

**From:** [Johnson, Sandra](#)  
**To:** [Skandarajah, Sukanya](#); [Christian, Qiana](#); [Gan, May](#); [Jacobs, Paulette](#); [Pastorek, Debra](#); [Schroeder, Katy](#); [Zindars, Stacey](#); [Bates, Brittney](#); [Croatt, Lisa](#); [Fitzgerald, Mary Ann](#); [Kempf, Donna](#); [Linde, Marilyn](#); [Manteufel, Jessica](#); [Mikulice, Kristin](#); [O'Connor, Carreen](#); [Price, Michelle](#)  
**Cc:** [Bergholte, Jo](#); [Fiebelkorn, Adam](#); [Thuemling, Rachel](#); [Bollmer, Jennifer](#)  
**Subject:** FYI on Undo Suspend vs. Open  
**Date:** Thursday, June 15, 2017 11:51:00 AM  
**Attachments:** [image003.png](#)  
[image006.png](#)  
[image007.png](#)  
[image001.png](#)  
[image002.png](#)  
**Importance:** High

Hi all,

I wanted to share something that I just found out has been happening incorrectly and therefore wanted to clarify. When a study is Suspended and re-opens, you need to hit the Open button under the Status tab and NOT the Undo Suspend button. There are a few reasons for this. When you hit the Open button the notification that the study is (once again) Open to Accrual will be sent out. If you hit the Undo Suspend button the notification will NOT go out.

Status		Task Lists	ClinicalTrials.gov		
Protocol Status <span style="float: right;">History</span>					
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
06/15/2017	SUSPENDED	Cooperative Group	Amendment pending		Johnson, Sandra
06/15/2017	OPEN TO ACCRUAL				Johnson, Sandra
04/20/2017	SUSPENDED	Sponsor	Amendment pending		Monson, Katrina
07/22/2016	OPEN TO ACCRUAL				Christian, Qiana
07/22/2016	RESEARCH MANAGER-DTL SIGNOFF				Christian, Qiana
06/14/2016	IRB INITIAL APPROVAL				Hecht, Hannah
02/22/2016	SRC APPROVAL	Cancer SRC A			Bollmer, Jennifer
02/12/2016	NEW				Christian, Qiana

[SRC Submission Form 1](#)

Also, using the Undo Suspend will actually remove the Suspension from the Status tab (first screen shot below). It can still be seen in the History tab (second below), but not under the Status itself – which is incorrect.

Protocol Status		
Status Date	Status	Initiator
02/03/2017	OPEN TO ACCRUAL	
02/03/2017	RESEARCH MANAGER-DTL SIGNOFF	
01/10/2017	IRB INITIAL APPROVAL	
07/29/2016	SRC APPROVAL	Cancer SRC A
06/21/2016	NEW	

Status Change History				
Action	Action Date/Time	User	Status Date	Status
Deleted	06/15/2017 09:02:59 AM	Pastorek, Debbie	05/19/2017	SUSPENDED
Updated	05/22/2017 07:25:31 AM	Pastorek, Debbie	05/19/2017	SUSPENDED
Created	05/22/2017 07:24:39 AM	Pastorek, Debbie	05/19/2017	SUSPENDED
Created	02/03/2017 03:48:57 PM	Pastorek, Debbie	02/03/2017	OPEN TO ACCRUAL
Created	02/03/2017 03:48:50 PM	Pastorek, Debbie	02/03/2017	RESEARCH MANAGER-DTL SIGNOFF
Created	01/23/2017 09:28:16 AM	Manteufel, Jessica	01/10/2017	IRB INITIAL APPROVAL
Created	07/29/2016 10:58:22 AM	Bollmer, Jennifer	07/29/2016	SRC APPROVAL
Created	06/21/2016 08:24:12 AM	Pastorek, Debbie	06/21/2016	NEW

Lastly, the status of Suspended needs to be viewable/available for accrual monitoring. The SRC sends letters to 'low accruing studies', but the calculation of how long the study is open takes into account if the study has been suspended – and if so, how long. So, if a study was open for 1 year, but suspended for 3 months, the SRC would not send out a letter at the 1 year point after it opened, but a year plus the 3 months when it was suspended. This is also EXTREMELY important for leadership reporting purposes, as well.

Please make sure from here forward you ONLY use the Undo button when you actually suspended the study in error. Otherwise you must use the Open button after a suspension.

Thank you,  
Sandi

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