Boys Town National Research Hospital

HUMAN RESEARCH SUBJECTS CORE (HRSC)

THE QUERY PROGRAM USER'S GUIDE

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INTRODUCTION

The Human Research Subjects Core (HRSC) Query program is a powerful tool in the recruitment of human subjects. The program provides access to a large centralized pool of children and adult volunteers with normal hearing and/or a hearing loss. Some volunteers with hearing loss also have cochlear implants. Eligible volunteers are identified using a wide variety of search parameters including age, gender, hearing status, as well as a number of audiological test results obtained in routine evaluations. It is also possible to query specific degrees and configurations of hearing loss.

In addition to helping researchers recruit human subjects for current projects, the Query database can also be used to determine the number of potential volunteers for future projects. The Human Research Subjects Core also helps researchers by providing information necessary to fulfill NIH requirements related to the recruitment of human subjects.

OVERVIEW

To access the HRSC Query program, the user must have an approved IRB protocol and CITI* certification. The user may then search for potential research subjects based on general and/or specific parameters relating to demographics and hearing status. Once the search parameters have been defined, the program queries the database for those volunteers matching the specified parameters. If the number of resulting volunteers is too small or too large, the search parameters may be revised and the database queried again. The search parameters may also be saved for future use. The user may scroll through the demographic and audiometric information of each volunteer and select those individuals for whom he or she would like to receive contact information. The contact information for selected volunteers is available immediately and is automatically saved for future reference.

*Collaborative IRB Training Initiative, a course in the protection of human research subjects.

LIMITATIONS

It is the policy of the Human Research Subjects Core to enter volunteers into the database once complete demographic information has been obtained (i.e., name, address, phone, and date of birth). All other information may be absent. For that reason, it is important for the user to remember that queries may result in fewer matches until complete audiometric and cochlear implant data can be obtained for more volunteers.

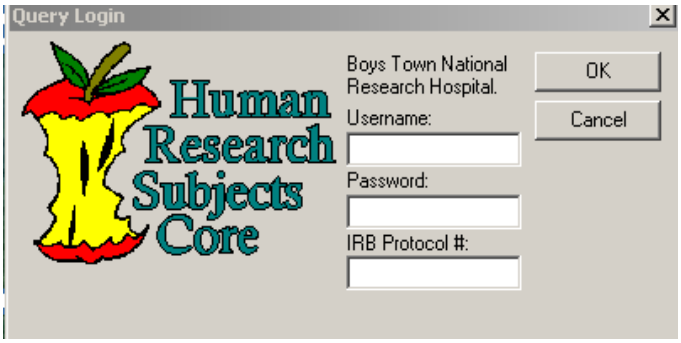
The audiometric and cochlear implant data in the HRSC database are provided to help researchers locate potential volunteers only. Because the quality of the data cannot be assured (e.g. data originate from various internal and external sources), researchers wishing to conduct retrospective studies are advised to use the BTNRH medical records once the appropriate IRB approval has been obtained.

SETUP

To obtain access to the HRSC Query program, the user must first contact the HRSC Coordinator to open a user account based on his or her network username. The coordinator will then set up a database account for the user and send a request to the Computing Department for access to the required files. The user should receive a setup program via e-mail from the Computing Department within 24 hours. The setup program should be copied to the desktop and run. The HRSC icon will appear after the necessary drivers have been installed.

LOGGING ON

To open the program, click on the HRSC icon and enter the username, password, and IRB protocol number in the appropriate fields of the login screen.



Username

The user name required for the HRSC query program is the same as that used to log on to the BTNRH network.

Password

The password for a new user is determined at the first log in. Leave the password field blank to select and verify a new password. The password is case sensitive. To change a password at any time, select the Change Password function under the Tools command.

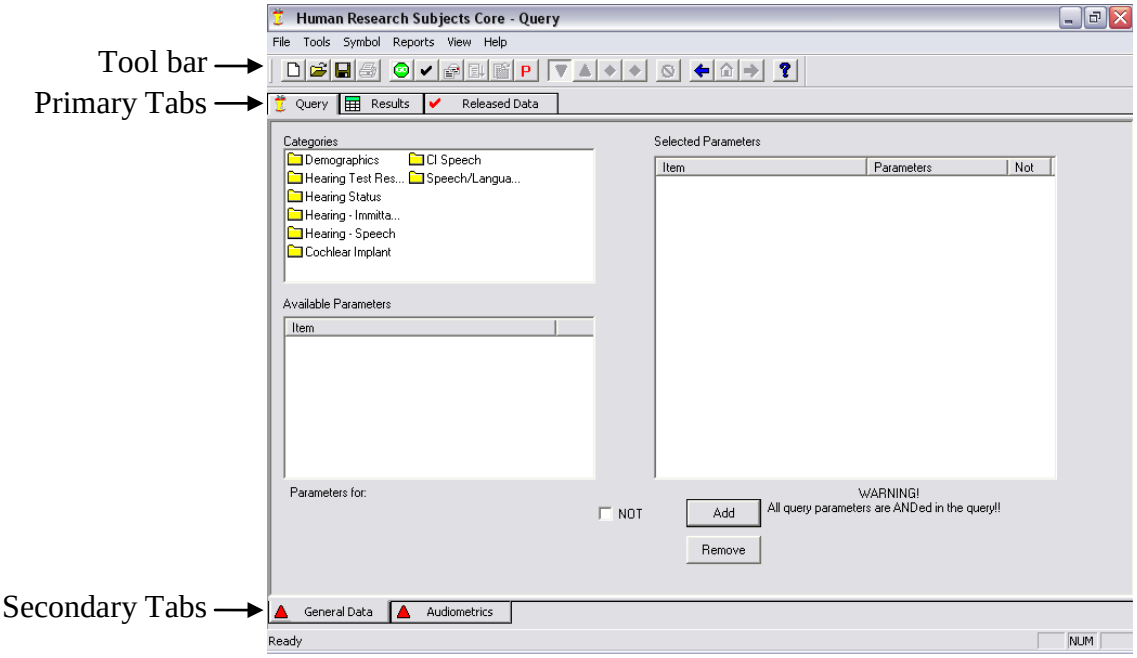
Users with current Phone Man and Hearing Aid Tracker accounts are not considered new users. The password for these programs and the HRSC Query program are the same. If the password is changed in one program it is changed for all three programs.

IRB Protocol Number

An IRB protocol number is mandatory. The number is entered with the hyphen (e.g., 03-04) and can be found on the IRB approved consent form. The IRB number is confirmed during the log-on procedure, along with CITI certification. Once inside the program, the user has access to all program features. Users with multiple IRB protocols are advised to search for volunteers using separate queries for each protocol. This will ensure that the user receives accurate reports from the HRSC office regarding subject recruitment for use in NIH and IRB reports.

PROGRAM FEATURES

The HRSC Query program has three main sections: **Query**, **Results** and **Released Data**. These sections are designated by the primary tabs located just below the tool bar. Each of these sections has a number of subsections that are accessed by secondary tabs located at the bottom of the screen.

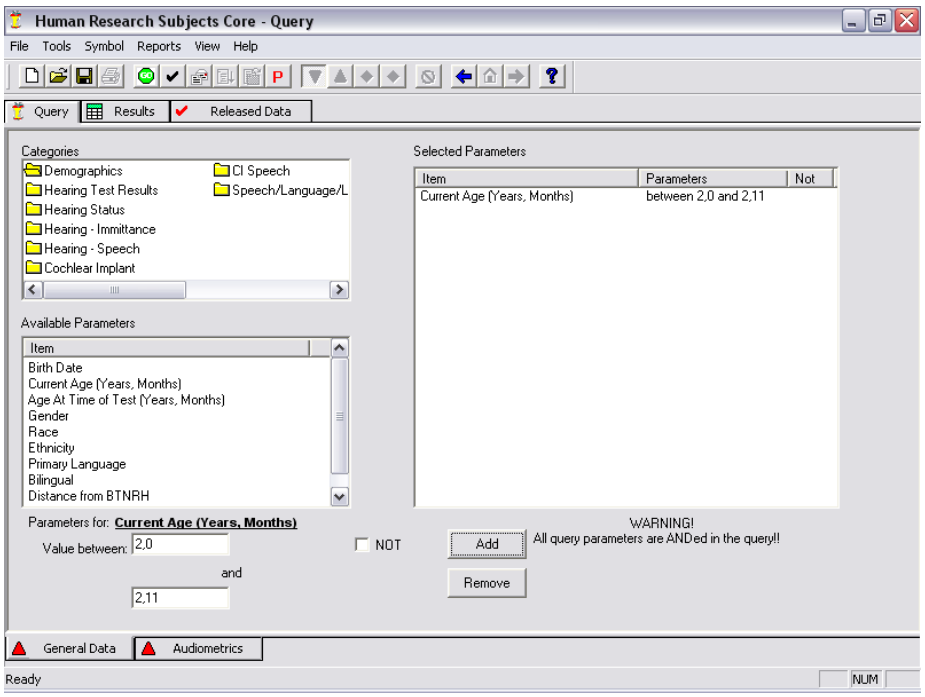


Query

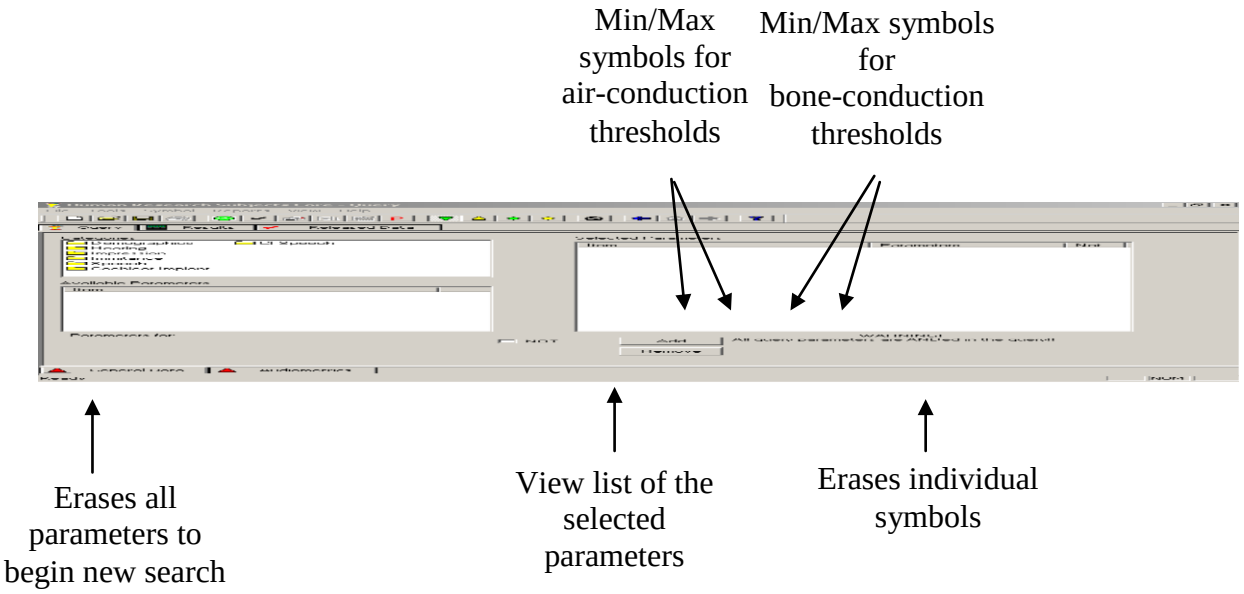
The Query tab contains the data fields used to select search parameters. The first page contains several categories of specific search parameters. Specific audiometric thresholds may be defined on the second page. These pages may be accessed using the secondary tabs at the bottom of the screen. Both general data and audiometric data can be queried using the secondary tabs. The demographic information is obtained directly from the volunteer and is kept current by the Core Coordinator. The audiometric data are obtained from either clinical records with signed permission from the volunteer or from participating in a prior research study. Cochlear Implant data are obtained from clinical records with signed permission from the volunteer. Speech/Language/Learning data are obtained from volunteers only through participation in a research study. To obtain the most volunteers possible, it is recommended that query searches begin by using as broad as selections as possible, such as the volunteer's current age range and impression of hearing. When searching for volunteers with specific audiometric or cochlear implant data the user is advised that this information may be limited. For example, a volunteer's hearing may not have been tested at all frequency levels.

Categories. Search parameters are divided into the following categories: Demographics, Hearing Test Results, Hearing Status, Hearing- Immittance, Hearing-Speech, Cochlear Implant, CI Speech and Speech, Language, Learning, Miscellaneous. Each category has a subset of available parameters, which appear when a category is selected. For a detailed description of the available query parameters, see Appendix B.

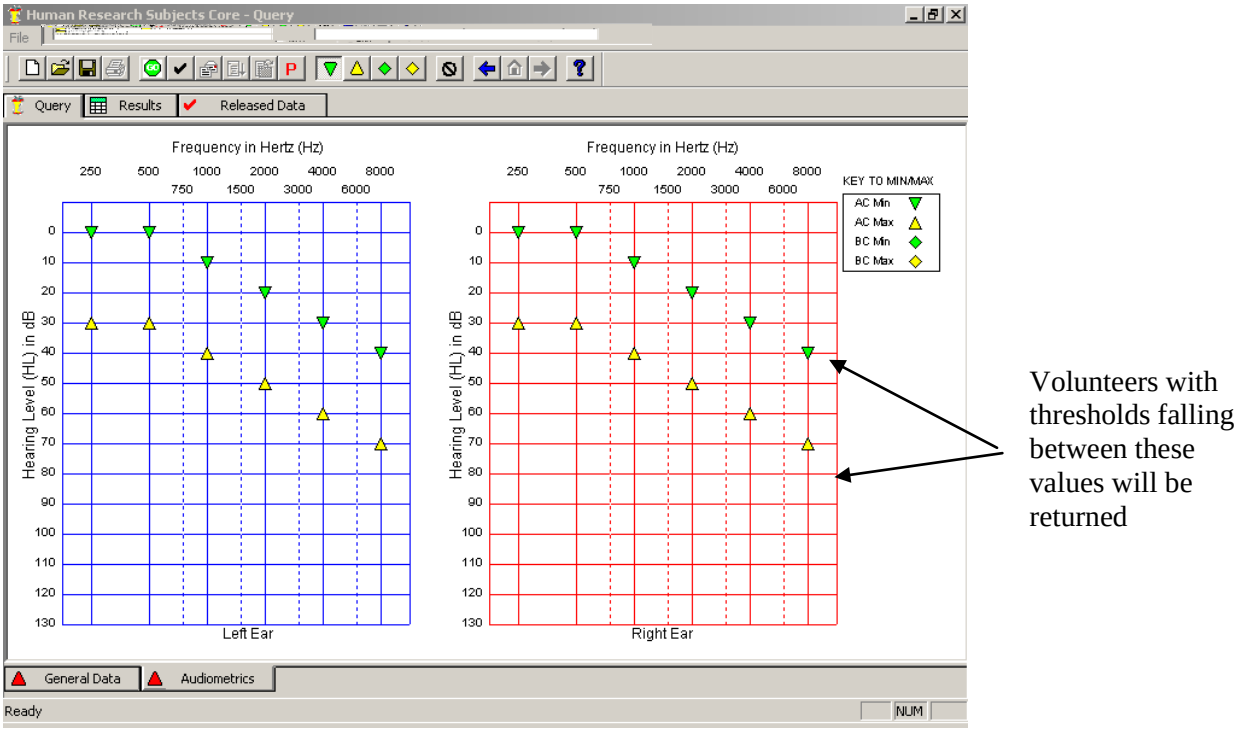
- All searches are **AND** specific, meaning that matches will result only when a subject has data in all fields selected. However, selecting the **NOT** box will search for the subjects that are Not Equal or Not Between the indicated parameters.
- Items can be modified using the Add and Remove buttons at the bottom of the screen.
- The parameters of each item selected for a query are shown on the right-hand side of the Query window.



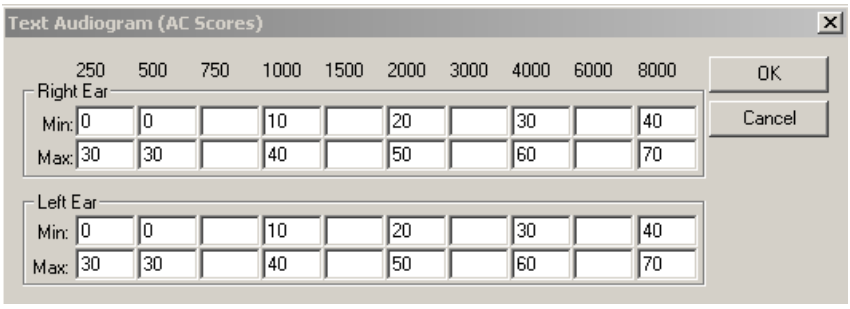
Audiometrics. Specific configurations of hearing loss may be defined using the features under the Audiometrics tab. This page allows the user to define the minimum and maximum allowable threshold levels at one or more frequencies for the right and/or left ears. The min/max buttons for both air and bone conduction thresholds may be selected from the tool bar.



Minimum and maximum threshold values are defined by clicking on either the right or left ear audiogram at the desired frequency and hearing level. Thresholds exceeding the limits of the audiometric test equipment may be included in the search parameters by placing the maximum symbols at 130 dB HL.

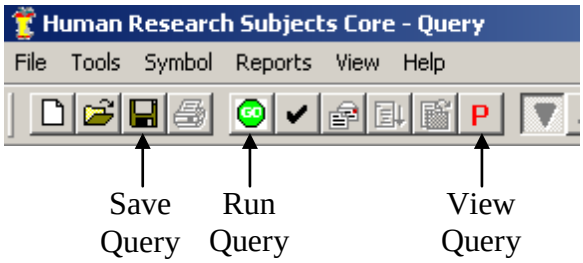


Minimum and maximum air-conduction thresholds may also be defined using the Text Audiogram window. This window is obtained by right-clicking anywhere in the Audiometrics window. Thresholds entered and modified using this window, apply to air-conduction thresholds only.

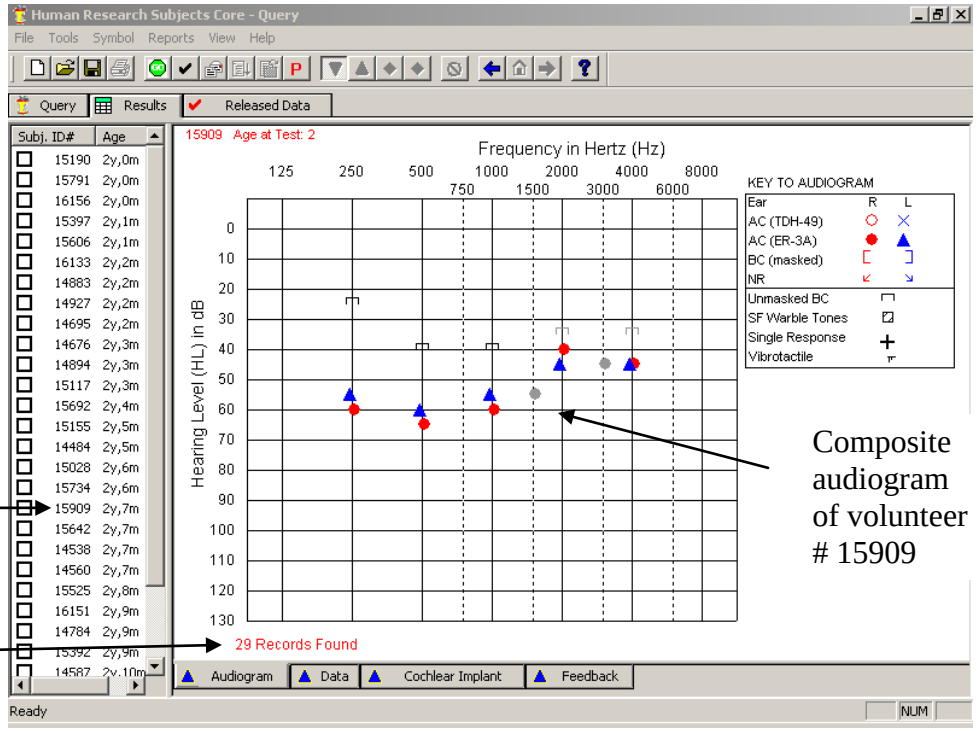


Results

Once the parameters have been defined, the query is run by selecting the **Go** button on the tool bar. The parameters of a query may then be viewed by selecting the red P on the tool bar. The user may also save the parameters of a search by selecting the save button on the tool bar. Parameters are saved as *.qry files.



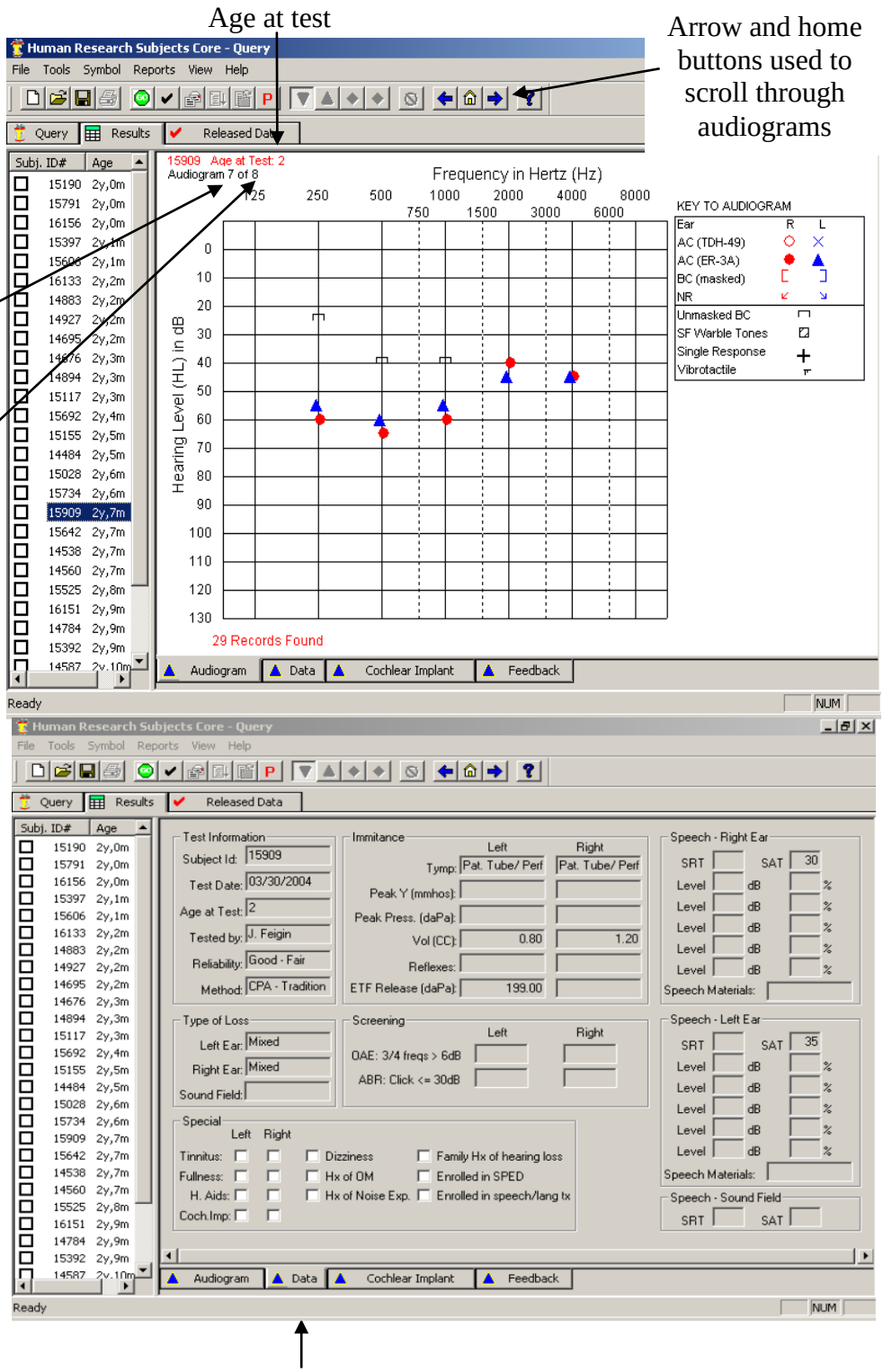
The results of the query may be viewed under the primary tab: **Results**. The secondary tabs include Audiogram, Data, Cochlear Implant, and Feedback. The first page under Results shows a unique identification number and current age of each volunteer meeting the search criteria in the left-hand window. The volunteers are listed according to age from youngest to oldest. An apple symbol next to an identification number indicates that the volunteer's contact information has been released via another query. The contact information is still available, but the volunteer may also be involved in another study.



The most recent audiogram for each volunteer is displayed in the right-hand window. If thresholds are not present at each frequency, they are obtained from previous audiograms (as available) starting with the most recent. These composite audiograms are particularly useful for viewing the audiograms of young children. Red and blue symbols represent current thresholds and gray symbols represent composite thresholds.

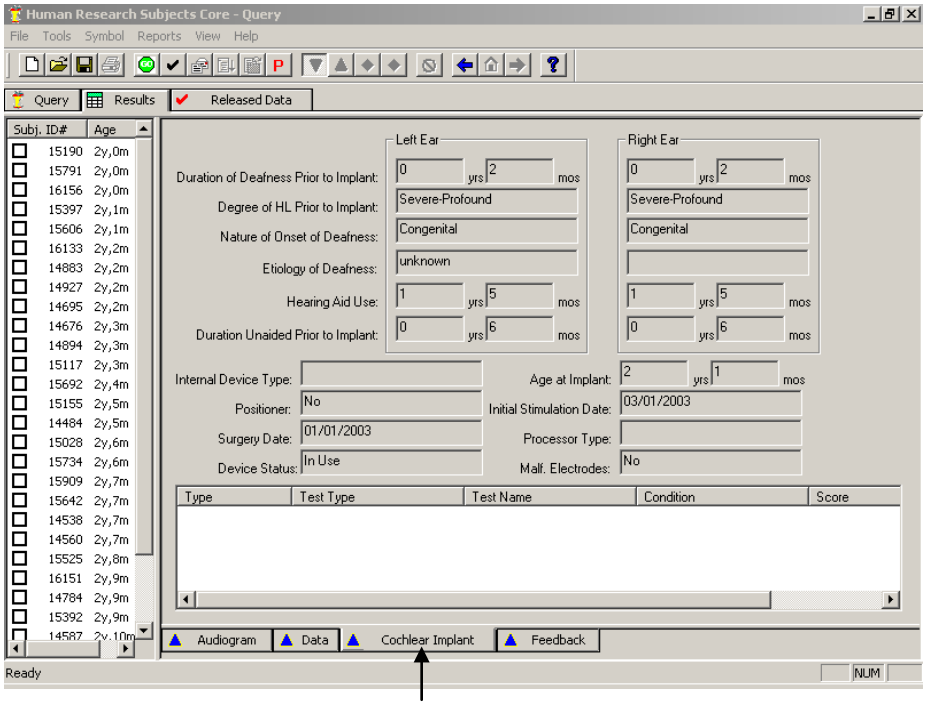
The total number of volunteers meeting the defined parameters is also displayed in the lower left-hand corner. Note: The program stops searching once it has reached 500 matches.

Viewing Audiometric History. Previous audiograms for a volunteer can be viewed by selecting the left facing arrow on the tool bar. The number of previous audiograms is displayed as well as the age at the time of each test. The user can scroll through serial audiograms using the right and left arrow keys on the tool bar. The audiograms are chronologically ordered. The home button brings the user back to the composite audiogram.

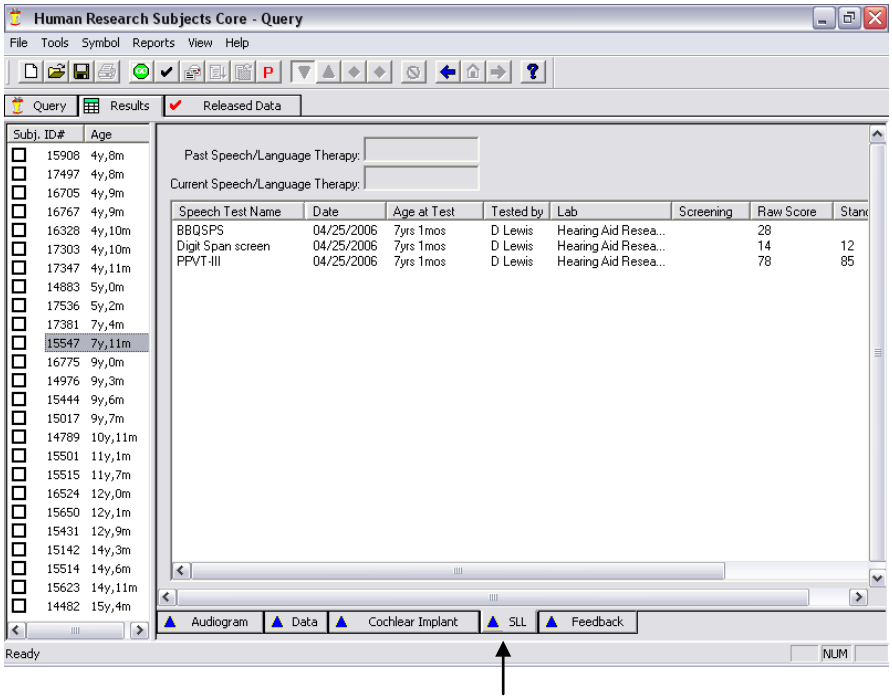


Additional audiometric information may be viewed for each volunteer under the secondary tab **Data**. The user may also scroll through previous tests using the left and right arrow keys on the tool bar.

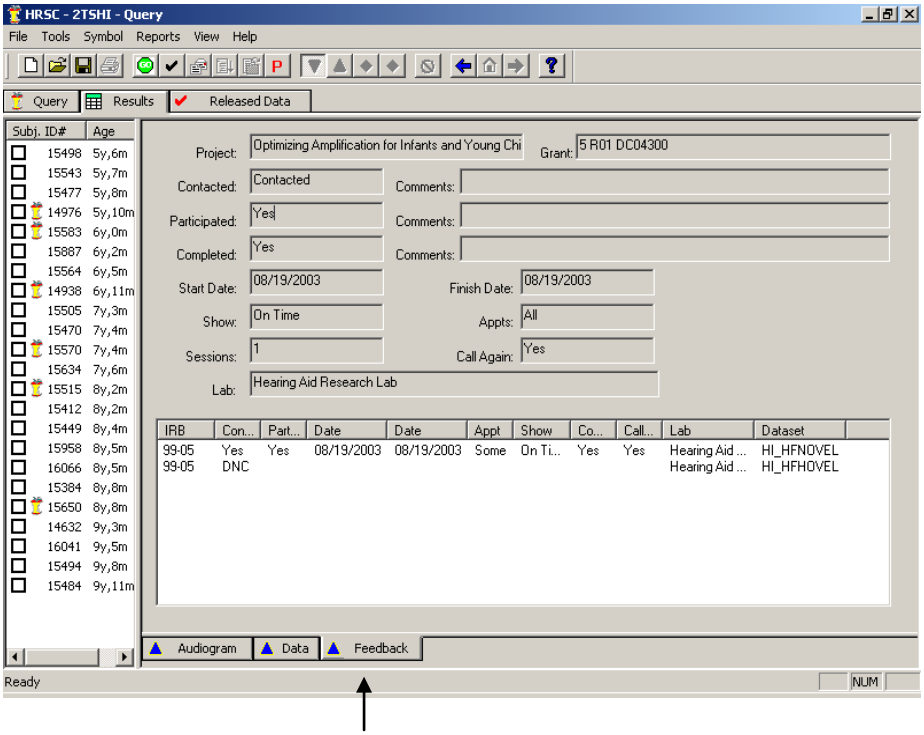
Viewing Cochlear Implant Data. Cochlear Implant data may be viewed for each volunteer under the Cochlear Implant secondary tab.



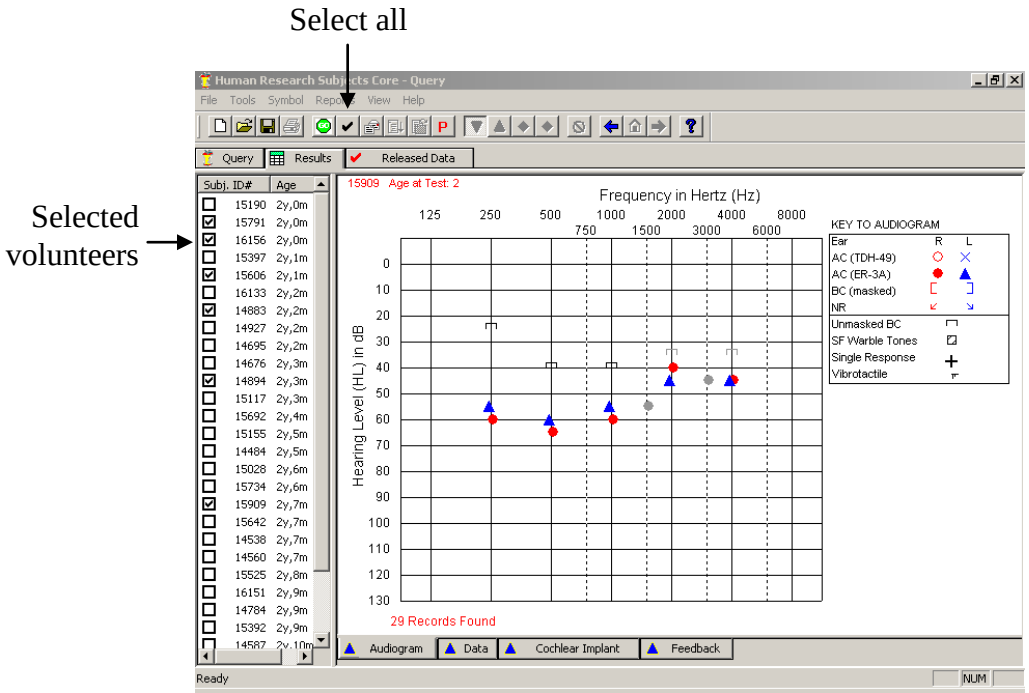
Viewing Speech, Language, Learning Data. If a subject has participated in a study and Speech, Language and Learning test scores were obtained those data may be viewed under the S/L/L secondary tab.



Viewing Feedback History. If a subject has participated in a previous study, data regarding his/her participation is available to view under the secondary tab: **Feedback**. This information is used so that investigators can make informed decisions regarding subject recruitment prior to the request of contact information.



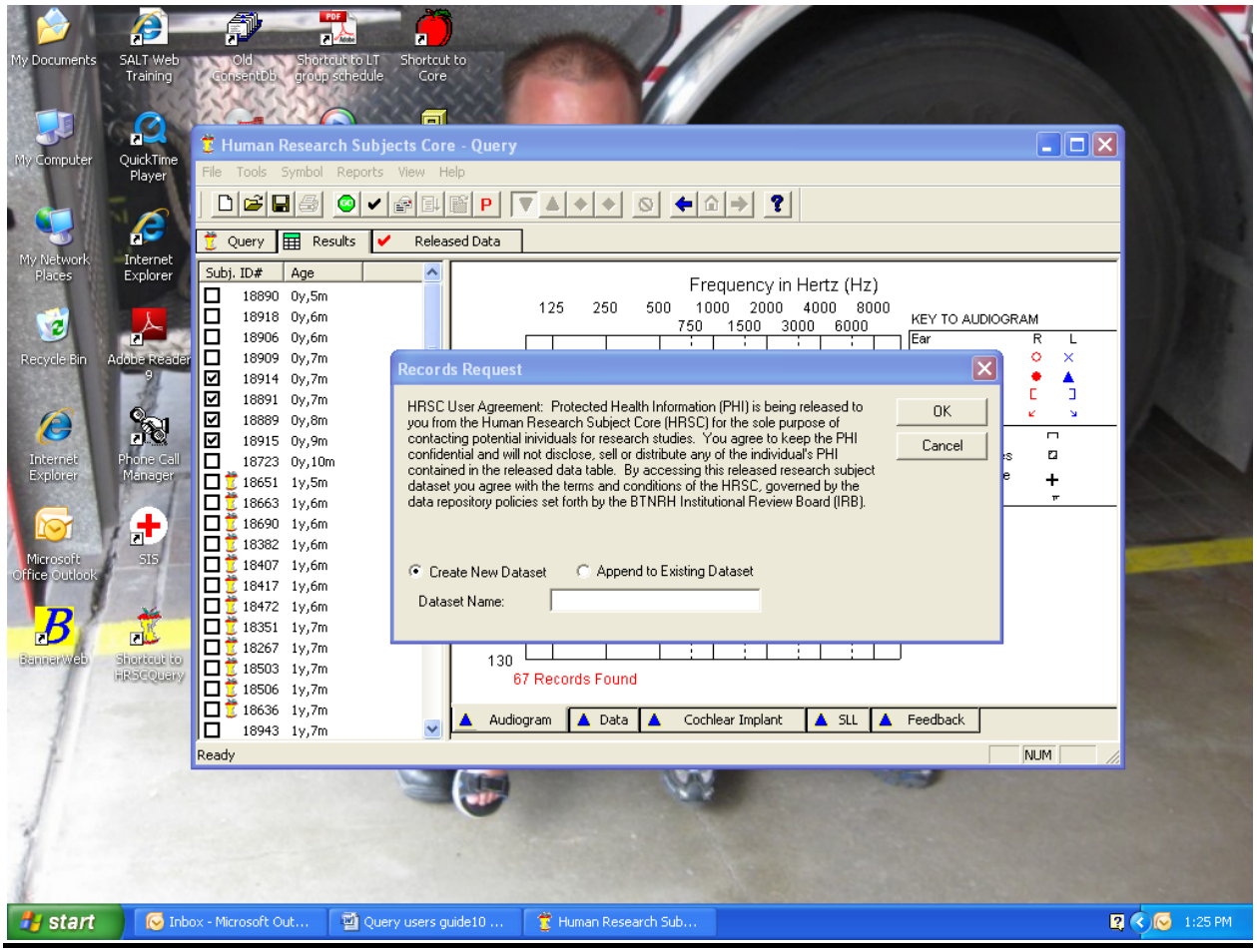
Selecting Potential Volunteers. Contact information for any or all of the volunteers meeting the search criteria can be requested by clicking the box to the left of each identification number. The checkmark button on the tool bar will select all of the volunteers in the list.



Obtaining Contact Information. Contact information for selected volunteers is released to the user with the Submit Request button on the tool bar. Two options will appear, a**) to create a new dataset name or b) to append to an existing dataset.** If append is selected a drop down field will appear and the existing dataset can be selected. The new search volunteers will be added to that dataset. Duplicate volunteers will not be added.

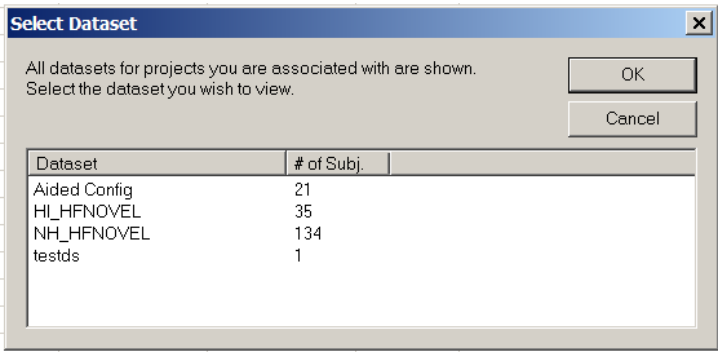
Submit Request

The program will prompt the user to name the dataset. It is suggested that the filename reflect the study in which the volunteers may participate. The saved file contains the query parameters and contact information that may be accessed by the user at any time. Summary information regarding subject participation also may be requested by the user for use in NIH and IRB reports.



Once the dataset has been named, the contact information is released to the user immediately. Datasets are saved according to the IRB protocol number and can only be accessed by the user. The program will prompt the user in the event of a duplicate file name.

The user may view the current query results or those of previous queries by selecting the desired dataset from a list of all datasets currently associated with the user's IRB protocol number. The Dataset window is opened by clicking the "New Dataset" button on the tool bar.



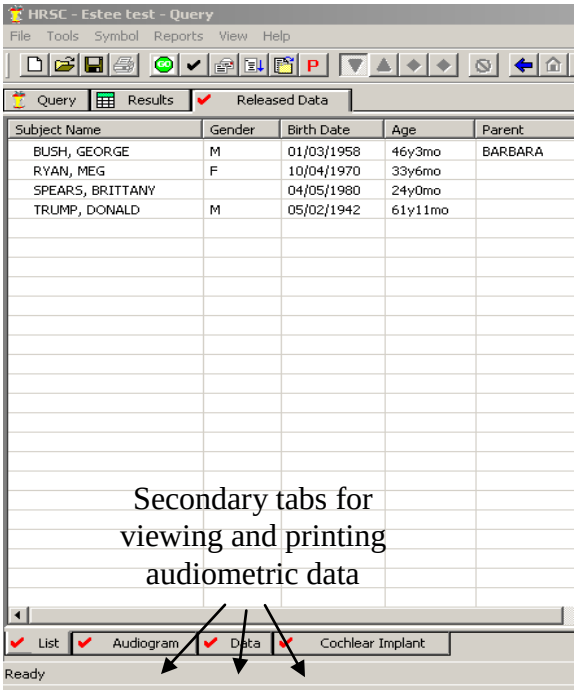
New Dataset

Released Data

Viewing Contact Information. Contact information for selected volunteers may be viewed under the primary tab: **Released Data**. All available contact information for each volunteer is displayed in spreadsheet form.

Fields include:

- Name
- Gender
- Birth date
- Current age
- Parent name (if minor)
- Sibling
- Phone number
- E-mail address
- Street address
- School District
- Preferred method of contact
- Ethnicity
- Primary language
- Pat. Impress (Volunteer's impression of own hearing)
- Hearing screen status (if known)
- Participation (Whether the volunteer has participated in previous studies).
- Availability
- Comments



The secondary tabs at the bottom of the screen allow the user to view the audiograms, other audiometric data, and cochlear implant data for each volunteer. These data are identical to those under the **Results** tab.

Saving Contact Information to a File. The contact information listed under the Released Data tab may be saved to a Comma Delimited File (*.csv). The saved file will contain all contact information as well as the parameters used during the search. The file may then be opened in Microsoft Excel for modification and/or printing.

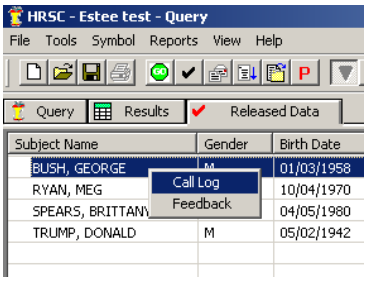
Printing Individual Volunteer Audiogram/Contact Information. A print option is available; however, the user is advised that this information contains the volunteer's Protected Health Information (PHI). It is recommended that the information be printed as a secure document, if possible, and disposed of at the earliest opportunity. The audiogram and contact information for an individual volunteer may be printed by:

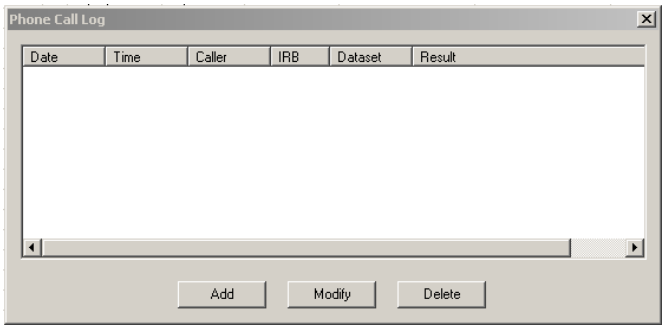
1) highlighting a volunteer under the List tab at the bottom of the screen,
2) viewing the audiogram under the Audiogram tab, and

3) selecting the Printer icon on the tool bar.

The audiogram is printed directly to the default printer. The audiogram shown is a composite of thresholds obtained from the most recent hearing test as well as thresholds obtained from earlier tests if necessary. Since color codes are used, distinguishing between current and composite thresholds will depend on the quality of the printer. Laser printers are recommended. An example of the printed audiogram is given in Appendix C.

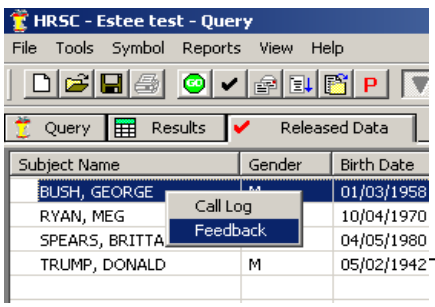
Call Log. The Call Log is designed to help document phone calls made to interested volunteers. To open the Call Log window, highlight the volunteer's name in the Released Data tab, double click, and select Call Log. The call log will display all calls logged for the past 12 months. A small + symbol will appear in the upper left hand corner by the volunteer's name when information is added to the call log from the time the dataset was created. A new contact comment can be added using the Add button. Current information may be modified using the Modify button.

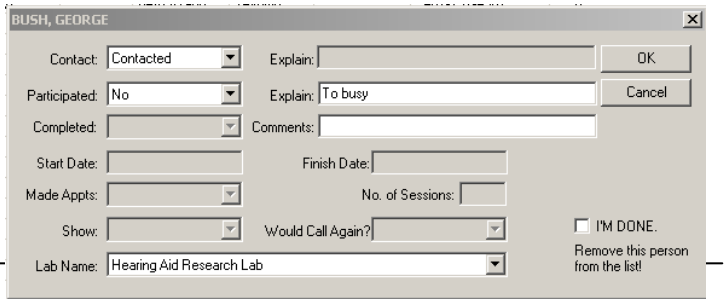




Participation Feedback. Feedback regarding each volunteer's participation is entered under the Released Data tab. This information is used to keep the database as current as possible. For example, the Core Coordinator will follow-up on all volunteers that could not be contacted and update their information if possible. Feedback is also used to provide Principle Investigators with subject participation information necessary for NIH and IRB progress reports. The feedback process also allows researchers to evaluate a volunteer's ability and willingness to participate in a study. This information is also useful so that investigators can make informed decisions regarding subject recruitment prior to the request of contact information.

Feedback may be provided by double or right clicking on a volunteer's name and selecting feedback to open the response window. The user may enter the information requested at any time during the study. Once feedback has been provided for a volunteer, a red check mark appears to the left of the volunteer's name. A description of the information needed to complete the feedback window is given below.





Contact. Was the user able to contact the volunteer? The choices include: 1) Contacted indicating that the user was able to contact the volunteer, 2) Could Not Contact indicating that the user was unable to contact the volunteer, and 3) Did Not Contact indicating that the user chose not to contact the volunteer.

Participated. Did the volunteer participate in a study? Yes or No.

Explain. The upper and lower Explain fields correspond to the Contact and Participated fields on the left. An explanation is required in the upper field if the volunteer could not be contacted (e.g., disconnected or incorrect phone number). No comment is necessary if the user chose not to contact the volunteer. A comment also is required in the lower Explain field if the volunteer was contacted but did not participate in a study (e.g. not interested at this time). This information is used to update contact information and determine the status of volunteers in the database.

Start Date and Finish Date. These fields may contain the same date if testing was completed in one day or a range of dates for longer studies. The date must be entered as MM/DD/YYYY.

Number of Sessions. How many visits were required of the volunteer to complete testing?

Made Appt. Did the volunteer come to all of the scheduled appointments? The choices are: All, Most, Some, and None.

Completed. Was the cooperation of the volunteer satisfactory or unsatisfactory? Unsatisfactory evaluations should be reserved for those volunteers who were uncooperative or disruptive. The HRSC Coordinator will inquire further to determine the future participation of the volunteer.

Would Call Again. Would you ask the volunteer to participate in future studies? Yes or no.

Lab Name. Select the name of the lab from the list provided. If the name of the lab or department is not listed, contact the Core Coordinator. This information only needs to be added once. After feedback has been completed for one volunteer, the lab name will automatically be applied to all other volunteers on the list.

I'm Done. The user may check this box if he or she has no more need for this volunteer's contact information and wishes to return the information to the HRSC Coordinator. Once a name is returned however, it cannot be retrieved. This feature is useful for long lists of names for which feedback is required.

Feedback for each volunteer is returned to the HRSC Coordinator in one of two ways. First, feedback may be returned for individual volunteers by simply placing a checkmark in the "I'm Done" box on the feedback window. This will remove permanently the volunteer's name from the list of volunteers for this user even if new names are added to the dataset during another query. This option is recommended when feedback is necessary for large numbers of volunteers and the user will not need access to the volunteer information in the future.

Second, the user may return the dataset to the HRSC Coordinator when feedback has been completed for all the volunteers by clicking on the Return Dataset button on the tool bar. This

option is recommended for users who wish to refer back to a dataset throughout the course of a study.

Siblings: view column 'sibling' on released data page indicated by yes/no. To view list of siblings double click on name of volunteer. Click the box to have the sibling name added to your dataset list.

Comments: double click on name of the volunteer to view available comments field.

APPENDIX A Step-By-Step Example

This example describes the step-by-step procedures for obtaining a list of potential volunteers between the ages of 20 and 40 years with normal hearing. For an explanation of any step, the reader is referred to the chapter on Program Features, which follows the order of these procedures closely.

Logging On

Enter your username, password, and the IRB protocol number for your project. If you are using the program for the first time, leave the password field blank and the program will prompt you to select one. If you have accounts on Phone Man and/or Hearing Aid Tracker your password will be the same for all three programs.

Setting up the Query

1. On the first screen, select *Demographics* from the categories list, select *Current Age (Years, Months)* from the available parameters list.
2. Enter the minimum and maximum ages of 20 and 40 in the *Values between* fields at the bottom of the screen.
3. Click the *Add* button to add these values to the parameters in the right-hand window.
4. Select *Impression* from the categories list, select *Left Ear* from the available parameters list.
5. Select *Normal* from the drop box at the bottom of the screen.
6. Click the *Add* button to add these values to the parameters in the right-hand window.
7. Select *Impression* from the categories list, select *Right Ear* from the available parameters list.
8. Select *Normal* from the drop box at the bottom of the screen.
9. Click the *Add* button to add these values to the parameters in the right-hand window.

Running the Query

10. Click the green  button on the tool bar. The program will move to the Results tab automatically.
11. The number of matching volunteers will be displayed in the lower left hand corner of the audiogram window. If no matches were found, recheck the parameters and run the query again.
12. Click on the ID number of one of the matching volunteers to view the audiogram.
13. Click the blue  button on the tool bar to scroll through any previous audiograms for this volunteer.
14. Click the Data tab at the bottom of the page to view additional audiometric information.

Requesting Contact Information

15. Click in the box to the left of the ID number for one volunteer. This will place a checkmark in the box and indicate that contact information will be requested for this volunteer.
16. Click on the  Submit Request button on the tool bar to request contact information for this volunteer.
17. When prompted, name the *Dataset Name* "Practice" and click *OK*.

18. The contact information will be released immediately.

Viewing the Contact Information

19. Click on the Released Data tab.
20. A window will appear asking you to choose a dataset. Choose the Practice dataset and click *OK*. If the window does not appear, select New Dataset under the Tools command.
21. One name should appear on the spreadsheet. Scroll to the right to view all the fields.
22. Using the mouse, left-click on the volunteer name.
23. Click on the Audiogram, Data and Cochlear Implant tabs at the bottom of the page to view additional information for this volunteer.
24. Return to the list by selecting the List tab.

Providing Feedback

25. Double-click on the volunteer name to obtain the feedback window.
26. In the *Contact* field, select *Did Not Contact*.
27. In the *Explain* field, type "Practice."
28. Choose your lab name from the drop down list at the bottom of the window and click *OK*.
29. A red checkmark should appear to indicate that feedback has been completed for this volunteer.
30. Return the dataset to the HRSC Coordinator by clicking on the  Return dataset button on the tool bar.
31. Select the New Page button on the tool bar to refresh the program and start a new search if desired.

APPENDIX B Descriptions of Available Query Parameters

Demographics: [1] Available Parameters:

Birth date: enter a range of birth dates to select volunteers who were born during a certain period or who fall within a specific age range. Input is MM/DD/YYYY.

Current age: enter a range of ages to select volunteers who are a currently within a specific age range. Input is Years, Months.

Age at time of test: enter a range of ages to select volunteers who were a specific age or range of ages when they were tested. Input is Years, Months.

Gender: select Male or Female to obtain volunteers of a particular gender.

Race: a specific race may be selected from a list of choices consistent with those appearing in NIH guidelines. The options are: American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian, White, More than one, and Other.

Ethnicity: a specific ethnicity may be selected from a list of choices consistent with those appearing in NIH guidelines. The options are: Hispanic/Latino or Not Hispanic/Latino.

School District: select a specific school district to select volunteers who attend a specific school district. *Caution this information is not available for all student volunteers in the database. [Omaha Public, Home Schooled, Millard Public, Westside, Council Bluffs, Papillion/LaVista, Lincoln, etc…]

Bilingual: select yes, no or unknown to select volunteers who are bilingual.

Primary Language: select from a list of languages to obtain volunteers who consider a specific language their primary language. Primary in this case does not suggest a native language. The options are: English, Spanish, Chinese, Mong, French, German, Italian, Swahili, Japanese, Korean.

Zipcode: Enter a zipcode to select a list of volunteers who live within a certain zip code.

Distance from BTNRH: select the maximum distance a volunteer may live from BTNRH. The options are: 10 miles, 25 miles, 50 miles, or 100 miles.

Availability: the availability of volunteers may be restricted to specific periods if desired. The options are: Workday, Evenings, or Weekends.

Hearing Test Results: Available Parameters:

Test Date: enter a range of test dates to select volunteers who were tested during a certain period. Input is MM/DD/YYYY.

Method: select the method of audiometric testing. The options are: Conventional, Visual Reinforcement Audiometry, Play Audiometry, Computer Play Audiometry, ABR or OAE.

[1] The Boolean operators "AND" and "NOT" are available for all searches and apply to all parameter items. There is currently no "OR" operator.

Reliability: select the reliability of the volunteer during testing. The options are: Good, Good-Fair, Fair-Poor, or Poor.

Left/Right Hearing aid: select None or Present to obtain a list of volunteers who do or do not currently wear a hearing aid in the left/right ear.

Left/Right cochlear implant: select None or Present to obtain a list of volunteers who do or do not currently have a cochlear implant in the left/right ear.

Tinnitus – left ear/ right ear: select Yes or No to obtain a list of volunteers who do or do not complain of tinnitus in their left/right ear.

Fullness – left ear/right ear: select Yes or No to obtain a list of volunteers who do or do not complain of fullness in their left/right ear.

History of OM: select Yes or No to obtain a list of volunteers who do or do not report a history of otitis media in either their right or left ear.

History of noise exposure: select Yes or No to obtain a list of volunteers who do or do not report a history of noise exposure.

Family history of hearing loss: select Yes or No to obtain a list of volunteers who do or do not report a history of hearing loss in the family.

Dizziness: select Yes or No to obtain a list of volunteers who do or do not complain of dizziness.

Enrolled in SPED: select Yes or No to obtain a list of volunteers who are or are not currently enrolled in special education.

Enrolled in Speech/Language therapy: select Yes or No to obtain a list of volunteers who are or are not currently enrolled in speech/language therapy.

Hearing Status: Available Parameters:

Patient Impression: select the hearing status as indicated by the volunteer. The options are Normal or Hearing Impaired.

Left/Right Ear Impression: select the hearing status of the left/right ear as determined through audiometric testing. The options are: Normal, Conductive, Sensorineural, Mixed, or Undetermined.

Sound Field: select the hearing status of volunteers for which ear-specific information was unavailable, but sound-field testing was completed. The options are Normal or Undetermined.

Screening Impression: select the hearing status of volunteers for which only pure-tone screening information was available. The options are Normal or Hearing Impaired.

Loss Type: select the hearing status as indicated by the volunteer or by previous audiogram results: The options are: Unilateral, Bilateral or Unknown.

Cochlear Implant: select Yes or No.

Bilateral Cochlear Implant: select Any, None, Sequential, Simultaneous

Hearing Immittance: Available Parameters:

Status-left/right ear: select the middle ear status of the left/right ear as determined using clinical tympanometric measures. The options are: Normal, Abnormal, Patulous Tube/Perforation.

Peak Y- right/left ear: select a range of values between 0 and 10 mmhos indicating the amount of sound pressure admitted into the middle ear.

Peak Pressure-right/left ear: select a range of values between –200 and 800 daPa to estimate the amount of pressure in the middle.

Acoustic Reflexes: right/left ear: select Present or Absent to obtain volunteers with normal or abnormal middle ear reflex responses in the right/left ear.

Ear Canal Volume: left/right ear: select a range of values between 0 and 10 cm3 to estimate the volume of air in front of the immittance probe tip.

ETF Release left/right: select a range of values between 0 and 100 daPa to estimate the middle-ear pressure at which the Eustachian tube opens.

OAE right/left: select Pass or Fail for those volunteers (typically infants) given an OAE screening. Pass = OAE's for 3 out of 4 frequencies (2,3,4, & 6 kHz) with a SNR > 6dB.

ABR right/left: select Pass or Fail for those volunteers (typically infants) given an ABR screening. Pass = click evoked responses <= 30 dB nHL at selected frequencies.

Hearing Speech: Available Parameters:

SRT right/left: select a range of values between -20 and 120 dB HL to obtain volunteers having a certain range of speech reception thresholds.

Speech Scores: select a range of values between 0 and 100 percent to obtain volunteers having a specific range of speech recognition scores.

SAT right/left: select a range of values between -20 and 120 dB HL to obtain volunteers having a certain range of speech awareness thresholds.

Cochlear Implant: Available Parameters:

Duration of Deafness Prior to Implant right/left: enter a range of dates to select volunteers based on the length of time they were deaf prior to receiving a cochlear implant. Input is MM/DD/YYYY.

Degree of Deafness Prior to Implant right/left: select the degree of hearing loss as determined through audiometric testing. The options are: Moderate-Profound, Severe, Severe-Profound, Profound.

Nature of Onset right/left: select the nature of the onset of deafness. The options are: Progressive, Sudden from NH (normal hearing), Sudden from established SNHL (sensorineural hearing loss), Congenital.

Etiology right/left: select the etiology of deafness. The options are Menieres, CMV, Rubella, Otosclerosis, temporal bone fracture (T-bone fx), EVA, Meningitis, Connexin 26.

Length of hearing aid use right/left: enter a range of dates to select volunteers with varied duration of hearing aid use prior to implantation. Input is MM/DD/YYYY.

Duration unaided right/left: enter a range of dates to select volunteers based on the length of time they were unaided prior to implant. Input is MM/DD/YYYY.

Internal device: choose an internal device type to select volunteers based on a specific type of cochlear implant.

Positioner: select Yes or No to obtain a list of volunteers who do or do not have a positioner.

Surgery Date: enter a range of dates to select volunteers whose surgery date occurred during a certain period. Input is MM/DD/YYYY.

Age at Implant: enter a range of dates to select volunteers whose age at implant occurred during a certain period. Input is MM/DD/YYYY.

Initial Stimulation Date: enter a range of dates to select volunteers whose initial stimulation date occurred during a certain period. Input is MM/DD/YYYY.

Processor: choose a speech processor to select volunteers who use a specific type of speech processor.

Cochlear Implant Speech: Available Parameters:

Pre/Post Implant Type: select Pre implant or Post implant as the time interval for speech perception test results.

Test Type: select a category of test type. The options are: Discrimination, Parent Inventory, Phoneme Recognition, Sentence Recognition, Word Identification, Word Recognition.

Test Name: select a test name. The options are: CID Sentences, BKB-SIN, CNC phonemes, CNC words, CUNY Noise, CUNY Quiet, ESP, GASP, HINT-C, HINT Noise, HINT Quiet, PBK, WIPI, CNC, CUNY, HINT, NU-6, W-22. Only one test may be selected.

Score: select a value of scores between 0-100 to obtain volunteers having a certain range of speech scores.

Time Post IS: enter a range in Years, Months post implant to select volunteers whose speech perception testing was completed at a certain time post implantation. Input is Years, Months.

Speech/Language/Learning: Available Parameters:

Current Speech/Language Therapy: select Yes, No or Unknown to obtain volunteers who are known to currently receive speech/language therapy.

Past Speech/Language Therapy: select Yes, No or Unknown to obtain volunteers who are known with past speech/language therapy.

Speech Test Name: select a test name to obtain volunteers with test scores from a specific test. The options are: Test of Auditory Comprehension, MLU, PLS-4, Rosetti, CASL, CELF, Oral Written Language Scales, Digit Span Screen, Speech Intelligibility Measure, Preschool Language Assessment, Test of Problem Solving, MacArthur Communication Development, PPVT-III, Expressive One Word Vocabulary Test, GTFA, GFTA-2, and BBQSPS. Only one test may be selected.

Test Date: enter a range of test dates to select volunteers who were tested during a certain period. Input is MM/DD/YYYY.

Age At Test: enter a range of ages to select volunteers who were a specific age or range of ages when they were tested. Input is Years, Months.

Screening Test: select from options: No, Pass or Fail.

Raw Score: select a value of raw scores between 0-100 to obtain volunteers having a certain range of raw scores.

Standard Score: select a value of standard scores between 0-100 to obtain volunteers having a certain range of standard scores.

Age Equivalent: select a value of age-equivalent scores to obtained volunteers having a certain range of age-equivalent score. Input is Years, Months.

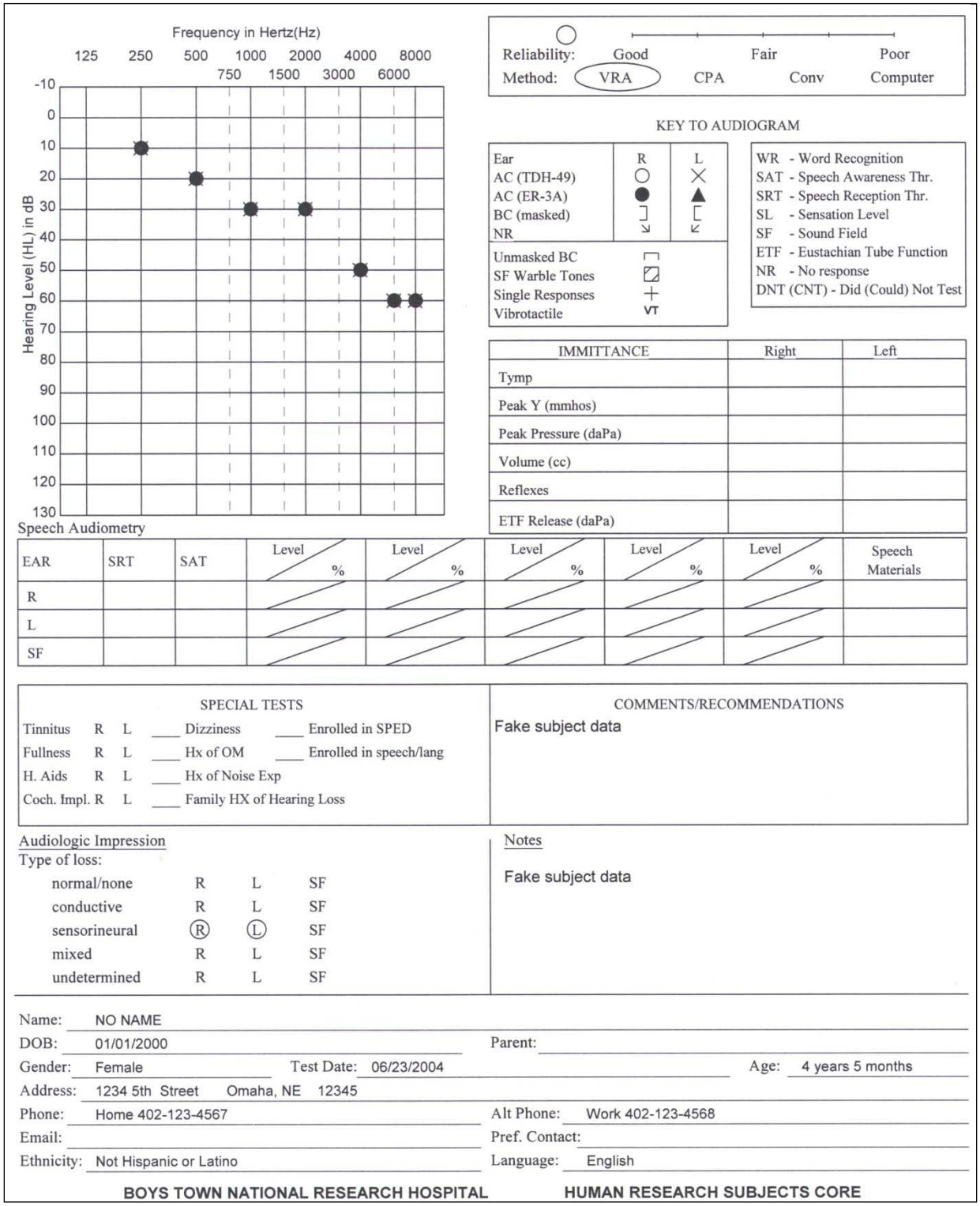
Percentile: select a range of percentile values to obtain volunteers with specific percentile scores on a particular test. Input is 0-100.

Standard Deviation: select a range of standard deviation values to obtain volunteers with specific standard deviations scores on a particular test.

Micellaneous: Available Parameters:

Date subjects added or renewed in database: enter a date range to obtain a list of volunteers who were added or whose information was added or renewed in the database within a certain time frame.
Previous participation in any IRB protocol: select Yes or No to obtain a list of volunteers who have participated in **any** IRB protocol.
Previous participation in IRB # : Select or enter an IRB number to search for volunteers who have previously participated in a specific IRB protocol. Select the [NOT] option to the right to search for volunteers who have NOT participated in a specific IRB protocol.

APPENDIX C Example of Audiogram and Contact Information



APPENDIX D Reports

Reports are designed to provide information for NIH and IRB progress reports. To view information regarding subject data and demographics select *Reports* then *Dataset Info* from the menu bar. The user may view dataset information by selecting (double click) the desired dataset(s) from the list of all datasets currently associated with the user's IRB protocol number. The user may choose the type of report by selecting from the field box on the right, labeled Reports. View the report by selecting Query in the top right corner of the box.

Other reports are possible, but are not developed at this time. Contact the HRSC Coordinator for specific requests.

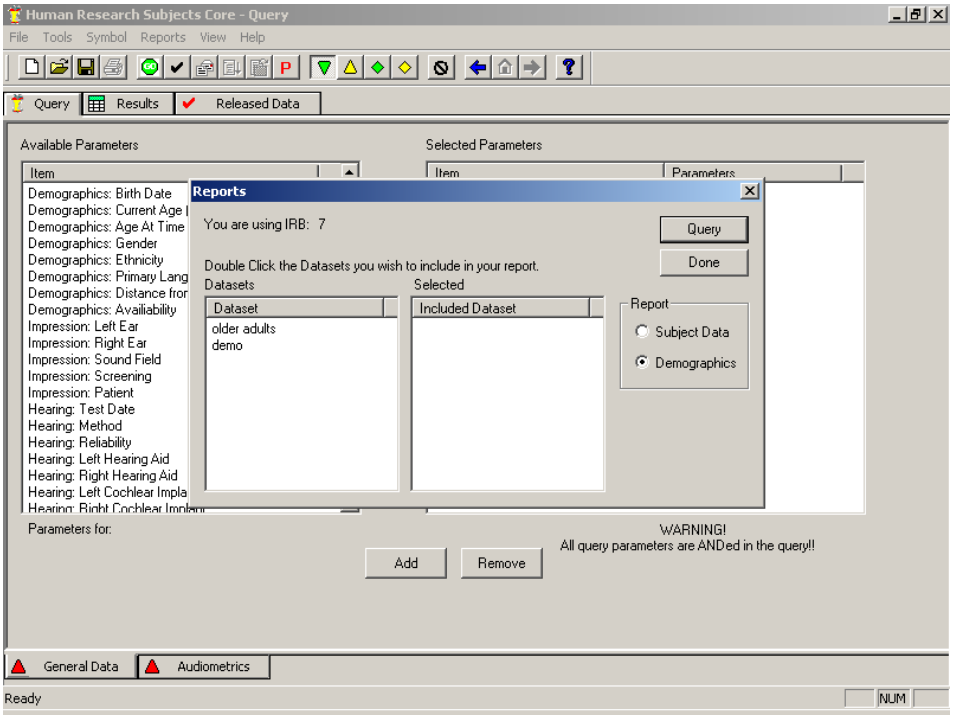
Subject Data:

Report information is given by subject names, age, gender, ethnicity, and the dataset name from which they were selected.

Demographics:

Report information is given on subjects in the database who participated in studies by age, gender and ethnicity. The user has the option to select one or all datasets associated with their IRB protocol number.

Caution: *Only subjects for whom feedback is given will appear on this report.*



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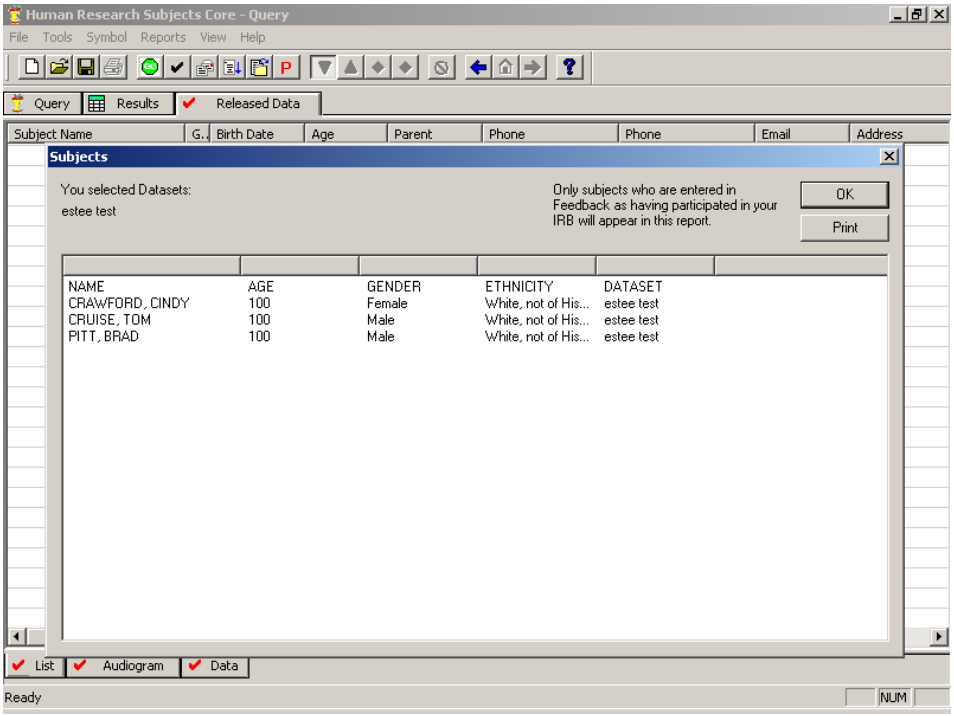
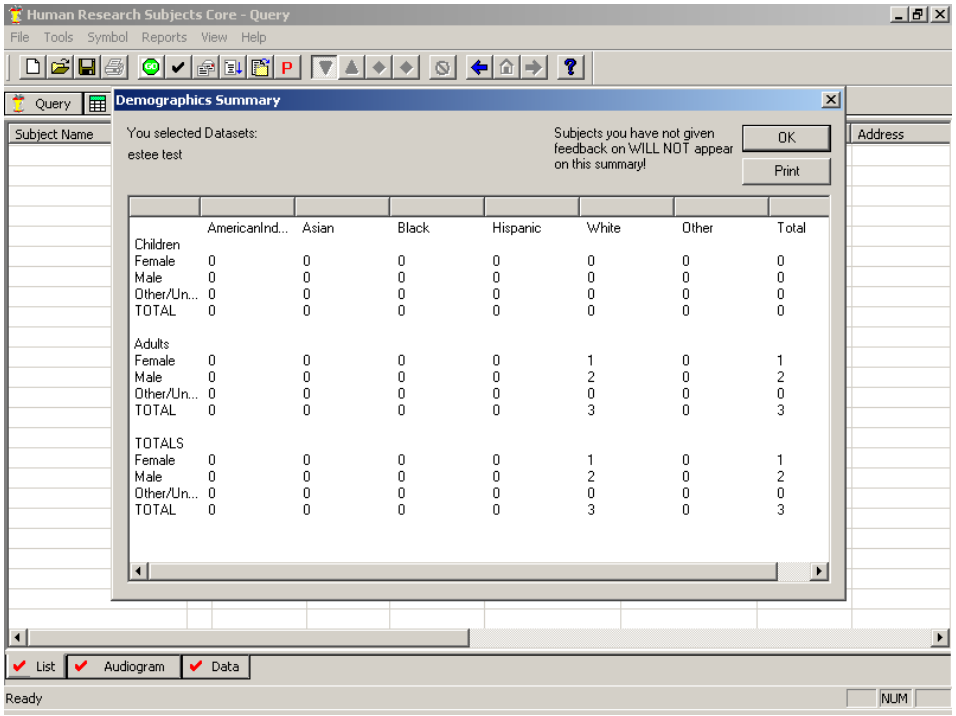


Demographics:



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