision to convert will be reevaluated at least annually.

5. REFERENCES:

VHA Directive 1200.05 (01/07/2019)

6. EXPIRATION DATE: N/A

7. FOLLOW-UP RESPONSIBILITY: Human Research Protection Program

APPENDIX A

2018 RCR Transition Assessment Checklist

Protocol #:		**Expiration:**	
Principal Investigator:			

#	Protocol Description Item	Y	N
1	**Does the protocol qualify as "Exempt" or "Not Research" under the Revised Common Rule (RCR)?** ☐ Exempt Category #____ ☐ Data/Specimen Repository only ☐ Other: _____ ***If YES, indicate project type above and STOP HERE. The protocol can be transitioned to the 2018 requirements.*** ***If NO, continue to #2.***		
2	**Is the protocol a "Clinical Trial" under the new RCR definition** *(i.e., human subjects prospectively assigned to one or more interventions, including placebo or other control, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes)?* ***If YES, STOP HERE. The protocol will NOT be transitioned to the 2018 requirements at this time*.*** ***If NO, continue to #3.***		
3	**Is the protocol FDA-regulated** *(i.e., meets any of the descriptions below)?* ☐ Study involves a drug under Investigative New Drug (IND) exemption ☐ Study involves a drug NOT under IND exemption ☐ Study involves a device under an IDE or an NSR device ☐ Study has been reviewed under any other 21 CFR series regulations (e.g., food, biologics, tobacco products, cosmetics, radiation-emitting electronic products, etc.) ***If YES, STOP HERE. The protocol will NOT be transitioned to the 2018 requirements at this time*.*** ***If NO, continue to #4.***		
4	**Is the protocol in data analysis only as reported at the most recent Continuing Review ?** ***If YES, STOP HERE. The protocol can be transitioned to the 2018 requirements.*** ***If NO, continue to #5.***		
5	**Has a waiver of consent or waiver of documentation of consent been approved?** ☐ Waiver was approved for screening and recruitment only ☐ Waiver was approved for entire study ***If YES, indicate waiver type above. Waiver must be re-evaluated before transition can occur.*** ***If NO, continue to #6.***		
6	**Are all enrollment and data collection activities complete, except for accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care?** ***If YES, the study must comply with all other RCR elements except ICF update before transition must occur.*** ***If NO, ICFs must be revised to comply with 2018 requirements before transition can occur.***		

***** *Not considered for transitioning at this time under local SOPs; re-evaluate at next CR*

Notes:

Disposition:

☐ Meets 2018 RCR requirements for IRB Exempt status. Remains under IRB oversight; no CR.

☐ Transition to 2018 RCR requirements now.

☐ Not eligible for transition to 2018 RCR requirements at this time as documented above.

Transition assessed by: _____ **Date**:_____