

NHATS-CMS Linked Files Modification Cover Sheet

Investigator Name: _____

Project Title: _____

Please indicate the type of amendment(s) you are requesting and complete the required forms listed below. Documents should be emailed to nhats-cms-data@umich.edu.

Adding new Research Staff

- Supplemental Agreement with **New** Research Staff
- Data Security Plan for each new staff member
- Updated List of Users Requesting LINKAGE Enclave Access

Adding a new Co-Investigator

- Co-Investigator form in the Data Use Agreement
- Data Security Plan for Co-Investigator
- Updated List of Users Requesting LINKAGE Enclave Access

Removing Research Staff or Co-Investigators

- Email nhats-cms-data@umich.edu to remove Research Staff or Co-Investigators from a project

Changing the Investigator

- Letter to NHATS letter explaining the change in Investigator
- Investigator amendment form
- IRB with new Investigator listed
- New Data Use Agreement (DUA) listing the new Investigator

Change in Data Access Location or Workstation

- Complete a new Data Security Plan

Adding new years of previously approved CMS files

- NHATS-CMS Linked Files Request Form

Adding new CMS files not previously approved

- NHATS-CMS Linked Files Request Form
- Update the Research Plan (**tracked and clean versions**)
- IRB approval for new work scope

Modifying or adding research aims for existing folders or files (Note: Modifying aims and adding folders or files may require a new application. Contact nhats-cms-data@umich.edu for guidance.)

- Update the Research Plan (**tracked and clean versions**)
- IRB approval for new work scope

Requesting a new external file linkage

- NHATS-CMS Linked Files External File Request Form

If extending work scope:

- Update the Research Plan (**tracked and clean versions**) to describe and justify the purpose and contents of the linkage(s)
- Submit IRB approval for new work scope

Extending a project

- Complete the NHATS-CMS Linked Files Data Use Agreement Extension form

Closing a project

- Complete the NHATS-CMS Linked Files Close Out form