

Sample Tutorial Slides

National Children's Study
Data Use Agreement Training

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development
Health research throughout the lifespan

Menu National Children's Study Data Use Agreement Training Resources Help

Whatever... I see or hear... which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

(Hippocratic Oath, circa 4th Century B.C.E.)

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Data Use Agreement Training

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Menu Introduction Resources Help

The National Children's Study (NCS) Vanguard Study collected health related data from over 5,000 children and their families. Because of the sensitive nature of health data, NICHD enforces standards for data access to maintain our commitment of confidentiality to the NCS participants.

The template will include links for a Menu (Table of Contents), Resources (window with helpful links), and tutorial Help (overview of slide navigation)

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Accessed via the **Menu** option, this Table of Contents will overlay the tutorial on the left side of the screen. It can be accessed at any time, but it is only possible to jump to sections already viewed in their entirety.

The National Children's Study NCS Archive Data User Training

The following tutorial contains audio. Please turn your speakers on before proceeding.

Note: This training takes about 20 minutes to complete and concludes with a quiz. You must complete the training in one sitting, pass the quiz, and submit your score to receive credit for completion.

National Children's Study (NCS) Data User Training

- ❖ Whatever... I see or hear... which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. (Hippocratic Oath, circa 4th Century B.C.E.)
- ❖ Protecting the privacy of the individuals and institutions that are featured in your health research is imperative. The NCS data policy safeguards the confidentiality of Study participants and institutions.

1. Introduction

Welcome to the NCS Data User Training!

The National Children's Study Vanguard Study collected health related data from over 5,000 children and their families. Because of the sensitive nature of health data, the National Institutes of Health (NIH) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) enforce standards for data access to maintain our commitment of confidentiality to the NCS participants as described in the informed consent process. The standards are also enforced to support a relationship of trust between the federal government and the general public. During this course, we will explain important requirements of NCS data use:

- ❖ Describe NCS data at a high level
- ❖ Explain your individual responsibility when using NCS data
- ❖ Note the importance of maintaining privacy of individuals and institutions and confidentiality of information
- ❖ Reduce the risk of inadvertent violations

This course will take approximately 20 minutes to complete, and it concludes with a brief quiz. You must complete the training in one sitting and pass the quiz in order to proceed to signing any NICHD Research Materials Distribution Agreement (RMDA).

If you do not pass or if you exit the course, you must begin the course again.

2. How to Use this Tutorial

- Let's review the ways you can navigate this course.
- The **Menu** button allows you to view the Table of Contents and jump to different sections of the course. The menu will open on the left side of the screen. Once you have opened the menu, you can use the small arrows in the top-right corner of the menu pane to hide it again.
- The **Title** shows you the topic you are currently viewing.
- You can click **Resources** to open a new window with links to additional information.
- Click **Help** to view a slide like this one, with information about navigating the course.
- Use the **Playbar** at the bottom of the screen to pause, mute the audio, view the menu, or close the course.

3. NCS DATA(AUDIO)

NCS data collected during the NCS Vanguard Study are a valuable resource for the health research community, because they contain information about Study participants, their health, family medical history, and their physical, social, and family environments.

- ❖ All registered users of this site are required to take the Data User training.
- ❖ Investigators who wish to access NCS data must successfully complete this training before accessing any data.
- ❖ While the NCS Archive allows access to high-level NCS information, NCS datasets may be accessed only via secure virtual workstations within a Researcher Portal. After completing the training, investigators who wish to access the secure Researcher Portal must submit a data request form.
- ❖ Investigators with approved studies who execute a RMDA will be given access to relevant:
 - Participant data
 - Biospecimens and/or environmental samples (if part of approved study)
- ❖ Downloadable operational data files do not require an approved data request or a RMDA.

Note that standard datasets are made available without Personally Identifiable Information (PII) and Protected Health Information (PHI). We will review those terms in more detail later.

Click on each section of the graphic to learn more about NCS data and your role when using that data.

3. NCS Data (SLIDE CONTENT)

NCS data collected during the NCS Vanguard Study are a valuable resource for the health research community.

Investigators who wish to access the researcher portal must successfully complete this DU training before accessing any data within the researcher portal.

After completing the training, investigators who wish to access the researcher portal must submit a data request form and execute a RMDA.

Click on each section of the graphic to learn more about NCS data and your role when using that data.

❖ THE DATA (Graphic 1)

- ❖ NCS databases bring together information collected from questionnaires, body measurements, and biological and environmental samples.

❖ USING NCS DATA (Graphic 2)

- ❖ NCS databases also include the identities of institutions, such as hospitals and other health care providers. The identities of these institutions would need to be masked to protect confidentiality.
- ❖ Health researchers may access information about NCS data at <https://www.nichd.nih.gov/research/NCS/Pages/researchers.aspx>.

❖ PUBLISHING YOUR FINDINGS (Graphic 3)

- ❖ After disclosure review, investigators with approved studies are encouraged to publish their findings to promote improvements in child health.

4. Terminology

There are a few definitions you should be familiar with before we proceed.

First, what is the RMDA?

- ❖ A legally binding agreement with NIH that defines how you can use NCS data and materials.

Click on the other terms on this slide to learn more about how we use them in relationship to NCS data.

After you have opened a definition, click the button again to close it.

Some Definitions

- ❖ **Researcher Portal:** The secure environment in which approved investigators may access NCS data in order to perform research and analysis.
- ❖ **Data:** Data and information collected from participants in the NCS Vanguard Study.
- ❖ **PII/PHI:** PII is any data that could potentially identify a specific person, including name, phone number, address, and any other such identifying information. Similarly, PHI is any information about the health status or health care of an individual that may be used to identify that person.
- ❖ **Data User:** An individual who has requested access to the micro data available within the secure Researcher Portal and has been approved for use to meet a specific research objective.
- ❖ **Micro Data:** Data files in record format such that each variable has a coded value. Micro data are also referred to as participant-level data.
- ❖ **Summary Data:** Aggregate results from analysis of the micro data, such as frequencies, percentage frequencies, or rates

5. Your Responsibilities

When working with health information, researchers have a responsibility to maintain the privacy rights of the individuals and institutions featured in their data.

The RMDA contains specific requirements to protect the privacy rights of the individuals and institutions within the NCS data sets.

Your signature on the RMDA acknowledges that:

- ❖ You have read and understand the requirements for using NCS data.
- ❖ You agree to be bound by the federal regulations outlined in the RMDA.
- ❖ You understand the information subject to this agreement, who may have access to NCS data, the limitations on disclosure, the administrative requirements, and the security requirements.
- ❖ You understand that there are civil and criminal penalties for violating any provision of the RMDA.

6. Appropriate Uses of Data

As someone who works with confidential information, it is important for you to know what you can and cannot do with it. You are responsible for how you and others in your research group use the NCS data to which you have access.

- ❖ You may not directly remove any data from the Researcher Portal environment. Data within the secure Researcher Portal may not be downloaded, and you must not take screenshots, video, or otherwise reproduce data from within the secure environment.
- ❖ You may use NCS data for research, analysis, and aggregate statistical reporting.
- ❖ You may share NCS data with your immediate research group. Sharing information is critical to research projects, but you must not share NCS data outside of your immediate research group.
 - Please note that each member of the group is responsible for meeting all data access requirements, including taking this training and agreeing to the terms of data use.
- ❖ When linking any NCS data file to another source, the merging of data sources may increase disclosure risk. In turn, the resulting data file must be managed according to the terms of the RMDA.
- ❖ You may only use NCS data in accordance with the approved research plan.

7. Restrictions and Consequences

Data Use Restrictions

You are prohibited from:

- ❖ Using the data for commercial or competitive purposes.
- ❖ Using the data to determine the rights, benefits, or privileges of individual establishments.
- ❖ Contacting an institution to question, verify, or discuss the data.

Consequences

If you violate any of the terms and conditions of the RMDA, the following consequences may occur.

- ❖ **Revocation of data access:** Immediate revocation of access to NCS data now and in the future.
- ❖ **Legal consequences:** Any violation of this agreement may also be a violation of Federal criminal law under the Privacy Act of 1974, the Federal Information Security Management Act of 2002, and be subject to prosecution by the U.S. Attorney General.

8. Disclosure

Next, let's talk about disclosure.

Disclosure relates to inappropriate release of information associated with a study participant, whether an individual or an institution.

Disclosure occurs when

- ❖ a study participant is identified from a released file,
- ❖ sensitive information about a study participant is revealed through the released file

As mentioned earlier, NCS data contain information about Study participants, their health, family medical history, and their physical, social, and family environments. You must keep this information confidential.

Any attempts to identify individuals are prohibited, and information that could identify individuals directly or by inference must not be released or published.

9. Disclosure Policies

Here are the policies by which you must abide in order to minimize the risk of disclosure:

❖ **Do not share the identity of individuals or institutions, and prohibit others from doing so.**

Users are prohibited from making any effort to share the identity of any individual or institution in the data. This restriction includes Study participants or institutions. It is also your responsibility to prohibit anyone else who has access to NCS data from sharing the identities of individuals or establishments within the data. Furthermore, employers, hospitals, providers, or industries should not be named.

❖ **Do not report tabulated data in a cell size less than 10.**

In a small sample, an identity could be determined indirectly (e.g., a single case of AIDS in a small town). Such a disclosure would be a direct violation of the privacy rights of that individual.

Tabulated data refers to presented count data and data derivable from a presented table. Derived counts refer to tables where multiple rows and columns are presented allowing a careful reader to infer a smaller count.

Refer to the list on the slide for additional restrictions.

9. Disclosure Policies (cont.)

Policies (continued)

- ❖ **Do not contact any institutional NCS data source regarding data within the NCS data files.**
- ❖ **Do not report names of geographic areas that are smaller than the primary sampling unit.**
- ❖ **Do not include maps of geographic areas that depict secondary sampling units (or smaller).**
- ❖ **Do not describe participant demographics or health status at the individual level.**
- ❖ **Removal of data tables or text from the secure Researcher Portal is prohibited until disclosure review has been conducted and download has been approved.**

10. HIPAA & Other Relevant Laws

The HIPAA Privacy Rule sets national standards for patient rights with respect to health information. This rule protects individually identifiable health information by establishing conditions for its use and disclosure by covered entities.

NIH and the Definition of Covered Entities

NIH is not a covered entity because it does not fit the definition of a:

- ❖ Health plan
- ❖ Health care clearinghouse
- ❖ Health care provider that electronically transmits health information

NCS Data are Restricted-Use Data Sets

Published NCS data consist of aggregate data. Direct identifiers specified in the Privacy Rule must be removed. Values of less than 10 must be suppressed.

NCS is consistent with HIPAA regulations

The NCS data use policy is commensurate with HIPAA requirements for use of a limited data set.

For more information, visit the links on this slide:

- <http://www.hhs.gov/ocr/hipaa>
- <http://privacyruleandresearch.nih.gov/>.

11. Publishing Recommendations

NIH/NICHD must demonstrate that NCS data are used to generate significant research contributions that satisfy the mission of the Agency. Therefore, it is crucial to properly cite and acknowledge NIH and the NCS data used in your publication.

Investigators with approved NCS studies are strongly encouraged to publish their findings. Activities that qualify as “publication” include scholarly journal articles, and professional conference presentations or posters.

Publishing Recommendations

It is important that you properly acknowledge NIH and the data source used in your publication, by including the following statement:

“Data provided for this analysis was obtained as part of the National Children’s Study, supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and funded, through its appropriation, by the Office of the Director of the National Institutes of Health.”

Notifying the NCS Archive

Investigators are requested to provide the NCS Archive with citations of publications and presentations arising from their NCS Archive research projects.

12. Review (AUDIO)

During this course, you have learned the importance of adhering requirements of NCS data use.

Let's review key elements about the NCS and NCS data use.

Click each section on this slide to review key information. After you have finished reviewing, there will be a brief quiz to test your understanding.

12. Review (SLIDE CONTENT)

The NCS

The National Children's Study (NCS) Vanguard Study collected health related data from over 5,000 children and their families. Because of the sensitive nature of health data, the NIH and NICHD enforce standards for data access to maintain our commitment to protect privacy as described in the informed consent process.

Disclosure

Through deliberate and sophisticated technical analysis, it might be possible to ascertain the identity of particular persons, for whom investigators are not given PII. This would be considered a violation of NCS data use requirements. Any attempts to identify individuals are prohibited, and information that could identify individuals directly or by inference must not be released or published.

Policies

- ❖ Do not share the identity of individuals or institutions, and prohibit others from doing so.
- ❖ Do not report tabulated data in a cell size less than 10.
- ❖ Do not contact any institution to discuss data in NCS data files.
- ❖ Do not report names of geographic areas that are smaller than the primary sampling unit.
- ❖ Do not include maps of geographic areas that depict secondary sampling units (or smaller).
- ❖ Do not describe participant demographics or health status at the individual level

12. Review (SLIDE CONTENT, CONT.)

HIPAA

While NIH is not a covered entity, NCS data use requirements are consistent with HIPAA requirements for use of a limited data set.

Publishing

Properly acknowledge NIH and the data source used in your publication, by including the following statement:

“Data provided for this analysis was obtained as part of the National Children’s Study, supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, and funded, through its appropriation, by the Office of the Director of the National Institutes of Health.”

Provide the NCS Archive with citations of publications and presentations arising from your NCS Archive research projects.

Helpful Resources

- ❖ [NICHD NCS Web page](#) - Everything about NCS data, tools, and products, with a link to NCS Archive
- ❖ [Department of Health and Human Services/HIPAA Site](#) - The Office of Civil Rights
- ❖ [Privacy Rule and Research/HIPAA Site](#) - The National Institutes of Health

13. Quiz Scenarios

The next slides are designed to test your recall and make sure that you understand the concepts covered by this tutorial.

You will be presented with several scenarios. Listen to the scenario carefully, and then click in the answer area to select your response. Sometimes you will be asked to choose only one response, and other times you may need to select all answers that apply.

You will have two attempts to answer each question. If you don't answer correctly within that number of attempts, or if you exit the tutorial before completing the quiz, you must begin the tutorial again.

- ❖ If you are not ready to begin the quiz, use the **Menu** to jump to concepts you wish to review.
- ❖ If you are ready, click **Next** to begin the quiz.

Quiz Scenarios

Scenario 1

Sara: "Hi Donna. How is your research report coming along?"

Donna: "Great. I am using NCS data to study a rare medical condition, Kawasaki's disease in children. In certain populations, the incidence of the condition reveals only one or two cases of the disease in a given year. I would like to publish these findings and include a table recording the incidence of the disease for these areas. However, within the table there will be 'cell sizes' under 10. Can I get an exception for this restriction and publish it with these smaller cells?"

Can Donna publish her findings of the incidence of Kawasaki's disease?

Choose the best answer.

- A. Yes, since this is a rare disorder, Donna can publish her findings.
- B. Yes, if she receives approval from Sara, her supervisor.
- C. No, this would be in violation of NCS data use requirements.

Quiz Scenarios.....(cont.)

Scenario 1 Answer:

C. No, this would be in violation of NCS data use requirements.

All published results must be reported with cell sizes greater than or equal to 10. One or two cases of a rare medical condition in a given geographic area are too few to report while protecting privacy. Cell sizes fewer than 10 could inadvertently reveal identity. These cases will need to be reported by combining the geographic areas up to a cell size greater than or equal to 10.

This information is in the section related to **Disclosure Policies**.

Quiz Scenarios.....(cont.)

Scenario 2

John is a new research contractor with Health Research Services, Inc. How can John and his colleague abide by NCS data use requirements?

John: "I'd like to do a primary sampling unit-level comparison that incorporates health and demographic data. I want to include health provider information, health outcomes, and race/ethnicity data in my report. How can I use NCS data within my report?"

Tom: "Perhaps you could link extant data from county records concerning demographics with health information contained in the NCS data residing in the Researcher Portal."

Under what conditions can John use the NCS data within the Researcher Portal?

(Choose all that apply).

- A. If he signs a RMDA
- B. If John doesn't disclose geographic detail more specific than the primary sampling unit level
- C. If John doesn't identify health care providers
- D. If he uses his research for marketing purposes

Quiz Scenarios.....(cont.)

Scenario 2 Answer:

- A. If he signs a RMDA,
- B. If John doesn't disclose geographic detail more specific than the primary sampling unit level, and
- C. If John doesn't identify health care providers.

Health care provider-level analysis can be done, but the identification of providers must be protected. John can enhance his data with links to other data, but he must stay within the limits of the approved research plan. Also, as a member of the research group, John must sign the RMDA. Use of NCS data for marketing purposes, such as using the information in the NCS data for commercial or competitive purposes involving individual hospitals, is a violation of the NCS data use requirements.

This information is covered in the sections related to **Accessing Data Analysis Files** and **Disclosure Policies**.

Quiz Scenarios.....(cont.)

Scenario 3

Lisa: "Lakeview Hospital. This is Lisa speaking."

Stephen: "Hi Lisa, my name is Stephen Gossling. I am a health care researcher with Burnside University. I am using NCS data to research the prevalence of newborn respiratory illnesses within the western United States. I have some questions about your data on newborn respiratory illness and would like to verify the number of cases that were admitted to your hospital three years ago."

Which of the following is a violation of NCS data use requirements?

(Choose all that apply).

- A. Contacting an institution to question, verify, or discuss NCS data
- B. Identifying individuals within NCS data
- C. Linking NCS data to another data source
- D. Comparing (benchmarking) results from the NCS data to another data source

Quiz Scenarios.....(cont.)

Scenario 3 Answer:

- A. Contacting an institution to question, verify, or discuss NCS data and
- B. Identifying individuals within NCS data

Stephen's actions are in violation of NCS data use requirements. Stephen cannot contact an institution to question, verify, or discuss NCS data, or to identify individuals within the data. However, Stephen can link NCS data to additional data sources that reside in the Researcher Portal. Stephen may also benchmark his results from NCS data to another data source.

This information is included in the sections related to **Appropriate Uses of Data, Data Use Restrictions, and Disclosure Policies.**

Quiz Scenarios.....(cont.)

Scenario 4

If an investigator violates NCS data use requirements, s/he:

Choose all that apply.

- A. Loses access to the NCS data
- B. Becomes subject to prosecution by the U.S. Attorney General
- C. Could force the NIH to discontinue release of NCS data
- D. Could violate confidentiality of NCS participants

Quiz Scenarios.....(cont.)

Scenario 4 Answer:

S/he:

- A. Loses access to the NCS data
- B. Becomes subject to prosecution by the U.S. Attorney General
- C. Could force the NIH to discontinue release of NCS data
- D. Could violate confidentiality of NCS participants

If you violate any of the terms and conditions of NCS data use requirements, consequences may include:

- immediate revocation of individual and institutional access to NCS data
- prosecution by the U.S. Attorney General

This information is included in the sections related to **Data Use Restrictions** and **Consequences**.

End of Tutorial

A. (Passed quiz)

You have reached the end of this tutorial.

- Congratulations! You passed the quiz.
- Now that you have successfully completed NCS Data User training, you are eligible to execute RMDAs for approved data requests.
- Click the X in your browser window to exit this tutorial.

End of Tutorial

B: (Did not pass quiz)

- You did not pass the quiz. You cannot execute RMDAs for approved data requests until you answer all items on the quiz correctly.
- Because you did not successfully complete the NCS Data User training, you may restart the tutorial now by clicking on the button below, or choose to come back and complete it at a later time.