SEER Specialized Databases

DATA ACCESS COMMITTEE (DAC)

STANDARD OPERATING PROCEDURES (SOP)

NIH **NATIONAL CANCER INSTITUTE**

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PURPOSE

The Surveillance Epidemiology and End Results (**SEER) Specialized Databases (SD) Data Access Committee (DAC), (SEER SD DAC),** is responsible for assessing Requestors' credentials, their intent for the use of the data requested, and whether the study request conforms to NIH policies and procedures including consistency of the proposed research use with any data limitations. The **SEER SD DAC and/or SEER SD DAC Staff** have sole responsibility to authorize data access for Approved Users.

The SEER SD DAC oversees datasets generated by combining SEER Research Plus databases, which are non-Controlled Access Data Repository (CADR) with additional "specialized" fields. These fields generally contain more sensitive information (e.g. county codes, census tract attributes, genomic data). In addition, SEER SD DAC oversees SEER-CAHPS and SEER-MHOS DBs both created by linking SEER data with additional attributes. Access decisions are made based on whether the requested specialized database can support the proposed research (has the data the requestor wants). The SEER SD DAC ensures that all Data Access Requests (DAR) by extramural and intramural data users proposed for SEER Specialized Databases, SEER-CAHPS and SEER-MHOS are consistent with the Data Use Agreements and any other data limitations or clauses prescribed by the data providers, database administrators, and identified on the public website for each specialized dataset.

The SEER SD DAC reviews and approves or disapproves all DARs for access to NCI/SEER controlled-access datasets for extramural or intramural investigators who request access to datasets for research purposes and NCI employees for programmatic oversight. The SEER SD DAC Staff notify the NIH Office of Science Policy (OSP) staff of significant policy deviations or violations, identify issues and suggest changes in policies or procedures.

MEMBERSHIP

The SEER Specialized DBs DAC has Chair and Co-Chair who have equal and independent responsibilities. The Chairs and members are senior Federal employees of the NIH with appropriate scientific, bioethics, or human subject protections research expertise who review and approve or disapprove DARs from extramural and intramural investigators for proposed secondary research use of controlled-access datasets under the NIH Policies and program specific requirements or procedures (if any).

Currently, the SEER Specialized DB DAC is comprised of twelve (12) NCI staff members (all federal employees; of which 2 Co-Chairs, 8 voting members and 2 non-voting staff). The DAC Chairs are appointed by the DCCPS Director and DAC Members are confirmed by their DCCPS Program Associate Directors for a two (2) year term and may serve more than one term.

GUESTS

The SEER Specialized DB DAC meetings are closed meetings. Individuals with specific expertise may be invited to attend meetings or to provide written consultation on a particular matter such as learning

about DAC procedures or providing consultation. These consultants may be Federal or non-Federal employees and are not voting members of the DAC. Non-Federal consultants may provide their individual expertise to the DAC on an *ad hoc* basis and are limited to activities per the guidelines and policies of the Federal Advisory Committee Act (https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/federal-advisory-committee-act). Generally, these individuals are not expected to be participants in SEER SD DAC discussions. They may raise relevant points during meetings, are expected to yield the discussion to DAC members, and must have the permission of the SEER SD DAC Chairs to attend. Permission will generally be granted when the criteria for guest attendance are met.

SCOPE OF WORK

WHAT SEER SPECIALIZED DBS DAC WILL DO

The SEER SD DAC reviews and approves or disapproves all requests from the research community for access to datasets assigned to them within the SEER portfolio of Specialized DB, SEER-CAHPS and SEER-MHOS datasets. The SEER SD DAC members and guests are expected to review and evaluate ALL DARs. Data access decisions are made based on whether the request conforms to dataset specifications, limitations, and requirements.

The SEER SD DAC members and/or staff identify DARs that require additional information or discussion, such as requests with proposed research use that appear inconsistent with the data limitations, the research intent is unclear, or there is concern about potential harm to groups or populations (i.e., stigmatization).

Submission of a DAR indicates that the requesting investigator (Requester) and their collaborators who requested access to the data agreed to the terms and conditions in SEER Research, SEER Research Plus, and National Childhood Cancer Registry (NCCR) Data Use Agreements (DUAs). All DUAs require that Requesters, at minimum agree to

- Not attempting to identify any individuals in SEER DBs.
- No attempt to identify any geography not specifically provided in the dataset.
- Not seeking to link case level data with any external or other SEER databases.
- Not distribute the data in any form to any entity or individual other than their research staff, trainees, or independent collaborating investigators listed in the Data Access Request.
- Report any data management incidents (DMI) to SEER.
- Acknowledge the NCI SEER DBs use in publications and presentations.

If requested, the SEER SD DAC Chairs and Staff review progress updates from approved   users and prepare summary reports for the Office of Science Policy on an as-needed-basis.

The SEER SD DAC Chairs' primary responsibility is (1) managing the review of DARs for controlled-access data from designated data repositories, and (2) the oversight of data access and use practices by approved users through the review of their annual renewal of access to the SEER Research Plus data released in mid-April each year. Annual reporting on data access and use practices are provided by the

SEER SD DAC Chairs to the NIH Office of Science Policy by request. The SEER SD DAC Chairs lead responses to data management incidents (DMIs) and communications with the involved Principal Investigators (PI/Requesters), SEER staff, and Office of Science Policy (OSP) staff, as necessary.

WHAT SEER SPECIALIZED DBS DAC WILL NOT DO

This DAC **is not** charged with:

- determining whether a dataset should be available and distributed ensuring that, before the dataset is submitted for distribution through the NIH, the requesting investigator:
  - o   is in compliance with any applicable Federal, State, and Local laws,
  - o   is in compliance with local human subjects' protections, and
  - o   has adequate participant consent for the proposed study; or
- evaluating the scientific merit of a Data Access Request.

CONFLICT OF INTEREST

The determination of conflict-of-interest is consistent with NIH definitions and policies for Program Officials as described in the NIH Policy Manual (https://policymanual.nih.gov/2400-04). Conflict includes, but is not limited to: scientific publication with a Requester or co-investigator listed on a Data Access Request within three years of the submission date of the Request (excluding consortium publications with large numbers of authors, e.g., publications by the all SEER PIs); supervisory relationship with a Requester or a co-investigator listed on a Data Access Request; or listed as a Requester or a co-investigator on a Data Access Request.

SEER Specialized DBs DAC members and guests are expected to recuse themselves from, and will not be present for, discussion and voting for DARs for which they are in conflict. All identified conflicts should be documented in the SEER Specialized DBs Request System as "ABSTAIN - Conflict of Interest" and communicated to the SEER Specialized DBs DAC staff.

OPERATIONS

The SEER Specialized DBs is a repository of datasets providing more data than the regular SEER non-CADR databases. The list of current datasets is listed at https://seer.cancer.gov/data/specialized/available-databases/

The SEER-CAHPS is a data resource based on linkage between SEER cancer registry data and the Centers for Medicare and Medicaid Services (CMS) Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient surveys. This dataset can be requested at https://healthcaredelivery.cancer.gov/seer-cahps/

The SEER-MHOS is a data resource based on linkage of SEER data and CMS Medicare Health Outcomes Survey (MHOS) This dataset can be requested at https://healthcaredelivery.cancer.gov/seer-mhos/

DATA ACCESS REQUEST (DAR)

The Requester selects the specific database from the list of SEER specialized DBs. The link to a specific

database opens a webpage that describes the database and has a link (button) to submit a request for that DB. The requestor must have approval to access the current SEER Research Plus DBs before he/she can submit a request for a specialized DB.

SEER Research Plus DBs access can be obtained at https://seer.cancer.gov/data/access.html

The data access requirements for SEER Research Plus (non-CADR DBs) are listed below

- Institutional affiliation as supported by the Office of Data Sharing (ODS), e.g., 1) eRA Commons or 2) Department of Human Health Services (HHS) PIV cards
- Provide Signing Official contact information (must be affiliated with same institution/company)
- Valid institutional email as pulled from eRA Commons or HHS directories
    o All communications concerning data requests and approval will use institutional email.
- Completed application form
- Acknowledgement of the following:
    o SEER Research Data Use Agreement
    o SEER Treatment Data Limitations
    o NCCR Data Use Agreement

The access is valid until the next release of SEER Research Plus DBs which happens in mid-April each year. At that point all users of any SEER product must renew their SEER Plus Research access in order to continue their access to a specialized DB they had approval to use.

REQUESTS TAB

Once a requestor selects "Submit a Request" the system prompts the requestor to sign in with Login.gov (extramural) or NIH Network (intramural).

The request form collects the following information:

- Name
- Organization
- Adress/phone/user profile email
- Signing official name
- Signing official institutional email
- Role (e.g. cancer researcher, cancer patient/family member, cancer registrar, etc.)
- Version of DB requested
- Planned use of data
- Purpose of using the data (Research question/Hypothesis)
- Analytical plan

Some DBs may have additional Agreements and Terms of Use such as not using the data for any other than specified purpose, being U.S. Researcher from U.S. institution, data destruction notification.

After the requestor submits their data request, the system creates a couple of automatic emails

- An email to the requestor acknowledging the receipt of the request.
- An email to the SEER Specialized DBs DAC Chair, Co-Chair and a primary reviewer (if applicable).

OVERVIEW OF THE DATA ACCESS REQUEST AND REVIEW SYSTEM

The Data Request and Review System has the following tabs and functionality:

Status	Requested By	Date Requested	Last Modified
Pending Requestor Input	Test Requestor	Sept. 19, 2023, 10:45 a.m. EDT	Sept. 19, 2023, 11:33 a.m. EDT

View Request | **Comments** | **Internal Comments** | **Collaborators** | **Documents** | **Contact Info** | **More ▾**

'**View Request**'- The reviewers can access and review the DAR through this tab.

"**Comments**" – This tab allows for official communication between the primary reviewer(s), requestor and DAC Chairs. Questions, clarifications, approvals or disapprovals are communicated through this tab. Posting updates by the DAC reviewer or Chair generates an email notification to the requestor prompting them to log in to the system and review the content. The requestor's communication back notifies the primary reviewer and the two Chairs for posted updates through an email notification with prompt to log in and review the updates. Sending inquires to the requestor is associated with changing the status of the DAR from "Pending Review" to "Pending Requestor Input". Upon submission of the updated request, the status changes back to "Pending Review". After review and approval of DAR for DBs that do not require IRB review, the status is changed to "Approved, Pending

Final Review". The final check is technical in nature confirming that all requirements are met before access to the data is provided.

For DBs that require IRB approval the status is changed to "Provisional Approval-Pending IRB review". This status generates an email to the requestors with instructions for central IRB submission. Once the IRB letters are uploaded to the system, a final approval is granted. The disapproval of a DAR is communicated through "Denied" status.

"Internal Comments"-This allows for communication between the DAC members as well as documentation of the review and voting on DAR.

"Collaborators"- Lists collaborators who will have access to the data. All of them must have approval for access to the current SEER Research Plus DBs.

"Documents"- Provides options to upload Purpose and Analysis Plan, IRB letters, or any other relevant documents.

"Contact Info"- Provides Requestor contact information.

DATA ACCESS REQUEST (DAR) REVIEW

Submission of a DAR assigns one of two statuses

1. "Pending Review"
2. "Pending Eligibility Review". This status is associated with DBs that per agreements with data owners are allowed to be released to U.S. based researchers associated with U.S. institutions.

The DAC Chair or Co-Chair, or the primary reviewer, strive to review the request within one week.

In the case when no further questions or clarifications are needed, the primary reviewer makes a recommendation in the "Internal Comments" tab. One of the co-chairs reviews the DAR and recommendations of the primary reviewer and communicates the decision to the requester through the "Comments" tab.

In cases that a DAR needs additional information or clarification, the primary reviewer communicates with the requester and provides feedback if more information is needed or if there are data limitations that would not support the proposed research.

Typically, the review is conducted by a primary reviewer and one of the Co-Chairs, and the Chair communicates the approval status.

DARs that meet the following scenarios require review by DAC members at bi-monthly meetings with at least 3 voting members available to vote.

DARs that are for sensitive data (e.g. DBs with county codes or genetic data),

DARs that need additional expertise,

DARs associated with COI,

DARs in which the primary reviewer expressed concerns.

All review discussions and voting are documented in the "Internal Comments" section and communication of the final decision to the requester is carried out by one of the Chairs in the "Comments" section.

EXPEDITED REVIEW

The SEER Specialized DBs are updated periodically to include the latest diagnosis years and outcomes follow-up for all incident cases included in the database. Requesters granted access to previous versions of a specialized DB may request access to the latest version of a specialized DB. If there are no changes to the purpose and analysis plan, such requests are subject to Expedited Review in which one of the DAC Chairs can grant approval. Changes to intended use of data constitute a new DAR.

ANNUAL REVIEW

Annual reviews are associated with the release of new SEER Research Plus DBs which happens in mid-April each year. In order to maintain access to any previously-approved SEER Specialized DBs. a requester needs to apply for access to the new SEER Research Plus DBs following the same steps outlined in Data Access Request section on page 6. Approval to access the latest SEER Research Plus DBs will allow the account to remain active, and the requester will maintain access to any Specialized DBs for one year until next release of SEER Research Plus DBs in mid-April.

CLOSE OUT

Requesters with approved access to SEER Specialized DBs that did not renew their SEER Research Plus access in 3 months will have their accounts disabled. After 6 months, if they still have not renewed access to the new SEER Research Plus DBs, the account will be deleted, and they will lose all previously obtained access to all data including any SEER Specialized Databases. At this point the project is considered closed out. Records of deleted accounts are kept in an audit trail.

After 5 years of renewal, an email asking for close out and data destruction is sent by the system. The requester has an option to renew or close out the project. Data destruction communicated in writing through the "Comments" tab is required.

DATA MANAGEMENT INCIDENTS

A Data Management Incident (DMI) is defined as a violation of DUAs or approved data use. A DMI may originate from errors made during data submission or release from an NIH-designated controlled- access data repository, or when the terms of access as outlined in the DUAs or in Terms of Use are not honored. Examples of DMIs may include, but are not limited to:

- Incorrect assignment of data use limitations to datasets, either by the submitting investigator or by NIH.
- A breach of, or the potential to breach, the security measures in place to protect datasets.
- Inadvertent or intentional sharing of datasets with unapproved users.
- The use of datasets that is inconsistent with its data use limitations.
- The use of datasets that is inconsistent with the research use statement approved for secondary use.

- The sale of data.
- An attempt to re-identify individuals whose data are in a dataset.

SOP VERSION CONTROL

Version 1, 7/31/2025