

MWCCS substudy data release (Updated Oct 8, 2025)

Substudies include studies that are not part of the core MWCCS protocol at every visit. This includes some studies that are part of the MWCCS main grant and by design occur only once or twice (eg PFT, ECHO, MRI), others that are added by supplements, and others that are investigator-led grants nested in the cohort. Some of these studies are at all sites in all participants, while others are at select sites or among select subgroups of participants. *Release of MWCCS data falls into three categories: Immediate release, Delayed Release, and Investigator Approved Release.*

Immediate Release: Core MWCCS data collected at every visit in Gemini has immediate release.

- Once the visit is completed, quality assurance is performed and visit data and summary files relayed, that data is immediately available for use in approved concept sheets (CS) and inclusion in data sent to study sites.
- Also included in this category:
 - CS that add a few questions to any of the Gemini forms.
 - Some substudies that are considered core (see Table 1 for details).
 - All substudy NOTI enrollment forms and other screening forms (ex: MRISCR) in Gemini are considered core.

Delayed Release: Many substudies fall in this category. Data is released one year after data collection is complete (i.e., substudy data for a substudy that ended in V102 will be included in the V103 data release). This allows time for those leading the substudy to perform quality assurance.

- Tables 2 & 3 below summarize current approved substudies that fall under the delayed release category.
- When external investigators (or internal investigators who were not the study leads) are interested in using sub-study data, it's recommended they involve the substudy lead to collaborate and approve proposed CS.
 - Relevant working groups are assigned to review concept sheets proposing use of substudy data under delayed release and will outreach substudy leads during the review process if they are not already members of the working group. If for some reason a concept sheet proposing the use of substudy data under delayed release does not receive review by the study leads before it is approved, data will not be released until substudy leads have the opportunity to review and approve.
 - Working groups will suggest relevant co-authors (e.g. substudy leads) in the comments section of their review and DACC will assign as required co-author(s). Substudy lead(s) can designate a different co-author instead of themselves if desired.

Investigator Approved Release: Most investigator funded studies (R01, K01, etc.) fall in this category. This data needs approval by the study lead for release.

- Relevant working groups are assigned to review concept sheets proposing use of substudy data under investigator approved release and will outreach substudy leads during the review process if they are not already members of the working group. If for some reason a concept sheet proposing the use of substudy data under investigator approved release does not receive review by the study leads before it is approved, data will not be released until substudy leads have the opportunity to review and approve.
- Working groups will suggest relevant co-authors (e.g. substudy leads) in the comments section of their review and DACC will assign as required co-author(s). Substudy lead(s) can designate a different co-author instead of themselves if desired.
- Restricted data is shared with investigators on the CS upon request.
 - If an affiliated investigator asks for the data, but isn't listed on the CS (e.g., student, collaborator), DACC confirms with the lead investigator that they should be added to the CS and then can provide the data.
- Substudy data under investigator approved release is available for distribution without restriction when the study lead(s) has notified and provided the data to the DACC to make it available for use by approved CS.

Table 1. Immediate Release MWCCS Substudies

Substudy	Study Visit(s)	Gemini Form(s)
STI Testing	V101-V105	LABSTI
CAT-MH (Computerized Mental Health assessment)	V102-V106	N/A- released with summary files
BRACE/BRACE+ (Neurocognitive Function assessments)	V102-V106	N/A- full NP battery is released with summary files Auxiliary forms: NP-IADLLF; NPIADLSF; NP-WRAT; NP-EDUC; NP-PTSD; NP-PTINFO; NP-EFFORT
Fibroscan	V101-V106	None
Oral Health Questionnaire	V102-V106	ORAL

Table 2. Delayed Release MWCCS Substudies with Gemini Forms

Substudy	Study Visit(s)	Summary File Data Release(s)	Gemini Forms
Hearing & Balance	V101-V102	V103	BAL HEAR
Microbiome (Silver)	V101-V106	V107	SILVER
COVID Vaccine Acceptance and Hesitancy	V101-V102	V103	VACACC
Sleep	V103-V106	V107	SLAMS; SLBERLIN; SLEPWORDH; SLMCTQ; SLRLS
PFTs (Pulmonary Function tests)	V102-V105	V106	PFTMMRC, PFTSGRQ, PFTLAB
Tooth Count	V103-V106	V107	DENT
Fractional exhaled nitric oxide (FeNO)	V102-V105	V106	PFTNOTI
Assessing the prevalence, severity, and correlates of age-related musculoskeletal pain	V105-V106	V107	JOINT
Patterns of DoxyPEP Use in the MWCCS	V105	V106	DOXYPEP

Table 3. Delayed Release MWCCS Substudies without Gemini Forms (aside from NOTI/screening forms)

Substudy	Study Visit(s)	Summary File Data Release(s)	Gemini Forms
Echocardiogram	V103-V105 V103-V106	V106	ECHONOTI; fillable PDF sent to Echo Reading Center
CIDI (World Health Organization World Mental Health Composite International Diagnostic Interview)	V102-V105	V106	CIDINOTI
Brain MRI	V103-V106	V107	MRINOTI
Pathogenesis	V105-V106	V107	None
Blood Pressure Crosswalk	V103	V104	None
InBody (Bioelectric impedance analysis (BIA) machine)	V101-V106	V105 <i>(and then annually until complete)</i>	None

For information on data sharing for a specific substudy, please contact mwccs@jhu.edu