

IRB Wise Study Closure Example and Guidance

This presentation includes an example of a Study Closure submission in IRB Wise and also includes guidance for each section of the submission. The screen shots are of an example and the responses are not to be taken as the correct response. Each study is different, and therefore each response and each section will need to be filled out to tailor to your study. Please contact the Office of Research Integrity Assurance if you have any questions.

Start Page on IRB Wise

The screenshot shows the IRB Wise web application interface. At the top right, there are links for Home, Feedback, and Logout. Below the header, there is a search bar for Protocol Numbers and a 'Go' button. A 'Tasks' dropdown menu is set to 'Select One', and a welcome message reads 'Welcome to IRBWISE, Principal Investigator.' A navigation bar contains buttons for 'alerts', 'my protocols' (circled in red), and 'my account'. Below this, there is a 'Show:' dropdown menu set to 'All of My Submissions' and a 'Submit New Protocol' link. The main content is a table with columns for Submission, Protocol Title, Current Status, Current Approval Period, and Last Update. The table lists 20 submissions, including 'Amendment #1 for TEST STUDY - 1', 'Protocol TEST STUDY - 1', and 'Protocol TEST2016'. The 'my protocols' button is circled in red.

Submission	Protocol Title	Current Status	Current Approval Period	Last Update
Amendment #1 for TEST STUDY - 1	Test Study	Approved		12/12/2019
Protocol TEST STUDY - 1	Test Study	Approved	12/12/2019 - 12/11/2020	12/12/2019
Protocol		New		02/19/2018
Protocol		New		02/06/2018
Protocol TEST2016	Examining the clinical motivations for personalized health technology	Withdrawn		08/26/2016
Protocol		New		07/22/2016
Protocol	Demo BME 1300	Withdrawn		06/02/2016
Protocol	BME1300	Withdrawn		06/02/2016
Protocol	Test 123	New		01/19/2016
Protocol	Demo for HCI	Withdrawn		08/28/2015
Protocol Test123	Renu Test with OIT 508	Closed	11/22/2013 - 11/21/2014	09/22/2014
Protocol	testing #2 mpowell	New		11/22/2013
Protocol	Test Protocol	Withdrawn		04/09/2009
Protocol	222	Withdrawn		10/29/2008
Protocol	Test Protocol	Withdrawn		10/29/2008
Protocol	BME 1300 Demo 2008	Withdrawn		10/29/2008
Protocol	BME PM Lab 2008	Withdrawn		10/29/2008
Investigator Brochure #1 for null	222	Withdrawn		09/03/2008
Protocol	bmed1300 demo protocol	Withdrawn		10/11/2006
Protocol	BME 1300-	Withdrawn		10/11/2006

To submit a Study Closure, please click “My Protocols” (circled in red) at the top of the screen and then select the study that you wish to close.

Reporting a Study Closure

The screenshot displays the IRBWISE web application interface. At the top, there is a search bar for Protocol Number and navigation links for Home, Feedback, and Logout. Below the search bar, a progress bar shows the study's status: With PI, With Department Head Approval, Submitted to IRB, Under Review, and Final Disposition (selected). The main content area shows the protocol details for 'TEST STUDY - 1', including the title, principal investigator, and current status (Approved). A dropdown menu is open on the right side, listing various tasks, with 'Report Study Closure' highlighted in red. Below the protocol details, there is a 'Protocol Summary' section with a table of key information.

Field	Value
Protocol Description:	
Protocol Department:	
Research Personnel:	1 personnel
Researcher Certifications:	! 1 researcher has no active certification !
Amendments:	1 Amendment request created, 1 approved
Continuing Reviews:	none
SAE's/Adverse Event's:	none
Protocol Deviations:	0 Protocol Deviations created » Report Protocol Deviation
Study Closures:	0 Study Closures created
Research Funding:	none
Research Locations:	none
Research Subjects:	none
Vulnerable Populations:	none
Key Words:	none
Documents:	none

Once in the selected study, please click the Tasks drop-down menu and select "Report Study Closure."

Study Closure - Submission

Search by Protocol Number: Go Tasks: **Select One**
Welcome to IRBWISE, Principal Investigator.

▶ Report Study Closure With Department Head Approval > Submitted to IRB > Under Review > Final Disposition

Study Closure for TEST STUDY - 1 As Of: March 2, 2020 11:25 AM

Admin Assigned:	Current Status: New
Committees Assigned:	Last Activity: 01/10/2020 - Created
Review Type:	Date Approved:

Protocol TEST STUDY - 1 As Of: March 2, 2020 11:25 AM

Title: Test Study	Current Status: Approved
Principal Investigator: Principal Investigator	Last Activity: 03/02/2020 - AE #1 for TEST STUDY - 1 Submitted to IRB
Admin Assigned: Scott Samuel Katz	Original Approval Start: 12/12/2019
Committee Assigned:	Current Approval Period: 12/12/2019 - 12/11/2020
Review Type:	

[view approved Protocol details >>](#)

Study Closure Questions

Requests that the Study Be Closed

A Is enrollment of subjects closed?

No, additional subjects will be enrolled. (In this case, the study CANNOT be closed. A request for continuing approval must be submitted).

YES, enrollment is closed, and no additional subjects will participate.

B If enrollment is complete, provide the date the last subject enrolled.

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C Is data analysis continuing?

No, all analysis is complete.

Yes, analysis is ongoing. Data contain identifiers such that individual subject might possibly be identifiable. (In this case, the study CANNOT be closed, and a request for continuing approval must be submitted).


Yes, analysis is ongoing. Data have been stripped of all identifiers. (In this case, the study may be closed, even though analysis will continue).

When reporting a Study Closure, please be sure to answer all of the questions within the submission.

Study Closure - Submission

D How many subjects were enrolled in the past approval period?

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E What is the TOTAL number of subjects enrolled to date in this study? 

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F What was the age range of the subjects?

18-25 [editor window](#)

G If any subjects withdrew themselves from the study during the past year, state how many subjects and the reason(s) for withdrawal.

N/A [editor window](#)

H If any subjects were withdrawn by the study team in the past year, state how many subjects and the reason(s) for withdrawal.

N/A [editor window](#)

I Has any regulatory agency or other entity audited this study during the current approval period? If yes, by whom and the date.

No, there is no audit to report
 Yes, the audit report is attached

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This is a continuation of the Study Closure request. Please be sure to answer all of the questions within the submission. Additionally, please be sure to state how many subjects were enrolled both since the past approval period (question D) and total (question E).

Study Closure - Submission

J Provide citations of any abstracts or publications resulting from this study. Studies involving the Department of Defense require that copies of abstracts & publications be provided to the IRB. Upload these documents by using Attach Supplemental Documents in the task drop down list.

PI Name., Co-PI Name. Journal Name (2020) 21: 114.

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K If any subject enrolled in the study at any site suffered an unexpected or serious adverse event in the past year, so state here and provide brief details. (Adverse events should be reported to the Office of Research Integrity Assurance when they occur).

N/A

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L If any problems occurred in the process of obtaining and documenting informed consent, describe what happened and how the problem was resolved.

N/A

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M Describe if there were any incidental findings?

Incidental findings are possible medical abnormalities that may have clinical implications and that are observed in the course of research studies but are unrelated to the topic under study. Examples include a screening protocol for an exercise intervention that identifies a cardiac insufficiency, or a brain imaging study of depressed individuals that reveals a potential structural abnormality.

N/A

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N Provide a brief summary of any changes that have been made to the project during the last approval period (changes in consent/assent form or process, investigators, protocol amendments). If the study was terminated before completion, explain why.

We submitted several amendments to change the procedures, enrollment numbers, and consent process...(more detail)

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O Provide a brief summary of the results obtained in the study. If there are no results to report at this time, so state and explain why.

This study showed how to submit multiple type of IRB submissions...(more detail)

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This is a continuation of the Study Closure request. Please be sure to answer all of the questions within the submission.

Study Closure - Submission

P * required * Have you or will you (PRINCIPAL INVESTIGATOR), your spouse, domestic partner, or minor dependents:

Receive compensation from a company/entity including salary consulting fees or honoraria related to this research (do not include salary, grant support, and other payments for services from Georgia Tech)?

Receive royalty or licensing payments from a company/entity related to this research?

Have any intellectual property rights or royalties from such rights whose value may be affected by the outcome of this research, including royalties under any royalty-sharing agreements involving the University?

Receive gifts/benefits, including reimbursed or sponsored travel, from a company/entity related to this research?

Have equity or ownership interest (includes stock options) in a public or private company/entity related to this research?

Be a director, officer, partner, trustee, employee, or do you hold any other type of management position with a company/entity related to this research?

Received in the past 12 months, or do you anticipate receiving in the next 12 months, any combination of remuneration, fees, royalties, or honoraria, which exceeds \$5,000 when aggregated, from an entity whose products or services are used or studied in this research or who are developing products or services that this research is intended to study or evaluate?

Receive any compensation whose value could be affected by the outcome of this research (excluding compensation paid from the research grant)?
If the answer is YES to any of the above, upload a copy of your Conflict of Interest Management Plan approved by the Office of Conflict of Interest Management.

No, there is no conflict of interest to report.
 Yes, my approved conflict of interest management plan is uploaded.

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Q Has/will ANY OTHER MEMBER OF THE RESEARCH TEAM, his/her spouse, domestic partner, or minor dependents:

Receive compensation from a company/entity including salary consulting fees or honoraria related to this research (do not include salary, grant support, and other payments for services from Georgia Tech)?

Receive royalty or licensing payments from a company/entity related to this research?

Have any intellectual property rights or royalties from such rights whose value may be affected by the outcome of this research, including royalties under any royalty-sharing agreements involving the University?

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[Save and Stay Here](#) [Save and Finish Later](#) [Save and Submit Application](#)

This is a continuation of the Study Closure request. Please be sure to answer all of the questions within the submission. When finished, please select "Save and Submit Application" (circled in red).

Study Closure - Submission

P *required* Have you or will you (PRINCIPAL INVESTIGATOR), your spouse, domestic partner, or minor dependents:
Receive compensation from a company/entity including salary consulting fees or honoraria related to this research (do not include salary, grant support, and other payments for services from Georgia Tech)?
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Have equity or ownership interest (includes stock options) in a public or private company/entity related to this research?
Be a director, officer, partner, trustee, employee, or do you hold any other type of management position with a company/entity related to this research?
Received in the past 12 months, or do you anticipate receiving in the next 12 months, any combination of remuneration, fees, royalties, or honoraria, which exceeds \$5,000 when aggregated, from an entity whose products or services are used or studied in this research or who are developing products or services that this research is intended to study or evaluate?
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Have equity or ownership interest (includes stock options) in a public or private company/entity related to this research?
Be a director, officer, partner, trustee, employee, or hold any other type of management position with a company/entity related to this research?
Received in the past 12 months, or anticipate receiving in the next 12 months, any combination of remuneration, fees, royalties, or honoraria, which exceeds \$5,000 when aggregated, from an entity whose products or services are used or studied in this research or who are developing products or services that this research is intended to study or evaluate?
Receive any compensation whose value could be affected by the outcome of this research (excluding compensation paid from the research grant)?
If the answer is YES to any of the above, upload a copy of the Conflict of Interest Management Plan approved by the Office of Conflict of Interest Management.

No, there is no conflict of interest to report.

<< Edit Study Closure Request | **Submit Study Closure Request to IRB**



After clicking "Save and Submit Application," you will be asked to review all of the information to ensure it is accurate. If the information needs to be revised, please click "Edit Study Closure Request." If the information is accurate, then please click "Submit Study Closure Request to IRB" (circled in red).

Congratulations! You have officially submitted your Study Closure Request to the IRB.

Please contact the Office of Research Integrity Assurance if you have any questions regarding the submission process.

Office of Research Integrity Assurance
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Website: <https://oria.gatech.edu/irb>