Attachment 1: Documentation of the dbGaP registration and access system, including changes since 2015 PRA approval

Study Registration Web Forms

Investigator

OMB Control Number: 0925-0607
Expiration Date: July 31, 2019

Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0670). Do not return the completed form to this address.

For 2018 dbGaP PRA Renewal

Instructions

Please download the Institutional Submission Certification form (https://osp.od.nih.gov/scientific-sharing/institutional-certifications/), complete the form and upload it to the system under Policy section. When finished click "Update Study" button at the bottom of the page. Complete any missing information by clicking on the title of the missing items listed on the top right corner of the manage study page. Please review all three sections (study Registration information, Policy and consent group) and make any changes if needed or report it to your GPA if it is not editable. When finished, click on "Ready for review by GPA" button at the bottom of the Manage Study page.

Click on video tutorial to see how to get started from this page.

Study Registration Information Edit

Admin. IC: N/A
PI: Cheryl Smith (NIH)
re-Grant PI access to this page

Submission certification: not yet
Release Type: Controlled access
Submission expected for: Metagenomic
Est. study participants: 1000
SRA submission is expected: no
Trusted partners: NCI Genomic Data Commons (GDC)

Parent study: test registartion of a new study

SA Study Management Edit

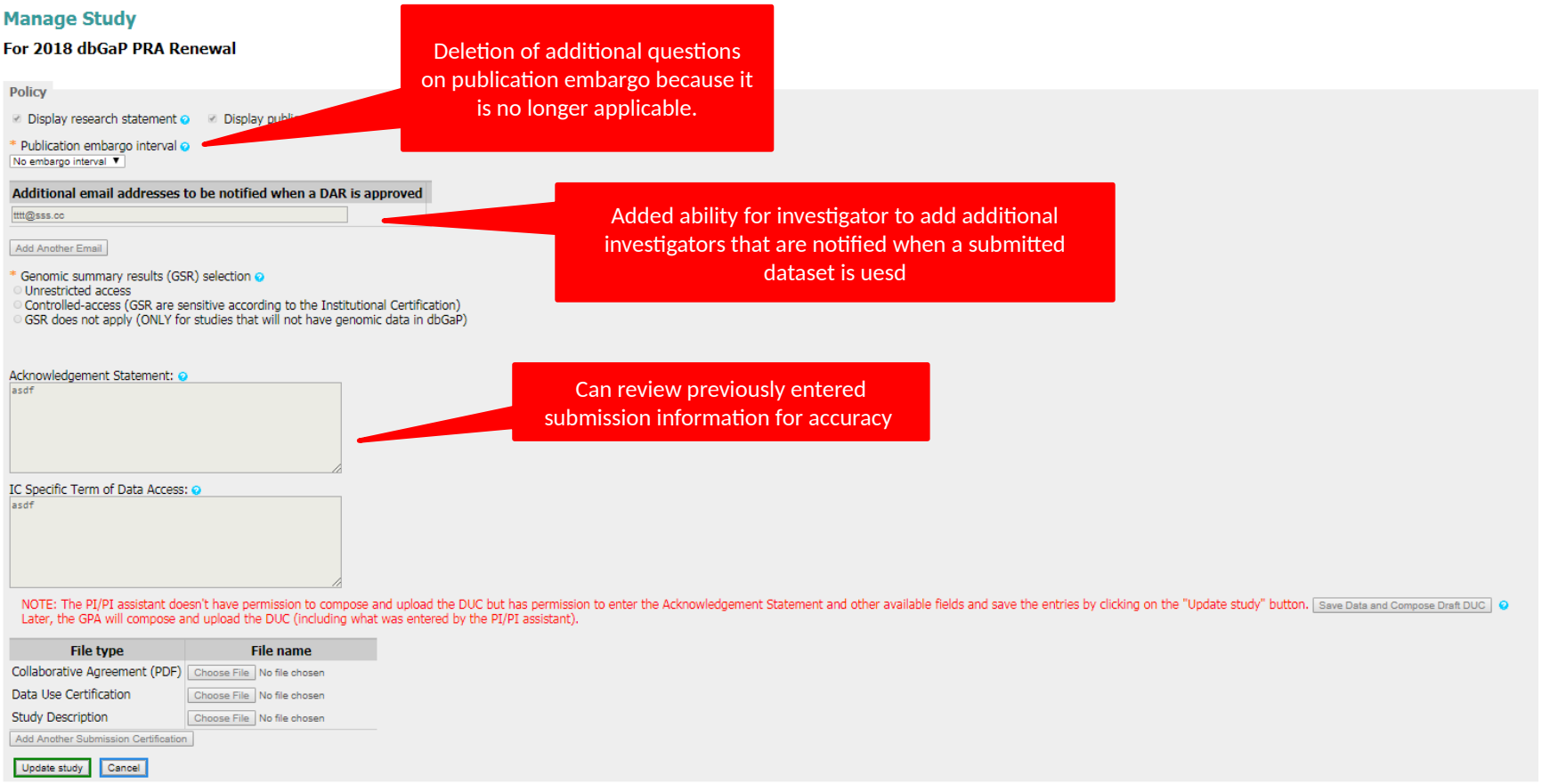
PI: Cheryl J. Smith (email: smithcj6@mail.nih.gov)
Upload Mode: Submission Portal

Policy Edit

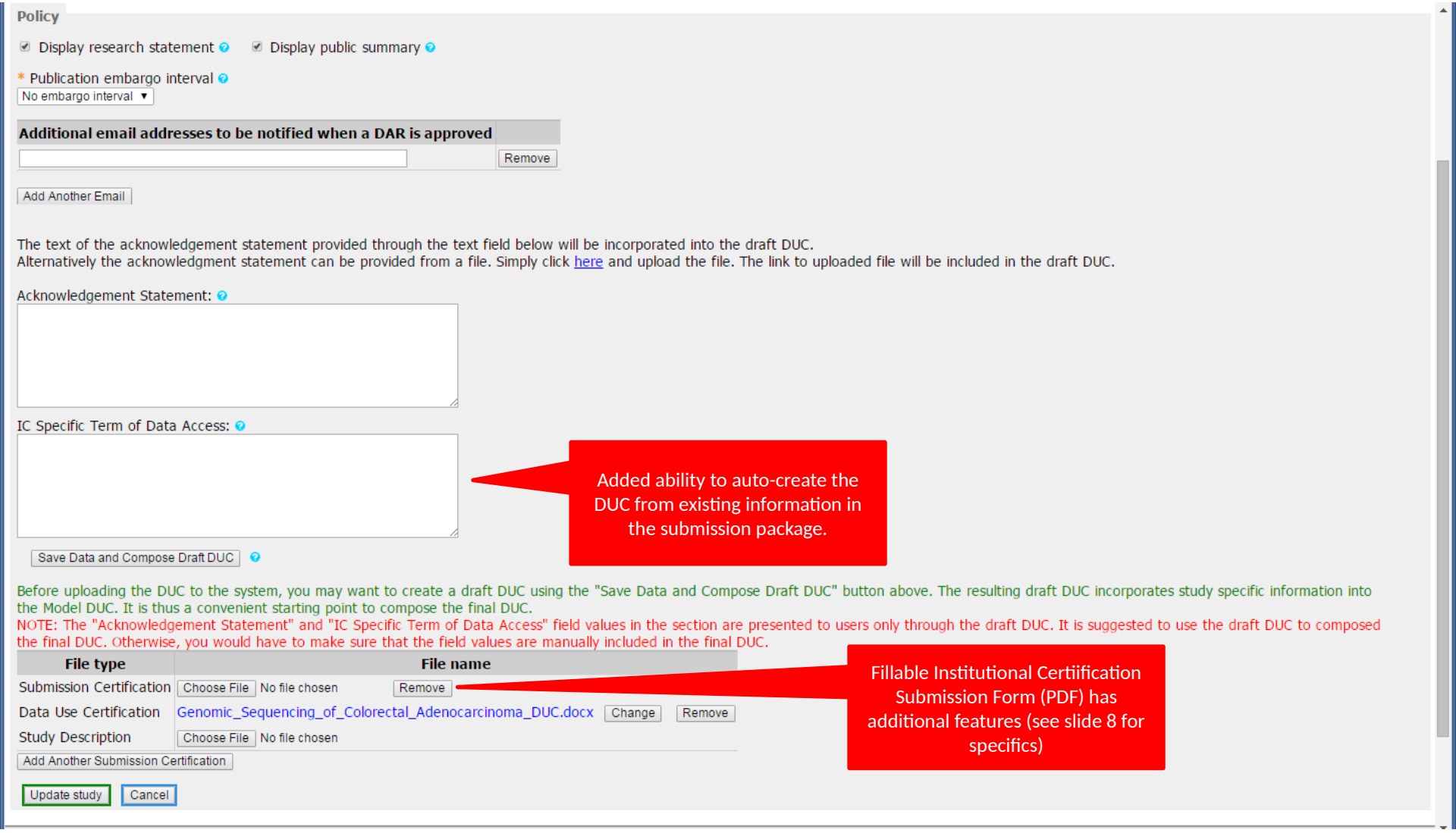
Research statement: display
Public summary: display
Years until renewal: 1

DAR appendices: none
Weeks to cancel request: 8
Acknowledgement Statement: asdf
IC Specific Term of Data Access: asdf

Investigator



Investigator



Investigator

Extramural Institutional Certification*

OMB Control Number: 0925-0670
Expiration Date: July 2019

For studies using data generated from cell lines created or clinical specimens collected after January 25, 2015

Date: [MM/DD/YYYY] 10/18/2018
Name of GPA:
Genomic Program Administrator
Select IC [, NIH, HHS
9000 Rockville Pike
Bethesda, MD 20892-7395

Re: Institutional Certification of _____ [NAME OF INSTITUTION] to Accompany Submission of the Dataset from _____ [ORIGINAL STUDY NAME[1]] for _____ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear ,
The submission of data to the NIH-designated data repository is being made with institutional approval from _____, along with appropriate institutional approvals from collaborating sites, as listed here:

[IF APPLICABLE ENTER COLLABORATING SITE NAMES HERE AND CLICK 'ADD TO LIST'] | LIST OF COLLABORATING SITES

Add to list >> | Clear list

The _____ hereby assures that submission of data from the study entitled _____ to an NIH-designated data repository meets the following expectations, as defined in the NIH Genomic Data Sharing Policy:

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board (IRB), and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:
  - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;[2]
  - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
  - Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results;
  - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results; and
  - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the NIH Genomic Data Sharing Policy (See section IV.C.1).

* Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide its own Institutional Certification.

The individual-level data are to be made available through (check one)

- (•) **controlled-access** [3]
- ( ) **unrestricted access** [4]

If **unrestricted access** is marked, the data use limitations table on the following page(s) does not need to be completed.

NIH provides genomic summary results[5] (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular 'sensitivities' related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as "sensitive" by .

In such cases, "controlled-access" should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

The genomic summary results (GSR) from this study are only to be made available through ☐ **controlled-access.**

Explanation if controlled-access was selected for GSR.

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Investigator

Institutional Certification

NIH expects the submitting institution(s) to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s).

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitation Modifiers (Optional)

IRB Approval Required	IRB	Requestor must provide documentation of local IRB approval.
Publication Required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration Required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit Use Only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development and testing of software or algorithms).
Genetic Studies Only	GSO	Use of the data is limited to genetic studies only.

Using the tables above, please indicate in the table below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	Data Use Limitation	Data Use Limitation Modifiers (optional)
Eg: Cold Cohort Study	*Health/Medical/Biomedical*	IRB☐ PUB☐ COL☐ NPU☐ MDS☐ GSO☐
Eg: Cold Cohort Study	*Disease Specific Research [Lung Cancer]*	IRB☐ PUB☐ COL☐ NPU☒ MDS☐ GSO☐
	Select consent group title	IRB☐ PUB☐ COL☐ NPU☐ MDS GSO
	Select consent group title	IRB☐ PUB☐ COL☐ NPU☐ MDS GSO
	Select consent group title	IRB☐ PUB☐ COL☐ NPU☐ MDS GSO
	Select consent group title	IRB☐ PUB☐ COL☐ NPU☐ MDS GSO

Column "Collaborating Site" automatically adds additional rows to form when information is entered for all rows and columns.

Investigator and Institutional Official

New ability for investigators and Institutional Officials to digitally sign form

Sincerely,

Investigator:

Name: _____ Title: _____

Signature: Validate and sign... Date: 08/23/2018

Institutional Signing Official:[6]

By signing below, I certify on behalf of
that, in addition to myself, an IRB or Privacy Board or equivalent body, as applicable, and other relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) have reviewed the requirements in this certification and agree that the submission meets them.

Name: _____ Title: _____

Signature: _____ Date: 08/23/2018