

## MWCCS substudy data release

(Updated April 1, 2022)

Sub-studies 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, meaning once the visit is completed, quality assurance performed and visit data and summary files relayed, that data is immediately available for use in approved CS and inclusion in data sent to study sites. CS that add a few questions to any of the Gemini forms are included in this category.

**Delayed Release:** Many substudies fall in this category. Data is released one year after completion of data collection (i.e., substudy data with collection completed in V102 will be included in the V103 data release). This allows time for those leading the substudy to perform quality assurance and publish core aims.

- Default data process for these studies will be delayed release unless otherwise discussed and approved
- 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
  - Substudy leads will be assigned as a Scientific Reviewer for any CS proposing use of substudy data. They can approve, request revisions, or reject CS during their review
  - Leads will always be assigned as a required co-author for related CS. The lead can designate a different co-author instead of themselves if desired
  - Once the substudy is closed/completed the data is available for distribution to all without restriction

**Investigator Approved Release: Most investigator funded studies (R01 K01 etc.)** fall in this category.

- This data needs approval by the study lead for release. Substudy leads will be assigned as a Scientific Reviewer for any CS proposing use their grant data. They can approve, request revisions, or reject CS during their review
  - Investigator will always be assigned as a required co-author for related CS. The investigator 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 then provide the data
- Once the CS is closed/completed the data is available for distribution to all without restriction

**For information on data sharing for a specific sub study, please contact [mwccs@jhu.edu](mailto:mwccs@jhu.edu)**

