SEARCH MOP - Section 7
Tracking Database System
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7. Tracking Database System

7.1. OVERVIEW

A tracking database system (TDBS) was developed by the Coordinating Center to assist *local* SEARCH centers with case identification and validation. All centers may use this TDBS but are not mandated to. The TDBS will also assist center personnel in assigning Participant Identification (PID) numbers, maintaining Participant information and prompting for Participant communication. Most of this information will remain solely with the local center and not shared with the Coordinating Center. The TDBS is available, via download, from the SEARCH web site. The Coordinating Center will work with each center not using the TDBS to assure that their local database is able to perform key functions, i.e., Participant identification assignment, code restrictions, and download of key registration data. The remainder of this section provides a description of procedures of the TDBS developed by the Coordinating Center.

7.2. ASSIGNING A PARTICIPANT IDENTIFICATION NUMBER

A PID is a consistent identification number that follows the Participant throughout the SEARCH study. The PID is in the form:

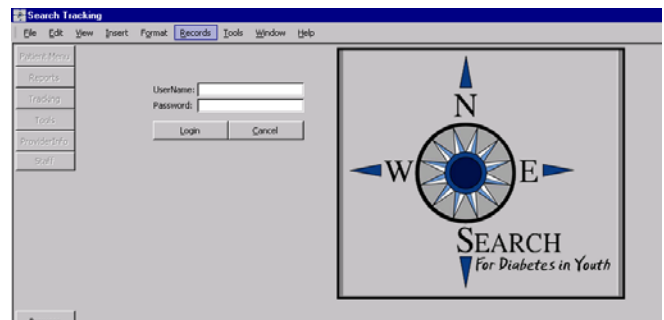| A	B	B		1	2	3	4	5

where A is the site number, BB is the sub-site number, and **12345** is a 5-digit number that references the Participant within the study.

A PID is generated automatically by the TDBS when a center enters a case.

7.3. DIRECTIONS FOR USING SEARCH TDB

7.3.1. *Starting the Database*

- Open the SEARCH TDBS Access database. It will be a file name that resembles the following name: *SearchTrackv04_004.mdb*.

- Upon opening the database, the user will be presented with a log in screen. The user must enter a verified username and password to be able to use the system

- Once login is complete, a series of buttons located on the left side of the screen, will allow the user to navigate through different components of the system

7.3.2. *The Patient Menu*

The Patient Menu contains five tabs: "Pat Info," "Case," "Address," "Phone," "Guardian."

7.3.2.1. Patient Information Tab

- The user (person entering data) can enter personal information about the participant on this page. Participant information held in this field is: name, date of birth, sex, race, social security number, tribe, birth county and state, and mother's maiden name.

The following is a table of fields for the Patient Information Tab:

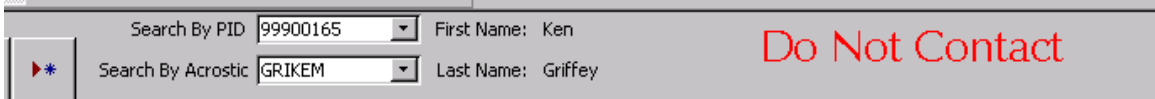| Field	Description	Options
PID	An automated field that will appear when a case is selected.	
Acrostic	An automated field that will appear when a case is selected.	

Field	Description	Options
Patient Name	Text fields are provided to enter the Participant's first, middle, and last name. Additional fields are provided for a suffix, e.g., Jr., for the Participant's name as well as the ability to document the Participant's maiden name, if necessary.	Text fields
Date of birth	Numerical display of the Participant's date of birth in MM/DD/YY format	Numerical text field
Sex	Participant's sex	Female, male
Race	Participant's race	American Indian Asian Black/African American Hispanic Native Hawaiian or other White Other Unknown
Race specification	If race was designated as other, this text field allows for the specific type designated by the Participant	Text field
Site specific race	This text field is for center use when a specific race requires notation that is indigenous to that center	Text field
SSN	This is a numerical text field for entering the Participant's social security number. This is for local use only	Numerical text field
Tribe	Text filed to document center specific tribes	Text field
Local Patient ID	Numerical text field for identification of a corresponding center identification number. This is for local use only.	Numerical text field
Birth county Birth county code	Text field for elements necessary for eligibility. Birth county code is a drop down box that shows a county name, but stores a code number for the county.	Text field
Mother's maiden name	Participant identifier for center use only	Text field

7.3.2.2. The Case Tab

The user can enter case specific information on this page. This is also the page where the user registers or un-registers a participant.

- If a participant has chosen not to participate in the study, a warning is displayed at the top of the page.

- Likewise, registered, duplicate, or ineligible will be displayed according to the participant's information.

The following is a table of fields for the Case Tab:

Field	Description	Options
Local medical record numbers	Center specific medical record numbers. For local use only	Text field
Diagnosis date	A numerical text field to enter the date the Participant was diagnosed with diabetes. Use this field if the entire date is known (MM/DD/YY)	Numerical text field

Field	Description	Options
Diagnosis month, day, year	Numerical text fields used when only a portion of the Participant's date of diabetes diagnosis is known.	Numerical text field
Case status	Drop-down box to determine the status of the particular case	Prevalent Incident with corresponding year Unknown Ineligible
Data source	Drop-down box to determine if the information provided was a primary source (the Participant) or secondary source (anyone else).	Primary Secondary
General case source	Drop-down box to determine the source of case identification	Administrative source Clinical source Death Certificate Self-referral or other
Source provider ID	Text field provided for center use to denote a specific identifier for physicians that Participant information may be shared with.	Text field
Validated	Drop-down box identifying the validation status of a case	Validated Needs validation Not validated
Verification method	Drop-down box identifying the method used to validate a case	Medical record review Direct validation by clinician Clinically verified by database search Death certificate Self report
Secondary diabetes	Drop-down box signifying if the Participant has been diagnosed with secondary diabetes	Yes/No/Unknown
Presumed diabetes type	Text field indicating the presumed diabetes type	Text field

Field	Description	Options
SEARCH diabetes type	Drop-down box to determine the Participant's diabetes type based on SEARCH criteria	Type 1 Type 1a Type 2 Hybrid Unknown
Duplicate	Drop-down box indicating if the Participant is or is not a duplicate case	Primary Record Duplicate Record No Duplicate (Default Value)
Duplicate PID	Numerical text field to be completed if the Participant is a duplicate case. The number to be entered is the *duplicate* number (the PID that will be archived)	Numerical text field
The following fields are drop-down boxes to determine eligibility - all options are the same		
Age	Eligibility by age	Eligible Pending (Default for all) Ineligible
Geography	Eligibility by geography	
Health Plan	Eligibility by health plan membership	
Institutionalized	Eligibility by non-institutionalization	
Military	Eligibility by non-military status	
Gestational diabetes	Eligibility by non gestational diabetes	
Lock this record	This field only appears if Allow Record Locking is checked. It is located on the Admin tab in the tools section. When Allow Record Locking is checked, no edits are allowed to be performed to the record.	Checkbox
DiagZip	The zip code of the home where the participant was living when he or she was diagnosed with diabetes.	Text field
DiagCounty DiagCountyCode	The county of the home where the participant was living when he or she was diagnosed with diabetes. The site-specific numeric code for the county.	Text field

- For Zip code and county at diagnosis, use the following strategy:

     a) use IPS information first;

     b) if IPS is not available, use registration zip code/county;

c) if IPS is not available and more accurate zip code/county information becomes (beyond b) available, then sites should go ahead and use the information deemed most valid.

It is understood that the order of events is different across sites. If the site typically starts with registering a case (hence will start with entering a zip code/county based on registration information/med record), then obtains an IPS, then the zip code/county at diagnosis field should be updated based on the self-reported information.

7.3.2.3. Address Tab

The address tab contains information regarding the Participant's address. The "*primary*" field indicates which address will be used for the Participant's mailing address. Primary must be set to YES if the address entered is the mailing address. A backup copy of all changes is made so that previous addresses can be tracked.

Field	Description	Options
Primary	Drop-down box designating if the address provided is to be considered the primary address for Participant contact	Yes/No
Relation	A drop-down box that allows the user to indicate if this address is for a participant, a guardian, or someone else.	Guardian Patient Other

Field	Description	Options
Guardian DBID	A drop-down box that allows the user to select the guardian to assign to the current address if the address is not specific for the participant	Numeric field
Address Apt. number City, State, Zip Reservation County	Text fields denoting the Participant's exact address. The reservation field is completed if the Participant resides on a reservation.	Text field
Address directions/notes	For center use to document any specific information regarding the Participant's address. For local use only	Text field
Address year	Numerical text field denoting the year the documented address was valid	Numerical text field
ADM/ADD/ADY	Specific numerical text fields denoting the month, day, and year the documented address is valid	Numerical text field

7.3.2.4.   Phone Tab

Contact information is stored on this page. Like Address Information, a backup copy of all information is made. The phone tab contains contact information.

Field	Description	Options
Primary contact	Drop-down box designating if the telephone number provided is to be considered the primary number for Participant contact	Yes/No
Relation	A drop-down box that allows the user to indicate if this address is for a participant, a guardian, or someone else.	Guardian Patient Other
Guardian DBID	A drop-down box that allows the user to select the guardian to assign to the current address if the address is not specific for the participant	Numeric field
Extension	Numerical text field to add an extension to the above documented telephone number	Numerical text field
Other phone	Numerical text field indicating an alternate phone number	Numerical text field
Home Phone	Numerical text field indicating the Participant's home phone number	Numerical text field
Work phone	Numerical text field indicating the Participant's work phone number	Numerical text field
Other phone2	Numerical text field indicating a second alternate phone number	Numerical text field
Best time	Drop-down box denoting the best time to contact the participant	Evening 5-9 PM During the day 9A – 5 P Weekend Day / Evening Evening / Weekend Day / Weekend Anytime
Email	Text field denoting an email address that can be used to contact the Participant	Text field
BestTimeFree	Text field allowing for free text regarding best times to contact the Participant. For local use only	Text field

7.3.2.5. Guardian Tab

The Guardian tab is where information is stored on guardians. Multiple guardians can be entered.

Field	Description	Options
Salutation	Drop-down box denoting the type of salutation to be used when labels are printed	Mr. & Mrs. Mrs. Mr. Dr. & Mrs. Dr. Drs.
Name	Text field denoting the Participant's Parent or Legal guardian's first, middle, and last name	Text field
Local Guardian ID	Text field allowing the centers to designate a specific identification number for the Guardian. For local use only	Text field
Relationship	Drop-down box denoting the relationship of the Guardian field to the Participant	Patient Mother and Father Mother Father Grandmother Grandfather Uncle Aunt Legal guardian Foster parent Child Protective Services Other Husband

Field	Description	Options
		Wife Significant other Step mother Step father Spouse
Primary contact	Drop-down box denoting the person that should be contacted for the Participant.	Yes/No
SSN	Numerical text for the entry of the Guardian's social security number	Numerical text field
LegalGuardian	Check box denoting that the person identified within this tab is the Participant's legal guardian	

7.3.3. *Reports Menu*

The reports menu will allow the user to print various reports and labels.

- Eligible Patients (not yet registered): Returns a list of participants who can be registered.

- Registered Patients: Returns a list of registered participants.

- Unregistered Patients: Returns a list of unregistered participants.

- Customizable Registration Report: Lets the user create a report by picking county, zip-code, and registration status.

- Upcoming Birthdays: Returns a list of upcoming birthdays.

- Help, My labels won't print right! Gives instructions on how to make labels print correctly. Access 2000 has a known bug that causes reports and labels to lose margins when it closes.

- Barcode Labels for Registered Patients: Returns a sheet of labels with barcodes for all registered participants.

- Barcode/Mailing Labels for One Patient: Allows the user to print a whole sheet of mailing labels or barcode labels for one participant.

- Barcode Labels All Patients: Returns a sheet of labels with barcodes for all participants in the tracking database.

- Mailing Labels for Registered Patients: Returns a sheet of mailing labels for all registered participants.

- Mailing Labels (All Patients): Returns a sheet of mailing labels for all participants in the tracking database.

- Acrostic Labels: A set of labels containing acrostics for all registered participants.

- Multiple Unique PIDs: Allows the user to print labels (mailing, barcodes, or acrostics) for a set of PIDS that the user selects.

- Guardian vs. Patients: Lets the user select a group of PIDS, generate labels for this group, and dictate if the labels are addressed to parents or participants.

7.3.4. *Tracking Menu*

The Tracking Menu provides centers the ability to track the status of each participant. It provides information regarding mailings, information/questionnaires completed, and visits both scheduled and completed.

7.3.4.1. Consents Tab

The Consents tab is where information about consents the Participant or their Parent/Legal guardian have signed or need to sign is stored. Note that a backup copy of every record change is made so that there will be a complete audit trail.

Field	Description	Options
Permission to contact Patient	Drop-down box signifying SEARCH personnel's ability to contact the Participant. **Note**: If NO is selected, a **red** flag will be displayed at the top of the page when this Participant's file is accessed.	Yes/No
No contact reason	Drop-down box designating the reason this Participant no longer wishes to be contacted.	Consent denied Consent withdrawn Death Unknown Denies Diabetes
Personal Physician/Provider ID	Text field provided for center use to denote a specific identifier for physicians that Participant information may be shared with.	Text field
In-Person visit Share In Person Results Suppl. Question. Save Fluids Save DNA Future studies Interview Question.	Drop-down box stating the status of the Participant's consent for that particular set of data. The field along side of the drop-down box is to enter the date the consent was obtained. A second set of similar boxes are provided for the Parent/Legal guardian consents	No Yes Rescinded Unknown One Parent N/A Date is a numerical text field

Field	Description	Options
Medical Record review		
Stimulated C-pep		
Share C-pep results		
Future DNA		

7.3.4.2. Appointment Tab

Field	Description	Options
PID	Participant Identification Number.	
Staff ID	A 3-digit code assigned to all SEARCH personnel. This code will be selected either by a designated person at each center or by an individual and given to a designated individual at their center. This Staff Identification number will be used for the TDBS as well as forms completed and data entered. The Project Manager will provide a copy of all Staff ID codes to the Coordinating Center.	3-digit numerical text
Visit type	Drop-down box designating the type of visit being referenced.	In-Person IPS (via phone) Blood Re-draw Stimulated C-peptide Urine only Other

Field	Description	Options
Date due	Numerical text field denoting the date the above visit is due.	Numerical text field
Date Scheduled	Numerical text field denoting the date the above visit was scheduled.	Numerical text field
Time scheduled	Time field denoting the time of day the appointment is scheduled for.	Time field – non-military time
EMLA needed	Drop-down box denoting if the Participant requires EMLA cream to be applied prior to obtaining a blood sample.	Yes/No
Directions needed	Drop-down box denoting if the Participant requires any type of directions for the scheduled visit.	Yes/No
Came for Apt	Drop-down box designating if the Participant kept the scheduled appointment.	Yes/No
Comments	Text field allowing description of Participant instructions needed for the scheduled visit. Example: directions to the center; fasting instructions for obtaining laboratory specimen; instructing the Participant to bring family information.	Text field

7.3.4.3. Mailing Tab

Field	Description	Options
PID	Automatic Participant Identification Number. This number automatically appears in this field when a case is selected.	
Staff ID	A 3-digit code assigned to all SEARCH personnel.	3-digit numerical text
Type of mailing	Drop-down box designating the type of visit the mailing is to provide information for.	Initial Participant Survey In-Person Visit Stimulated C-peptide Annual Follow-up Other
EMLA needed	Drop-down box denoting if the Participant requires EMLA cream to be applied prior to obtaining a blood sample.	Yes/No
Directions needed	Drop-down box denoting if the Participant requires any type of directions for the scheduled visit.	Yes/No
Date sent	Numerical field denoting the date the specific information was sent.	Numerical text field
Mail Cycle completed	Drop-down box designating if the Participant responded to the mailing.	Yes/No
Complete Date	Numerical text field denoting the date the cycle was complete.	Numerical text field
Comments	Text field allowing description of Participant instructions needed for the mailing. Example: form completion instructions; fasting instructions for obtaining laboratory specimen; instructing the Participant to bring family information.	Text field

7.3.4.4. Results Tab

Field	Description	Options
PID	Automatic Participant Identification Number. This number automatically appears in this field when a case is selected.	
Staff ID	A 3-digit code assigned to all SEARCH personnel.	3-digit numerical text
Type of Result	Drop-down box denoting the type of test results are available from. Only a single test can be designated at one time.	Core Blood Redraw DAA only C-peptide Stimulated C-peptide Urine Only Other
Date sent to Patient	Numerical text field denoting the date the result was sent to the Participant. **Note:** Section 15 provides model letters that can be used when sending SEARCH results to the Participant/Parent/Provider	Numerical text field
Provider ID	Identification number of the Provider approved to share SEARCH information with. Local use only.	Text field

Field	Description	Options
Date sent to Provider	Numerical text field denoting the date the results were sent to the designated provider.	Numerical text field
Date put in chart	Numerical text field denoting the date the results were filed in the Participant's medical record	Numerical text field
Comments	Text field providing space for notes personnel wish to enter regarding the results.	Text field

7.3.4.5. Communication Log Tab

Field	Description	Options
PID	Automatic Participant Identification Number. This number automatically appears in this field when a case is selected.	
Staff ID	A 3-digit code assigned to all SEARCH personnel.	3-digit numerical text
Comm Type	Drop-down box denoting the type of communication that was made with the Patient/Parent/Guardian	Phone call Email Letter Fax Other

Field	Description	Options
Who was communicated with	Drop-down box denoting the individual SEARCH personnel communicated with.	Patient Mother and Father Mother Father Grandmother Grandfather Uncle Aunt Legal guardian Foster parent Child Protective Services Other Husband Wife Significant other Step mother Step father Spouse
Date	Numerical text field denoting the date SEARCH personnel spoke with the above designated person	Numerical text field
Time	Time field noting the time the contact was made	Time field
Result	Drop-down box denoting the result of the communication attempt.	Contact made Left message No answer Wrong number Disconnected Wrong email Other
Specify	If 'Other" is selected in the above field, enter the reason in this text field.	Text field
Notes	Text field to describe any information regarding the communication.	Text field
Follow up needed	Check this if a follow up communication is needed.	Checkbox
Follow up when	What date should the user call back?	Date
Follow up time	What time should the user call back?	Time
Follow up complete	This is a check box. Until it is checked, the current message will show up in the appointment list as a scheduled task.	Checkbox

7.3.4.6. Visit/Data Collection Tab

Field	Description	Options
PID	Automatic Participant Identification Number. This number automatically appears in this field when a case is selected.	
Visit number	Numerical text field denoting the visit number	Numerical text field
Visit Date	Numerical text field denoting the date of the visit	Numerical text field
The following fields are visit types with drop-down boxes denoting if that item was performed at the above designated visit.		
Initial Survey In-Person DAA Only Core samples Blood re-draw Urine only Physical exam Health Question Family medical history Supp. Question.	Drop-down box denoting if this item was performed.	Yes No Refused NA

Field	Description	Options
Depression Question. Food Frequency Peds QL Stimulated C-peptide Medical Record Review Annual Survey Annual In-Person Visit		
Comments	Text field explaining any information regarding these procedures.	Text field

7.3.4.7. Incentives Tab

Field	Description	Options
PID	Automatic Participant Identification Number. This number automatically appears in this field when a case is selected.	
Incentive	Drop-down box denoting the reason for the incentive.	Initial Participant Survey In-Person Visit-Participant In-Person Visit-Parent Stimulated C-peptide Custom Not eligible for additional incentive
Amount	Drop-down box denoting the incentive amount	$0.00 $2.00 $20.00 $40.00
Date	Numerical text field denoting the date the Participant/Parent was given the incentive	Numerical text field
Staff ID	A 3-digit code assigned to all SEARCH personnel.	3-digit numerical text
Notes	Text field for any information relating to incentives	Text field

7.3.4.8. Appointments and Follow-up Communications

The user can review appointments and follow up communications by entering a start date and end date and then selecting what to review.

7.3.5. *Tools Menu*

The tools menu is where scheduling and tracking information are entered. This field is a center based/driven menu based on the centers needs.

- ▪ Duplicate Check: Allows the user to find potential duplicate cases, based on user defined criteria. The user can refine the search using the precision fields.

- ▪ Custom Consents: Since each clinic is unique, each one will have the ability to enter custom consents not covered by the main categories on the Consents tab of the Patient Menu.

- ▪ Export: Exports registered Participants to text file and uploaded to the SEARCH web site.

- ▪ Field List Report: Allows the user to generate a report showing all fields in any table.

- ▪ Gen Mult PID: After importing data from a local database, allows for the assignment of multiple PIDs at once.

- ▪ Admin Tools: Several items that allow for customization of the system.
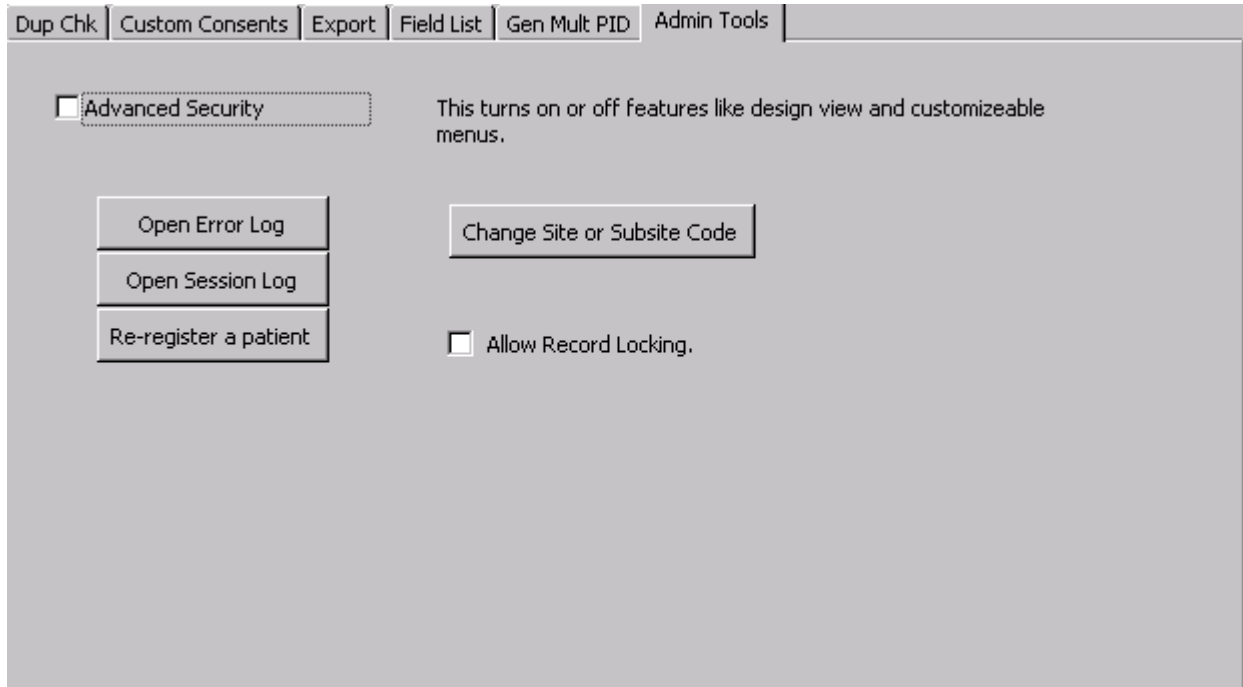
Field	Description	Options
Consent description	Text field allowing any center to designate their own specific consent type based on the requirements of their IRB.	Text field
DateAdded	Text filed denoting the date the special consent was added.	Text field
Notes	Text field explaining any information about the specific consent.	Text field

7.3.5.1. Admin tools

Field	Description	Options
Advanced Security	By checking this field, the user will not allow Access menus to be displayed or bypass the login screen on startup. It "locks" the form to the open state so that tables and queries cannot be accessed	Checkbox
Open Error Log	Used for debugging when unforeseen errors happen	
Open Session Log	Allows the user to see who has logged in at what time.	
Re-register a patient	Allows the user to re-register a participant who has been unregistered by accident.	

Field	Description	Options
Change Site or Subsite Code	Allows the user to change the default site and subsite used by the tracking system. Could be useful for mass importing data from a subsite where the PID was not generated.	
Allow Record Locking	If checked, all participant records marked as locked will not be editable. Records are locked on the participant form.	Checkbox

7.3.6. *Staff*

In this section, the user enters information about staff members and their access to various areas of the TDB. This section will be customized by each center based on their specific needs and requirements.

7.3.7. *Browser*

This button opens the SEARCH web site from inside the TDB.