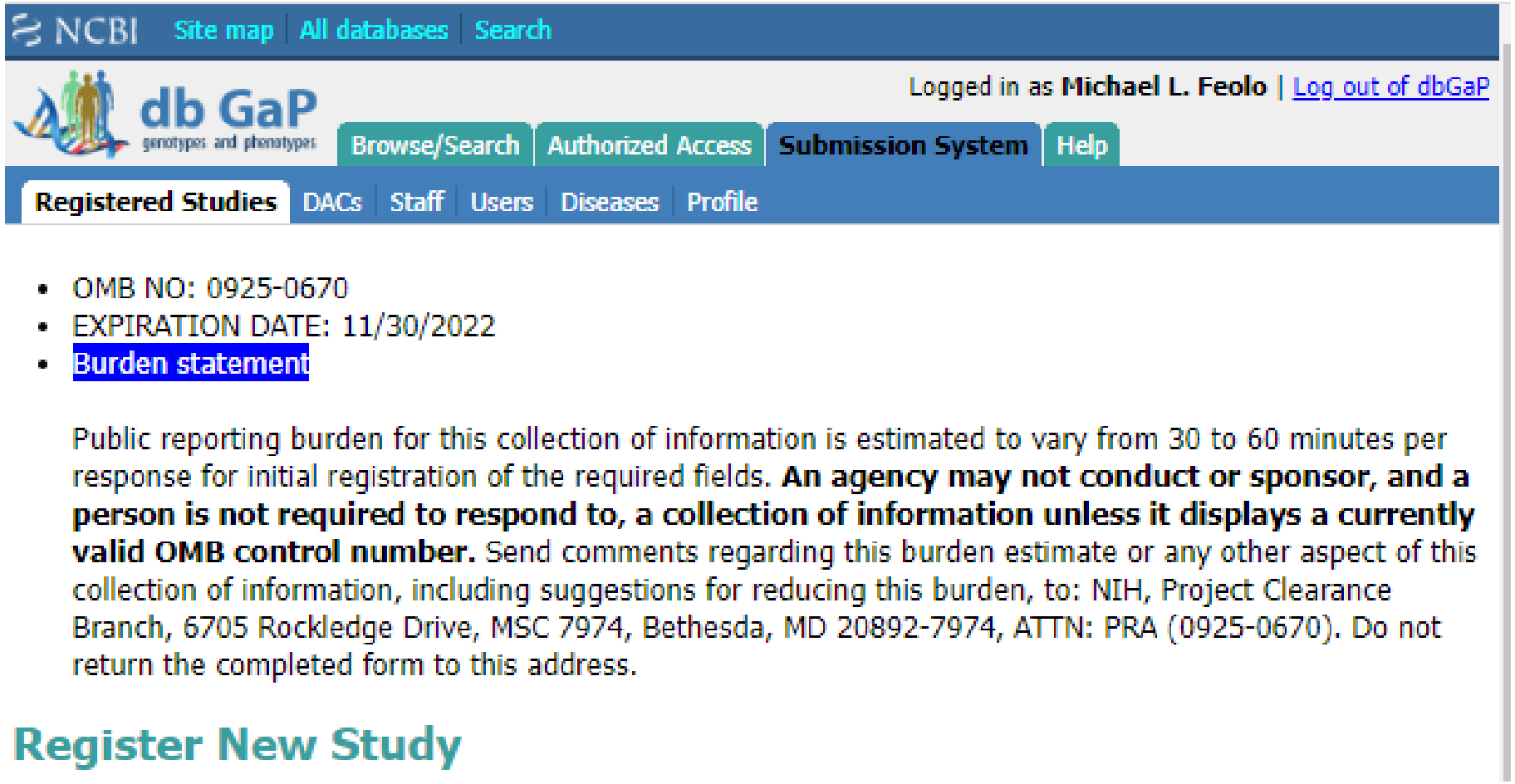
Attachment 1: Documentation of the dbGaP registration and access system web forms, including changes since 2019 PRA approval

Submitting Investigator: Registration Web Form



Submitting Investigator: Registration Web Form

Manage Study

RADx TEST STUDY

Study Registration Information

* Study Name: RADx TEST STUDY

Study Accession: phs 002370 .v 1 .p 1

* Study Mode: Normal Collection

* Institutes or Centers supporting the study:

OD Admin and Funding Show all NIH ICs

Admin. IC: OD

Primary GPA: Cheryl J. Jacobs

Target data delivery date: 2021-05-18 *(YYYY-MM-DD)*

Target public release date: 2021-09-20 *(YYYY-MM-DD)*

Estimated number of study participants: 1000

Sequence Read Archive (SRA)

* Sequence Read Archive submission is expected: No

* Data submission to dbGaP is expected: No

External data source

Name of External DB RADx Data Hub

URL of External DB download interface https://test.radx-hub.nih.gov/home

Help-desk of External DB sarah.yang2@nih.gov

Will subject or sample ids be registered to dbGaP with minimally required metadata? No

Will Sequence data be submitted to NCBI/SRA? No

Will Genotype/Phenotype be submitted to NCBI? No

Does External data source have data not at NCBI? Yes

Remove this data source

Add external data source

Added the option to add an external data source

Page continues on next slide

Submitting Investigator: Registration Web Form

* Data submission to dbGaP is expected: Yes

Please check all data types expected for this study:

Study data type	Study data outline - expected data
1. Subjects and Samples	○ yes ◉ no
2. Phenotype	○ yes ◉ no
3. Molecular (doesn't include Next Generation Sequencing (NGC))	○ yes ◉ no
4. Links to public NCBI databases	○ yes ◉ no
5. Sequence	○ yes ◉ no
6. Association Analysis	○ yes ◉ no
7. Documents	○ yes ◉ no
8. Images	○ yes ◉ no
9. Other files not covered and / or any other notes about expected data	

Added new radio button selector for data types for those submitting data to dbGaP

Requesting Investigator: Access Web Form

Please make it clear whether you plan to combine requested datasets with other datasets outside of dbGaP, and, if so, whether you plan to analyze these datasets independently or together. If you do plan to combine datasets in any way, please describe your plan and also please discuss whether it creates any additional risks to participants. If you are focusing on outcomes or hypotheses that were not the focus of the primary study (or studies), please describe the outcomes you propose to examine.

Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you ar
requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at GDS website. Please limit your RUS to 4500 characters.

use for test.
1111
222<2
333>3

New select box

☑ **I am requesting permission to use cloud computing to carry out the research as described in my Research Use Statement.**

Cloud Use Statement
Describe the type(s) of cloud computing service(s) you wish to obtain (e.g., PaaS, SaaS, IaaS, DaaS) and how you plan to use it (them) to carry out the work described in your Research Use Statement (e.g., datasets to be included, process for data transfer, analysis, and storage, and tools and/or software to be used). Also describe the role of any collaborators. Please limit your statement to 2000 characters.

asdf

***Non-technical summary**
Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1300 characters.

asdf

***Choose your Signing Official (SO):**
Your SO is typically the same person who signs your grant applications and is an individual listed in eRA Commons as a SO for your institution and who has the authority to certify your application on behalf of your institution.

◉ Doe, Jane (ssergey@ncbi.nlm.nih.gov)

Applicant organization

*Institution Name	Department	Division
NIH		

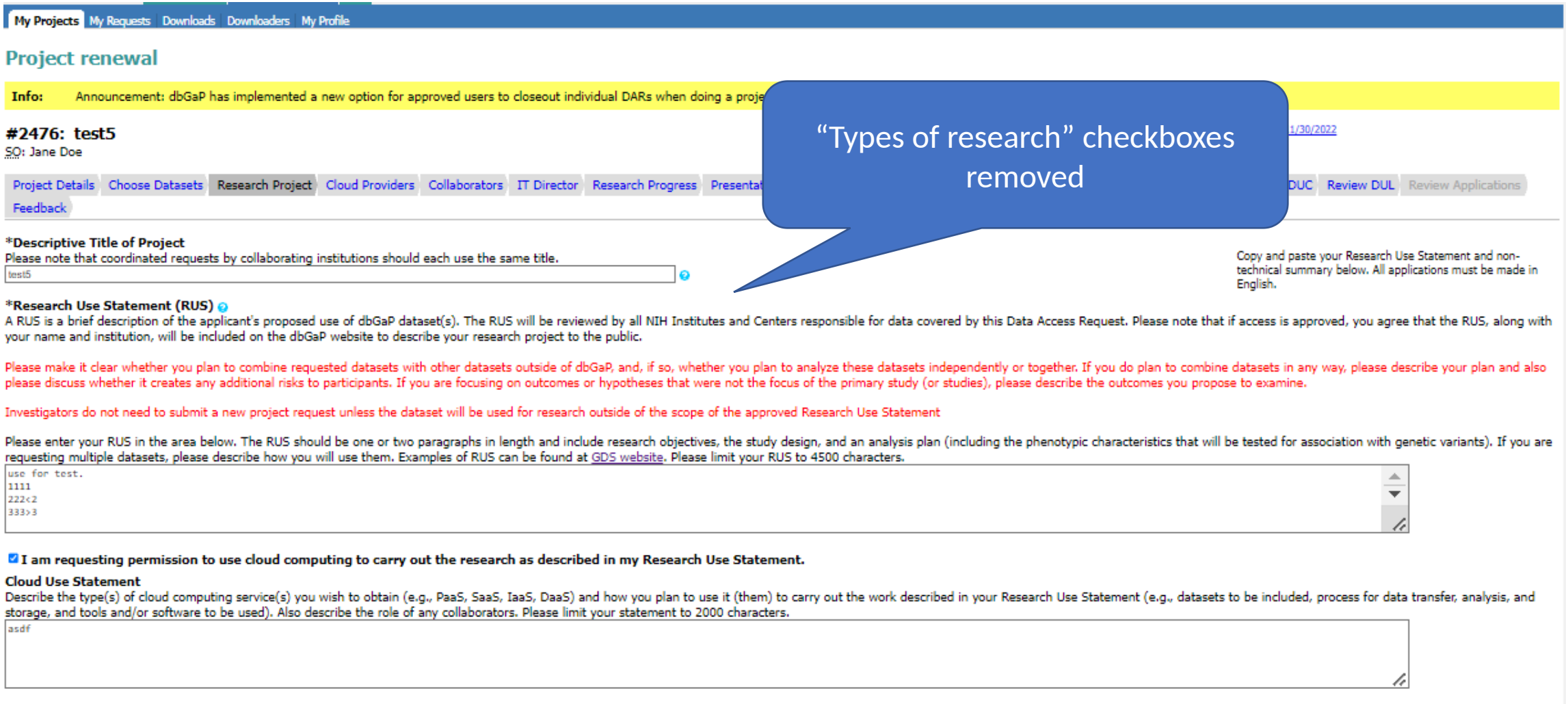
*Street 1	Street 2	*City	*State	*ZIP/Postal code	*Country
easyggg		bethesda	md	12345	United States

Back | Return to My Projects | Save | Save and Continue

Feedback

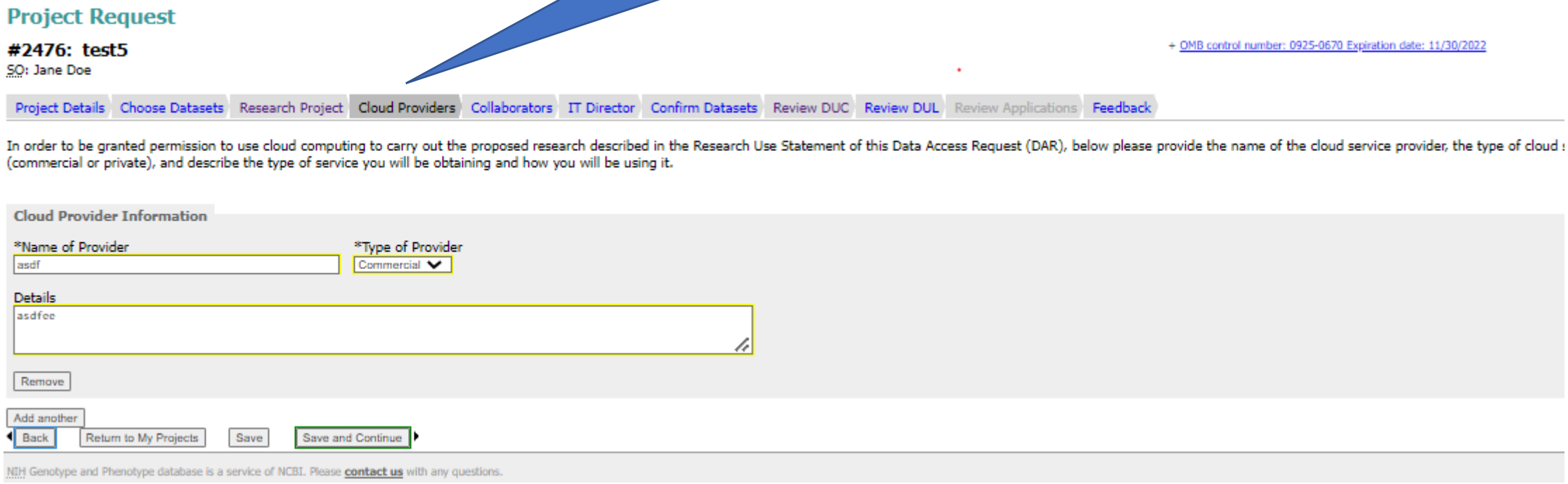
Encryption options removed from page because encryption is now automatic

Requesting Investigator: Access Web Form

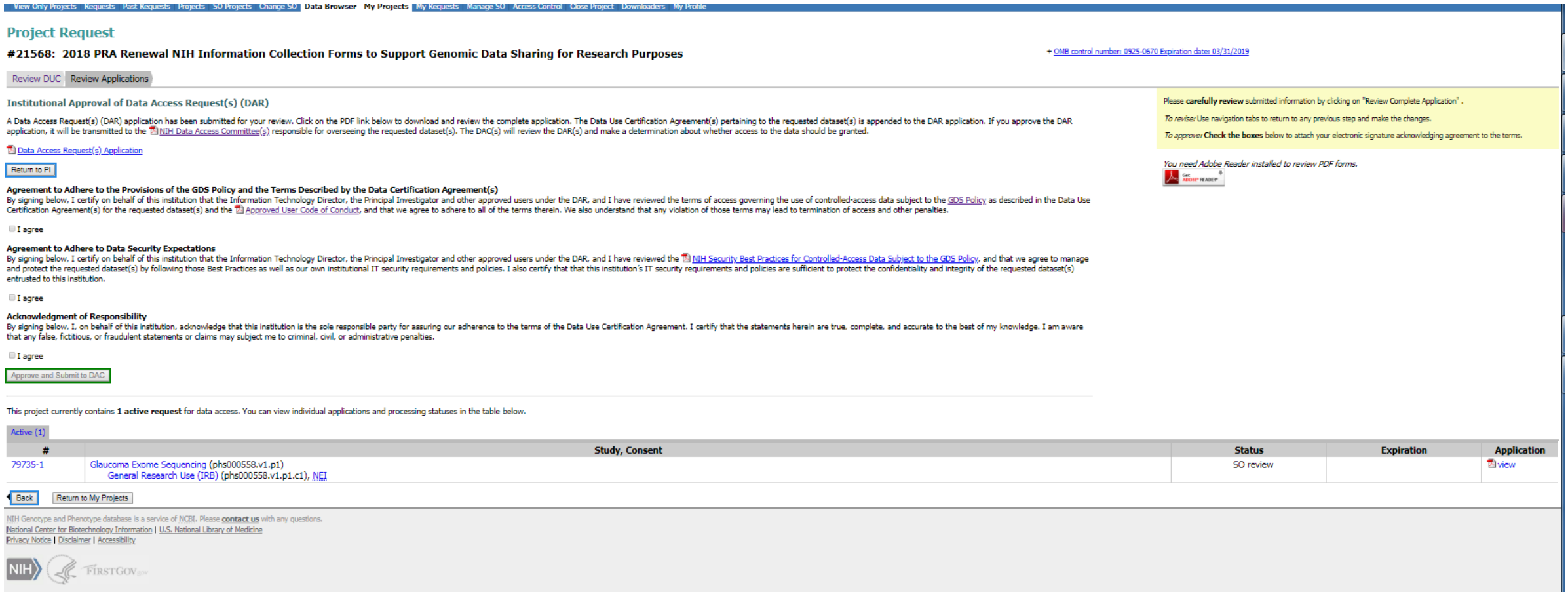


Requesting Investigator: Access Web Form

New tab added for investigators who choose to use cloud platforms for data analysis



Institutional Signing Official: Access Web Form



Requesting Investigator: Access Web Form

Alzheimer's Disease Genetics Consortium		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
Alzheimer's Disease Sequencing Project (ADSP)		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
CARDIA Cohort		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
Exome Sequencing of Clear Cell Endometrial Tumors and Paired Non-tumor Samples		
Letter of Collaboration is required;	download	Delete (uploaded on 2021-10-05)
Framingham Cohort		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
Glaucoma Exome Sequencing		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
NHLBI TOPMed: Genomic Activities such as Whole Genome Sequencing and Related Phenotypes in the Framingham Heart Study		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
NHLBI TOPMed: The Jackson Heart Study (JHS)		
Local IRB approval is required, Do NOT include FULL protocol;	download	Delete (uploaded on 2021-10-05)
San Francisco Bay Area Latina Breast Cancer Study		
Letter of Collaboration is required;	download	Delete (uploaded on 2021-10-05)

Load one document for all requests Choose File No file chosen

Upload Selected files Only PDF files (up to 10M in size) accepted.

Please note that some of your data access requests require additional documentation. Th ed to be updated if they have expired. Please check the expiration dates of these documents before proceeding.

Back Return to My Projects Continue

New check box allows requesting investigators to upload one document for multiple requests

Requesting Investigator: Access Web Form

New tab added to allow user to close out some DARs within a project during a project renewal.

Project renewal

Info: Announcement: dbGaP has implemented a new option for approved users to closeout individual DARs when doing a project annual renewal.

#2476: test5
SO: Jane Doe

+ OMB control number: 0925-06 ation date: 11/30/2022

Project Details | Choose Datasets | Research Project | Cloud Providers | Collaborators | IT Director | Research Progress | Presentations | Publications and Manuscripts | Data Security | Confirm Datasets | Closeout | Review DUC | Review DUL | Review Applications | Feedback

You are selecting the option to close out a dataset (from a Data Access Request (DAR)) during your dbGaP Project renewal period. Initiating this process means that the dataset(s) you select to close out is/are no longer needed for the research objectives described in this Project's Research Use Statement, and the dataset(s) you wish to close out did not result in publishable findings. If your use of the dataset(s) did indeed result in publication, the publication(s) should be reported and the dataset(s) should not be closed out until you close out your entire Project. This is because you will not be allowed to retain data for any reason if you wish to close out an individual dataset during this renewal process.

If you wish to closeout a DAR, please select a DAR to closeout in your project. It is expected at DAR closeout that all data are destroyed according to NIH expectations described in the Data Use Certification (DUC) agreement and addendum. The closeout request will be routed to your SO for confirmation. Once your SO confirms that data were destroyed according to the DUC and addendum, the DAR will be closed and removed from your project. No further action will be needed on your part regarding the DAR closed out.

Reasons for dar closeout:

- ☐ Unable to download data
- ☐ Dataset(s) not needed for dbGaP Project research objectives/not renewing
- ☑ Other. List reason(s) below.

Please feel free to add comments about the reasons for closing out your DAR(s)

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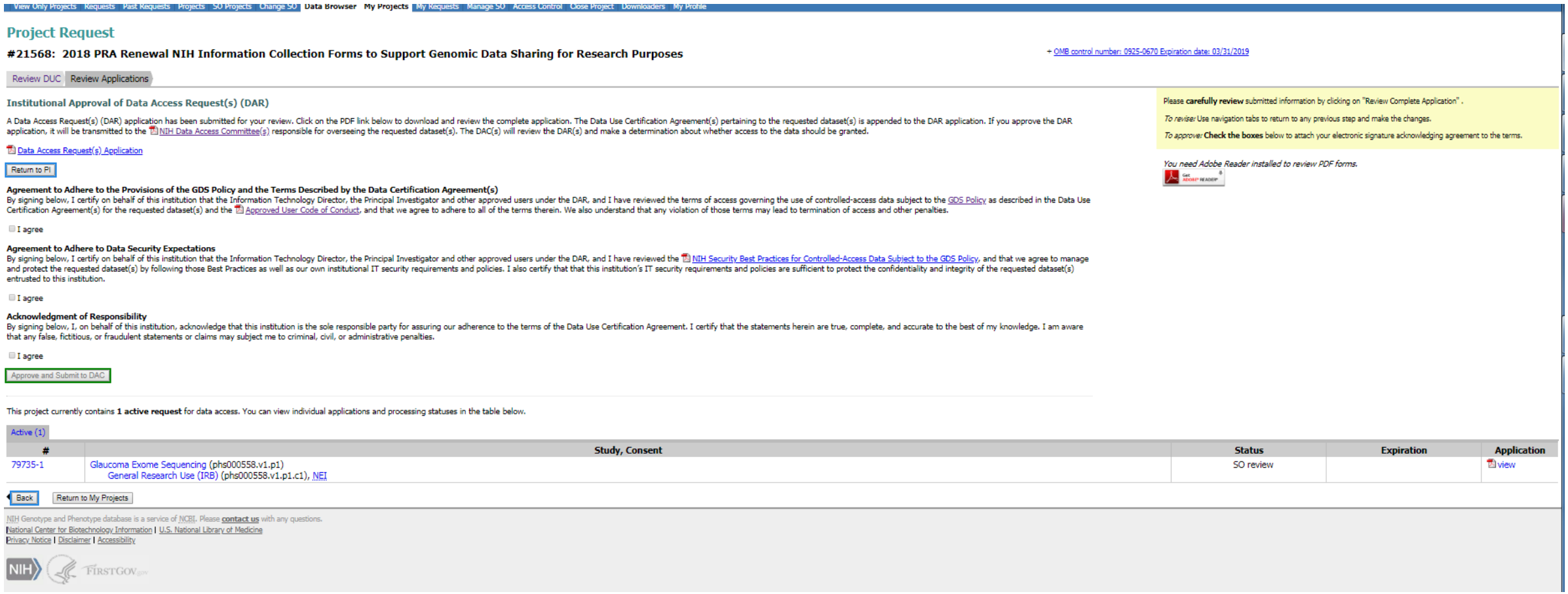
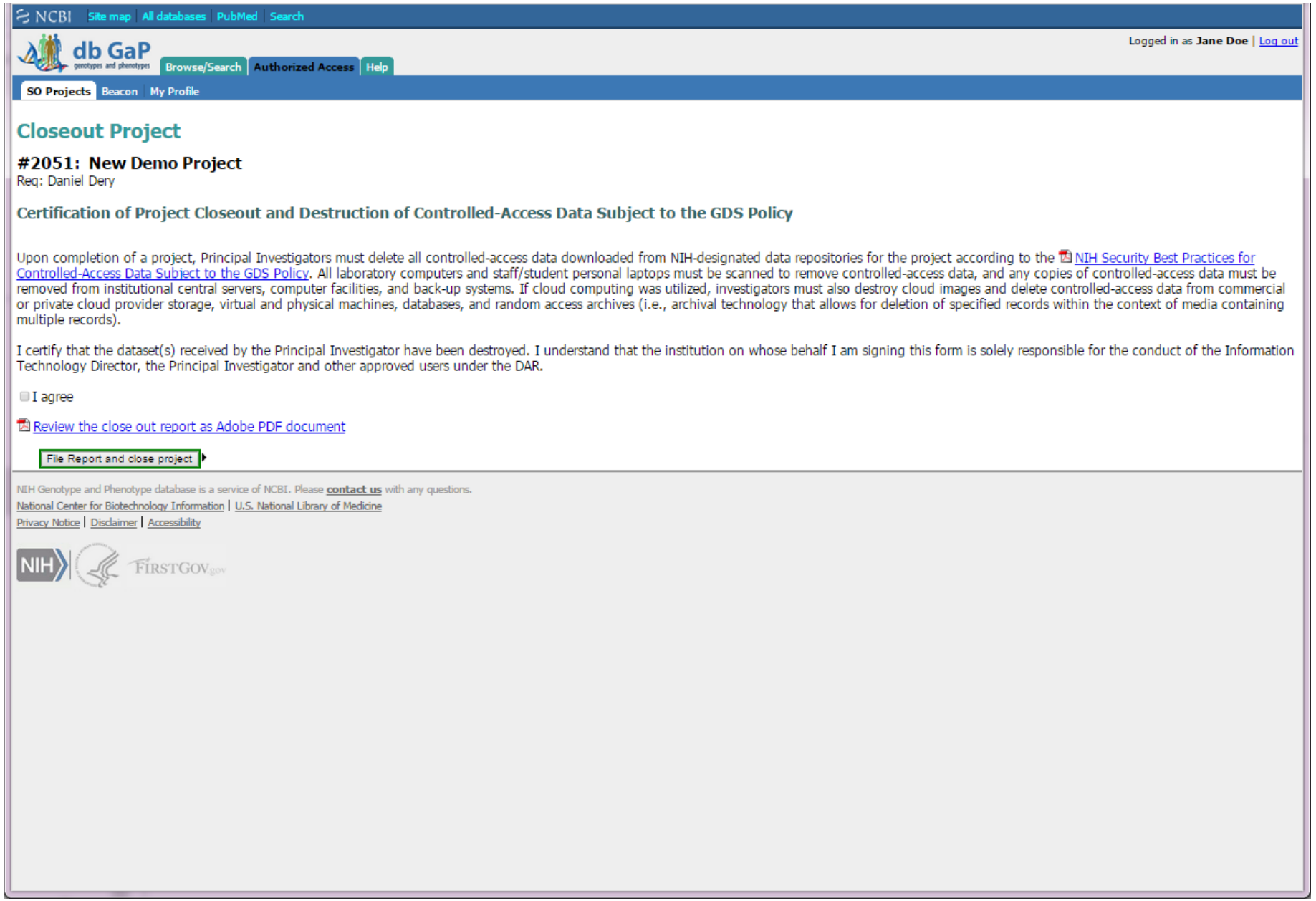
Institutional Signing Official: Renewal



Institutional Signing Official: Closeout