



Memorandum

Date December 15, 2020

From James Cope
Lead
Human Research Protection Office

Subject IRB Approval of Amendment 8 of CDC Protocol #2238, "Assisted Reproductive Technology Database - Protocol for Epidemiologic Research." (Expedited)

To Dmitry Kissin, MD, MPH
NCCDPHP/DRH

CDC IRB has reviewed and approved your request to amend protocol #2238. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b) (1), category 5.

The following changes were approved:

1. Personnel changes (page 1; redlined version)
2. Data access (page 7; redlined version): Protocol has been revised to describe all mechanisms for data access in addition to remote access through CDC's Research Data Center as listed below .
 - (a) Analyzing publicly available data using the Fertility Clinic ART Success Rates Excel spreadsheet.
 - (b) Submitting data requests through ARTinfo@cdc.gov.
 - (c) Working with DRH statisticians/scientists on collaborative projects.
 - (d) Accessing NASS data on site at DRH as guest researchers.
 - (e) Establishing partnerships through CDC Foundation.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Office Financial Resources (OFR), you are required to send a copy of this IRB approval to the CDC OFR award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided OFR with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

This protocol has been transitioned to the 2018 Common Rule, as such annual continuing review is no longer required.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-5256 or e-mail: huma@cdc.gov.

cc: Joan Redmond Leonard, ONDIEH/NCCDPHP