

## **IRB relational database**

Purpose: The IRB relational database tracks all relevant paperwork and monitors deadlines, durations between submission and approval, time lapsed since submission, Site PI trainings, and almost any aspect of the IRB process. Information for all sites or specific to project, site, or region can be extracted and presented as reports. The database is especially useful to track information at sites where the component submission approach is utilized.

Relevance: Using a database for information storage can increase efficiency and improve overall levels of organization, helping avoid delays as a result of missing time-sensitive deadlines. Having this information instantly accessible can be useful for an audit.

Note: We have included broad information to start a database using Microsoft ACCESS, including suggested tables, relationships, field names and data types, and a sample form with tabs for specific aspects of the IRB process. All of these items can be modified to best fit a particular research project and don't represent the only way to organize a database or data entry form. The Leszynski/Reddick naming convention is used throughout. More information on the naming conventions can be found at: [http://msdn.microsoft.com/archive/default.asp?url=/archive/en-us/dnaraccess/html/msdn\\_20naming.asp](http://msdn.microsoft.com/archive/default.asp?url=/archive/en-us/dnaraccess/html/msdn_20naming.asp).

The next eight pages including the following information respectively: list of suggested tables, basic relationships between the tables, three pages listing the field names, data types and descriptions of tblMAIN, the field names, data types and descriptions of tblSubmissionInfo, and a tabbed data entry form. Tabs were created to house relevant information on an IRB, Site PI, data security, and AE/SAE/Complaint/Withdrawal information and have been circled on the form. The tab approach breaks down the information from tblMAIN and keeps the form from getting too cluttered. The Submission Info tab is a sub-report that allows users to enter multiple submission information for one site. Look-up tables were created for information that is entered repeatedly in order to ensure consistency in data entry. Using the "zoom" feature in Adobe Acrobat Reader will allow users to read pages more clearly.

*These process aids have been developed and refined over the course of our projects, and we anticipate they will continue to evolve over time. Please feel free to use or adapt them to your projects as necessary.*

# Suggested tables

Microsoft Access - [IRB Paper DB : Database (Access 2000 file format)]

File Edit View Insert Tools Window Help

Type a question for

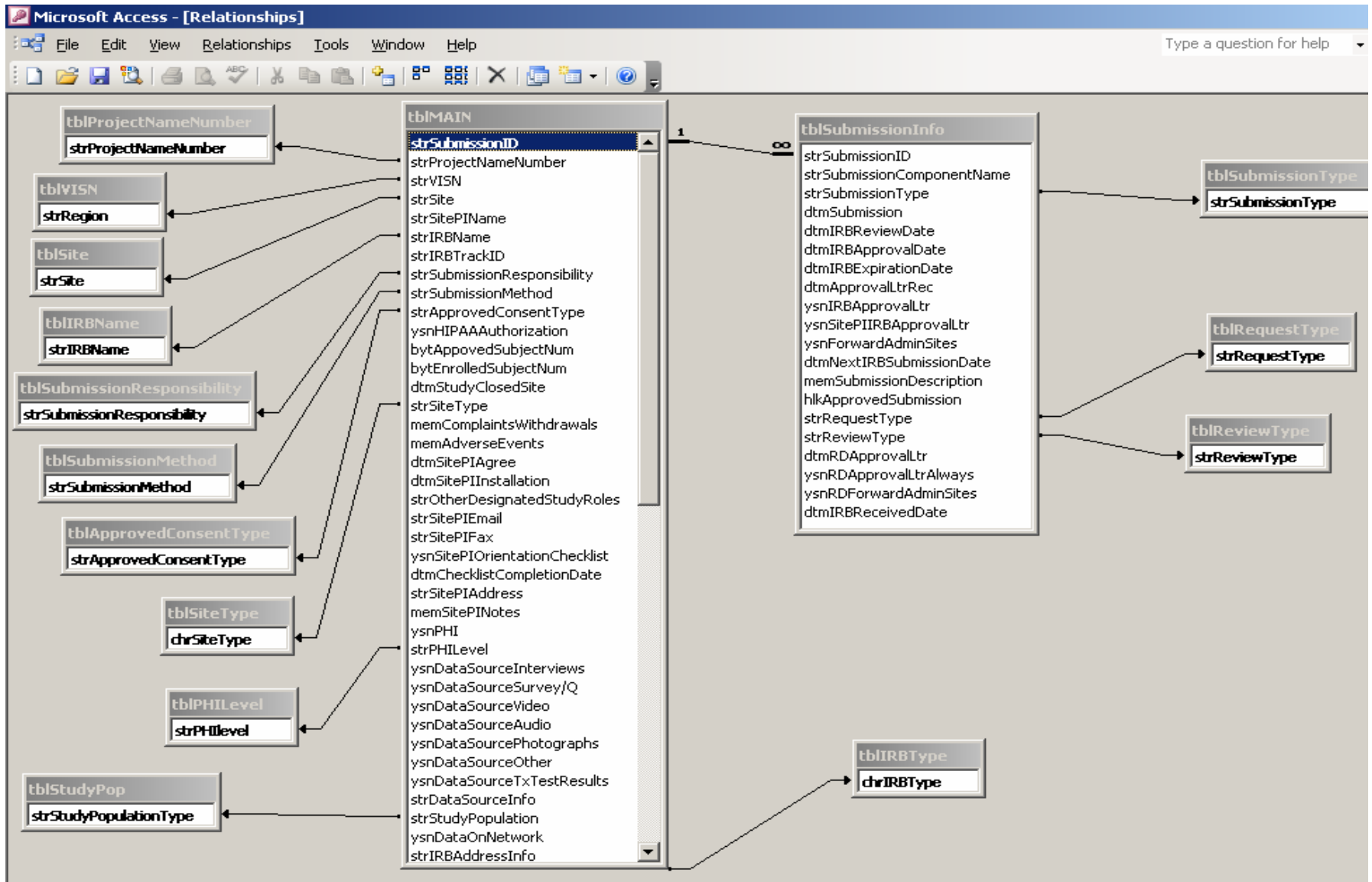
Open Design New

| Objects | Name                          | Description                                | Modified             | Created               | Type  |
|---------|-------------------------------|--|----------------------|-----------------------|-------|
| Tables  | Create table in Design view   |  |                      |                       |       |
|         | Create table by using wizard  |  |                      |                       |       |
|         | Create table by entering data |  |                      |                       |       |
|         | tblApprovedConsentType        | Look up table                              | 5/24/2007 2:57:59 PM | 4/9/2007 10:59:50 ... | Table |
|         | tblIRBName                    | Look up table                              | 6/5/2007 2:52:31 PM  | 4/6/2007 1:58:44 PM   | Table |
|         | tblIRBType                    | Look up table                              | 7/23/2007 8:40:32 AM | 6/4/2007 3:29:24 PM   | Table |
|         | tblMAIN                       |  | 6/7/2007 9:31:05 AM  | 4/6/2007 1:32:16 PM   | Table |
|         | tblPHILevel                   | Look up table                              | 7/23/2007 8:40:10 AM | 6/4/2007 9:17:31 AM   | Table |
|         | tblProjectNameNumber          | Look up table                              | 6/5/2007 2:37:23 PM  | 4/6/2007 1:56:45 PM   | Table |
|         | tblRequestType                | Look up table                              | 5/24/2007 2:58:24 PM | 4/9/2007 9:23:37 AM   | Table |
|         | tblReviewType                 | Look up table                              | 5/24/2007 2:58:30 PM | 4/9/2007 9:24:09 AM   | Table |
|         | tblSite                       | Look up table                              | 6/5/2007 2:41:41 PM  | 4/6/2007 1:58:05 PM   | Table |
|         | tblSiteType                   | Look up table                              | 7/23/2007 8:40:22 AM | 6/4/2007 3:07:52 PM   | Table |
|         | tblStudyPop                   | Look up table                              | 6/4/2007 9:19:34 AM  | 6/4/2007 9:06:49 AM   | Table |
|         | tblSubmissionInfo             | "Many" side of the relationship to tblMAIN | 6/6/2007 10:46:08 AM | 4/9/2007 10:29:26 ... | Table |
|         | tblSubmissionMethod           | Look up table                              | 5/24/2007 2:58:43 PM | 4/9/2007 11:06:23 ... | Table |
|         | tblSubmissionResponsibility   | Look up table                              | 6/5/2007 2:30:29 PM  | 4/9/2007 9:24:54 AM   | Table |
|         | tblSubmissionType             | Look up table                              | 5/24/2007 2:58:55 PM | 4/9/2007 9:22:30 AM   | Table |
|         | tblVISN                       | Look up table                              | 6/4/2007 9:15:00 AM  | 4/9/2007 10:23:07 ... | Table |

Groups

Favorites

# Suggested relationships



## Suggested field names, data types, and descriptions of tblMAIN (1 of 3)

Microsoft Access - [tblMAIN : Table]

File Edit View Insert Tools Window Help

Type a question for help

| Field Name                    | Data Type | Description   |
|-------------------------------|-----------|---|
| strSubmissionID               | Text      | Created by: First letter of project, Site letter, # in consecutive order, starting with 1                                     |
| strProjectNameNumber          | Text      | look-up field / Project name (or abbreviation) and funding #  |
| strVISN                       | Text      | look-up field / Geographical region   |
| strSite                       | Text      | look-up field / Site name   |
| strSitePIName                 | Text      | Complete first and last name, including suffixes  |
| strIRBName                    | Text      | look-up field / Official IRB name   |
| strIRBTrackID                 | Text      | Number/Letter string assigned to a submission by the IRB  |
| strSubmissionResponsibility   | Text      | look-up field / Admin Site A, Admin Site B, etc.  |
| strSubmissionMethod           | Text      | look-up field / paper, online   |
| strApprovedConsentType        | Text      | look-up field / oral consent, written consent, waiver of informed consent, waiver of informed written consent                 |
| ysnHIPAAAuthorization         | Yes/No    | Check if there exists HIPAA authorization from subject OR waiver of HIPAA authorization for the study has been granted by IRB |
| bytApprovedSubjectNum         | Number    | IRB approved # of subjects allowed to participate in the study AT THIS SITE   |
| bytEnrolledSubjectNum         | Number    | # of consented, enrolled subjects AT THIS SITE  |
| dtmStudyClosedSite            | Date/Time | Date study was closed AT THIS SITE (project may still remain open at other sites)   |
| strSiteType                   | Text      | look-up field   |
| memComplaintsWithdrawals      | Memo      | Detail any information on complaints or withdrawals involving this site   |
| memAdverseEvents              | Memo      | Detail any information on Adverse Events or Serious Adverse Events involving this site  |
| dtmSitePIAgree                | Date/Time | Date Site PI agreed to Site PI responsibilities. Not always formal. For example, may occur via email.                         |
| dtmSitePIInstallation         | Date/Time | Date Site PI has completed all required trainings and other responsibilities and is able to officially be Site PI             |
| strOtherDesignatedStudyRole   | Text      | Any additional roles the Site PI may be taking on in conjunction with being Site PI?  |
| strSitePIEmail                | Text      | Email address for Site PI   |
| strSitePIFax                  | Text      | Fax number for Site PI  |
| ysnSitePIOrientationChecklist | Yes/No    | Has the Site PI Orientation Checklist been completed?   |
| dtmChecklistCompletionDate    | Date/Time | Date Site PI Orientation Checklist completed.   |
| strSitePIAddress              | Memo      | Insert all address info. Using text box approach for easy cut & paste.  |
| memSitePINotes                | Memo      | Notes relating to Site PI   |

## Suggested field names, data types, and descriptions of tblMAIN (2 of 3)

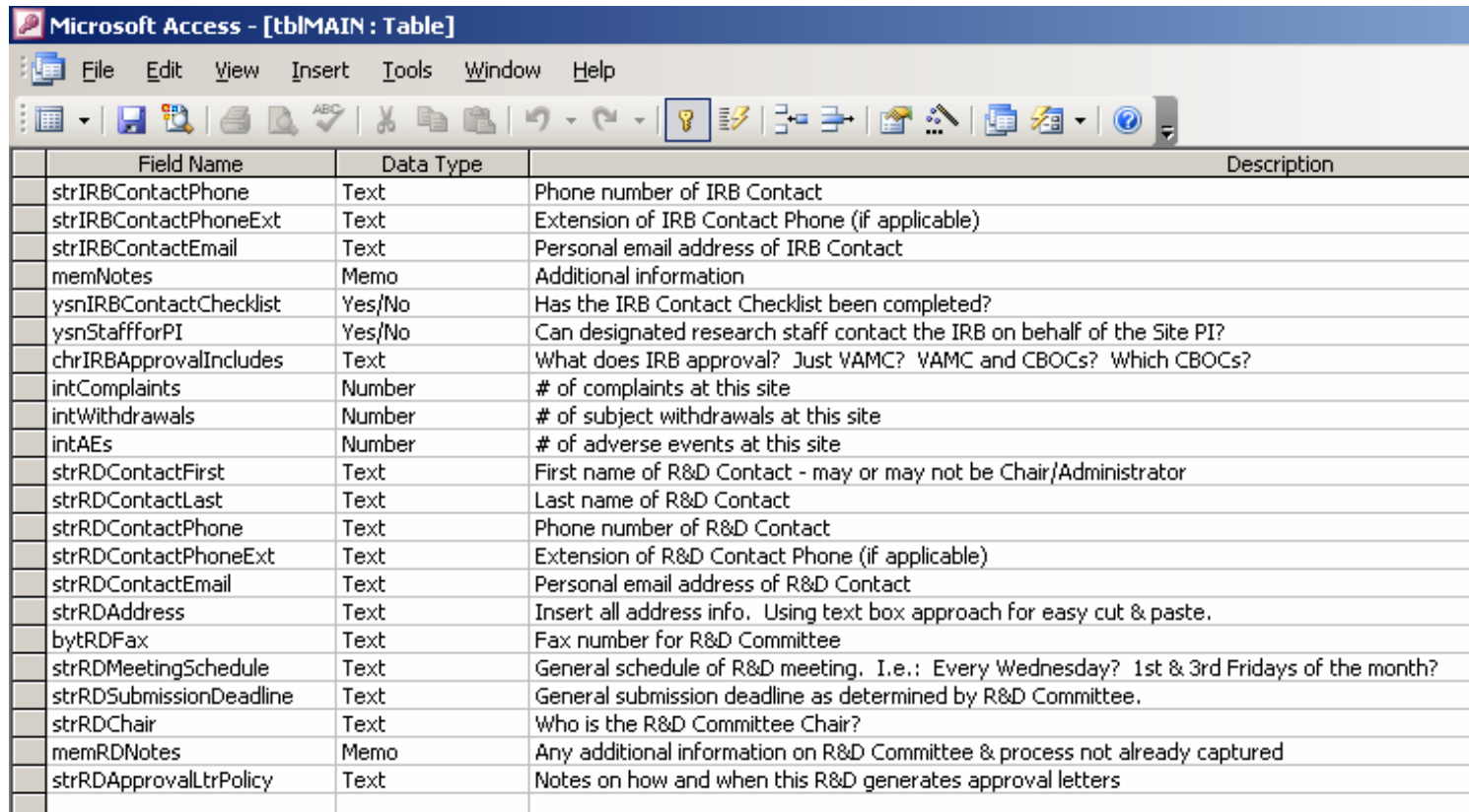
Microsoft Access - [tblMAIN : Table]

File Edit View Insert Tools Window Help

Type a question for help

| Field Name                 | Data Type | Description  |
|----------------------------|-----------|--|
| ysnPHI                     | Yes/No    | Check if any level of PHI be utilized, accessed, collected, or generated as a part of the study                                      |
| strPHIlevel                | Text      | Select the most stringent level of PHI being used in the study. de-identified; limited; fully identifiable                           |
| ysnDataSourceInterviews    | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourceSurvey/Q      | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourceVideo         | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourceAudio         | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourcePhotographs   | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourceOther         | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| ysnDataSourceTxTestResults | Yes/No    | Provide more detail on this selection under "Data Source Info" textbox in form   |
| strDataSourceInfo          | Memo      | Brief description of data source info and PHI levels. (interviews, surveys, medical records, audio, tissue samples, test results)    |
| strStudyPopulation         | Text      | Select one: VA; Non-VA; Both VA and non-VA   |
| ysnDataOnNetwork           | Yes/No    | Check if all project data is stored on HSRD network, behind firewall   |
| strIRBAddressInfo          | Memo      | Insert all address info. Using text box approach for easy cut & paste.   |
| bytIRBPhone1               | Text      | Phone number of IRB  |
| bytIRBPhone1Ext            | Text      | Extension of IRB Phone 1 (if applicable)   |
| bytIRBPhone2               | Text      | Alternate phone number of IRB  |
| bytIRBPhone2Ext            | Text      | Extension of IRB Phone 2 (if applicable)   |
| bytIRBFax                  | Text      | Fax number for IRB   |
| strIRBGeneralEmail         | Text      | General email address of IRB   |
| hklIRBwebsite              | Hyperlink | Official IRB website   |
| strIRBMtgSchedule          | Text      | General schedule of IRB meeting. I.e.: Every Wednesday? 1st & 3rd Fridays of the month?  |
| strIRBSubmissionDeadline   | Text      | General submission deadline as determined by IRB. Generally several weeks prior to expiration. I.e.: 2 weeks, 6 weeks, 8 weeks, etc. |
| strIRBType                 | Text      | look-up field - what kind of IRB? VA-in house; University affiliated; Other-VA   |
| strIRBContactFirst         | Text      | First name of IRB Contact - may or may not be Chair or Administrator   |
| strIRBContactLast          | Text      | Last name of IRB Contact   |
| strIRBContactTitle         | Text      | Title of IRB Contact   |

## Suggested field names, data types, and descriptions of tblMAIN (3 of 3)



| Field Name              | Data Type | Description   |
|-------------------------|-----------|---|
| strIRBContactPhone      | Text      | Phone number of IRB Contact   |
| strIRBContactPhoneExt   | Text      | Extension of IRB Contact Phone (if applicable)  |
| strIRBContactEmail      | Text      | Personal email address of IRB Contact   |
| memNotes                | Memo      | Additional information  |
| ysnIRBContactChecklist  | Yes/No    | Has the IRB Contact Checklist been completed?   |
| ysnStaffforPI           | Yes/No    | Can designated research staff contact the IRB on behalf of the Site PI?                 |
| chrIRBApprovalIncludes  | Text      | What does IRB approval? Just VAMC? VAMC and CBOCs? Which CBOCs?                         |
| intComplaints           | Number    | # of complaints at this site  |
| intWithdrawals          | Number    | # of subject withdrawals at this site   |
| intAEs                  | Number    | # of adverse events at this site  |
| strRDContactFirst       | Text      | First name of R&D Contact - may or may not be Chair/Administrator                       |
| strRDContactLast        | Text      | Last name of R&D Contact  |
| strRDContactPhone       | Text      | Phone number of R&D Contact   |
| strRDContactPhoneExt    | Text      | Extension of R&D Contact Phone (if applicable)  |
| strRDContactEmail       | Text      | Personal email address of R&D Contact   |
| strRDAddress            | Text      | Insert all address info. Using text box approach for easy cut & paste.                  |
| bytRDFax                | Text      | Fax number for R&D Committee  |
| strRDMeetingSchedule    | Text      | General schedule of R&D meeting. I.e.: Every Wednesday? 1st & 3rd Fridays of the month? |
| strRDSubmissionDeadline | Text      | General submission deadline as determined by R&D Committee.                             |
| strRDChair              | Text      | Who is the R&D Committee Chair?   |
| memRDNotes              | Memo      | Any additional information on R&D Committee & process not already captured              |
| strRDApprovalLtrPolicy  | Text      | Notes on how and when this R&D generates approval letters                               |

## Suggested field names, data types, and descriptions of tblSubmissionInfo

Microsoft Access - [tblSubmissionInfo : Table]

File Edit View Insert Tools Window Help

Type a question for help

| Field Name                 | Data Type | Description   |
|----------------------------|-----------|---|
| strSubmissionID            | Text      | This foreign key connects to the chrID primary key in table MAIN  |
| strSubmissionComponentNarr | Text      | Name of component submission - short & brief!   |
| strSubmissionType          | Text      | look-up field / component; initial; modification-amendment; renewal   |
| dtmSubmission              | Date/Time | Date submitted to IRB   |
| dtmIRBReviewDate           | Date/Time | Date reviewed by IRB - usually indicated by IRB meeting schedule  |
| dtmIRBApprovalDate         | Date/Time | Date approved by IRB - officially indicated on IRB submission with signature from IRB chair   |
| dtmIRBExpirationDate       | Date/Time | Date IRB approval will expire - officially indicated on IRB submission  |
| dtmApprovalLtrRec          | Date/Time | Date study staff received IRB approved submission   |
| ysnIRBApprovalLtr          | Yes/No    | Check if IRB approval letter has been received by study staff   |
| ysnSitePIIRBApprovalLtr    | Yes/No    | Check if Site PI has received a copy of the IRB Approval Letter   |
| ysnForwardAdminSites       | Yes/No    | Check if IRB information has been forwarded to other administrative sites   |
| dtmNextIRBSubmissionDate   | Date/Time | Date of next IRB required submission  |
| memSubmissionDescription   | Memo      | For any additional submission information   |
| hfkApprovedSubmission      | Hyperlink | Scan signed, approved submission into a PDF & hyperlink   |
| strRequestType             | Text      | look-up field / exempt; expedited; full committee   |
| strReviewType              | Text      | look-up field / exempt; expedited; full committee   |
| dtmRDApprovalLtr           | Date/Time | Date of R&D Approval  |
| ysnRDApprovalLtrAlways     | Yes/No    | Is an R&D approval letter (and date) generated for every IRB submission (initial, modification, renewal, etc.)? If yes, enter date as well. |
| ysnRDForwardAdminSites     | Yes/No    | Check if R&D approval letter has been forwarded to other administrative sites (applies only if R&D letter has been generated)               |
| dtmIRBReceivedDate         | Date/Time | Date submission was received by IRB (usually stamped on application, or noted in the approval letter)                                       |

# Suggested tabbed data entry form

Microsoft Access - [frmMAIN : Form]

Tahoma 8 B I U

File Edit View Insert Format Records Tools Window Help

Type a question for help

|                      |                      |                              |                                     |                                  |         |
|----------------------|----------------------|------------------------------|-------------------------------------|----------------------------------|---------|
| <b>Submission ID</b> | R-F-1                | <b>Site</b>                  | Seattle, WA                         | <b>Submission Responsibility</b> | Seattle |
| <b>Project</b>       | ReTIDES (MNT 03-215) | <b>Site PI Name</b>          |                                     | <b>Submission Method</b>         | Paper   |
| <b>VISN</b>          | VISN 20              | <b>Site Type</b>             | Admin/Control                       | <b>Approval for "N" Subjects</b> |         |
| <b>IRB Name</b>      |                      | <b>Approved Consent Type</b> | Written                             | <b>"N" Subjects Enrolled</b>     |         |
| <b>IRB ID</b>        |                      | <b>HIPAA Authorization</b>   | <input checked="" type="checkbox"/> | <b>Date Site Closed</b>          |         |

Submission Info | IRB Info | VA RD Info | Site PI Info | Data Security Info | AE, SAE, Complaint, Withdrawal Info | IRB Approved Research Staff

|   |  |  |
|---|--|--|
| <p><b>Submission Name</b> Initial Protocol Submission</p> <p><b>Submission Type</b> Initial</p> <p><b>Submission Date</b> 3/23/2005</p> <p><b>IRB Received Submission Date</b> 3/23/2005</p> <p><b>IRB to Review Date</b> 4/13/2005</p> <p><b>Review Type Requested</b> Full Committee</p> <p><b>IRB Review Type</b> Full Committee</p> <p><b>IRB Approval Date</b> 4/13/2005</p> <p><b>IRB Approval Expiration Date</b> 4/12/2006</p> <p><b>IRB Approval Ltr Received?</b> <input checked="" type="checkbox"/> Date</p> <p><b>Hyperlink to IRB Approval Ltr</b></p> <p><b>Site PI has IRB Approval Ltr?</b> <input checked="" type="checkbox"/></p> <p><b>Admin Sites have IRB Approval Ltr?</b> <input checked="" type="checkbox"/></p> | <p><b>Anticipated Next Submission Date</b></p> | <p>RD Approval Ltr for all Submissions? If yes, provide relevant date. See RD Info tab for more on this policy <input type="checkbox"/></p> <p><b>RD Approval Ltr Date</b> 8/16/2005</p> <p><b>Admin Sites have RD Approval Ltr?</b> <input checked="" type="checkbox"/></p> |
|---|--|--|

Record: 1 of 3

Created by: First letter of project, Site letter, # in consecutive order, starting with 1

NUM