



Intramural Research Program

Our Research Changes Lives

CONTINUING REVIEW APPROVAL

DATE: December 15, 2021

TO: Alex Martin, PHD
NIMH - M - Section on Cognitive Neuropsychology

FROM: National Institutes of Health (NIH)
Institutional Review Board (IRB)

RE: **IRB #:** 93M0170
Sponsor #: N/A
iRIS Reference #: 567424
Regional Cerebral Blood Flow Studies of Object Perception, Identification, Localization, and Memory

Study Status: Open - Recruiting
Approval Date: 12/14/2021
Expiration Date: 12/13/2022
Review Level: Expedited (**Category 9**)
Subjects Approved: 4100
Risk Level: Minimal Risk under 45 CFR 46 / 21 CFR 56

This continuing review was reviewed and Approved under the National Institutes of Health's Federalwide Assurance (FWA00005897) in accordance with Federal regulations 45 CFR 46 and 21 CFR 56, including Good Clinical Practice.

The following regulatory determinations apply:
Expedited Review Category

Category 9: Continuing review of research, not conducted under an IND or IDE where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

Investigational Device Use

Non-Significant Risk Device under 21 CFR 812.66
[7T MRI]

Documentation of Informed Consent

Written consent in accordance with 45 CFR 46.117/ 21 CFR 50.27



Waiver of Informed Consent

Waiver/alteration approved 46.116(c) or (d)

for usage of video clips provided by participants visible in those clips for the sub-study

Federal regulations and NIH policy require prompt reporting of any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to the IRB. In addition, changes in research activities may not be initiated without prior review and approval by the IRB, except when necessary to eliminate apparent immediate hazards to subjects.

If you have any questions, contact the IRB Office at 301-402-3713 / email: IRB@od.nih.gov.