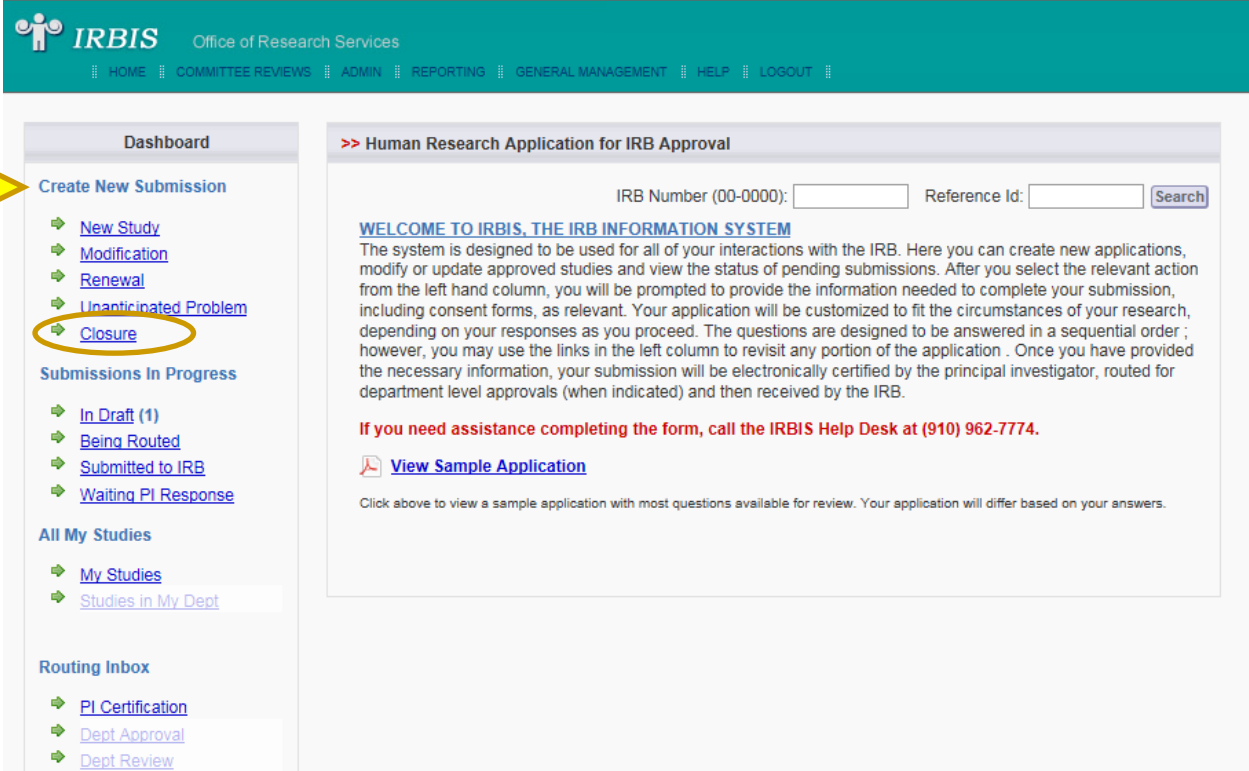


Closing a Study in IRBIS

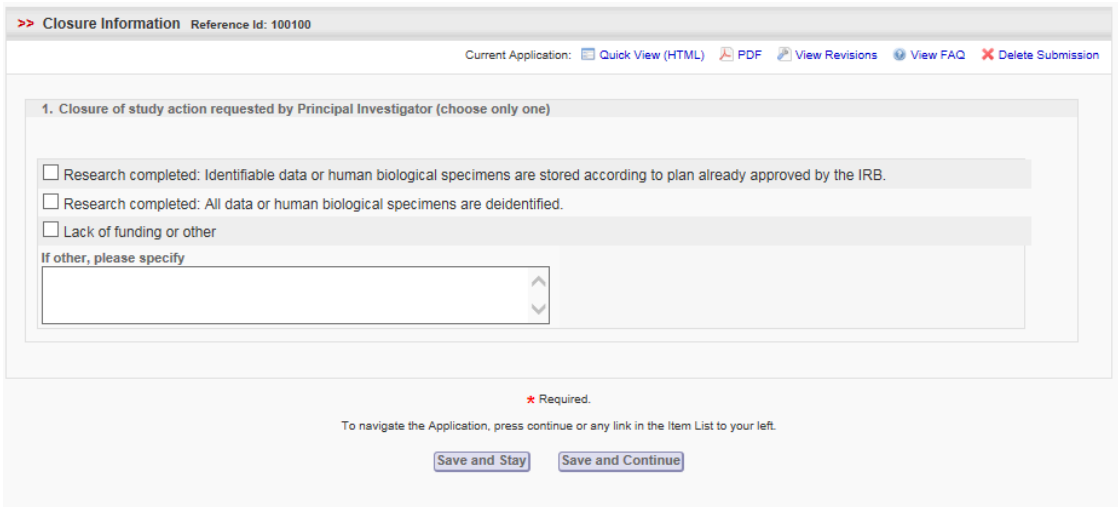
1. **Log into IRBIS using your usual UNCW username and password:**
<https://uncw.myresearchonline.org/irb/index.cfm>.
2. **On the IRBIS home page, find the section on the left titled “Create new Submission”**
3. **Select “Closure”**



The screenshot shows the IRBIS Office of Research Services dashboard. On the left, under the 'Create New Submission' section, the 'Closure' link is circled in yellow and pointed to by a yellow arrow. Other links in this section include 'New Study', 'Modification', 'Renewal', and 'Unanticipated Problem'. Below this are sections for 'Submissions In Progress' (In Draft (1), Being Routed, Submitted to IRB, Waiting PI Response), 'All My Studies' (My Studies, Studies in My Dept), and 'Routing Inbox' (PI Certification, Dept Approval, Dept Review). The main content area is titled '>> Human Research Application for IRB Approval' and contains a search bar, a welcome message, and a link to 'View Sample Application'.

4. **IRBIS will create a closure form. The questions are similar to those found on UNCW’s previous closure form. There are three screens in the closure form.**

Screen 1: Basic Closure Information – why are you closing the study?



The screenshot shows the 'Closure Information' form with Reference ID: 100100. At the top, there are navigation links: Quick View (HTML), PDF, View Revisions, View FAQ, and Delete Submission. The main question is '1. Closure of study action requested by Principal Investigator (choose only one)'. There are three radio button options: 'Research completed: Identifiable data or human biological specimens are stored according to plan already approved by the IRB.', 'Research completed: All data or human biological specimens are deidentified.', and 'Lack of funding or other'. Below these is a text area for 'If other, please specify'. At the bottom, there are two buttons: 'Save and Stay' and 'Save and Continue'. A note at the bottom states: '* Required. To navigate the Application, press continue or any link in the Item List to your left.'

Screen 2: Progress Report – similar information to annual renewal.

Please provide the final numbers for the study and report any problems.

Current Application: [Quick View \(HTML\)](#) [PDF](#) [View Revisions](#) [View FAQ](#) [Delete Submission](#)

1. Number of Subjects involved through direct contact or use of their data (for multi-site studies, include only subjects covered by this IRB) (Note: b+d should not be larger than a)

A. Total projected number as approved by IRB: *

B. Total number of subjects included/enrolled to date (do NOT include 'screen failures') *

C. Number of subjects included/enrolled since last renewal: *

D. Number to be included/enrolled in upcoming year *

2. Have any subjects withdrawn voluntarily or been withdrawn from the study? * Yes No

3. Have there been any complaints about the research from subjects or others? * Yes No

4. Have there been any findings (e.g., publications, new information, study results) that alter the risk/benefit ratio or otherwise impact the study? * Yes No

5. Have there been any relevant multi-site reports? * Yes No

6. Does this study have a Data and Safety Monitoring Committee (DSMC or DSMB)? * Yes No

7. Have there been any deviations since the last renewal? * Yes No

8. Have there been any unanticipated problems (including but not limited to adverse events and adverse subject outcomes) since the last renewal? * Yes No

9. Has this study been audited by a sponsor or monitor since approved or last renewed? * Yes No

* Required.

To navigate the Application, press continue or any link in the Item List to your left.

Screen 3: Submission Screen – the closure form is completed.

Item List [click on section name to expand](#)

- ✔ [Post Approval Submissions](#)
- ✔ [Closure Information](#)
- ✔ [Progress Report](#)
- ✔ [General Information](#)
- ✔ [Part B. Direct Interaction](#)
- ✔ [Part C. Existing Data, Records, Specimens](#)
- ✔ [Attachments](#)
- ✔ [Cover Memo](#)

The Application can be submitted at this time.

Routing >> **Submit To PI For Certification Application** Reference Id: 100100

Current Application: [Quick View \(HTML\)](#) [PDF](#) [View Revisions](#) [View FAQ](#) [Delete Submission](#)

Application: Title of study will appear here

Principal Investigator: Principal Investigator name will appear here

At this point you are ready to close your study. You may upload any documents that were referenced in your progress report (e.g. sponsor letters, DSMB reports, etc.), using the Attachments navigation link. When ready click the submit button.