

Boys Town National Research Hospital

HUMAN RESEARCH SUBJECTS CORE (HRSC)

Manual for the CORE database

Questions can be sent to:

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1.1 CORE database and Core software:

The CORE database is designed to provide a centralized pool of potential research volunteers for research studies to support the research staff who have IRB approved protocols and/or NIH funding. It is an easy way to extract volunteer contact information while maintaining the volunteer's confidentiality. The CORE database is used to enter the volunteers' data and to create reports concerning volunteers and their participation in research studies.

The volunteers' data are entered in the CORE database via Core software and are extracted through the use of the Query software. At BTNRH, the Coordinator for the Human Research Subjects Core and the System's Administrator are the only individuals with access to both the Core and Query software. Principal investigators, research assistants, and/or other key personnel may access, request and obtain volunteers' contact information through the use of the Query software.

Note: The words "volunteer" and "subject" are often used interchangeably throughout the context of this manual.

1.2 Parts of Core Software:

There are four main parts to the Core software: The Subject Page, the Audiogram Page, the Cochlear Implant (CI) data Page and the Other Page. The Save and the New buttons on the toolbar apply to all pages. Records must be saved to be stored in the database. The disk icon is the save button. The new button clears all data fields and resets the screen for the entry of a new volunteer or to lookup a volunteer.

1.3 The Subject Page: This page is used to enter the volunteer's data or to view a volunteer already in the database. Enter the appropriate data in the data fields obtained from the individual's research database agreement form. The minimum data required include the volunteer's last name, first name, date of birth, phone number, and initial date of consent. To find previously entered volunteer information type the first three letters of the volunteer's last and first name. Or, if known enter the volunteer's subject id number and click on the ? icon on the right of the subject ID field.

Data Fields on the Subject Page (Left Column):

- Subject ID: The volunteer is automatically assigned a unique subject ID number once data is entered. This number can only be referenced and not altered.
- Last Name: Enter the volunteer's last name
- First Name: Enter the volunteer's first name
- Parent: Enter one or both parent's names.
- Gender: Enter the volunteer's gender
- Ethnicity: Enter the volunteer's ethnicity if known. Select Hispanic/Latino, Not Hispanic/Latino or Null
- Race: Enter the volunteer's Race if known. Select from White, Black, Asian, Native Hawaiian, American Indian, More than one or Not Reported
- Birth Date: Enter the volunteer's date of birth by mm, dd, yyyy

- Address: Enter the volunteer's street address.
Note: The “L” Located to the right of the address field. This icon is used to retrieve the previously entered address information. To save time the “L” may be used when entering data for volunteers with the same address.
- City: Enter the volunteer's City
- State: Enter the volunteer's State
- Zip code: Enter the volunteer's Zip code
- Email: Enter the volunteer's email if known.
- Phone: Type: Select from cell, home, pager, work
- Alt phone: Type: Select from cell, home, pager, work.
- Pref Cont: Enter the volunteer's preferred method of being contacted. Select from home phone, work phone, email, U.S. Mail.

Data Fields on the Subject Page (Right Column):

- Primary Language: Enter
- Patient Impression: Enter the volunteer's Hearing Status from the volunteer form. This is what the volunteer perceives his/her hearing status to be. The drop down fields include, Normal Hearing, Hearing Impaired or Cochlear Implant.
- Screening Impression: If the volunteer has been in a research study and had a hearing screen or evaluation then enter the result of the hearing screen/test here.
- Date of Entry: The database automatically generates the current date for this field.
- Last Update: This field is generated automatically once the record is saved.
- Entered By: Enter the initials of person entering data.
- Status: **Active:** the volunteer has signed a database agreement form and agrees to be contacted for research studies.
Inactive: the volunteer has contact information that is no longer valid and should not be considered for contact for research studies.
Withdrawn: the volunteer has either voluntarily withdrawn their consent, or that a researcher has suggested to the HRSC coordinator, that a volunteer should not be contacted for future research studies.
Not available: the volunteer could not be contacted for research and after a letter has been sent new contact information could not be attained.
- Recruitment Method: Select the recruitment method used to add this person to the Core database. To add a new method use Tools/Recruitment enter new method and select Add.
- Date of Initial Consent: Enter the date the volunteer signed the research database agreement form.
- Date of Last DB consent: This field is used to update the volunteer's consent date in the future. It will be the same as the date of initial consent for newly entered volunteers.

- **Current Study:** The database will automatically enter the IRB protocol number for which the volunteer's contact information has been released.
- **Last Participation:** The database will automatically enter the date of the volunteer's last participation in a research study once feedback has been provided.

f.) **Notes:** Any notes added on the volunteer's main page will appear in the "released dataset" report requested by a researcher for contact information.

g.) To find volunteer information by name type the first three letters of the last name and first three letters of the first name and press enter. A list of volunteers will appear. Select correct name from this list.

1.4 The Audiogram Page: This page consists of three tabs located at the bottom of the screen. The first tab is the audiogram graph, the second is audiogram data, and the third is the comments page. The user may view the audiogram(s) of the volunteer by using the arrows on the menu bar.

a.) To enter an audiogram for a volunteer, select the 'Ed' (edit) button on the far right of the toolbar. Enter new threshold data points and other audiometric data and save the record. The audiogram symbols are color-coded. Right ear symbols are red and the left ear symbols are blue. The symbol ledger is on the right, select the appropriate symbols from the toolbar. To enter a no response symbol, select the symbol and then press the shift key.

b.) **Audiogram data:** All test data related to the audiogram can be viewed and entered on this page. The data fields on this page were designed to match the standard Audiogram Data Form used at Boys Town hospital. It is the responsibility of the person entering data to ensure that correct data is entered. Audiogram data can be paged through from this tab by using the left and right arrows on the toolbar. Test Date and Tested by are the minimum data required for this page.

e.) **Comments:** Add any additional relevant data. If the volunteer had an Audiogram completed as part of research study, then a note should be entered to reference the protocol number for which the audiometric data was collected. The comments can also be viewed from all records available. The comments field does not appear with the volunteer's audiogram in the Query program.

1.5 CI Data Page: This page consists of a number of data fields related to the use of cochlear implants. Cochlear Implant data: All test data can be viewed and entered on this page. It is the responsibility of the person entering data to ensure that correct data is entered.

- Duration of Deafness Prior to Implant right/left: enter a range of dates based on the length of time the volunteer was deaf prior to receiving a cochlear implant. Input is Years, Months.
- Degree of Hearing Loss Prior to Implant right/left: enter the degree of hearing loss as determined through audiometric testing.
- Nature of Onset right/left: enter 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 of Deafness right/left: enter the etiology of deafness.
- Length of hearing aid use right/left: enter the duration of hearing aid use prior to implantation. Input is Years, Months.
- Duration unaided prior to implant right/left: enter a range of dates based on the length of time the volunteer was unaided prior to implant. Input is Years, Months.

CI Device: Enter the volunteer's specific device information data using the Add, Edit and Delete buttons to the right of the data box.

Processors: enter the volunteer's specific type of speech processor.

- Ear: Enter ear implanted, either right or left
- Internal device: enter the volunteer's internal device type based on a specific type of cochlear implant.
- Positioner: enter either Yes or No for volunteers who do or do not have a positioner.
- Surgery Date: enter the volunteer's surgery date. Input is MM/DD/YYYY.
- Age at Implant: enter the volunteer's age at implant. Input is Years, Months.
- Surgeon: enter the surgeon's name.
- Hospital: enter the name of the hospital where the surgery was done.
- Initial Stimulation Date: enter the volunteer's initial stimulation. Input is MM/DD/YYYY.
- Device Status: enter the volunteer's device status. Options are Explanted, In-Situ/Non-Use, In-use
- Date of Explant: enter the date of the volunteer's explant (if applicable).

CI Speech

Pre/Post Op: Enter the volunteer's pre/post implant speech perception test data using the Add, Edit and Delete icons to the right of the data boxes.

The fields include:

Conditions: Monaural Left, Monaural Right, Binaural CI, CI + HA

Test Type: enter the volunteer's test type. The options are: Discrimination, Parent Inventory, Phoneme Recognition, Sentence Recognition, Word Identification, Word Recognition.

Test Name: enter the test name.

Score: enter the volunteer's test score.

Time Post-IS: enter the volunteer's age in years and months at the time of post implant speech test.

1.6 Other Page: This page is used to enter the volunteer's availability and to view the volunteer's study participation data.

a.) Enter the volunteer's availability data as indicated from their research volunteer database agreement form. Fields include: long term, short term, workday, evenings, weekends, other. More than one field may be selected.

b.) The volunteer's study participation data is viewed on this page once it has been entered from the **Query** program. Previous study participation information can be viewed on this page by selecting the data from the bottom of screen. This page can also be used to make any necessary updates/changes to the volunteer's participation data.

1.7 Tool Bar Functions: The main uses of the tool bar are Tools and Reports.

Tools:

a) **Users:** To add a new user (e.g., research assistant) as a user of the **Query** software, select tools from the menu bar, then users.

Select "**Add**" from the menu on the right.

The following fields appear:

- **Users Name:** At Boys Town the user name is the user's last name and first initial (Sally Smith's username "smiths"). Any convention may be used.
- **Last Name:** Smith
- **First Name:** Sally
- **CITI training:** Enter the date the user completed CITI training if applicable.

Note: CITI—Collaborative IRB training Initiative, is a course in the protection of human research subjects and is required by all users of the Query program at Boys Town Hospital.

- NIH training: Enter the date the user completed NIH training if applicable.
- Status: Field choices are: Active, Inactive, Active no-password and administrator.
 - Active: This field is for current **Query** program users.
 - Inactive: This field is for past program users.
 - Active no-password: Not applicable. This function was set up specific to Boys Town Hospital programs.
 - Administrator: This field is for people who have access to the **Core** database.

After data is entered select OK.

- **Reset Password Field**: To change a **Query** Users password check reset password.

Users: Modify. The modify field also appears in Users on the menu on the right. Modify is used to reset a User's password in **Query**. To do this select the User's name, then select modify. Check the reset password field then select OK. The next time the User logs into Query the user should leave the password field blank and will be prompted to create a new password.

Users: Delete. The Delete field also appears in Users on the menu on the right. The delete function is currently non applicable.

b.) Change Password: The **Core** database user may change his/her password by using this option and typing in a new password. To change a password for **Query** program users see above b.) Modify.

c.) Recruitment: Select Recruitment and enter the recruitment source in the field "New Method Description" then select Add. A drop down list will be created.

Reports: The **Core** database user(s) have access to the following:

a.) Consent: This field generates a list of volunteers who have a "Date of Last DB consent" date that is 24 or more months past and the volunteers have not been contacted in the last 24 months. "Date of Last DB consent" is a field on the Subject Page under the "Initial Consent Date" field.

At Boys Town, volunteers are sent a letter requesting updated contact information and consent to remain in the database. Also provided in this report is a list of volunteers who turned 19 years of age, these volunteers need to be re-consented as they have reached the state of Nebraska's majority age of 19 years.

b.) Contact: This is a list of volunteers who could not be contacted during their last release in a "dataset". To remove a volunteer's name from this list, go to the "Other" page. Double click on the feedback entry from the list at the bottom of the page. This information should appear in the box titled: Study Participation.

In the contacted filed **change the “CNC” (could not contact) to could not contact-checked**. Select Update to confirm the field change. The volunteer will no longer appear on the “Contact” Report.

c.) Datasets: This report includes a list of dataset names, the IRB #, the date the dataset was released, the number of persons contacted, the number of persons participated in the studies and the status of the dataset (open/close).

Options on this page:

- From: Use this option to select the range of dates in which to view datasets.
- Include open datasets: Select this field and then select the “Query” button on the right. This will provide a list of open datasets only.
- Order by Request Date: Select this field and then select “Query”. This will provide a list of datasets in order of request date.
- Order by IRB: Select this field and then select “Query”. This will provide a list of datasets numerically by the IRB protocol number.
- Close: Select “Close” to close this report.

d.) Demographics: This report provides the breakdown by age and gender for each race and ethnicity category and the overall totals in the database.

e.) Feedback: View feedback results by a specific dataset name or between a range of dates in which the datasets were released.

- Feedback data by dataset: Select the specific dataset and then select Query. The report includes the dataset name, IRB protocol number, the number of subjects for which feedback has been given, the number of subjects released. The list also contains feedback by the subject’s name, if the subject was contacted and if the subject participated.
- Feedback data by Dates: Select the specific range of dates and then select Query. The report includes feedback by the subject’s name, if the subject was contacted and if the subject participated.

f.) Monthly Numbers: This list provides the number of volunteers who were added to the database each month. Data appears in reverse chronological order by year and month and the total number of volunteers.

g.) Numbers: This report provides the overall total number of volunteers in database. To view only active volunteers select the box next to “Active Subjects Only”.

- By Status: Active, Withdrawn, Inactive and Not available
- By Audiograms: Number of children, Number of adults and Total number of persons in the database with audiograms.
- By Age: Children (0 to 18,11) Adults (19,0 to 100)
- By Gender: Female, Male

- By Ethnicity: Hispanic/Latino, Not Hispanic/Latino
- By Race: American Indian, Asian, Black, Native Hawaiian, White, Other, More than One.
- By Impression: As indicated by the volunteer. Cochlear Implant, Hearing Impaired, Normal Hearing
- By Recruitment Method: This lists the number of volunteers per recruitment method from highest to lowest.

h.) Participation:

Participation information may be view by date using the “From” and “To” fields at the top of the report. Enter desired date range and select “Query”.

Fields listed in this report include:

- Datasets: Total number of Datasets, Total number open and total number closed.
- Requests: Stated as, the total number of subjects in N of requests and for the number of different IRB protocols.
- Currently Released Data: Stated as, N subjects in N datasets for N IRB protocols.
- Participation Data: Stated as, N subjects from N datasets for N IRB protocols. Also reported are the number of subjects who participated in 1 or more IRB protocols.
- By Age: Number of children and number of adults
- By Gender: Female and male
- By Ethnicity: Hispanic or Latino, Not Hispanic or Latino, Null
- By Race: American Indian or Alaska Native, Asian, Black or African American, More then one, Not Reported and White.
- With Hearing Loss, by Age: Number of children with hearing loss that participated and the number of adults with hearing loss that participated.

The last line of this report states the number and percent of volunteers who participated out of the total number of volunteers listed in the database.

i.) Old Datasets: This report will pull up the volunteers in the feedback table associated with a dataset. The data can be saved to disk, or reopened in the **Query** for the user to view. Therefore, if a Query program user finds that they need data from an old dataset, they can get that information.