

Address Lookup Tool

General Requirements for Providers and Vanguard Centers

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1 ADDRESS LOOKUP TOOL OVERVIEW

The Address Lookup Tool is primarily designed to support healthcare providers in recruiting women into the NCS by providing them with a capability to determine whether the woman's primary residence is in a selected NCS segment. The tool and associated procedures are designed to encourage use by reducing the healthcare provider's level of effort as much as possible and ensuring use of the tool is as intuitive as possible.

The Address Lookup Tool may also be used by VCs to verify the healthcare provider's search results using the same matching algorithm.

Users will enter a patient's street address and match it against known addresses in selected segments, both those that have already been released and those that are selected but not yet released. The tool will only provide information on address eligibility and will not alert a user as to whether or not a woman is already enrolled in the NCS or other eligibility requirements.

2 HIPAA REQUIREMENTS

The use of the Address Lookup Tool by the healthcare provider and procedures the provider will follow to release patient Personal Health Information (PHI) (e.g., name and contact information) to the VC are dependent upon the healthcare provider's relationship to the VC and upon Privacy Board/IRB approvals for research relationships and HIPAA authorizations. VC Principal Investigators (PIs) must adhere to their local Study Center HIPAA policies and requirements and work with healthcare providers to obtain approval of the required HIPAA waivers or authorizations as necessary.

We anticipate the following HIPAA-related situations that the VCs will need to consider:

- 1) The health care provider is employed by a practice or facility that with the Study Center are considered part of the same covered entity for HIPAA purposes. The health care provider may look up the patient's address in the Address Lookup Tool without the need for a HIPAA waiver. If there is a match, the healthcare provider may request and obtain the *verbal permission* of the patient to share the patient's name and contact information with the researcher without obtaining a Waiver of HIPAA Authorization or a HIPAA Authorization under review preparatory to research provision of the HIPAA rule.
- 2) The healthcare provider is not employed by the VC as a covered entity and does not have a HIPAA waiver or a signed HIPAA authorization to release patient name to the VC. The healthcare provider has agreed to help the VC with recruitment and this has been approved by the VC IRB. In this situation, the provider may submit the patient's address to the Address Lookup Tool and if the patient is potentially eligible, give the patient information about the study and invite the patient to call the VC.
- 3) The healthcare provider does not work for the same covered entity as the investigator but the healthcare provider has obtained a HIPAA waiver from a privacy board/IRB allowing him/her to release her name and contact information to the NCS. In this situation, the provider may submit the patient's address to the Address Lookup Tool and release his/her name to the VC. We suggest that as a

courtesy the healthcare provider ask permission to the patient to release the name and contact information to the NCS.

- 4) The healthcare provider is not employed by the VC as a covered entity but the healthcare provider has obtained a HIPAA waiver from a privacy board/IRB to look at the patient's address for purposes of the NCS and has also obtained approval of a HIPAA Authorization for the patient to sign if she agrees to release contact information for purposes of the NCS. The provider may submit the participant's information to the Address Lookup Tool. If there is a match, the patient will be asked to sign a HIPAA authorization form allowing the physician to release her PHI (name and contact information) to the NCS. The health care provider will send the name and contact information for potentially eligible participants to the VC.

It is the responsibility of the VC PIs and their staff to determine how they will work with their healthcare providers. VC staff will develop the procedures that their healthcare providers will follow for discussing the NCS with the patient as appropriate to the healthcare provider's HIPAA status. As discussed in the scenarios above, the healthcare provider will either release the woman's name to the VC for recruitment of the woman, or the provider will present the woman with Study documentation, inform her that she may be eligible to join the Study, and invite her to call the VC site office to learn more about the Study. The path to be followed by each healthcare provider working with the VC will be dependent on the relationship between the healthcare provider and the VC and will be negotiated by the VC PI or their staff.

3 PROCEDURES FOR HEALTHCARE PROVIDER USE OF ADDRESS LOOKUP TOOL

The Coordinating Center (CC) will develop a Quick Start Guide for healthcare provider use of this Tool. The Quick Start Guide will describe the tool, and provide technical directions for its use.

To use the tool, the healthcare provider will enter the woman's address. The tool will identify a match to a released segment or a yet to be released segment based on address.

- a) If there is a match for a potentially eligible woman in a segment, the following message will be displayed:

Message: The address is a match. Your patient is potentially eligible to participate in the National Children's Study. Please refer to the NCS Address Lookup User Guide for guidelines on discussing the NCS with your patient.

- b) There is no matching address:

Message: Your patient's address did not match to an address in our system. There is no need to discuss the study with your patient at this time.

The Address Lookup Tool will only return the match result message on-screen; it will not retain (at the address level) the result of the match, it will not retain the address entered by the healthcare provider, and it will not return matched results to the Study.

As noted above in section 2, the VC staff will work with their local healthcare providers to delineate how they will communicate information regarding women identified as matches using the Address Lookup Tool to the VC site office. VC staff are required to develop, provide, and train their healthcare providers in the use of the Address Lookup Tool and these locally developed procedures.

Once contacted, the VC staff will need to conduct additional research using the Study Management System (SMS) to determine the current status of data collection at the address identified as a match by the Address Lookup Tool. The VC will be responsible for determining whether or not the woman has been enumerated, screened, or consented, and will evaluate all prior contacts with the woman prior to attempting to contact her.

4 PROCEDURES FOR VC USE OF ADDRESS LOOKUP TOOL

The CC will develop a VC version of the Quick Start Guide for the tool. The Quick Start Guide will describe the tool, provide directions for its use and provide guidelines for interpretation of the match/no-match results.

The VC will use the tool the same as the healthcare provider (presented in section 3.4) and the messages will be the same as for the healthcare provider. The VC will be presented with two additional variables on the screen for each match:

- a) Segment ID: identifier of the segment associated with the matched address.
- b) Release Date: Date segment was released or, for segments not yet released, listing date.

Any followup with the healthcare provider or contact of the potential participant will be dependent on the relationship between the healthcare provider and the Study Center and /or negotiations between VC and healthcare provider.

5 GENERAL REQUIREMENTS

5.1 USER BASE

The NCS Address Lookup Tool is primarily designed for use by healthcare providers and their staff members. The tool can be used by a healthcare provider to Look up the address of any woman in his/her practice. It may also be used by a birthing center to look up any woman checking in to deliver her child.

The tool will also be used by VC staff to monitor usage by their healthcare providers and confirm results of address matches using the same algorithm as used by the providers.

5.2 ACCESS

For the Version 1 release, only an internet-based application will be provided. Other needs will be explored with VCs after this has been in use for several months.

Each VC will receive a list of valid provider IDs. Each VC will also be assigned one generic password for all healthcare providers associated with that VC. VCs are responsible for assigning provider IDs and passwords and responding to user questions from healthcare providers. This information will be loaded into the access control for the application and will not require CC user administration.

VCs are expected to retain ID assignments to monitor and facilitate usage of the tool by participating healthcare providers.

The VC will be assigned a single VC ID and generic password for use by VC staff. This information will also be loaded into the access control for the application and will not require CC user administration.

5.3 PASSWORD POLICY

To encourage use by healthcare providers, the password policy will be simplified: strong passwords will not be enforced (e.g. use of upper/lower case and special characters/numbers), passwords will not expire, and users will not be locked out on failed attempts.

5.4 DEACTIVATION

For Version 1, the VC will call the NCS Support Desk if they want to deactivate a healthcare provider or change the VC password. The CC will deactivate/change VC passwords behind the scenes.

5.5 SPECIFICITY

The address matching algorithm will include:

- Exact match on house number
- Intelligent match on street name (narrowed by exact 5-digit zip code)

5.6 DATA LOAD AND REFRESHMENT

The data will be loaded from the SMS and will include both released segments (and updates to listing identified during enumeration) and unreleased segments (based on quality reviewed listing data). The data will be refreshed monthly.

5.7 MESSAGES

Welcome Message: Welcome to the National Children's Study Address Lookup Tool. Please type in your patient's street address, city, state and zip code. The address should be the location where she is currently living. This tool will match her address to the NCS database to determine if she is potentially eligible to participate in the NCS.

Other Messages: - See 3.4 above.

5.8 MATERIALS

The CC will provide:

- NCS Address Lookup Quick Start Guide for healthcare providers, including any general guidance, such as which address should be entered into the tool.
- NCS Address Lookup Quick Start Guide for VCs, including guidelines on interpreting both matching and no-match results and implications of segment release.
- A field memo that outlines procedures for researching address matches in the SMS and instructions for moving forward with data collection under a number of potential scenarios based on the current status of data collection at the dwelling unit.

5.9 USER SUPPORT

VCs will train their healthcare providers and provide first tier user support for their providers.

5.10 REPORTS

Reports will be developed to support VCs in monitoring usage by individual healthcare providers and overall. Version 1 will include:

- General website usage reports
- Usage by provider ID (PO/CC level for all, VC level for their assigned IDs)

5.11 ACCESS AGREEMENTS

The Program Office has drafted a template letter (Appendix B) to healthcare providers explaining our interest in their data and a request for their help. It also explains appropriate use of the NCS Address Lookup Tool and the information it provides.

The letter will be prepared on VC letterhead, signed by the VC PI, and administered by VC healthcare provider liaisons. Once countersigned by the healthcare provider, the letter of agreement will be tracked and retained by the VC, in accordance with local procedures for handling the HIPAA agreements.

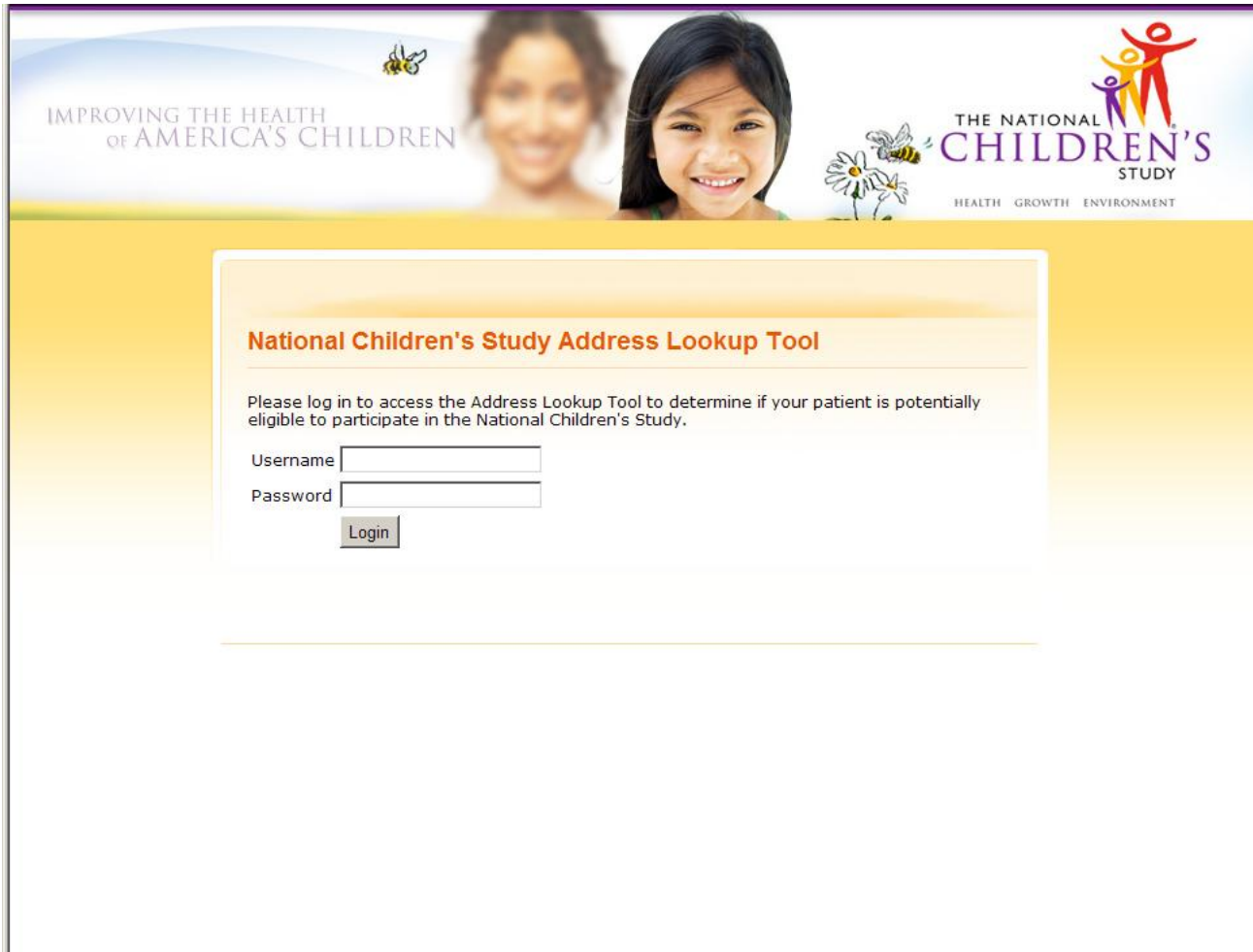
It is up to the VC to administer and track these materials, as well as ensure that healthcare providers do not access the NCS Address Lookup Tool without a signed agreement in place.

5.12 MAIN STUDY CONSIDERATIONS:

Healthcare providers may be associated with more than one PSU/VC. Matching shouldn't be a problem but reports could be an issue with a single provider ID. Note: Per HIPAA regulation patients are entitled to a list of disclosures made by the provider. We may receive a request from a Study Center to make these reports using our electronic system


APPENDIX A

Draft Screen Shots



The image shows a login screen for the National Children's Study Address Lookup Tool. At the top, there is a banner with the text "IMPROVING THE HEALTH OF AMERICA'S CHILDREN" on the left and "THE NATIONAL CHILDREN'S STUDY" on the right, with the tagline "HEALTH GROWTH ENVIRONMENT" below it. The banner also features a logo of three stylized figures in red, yellow, and purple, and a small bee icon. Below the banner is a yellow gradient background. In the center, there is a white box with a light orange header that reads "National Children's Study Address Lookup Tool". Below the header, there is a paragraph of text: "Please log in to access the Address Lookup Tool to determine if your patient is potentially eligible to participate in the National Children's Study." Below this text are two input fields: "Username" and "Password". Below the "Password" field is a "Login" button.

Healthcare Provider Login Screen



[Home](#)

[Logout](#)

Search

Welcome to the National Children's Study (NCS) Address Lookup Tool. Please type in your patient's street address, apartment number (if applicable), city, state and zip code. The address should be the location where she is currently living. This tool will match her address to the NCS database to determine if she is potentially eligible to participate in the NCS.

Street Number*

Street Name* Type

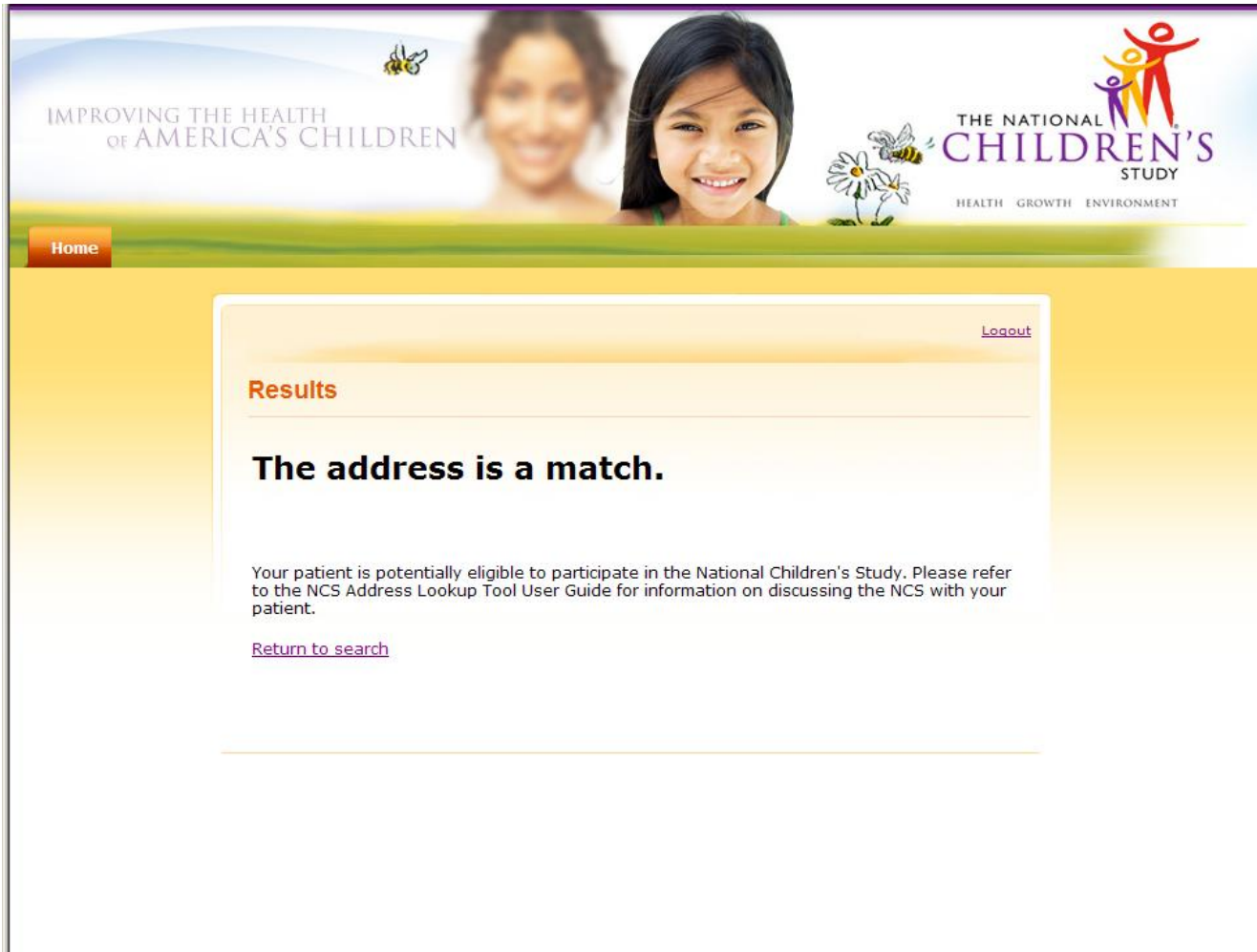
Apt/Unit

City

State Zip*

* Required Field

Healthcare Provider Address Lookup Screen



Address Match Successful Screen



Unsuccessful Address Match Screen

Appendix B
Draft Healthcare Provider Agreement Letter

[Study Center Letterhead]

Assisting the National Children's Study in **[Study Location]**
with Patient Eligibility Information

Dear Health Care Provider and Staff,

I am writing to you to ask for your help in determining possible eligibility of your patients for the National Children's Study (NCS). The NCS is an observational study that will help us understand the ways in which genes and environment affect children's health over time. It is supported by the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), and the Centers for Disease Control (CDC). The purpose of this Study is to better understand childhood asthma, allergies, autism and diabetes, among many other conditions.

We are now recruiting participants for this study, and we need your help in identifying women among your patients who may be eligible to join. We have developed a secure, web-based system that allows a provider to determine possible eligibility simply by entering a patient's address and receive a yes (eligible) or no (not eligible) response. Should a patient be identified as possibly eligible to join, we ask that you share that patient's name and address with us at the **phone number below**. Our staff will then contact that person and ask them to join the Study.

The attached sheet describes the Lookup tool procedures and guidance for physician offices with respect to HIPAA requirements. Participation is voluntary and data are kept confidential. *These activities do not constitute engagement in human subject research and do not require additional IRB review beyond approval already provided by [Study Center IRB] and the National Institute of Child Health and Human Development IRB.*

[Insert language describing incentives to be offered to health providers for assisting the study in this way. Incentives can be varied across Study Centers, but should not be tied to the rate of their success in identifying eligible patients.]

We need your help to support recruitment for this important study. If you agree to help, we ask you to **sign below and mail/fax the form to me**.

Thank you for your help with the National Children's Study. If you have any questions, please don't hesitate to contact me.

Sincerely,

[Study Center Principal Investigator signature block]

I agree to help identify female patients who may be eligible to join the NCS. I agree to keep this information confidential and to use the information only for the intended scientific purpose.

Signed: _____ Print Name: _____ Date: _____

Please fax this signed agreement to **[insert contact address]**.

If a patient may be eligible, please call: [NCS Study Center Contact Name and Phone Number]