November 8, 2024

TO: Office of Management and Budget (OMB)

Through: Reports Clearance Officer, DHHS

 Mikia Currie, NIH

 Jennifer Guimond, NICHD

FROM: Alison Cernich

 Deputy Director, NICHD

SUBJECT: Non-Substantive Change Request for 0925-0744, exp. 7/31/2027

Data and Specimen Hub (DASH) (NICHD)

[*https://www.reginfo.gov/public/do/PRAViewICR?ref\_nbr=202404-0925-001#*](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202404-0925-001)

This is a request for OMB to approve a modification of the submission for the NICHD Data and Specimen Hub (DASH). DASH has been established by NICHD as a data sharing mechanism for clinical research studies. It serves as a centralized resource for investigators to share and access de-identified study data funded by NICHD. DASH also serves as a portal for requesting biospecimens from select DASH studies. Researchers submit forms when registering to use DASH, uploading information to DASH, and requesting data or biospecimens through DASH.

Information collection was intended to be submitted through the online DASH system. However, due to a technical limitation, some users will need to complete Attachment A.2-5: NICHD DASH – Biospecimen Request as a fillable pdf form (titled the Manual Biospecimen Request Submission Form) and submit it via email instead of completing it online. DASH personnel will then review the information and use it to create the final Biospecimen Request Form, which will be returned for the submitter’s signature. The manual form contains the same items as the online form with a few additional fields that will need to be completed by users. The additional fields are selection or contact information that automatically populate in the online form based on previous selections or from a users account.  These fields are listed in the table on the following page and indicated by a red arrow in the attached Manual Biospecimen Request Form We have removed optional fields that automatically populate in the online version to reduce burden on the user.

| **Field** | **Online form** | **Manual form** |
| --- | --- | --- |
| Requested Study | Users select a study from a catalog | Users write in the name of the study |
| Requester Information | User contact information is autopopulated based on the user’s account.  The user must review the information to make sure it is correct. | Users must fill in name, email address, job title/position, institution type, and institution address |
| Principal Investigator (PI) | PI can be selected from a drop down list.  The user must review the information to make sure it is correct. | Users manually input PI name, email address, and title/position |
| Biospecimens Being Requested | Biospecimens are selected from a catalog | Users must list the specimen type, quantity needed, and amount needed |

The “Biospecimens Being Requested” table deviates from the online version in appearance. In the manual form, users must manually request specimens while the online version autopopulates a table with the selections the user makes prior to accessing this form. Most users will only populate one or two rows of this table. We have also added hover tooltips to the pdf form to help the user complete the manual form. These additional fields are not expected to substantially change the burden of completing the form for users.