



Clinical Research Operations & Management System (CROMS)

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A statewide partnership between the University of Michigan, Michigan State University, and Wayne State University to support dementia research.

- CROMS – NIA released NOT-AG-21-029 on June 17, 2021
 - New policy applies to all NIA grants active as of July 1, 2021
 - Provides NIA real-time tracking, reporting, and management of clinical research enrollment data, and activities
 - **Stages 1 & 2** - Investigators with grants that support AD/ADRD and non-AD/ADRD clinical trials, respectively
- **Stage 3** - Investigators with grant awards that support all other clinical studies that enroll human subjects
 - Enrollment data entry for clinical studies in Stage 3 will begin March 1, 2022
 - Investigators in Stage 3 will receive an email by January 1, 2022, informing them of the policy change and their anticipated timeline to begin the enrollment submission process

<https://www.nia.nih.gov/research/grants-funding/nias-clinical-research-operations-management-system-croms>

CROMS Participant Enrollment Data Elements (29)

Identifiers	Study Name, CROMS Assigned Site Identifier, Participant ID, Participant Type, ID of Primary Participant, Study Name
Participant Status	Study Enrollment Date, Participant Intervention Start /Off Dates, Reason for being off, Permanently Off Study Date/Reason, Study design (Group/Cohort ID)
Demographics	Age at time of Enrollment, Sex at Birth, Gender (2 Choices), Sexual Orientation, Race, Ethnicity
Characteristics	Cognitive Status, Education Level, Household Income Level, Occupation Category, Current Marital Status, Living Situation, Primary Language Spoken, Insurance Status, Zip Code



Discussion-

- Explore options with NACC to help with data upload to CROMS
- ADRC's have enrollment record for each participant prior to upload to NACC
- Example: UDS 3 Form A1: Subject Demographics (overlaps)
- Will UDS 4 have more overlap with CROMS?
- Can ADRC's request exemptions from NIACROMSsupport@niacroms.org

