

DDOTS™ 1997-2006 Navigator

Translating Technology to Improve Patient Outcomes, Enhance Quality, and Reduce Costs

CREDIT© Includes Regulatory Logs

Reviews, Revisions, and Adverse Events Submission Logs

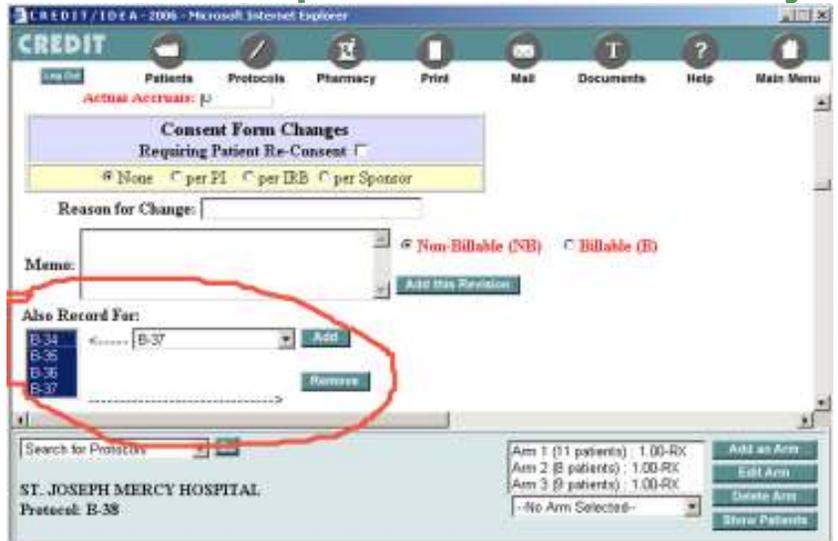
When a Protocol is entered into CREDIT, regulatory logs are automatically created. These placeholders are divided into four (4) separate logs: Office of Regulatory Contracts (ORC), Reviews, Revisions, and Serious Adverse Events (SAE). Knowing what is "Sent to IRB" becomes a focal point in staff preparations and expectations.

When staff documents that specific requests are sent to the Institutional Review Board "IRB", those entries are made directly into CREDIT. There is a complete section for pre-IRB documentation, ORC. This is where status notes are kept to log the phase that the proposed study is engaged. Once the initial submission for approval has been made, the entry is logged in CREDIT and tagged to a specific IRB Meeting.

When a Revision is logged into CREDIT under a protocol, that Revision can also be dynamically assigned to other protocols. This makes the task of multiple entries and eliminates it; one entry populates multiple protocols upon request. This feature is also echoed in the SAE Log. Many times an SAE applies to multiple studies. This would require multiple log entries being required under each protocol. CREDIT handles those duplicate entries with a single entry that can be echoed to all selected protocols. This "echo" insures that each study will have the logged entry for audit purposes.

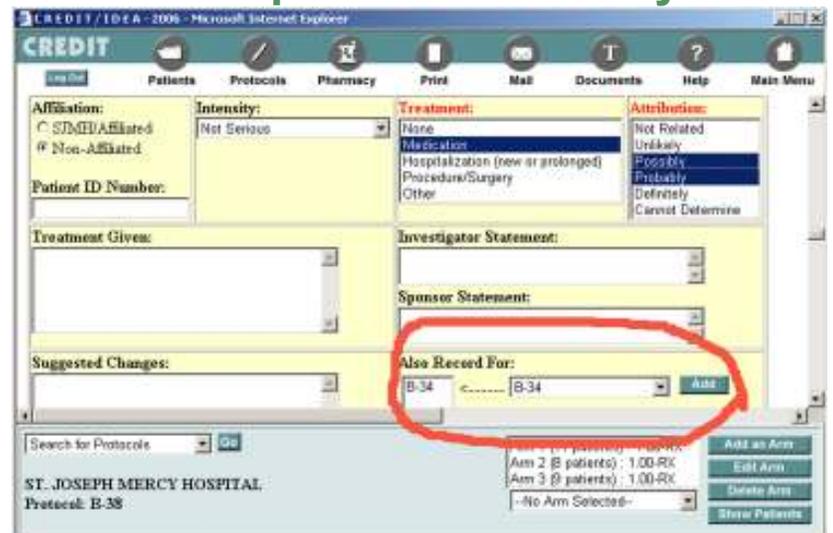
But what happens when the IRB acts on our submissions? How can I log that the documents have returned with a specific action? CREDIT has a simple solution: "Show me all the IRB Submission Logs for Meeting: mm/dd/yyyy". The logged entries are retrieved and immediately available for "bulk" processing. For instance, when 32 Continuing Reviews return with a Board action of "Continuation", only 2 mouse clicks are required to update the 32 logged entries from "Sent to IRB" to "Continuing". The same is true of all other regulatory submissions!

Select Multiple Protocols for Entry



The above illustration show just how easy it is to automatically assign this Revision to other studies. Note, if patient reconsenting were required, those flags would also get populated in the additional studies!

Serious Adverse Events Allows for Multiple Protocol Entry



Notice the section for including additional protocols for the SAE entry. A duplicate entry would be made in each and every protocol selected for inclusion.

All Revisions Recorded on One Page

#	Study ID	Event ID	Action	Reviewed By	(Submit Date) Action Date	Memo	Record
1	0146P (OP-04-0387)	Permanent Closure	Approved	Full Board	05 / 18 / 2006		all none
2	A8501003 (A8501003)	Activation	Approved	Full Board	05 / 18 / 2006	Protocol Version 20 December 2005 PF-3312676 IB Version July 2005	

All of the Regulatory Submissions made for all protocols get recorded per IRB action on one single page. Notice how the original status of the entries was "Sent to IRB". In the setup of CREDIT, each institution can set the "default" Board action; in this case "Approved". Of course the actions can be changed by staff at this point. The "Record" column has a link to automatically check "ALL" of the boxes indicating which ones should be recorded at this time. In our example, clicking "All", then the "Submit" button, all 4 submissions will be updated per IRB action.

Serious Adverse Events for One Meeting

#	Study ID	Event ID	Action	Reviewed By	(Submit Date) Action Date	Memo / Toxicities	Record
1	11961 (HSR-06-0642)	200510417BFR FU2	Approved	Full Board	05 / 18 / 2006	Expected: Skin Toxicity, Stomatitis Unexpected: Skin Ulcer	
2	11961 (HSR-06-0642)	200512090BWH FU4	Approved	Full Board	10 / 01 / 2005	Unexpected: Hypertension, Renal Failure, Malignant Pericardial Effusion,	

All of the SAEs come to this report page for changing the status of the submission. The entries were originally "Sent To IRB" (see black entry in the dropdown box), and were dynamically set to "Approved" for ease of recording. Simply clicking the "All" link in the "Record" column, then the button to submit, and all entries are updated per IRB action.

DDOTS Navigator

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The DDOTS Navigator is published to introduce news that has occurred in the ongoing development of Cancer Research Environmental Data Information Tracking (CREDIT)..

Since 1995 CREDIT© has been in constant growth. May of 2006, marked the 11th anniversary of this powerful system. Installed at sites across the country, CREDIT© is the leader in Collaborative Clinical Research Administration Software.

Annual Reviews Automatically Reported for IRB Submission

When it is time for studies to be reviewed by the IRB, CREDIT© automatically produces the report to demonstrate which studies need submitting to any selected meeting.

Unlike other simple databases that require the user to "tell" which meeting each study is to be reviewed at, CREDIT© does the math and calculates which meeting the study is due for review. The only intervention required by staff is to tell CREDIT© how many months between reviews for each study. If the number is 11, CREDIT© will display the future meeting that is 11 months away.

If the meeting date changes, there is no need to update each and every protocol. CREDIT© simply recalculates the meeting date for each protocol. This way, there is no data entry error that would cause a study to miss a review.