

LIFE Coded Dataset Access Policy – Main Trial

Principal Investigators and their designees at the sites have been given a link to the Coded Dataset in the menu bar of the LIFE website. This access is limited and we ask that the PIs and designees not to distribute the data to other site investigators and staff so that the DMAQC can track the download of data and distribute updates appropriately. This will allow the DMAQC to be in touch with investigators when updates to the datasets are made, ensuring that the most recent and accurate data are utilized for analysis.

The LIFE DMAQC can give direct, short-term access to the dataset to **members of the LIFE staff** at sites, when requested, for a period of 10 days. This is for any investigator or staff at a LIFE site listed as the study team with their IRB. To receive this access, the PI or designate should contact Cindy Stowe at the DMAQC (cstowe@wakehealth.edu) to request this access for their study team member.

If an investigator **outside of a LIFE study team** would like access to the LIFE coded dataset, this individual must go through the following steps:

1. A Non-LIFE Investigator would request access to the LIFE website for the purposes of submitting a P&P proposal to obtain access to the Coded Datasets by going to the LIFE website (www.thelifestudy.org) and clicking on the button “Request for Non-LIFE investigator Access” and completing the request form.
2. The Non-LIFE Investigator would be granted access to the LIFE P&P Tool where access to would be provided to the data dictionary, data documentation, and protocol, in addition to the Manuscript Proposal Submission Form.
3. The Non-LIFE Investigator would submit their proposal (per the current guidelines) to the P&P. The proposal would go through the usual channels for approval.
4. If approved the Non-LIFE Investigator would be sent a Coded Data Use Agreement document to be signed and sent back to the DMAQC for filing.
5. Access to the Coded Datasets would be granted for a period of 10 days.

Please note the following P&P policies, applicable to all users, regarding access to the LIFE data

- 1) All resulting publications and presentations will be developed in accordance to the LIFE Study’s P&P committee’s policies and procedures as outlined in the LIFE Study MOP.
- 2) Persons receiving access to LIFE data will not provide it to any person not approved to receive the data.
- 3) Writing group leaders will verify that the most up-to-date version of the data is used for the final version of any resulting manuscript.
- 4) Problems or issues with study data will be brought to the attention of the LIFE Data Management, Analysis, and Quality Control (DMAQC) Center in a timely fashion before the final paper draft is submitted to the P&P committee for approval.
- 5) If new variables are created from existing study data, the definitions and code for the newly created variables will be made available to the DMAQC at its request.

If you have any questions, please contact the LIFE DMAQC/Cindy Stowe at cstowe@wakehealth.edu or 336-716-0686.