

# Trent's ROMEO E-System

Applying for Research Ethics Board, Animal Care Committee or Biosafety

Certification - Researcher User Manual

#### Ethics certification for research

- All research (funded and unfunded) conducted by Trent-affiliated researchers (faculty, staff, students) that involves <a href="https://example.com/html/>human participants">human participants</a> or <a href="https://example.com/html/>live animals</a> requires ethics approval from the respective compliance committee before any activities can commence.
- Research involving human participants, including in-class activities for pedagogical purposes, and collaborative projects hosted at other institutions, must be reviewed and approved by the Trent **Research Ethics Board**.
- Research activities that involve live animals (vertebrates and cephalopods) are reviewed by the Animal Care Committee.
- The use of potentially pathogenic organisms (bacteria, viruses, fungi, parasites, protozoa, biotoxins) and potentially biohazardous material (blood, mammalian cell lines) requires a work permit from the **Science Safety Advisory Committee**.

#### Ethics certification for research

 ROMEO – an online award and <u>certification</u> system, used to create and review human and animal ethics applications as well as biosafety protocols. ROMEO is available through <u>myTrent/Services/Learning and Research</u> to internal investigators.

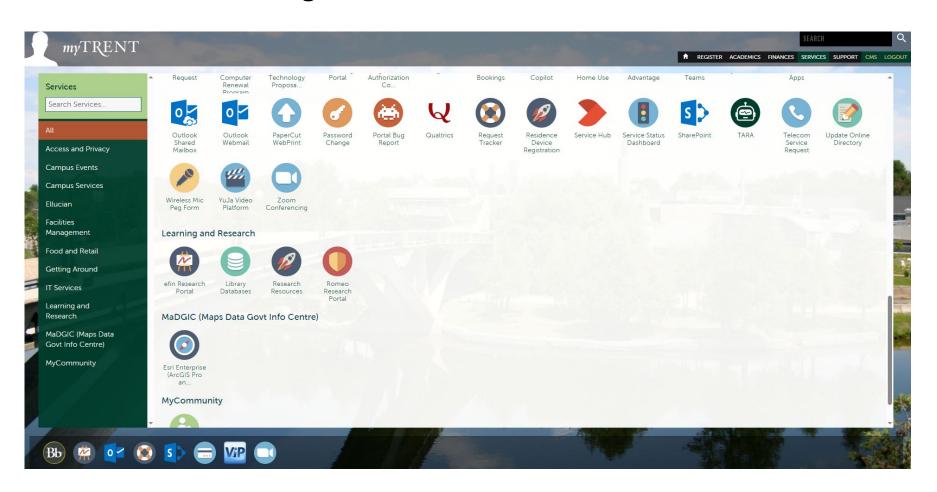
Website: <a href="https://www.trentu.ca/ori/research-services/ethics-and-compliance">https://www.trentu.ca/ori/research-services/ethics-and-compliance</a>

Contact: Coordinator, Research Conduct and Reporting at annakisiala@trentu.ca or researchintegrity@trentu.ca, (705) 748-1011 x. 7866, GCS 344.1

#### Accessing the ROMEO Research Portal

Faculty and Staff: ROMEO can be accessed through the MyTrent Portal

- Log in to MyTrent using Trent U credentials
- Select Services Learning and Research



### Accessing the ROMEO Research Portal

#### Trent students and external users:

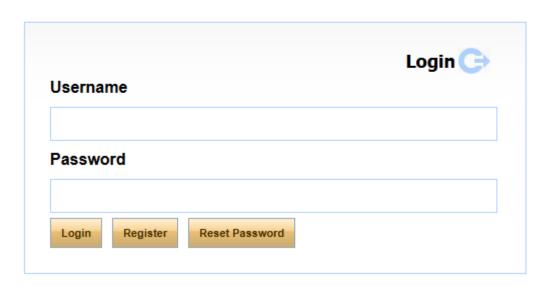
 Complete the <u>Self Registration Form</u> prior to login

#### Link to ROMEO for external users:

- Available on the Ethics and Compliance website
- Request by emailing researchintegrity@trentu.ca



Hello! Login to the Research Portal here. If you are already a registered user, but cannot remember your login username or password, do not create a new profile. Click Reset Password to reset your password, or contact your system administrator to request your username.

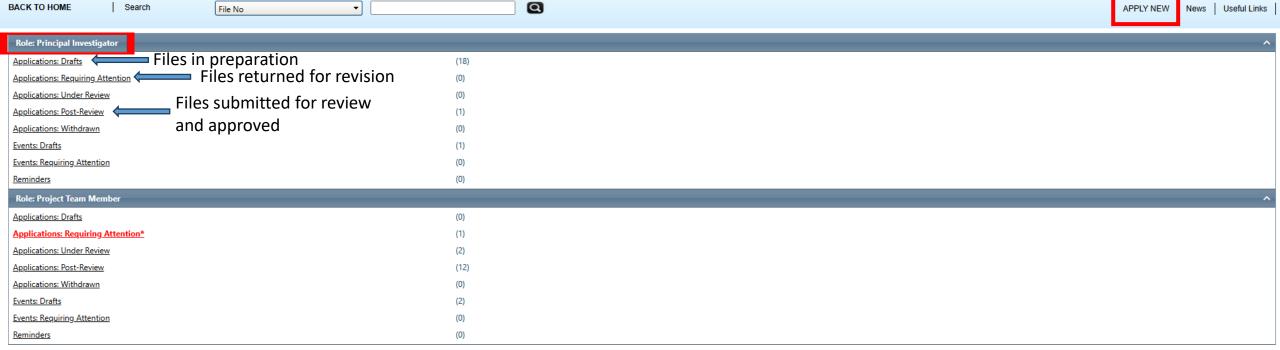


https://trentu.researchservicesoffice.com/ROMEO.Researcher/(S(yi4rkh0spyzg45ucvyq1ydbd))/Login.aspx?ReturnUrl=%2fR OMEO.Researcher%2fLogout.htm

#### Researcher's Home Page

Applications for human and animal research can be submitted via the "APPLY NEW" button.





# Researcher's Home Page



BACK TO HOME	Search File No •	APPLY NEW	Ne
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#### **New Application Forms**

#### Office of Research Services

Application Name	Description	Status
Residual Funds Application Form	NSERC and SSHRC residual funds can be accessed under certain circumstances following the terminal date of the award. This application must be completed and received by the Office of Research no later than June 30th following the end of the grant.	Open

#### Research Ethics, Animal Care, and Biosafety

Application Name	Description	Status
Faculty & Staff: Application for Approval of Human Participant Research - active form	This form is for faculty (including instructors and sessionals), postdoctoral fellows, visiting scholars and staff of Trent University, another university or college.	Open
Faculty & Staff: Application for Approval of Teaching/Lab Protocol Involving Human Participants - active form	This form is required for all activities that take place in classes at Trent University that can be defined as "course-based research activities" involving human participants (TCPS2 2022, Article 2.1), except independent research projects (e.g.: honours thesis). Please include course code or indicate that the submission is for lab/teaching protocol in the title of your application. If you plan to disseminate the results beyond the class in which the data is created, please submit an ethics protocol for research involving human participants. If you believe your activity is an above-minimal risk project, please contact the Coordinator, Research Conduct and Reporting.	Open
<u>Graduate or Undergraduate: Application for Approval of Human Participant Research - active form</u>	This form is for undergraduate, graduate and PhD students conducting their research under the supervision of Trent faculty/staff member.	Open
Request for Release of Funds Pending Certification-active	As a result of the Memorandum of Understanding (MOU), 2008 signed by Trent University and the Federal Granting Agencies (NSERC, SSHRC, & CIHR) Trent University is legally obligated to: o release Agency funds to researchers only after the Trent University Research Ethics Board and or the Animal Care Committee has approved the research. This review can be a formal review of the detailed protocol and related continuing review process or 'in principle' if the activities involving humans or animals will only take place in a future fiscal year and the methodology still needs to be determined. In any case the research must maintain REB or ACC approval for the duration of the project.' (MOU, 2008) o inform the Agency if REB approval for the project is not obtained within 6-months of the award date, and explain the reason for the delay, in which case the Agency will consider that this condition has not been fulfilled and may cancel the award and reallocate funds. In accordance with the MOU, funds will not be released for research projects involving human participants unless: 1. This form is submitted and approved by the Chair of the Trent University Research Ethics Board or ACC.	Open
Animal Use Protocol Application For Laboratory Research Faculty/Principal Investigators	Animal Care Protocol Application to be used by faculty principal investigators. Please visit SharePoint: Animal Care - SOP Library to access current list of Standard Operating Procedures (SOP). If available, use the SOP files from the library when submitting a new AUP. If edits are required to the existing SOP - tracked changes should be used in the SOP attached to your ROMEO submission. If you cannot find the SOP relevant to your animal use protocol, please contact the Manager of Animal Care.	Open
Animal Use Protocol Application For Wildlife and Field Work Research	Animal Care Protocol Application to be used by faculty principal investigators engaged in wildlife and field work research. This protocol will be reviewed in accordance with guidelines set by the CCAC. These may be located at https://ccac.ca/Documents/Standards/Guidelines/CCAC_Guidelines-Wildlife.pdf. Please visit SharePoint: Animal Care - SOP Library to access current list of Standard Operating Procedures (SOP). If available, use the SOP files from the library when submitting a new AUP. If edits are required to the existing SOP - tracked changes should be used in the SOP attached to your ROMEO submission. If you cannot find the SOP relevant to your animal use protocol, please contact the Manager of Animal Care.	Open
Animal Use Protocol for Fish	Animal Care Protocol Application to be used by faculty principal investigators engaged in wildlife and field work research involving fish (as the only species). Please visit SharePoint: Animal Care - SOP Library to access current list of Standard Operating Procedures (SOP). If available, use the SOP files from the library when submitting a new AUP. If edits are required to the existing SOP - tracked changes should be used in the SOP attached to your ROMEO submission. If you cannot find the SOP relevant to your animal use protocol, please contact the Manager of Animal Care.	Open
Animal Use Protocol Application For Teaching	Required by any course using live vertebrates or cephalopods as a teaching aid. Note that a letter of support from the departmental curriculum committee and the pedagogical merit review are required with the application. Please visit SharePoint: Animal Care - SOP Library to access current list of Standard Operating Procedures (SOP). If available, use the SOP files from the library when submitting a new AUP. If edits are required to the existing SOP - tracked changes should be used in the SOP attached to your ROMEO submission. If you cannot find the SOP relevant to your animal use protocol, please contact the Manager of Animal Care.	Open
Request for "In Principle" Review for Animal Work	As a result of the Memorandum of Understanding (MOU), 2008 signed by Trent University and the Federal Granting Agencies (NSERC, SSHRC, & CIHR) Trent University is legally obligated to: o release Agency funds to researchers only after the Trent University Animal Care Committee has approved the research. This review can be a formal review of the detailed protocol and related continuing review process or 'in principle' if the activities involving animals will only take place in a future fiscal year and the methodology still needs to be determined. In any case the research must maintain ACC approval for the duration of the project." (MOU, 2008) o inform the Agency if ACC approval for the project is not obtained within 6-months of the award date, and explain the reason for the delay, in which case the Agency will consider that this condition has not been fulfilled and may cancel the award and reallocate funds. In accordance with the MOU, funds will not be released for research projects animals unless: 1. This form is submitted and approved by the Chair of the Trent University Animal Care Committee within 6-months of the award date; or 2. A full application is made to and approved by the Trent University ACC.	Open
Biosafety Project Work Permit Application	This is the work permit application for personnel wishing to use biohazardous material for research or teaching purposes. The maximum length of Biosafety Work Permit is 3 years.	Open
Radiation Work Permit Application	An application for a permit to possess, use store, purchase radioactive material or devices containing radioactive material	Open
Animal Care Minimal Interaction Form	Animal-based activities that fall within CCAC's mandate but do not require animals be included in a full protocol. Examples are practicum placements or animals that will only be observed in formal teaching and in research, that are not being held captive for these purposes, and where there is no expected impact on these animals or those around them. Pedagogical merit reviews are still required on file.	Open

#### Your Application – Pre-Submission

- To save a draft protocol in progress, click the "Save" button followed by "Close" button. You can access it later through the Researcher's Home Page under the "Applications: Drafts" link.
- <u>Do Not</u> close your application by closing your browser. This will result in the application being "Locked", preventing other team members from accessing or editing it. Only the user who locked an application can unlock it. Instead, close your application by logging out.
- If you cannot unlock an application or contact the team member who locked it, email the Coordinator, Research Conduct and Reporting, at annakisiala@trentu.ca.

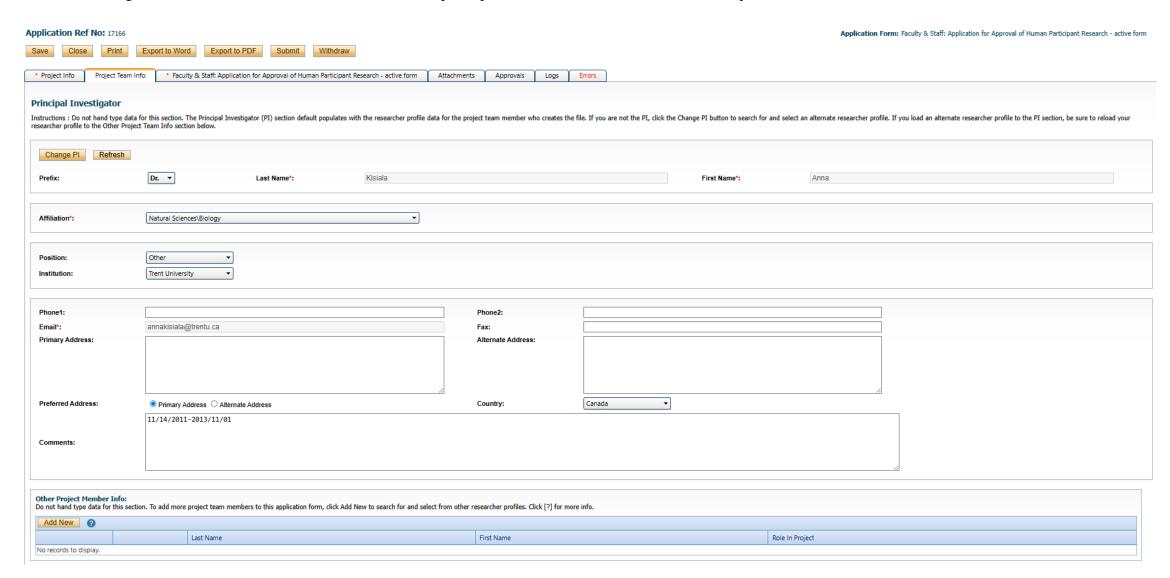
### Your Application – Project Info Tab

Enter the Project Title, proposed Start and End Date, and any keywords which describe your project. Keywords can be selected from the drop-down menu or typed directly into the text box.



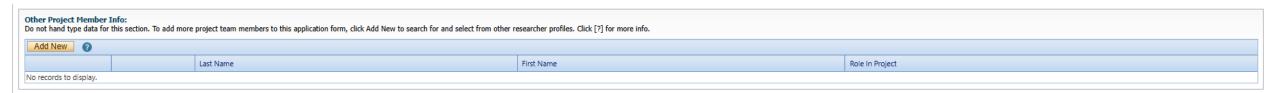
### Your Application - Project Team Info

The Project Team Info tab is populated with the protocol user's information.



### Your Application - Project Team Info

Applicants can add additional team members to their projects by scrolling down the page to the "Other Project Member Info" section and clicking the "Add New" button. This will open a new window.



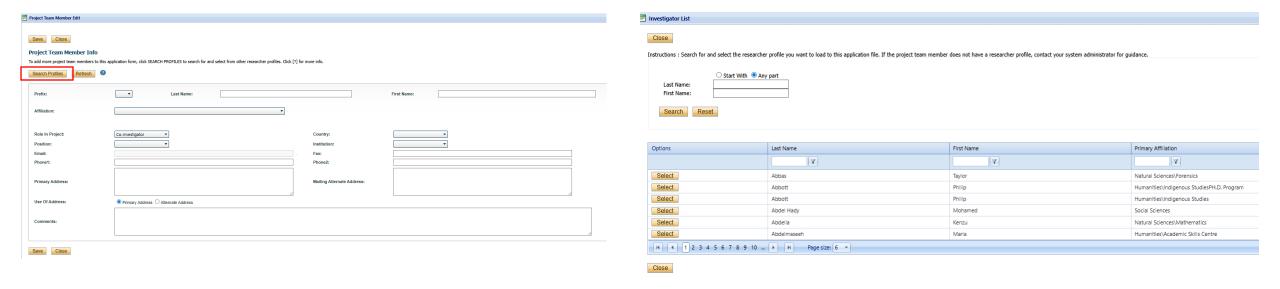
Collaborators/students who work directly with human participants or animals on your project, should be listed under the Team Member Info tab.

Supervisors <u>must</u> be included as team members on all graduate and undergraduate applications.

All listed Team Members have access to view and edit the application. Only the Principle Investigator can submit the application for review.

#### Your Application – Adding Team Members

The "Search Profiles" button opens the Investigators list in a new window. You can search the Investigator List for the name of the person to be assigned as team member.



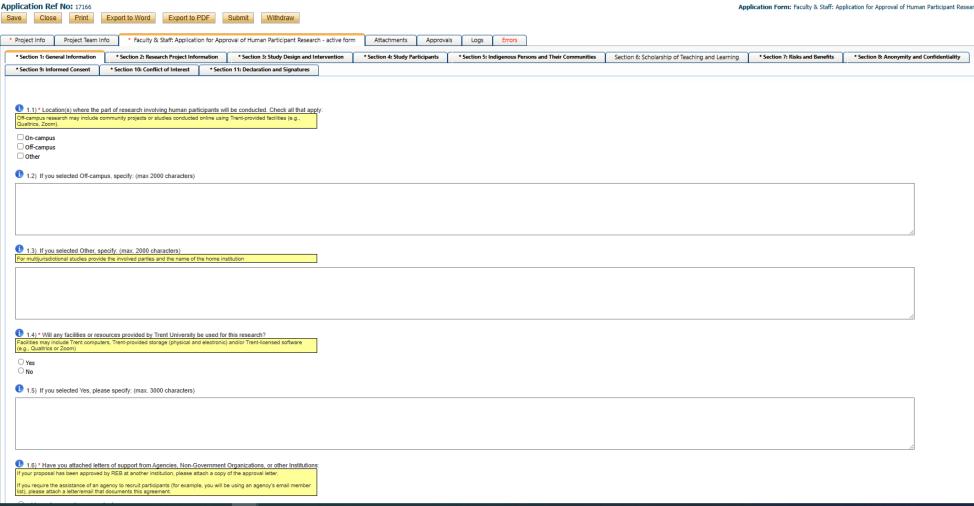
If you can't find the person you want to add to the Investigators list, contact them to register their investigator profile through the link for external users. Alternatively, email the Coordinator, Research Conduct and Reporting, at annakisiala@trentu.ca. Your email should contain the person's full name, title, affiliation, email address and role in the project.

#### Your Application – Ethics protocol

This is the body of the application, where you should explain to the review committee what your project is about, who it will benefit, and why it should be done.

Application Ref No: 17166

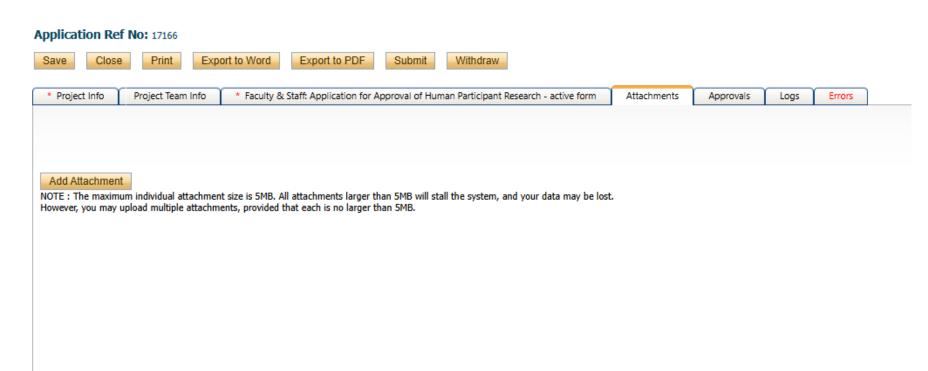
Application Feet No: 17166



#### Your Application – Attachments Tab

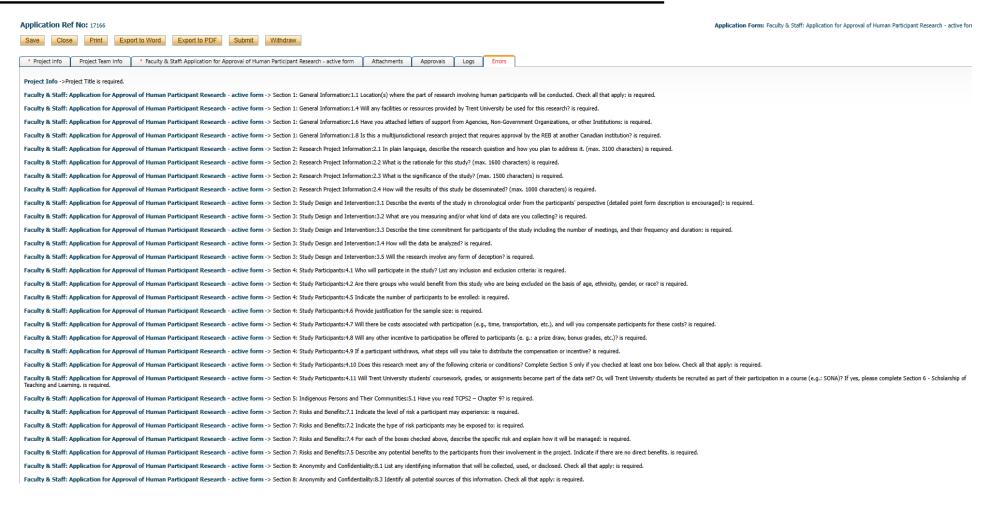
This tab is used to upload study documents, including advertisements, recruitment scripts, consent forms, interview scripts, certificates, support letters, permits, and animal handling protocols.

Be sure to include page and version numbers in each document, and a descriptive title and version number in the description.



#### Your Application – Errors Tab

The Errors tab keeps a log of required questions that weren't answered. If all required questions are answered, the Errors list disappears. The file can't be submitted for review until all Errors are resolved.

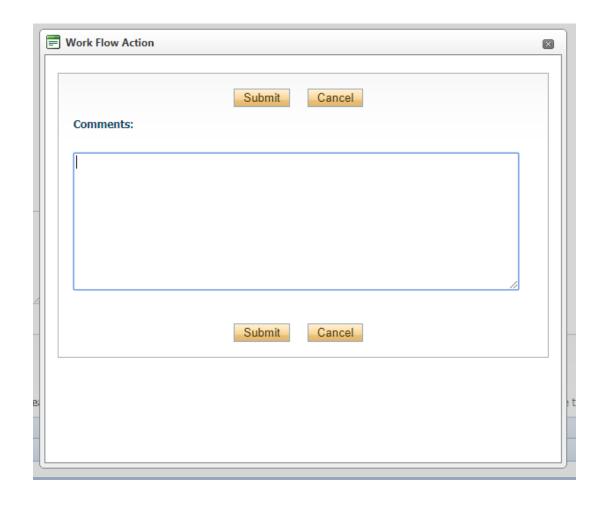


### Your Application – Submitting

When your application is ready for review, click the "**Submit**" button to open the Work Flow Action Window.

Enter a comment in the textbox provided. A comment can be a simple sentence (i.e., Submitting application for review). Do not include any important information in that box as it is not easily accessible to reviewers.

Click the "Submit" button to send your protocol for review.



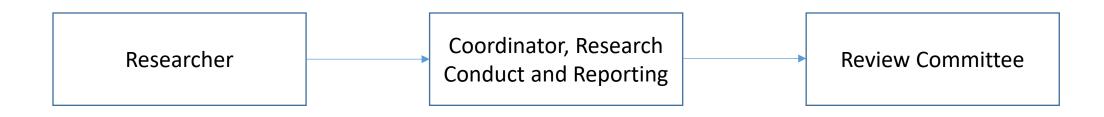
Once the application is successfully submitted, you will receive an automatic message confirming receipt of your submission. If the email doesn't arrive, recheck your **Applications: Draft** folder.

#### Your Application – Post-Submission

• Once you have submitted the application for review, you will **not** be able to make changes.

• Throughout the review process, the application can be viewed via the "Applications: Under Review" and "Applications: Post Review" links on the Researcher's Home Page.

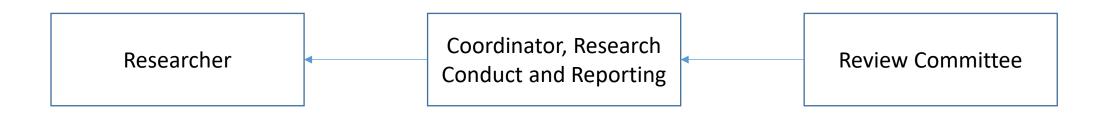
• Submitted applications are sent to the Coordinator, Research Conduct and Reporting, who assigns them to the appropriate review committee.



### Your Application - Applications Requiring Revisions

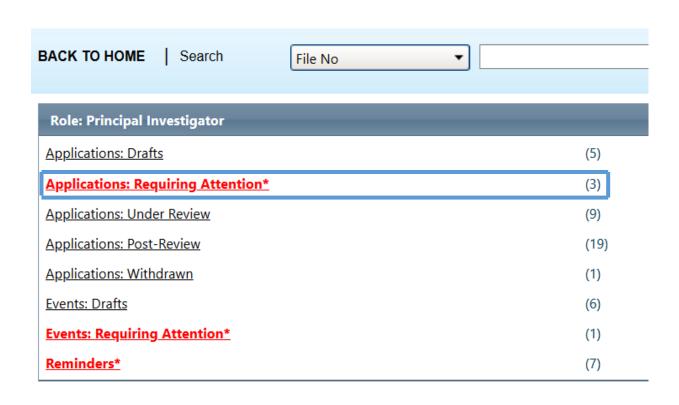
• If the review committee decides that an application needs revision, the Coordinator, Research Conduct and Reporting will email the study team a letter detailing any changes or additional information the committee has requested (Revisions Requested email).

• Next, the application will be returned to the research team for editing in ROMEO (Information Requested email).



#### Your Application – Revising prior to Approval

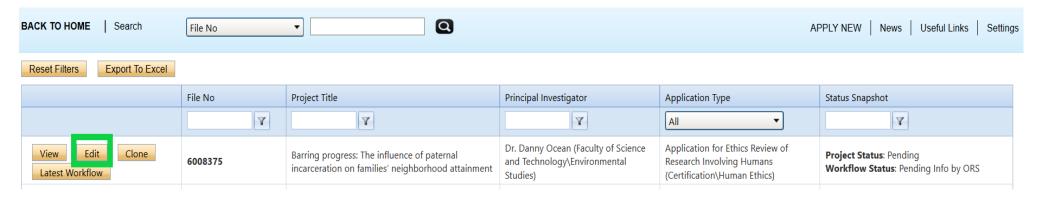
Once your application has been sent back to you, edits can be made.



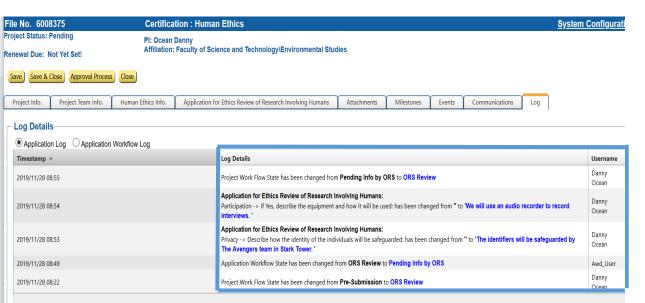
The protocol will appear in "Applications: Requiring Attention" folder.

## Your Application – Revising Prior to Approval

The edits can be made through opening the yellow Edit tab on the left side of the File no. The changes should reflect the comments of your review committee.



All changes are recorded in the application log.



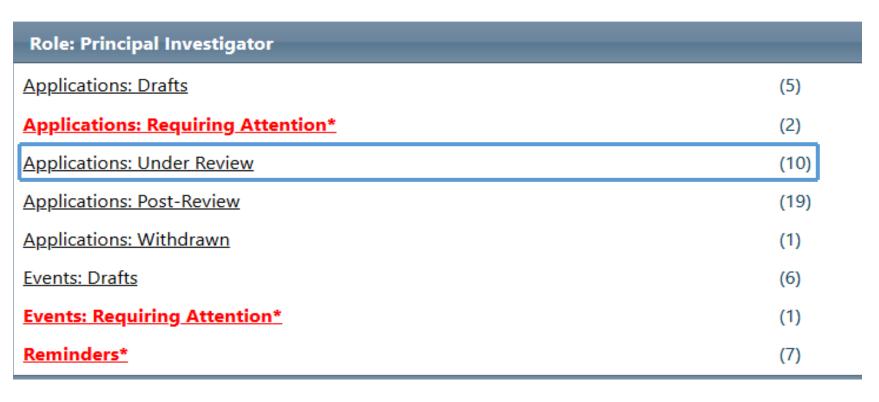
If your study documents require editing, delete the old version(s) from the Attachments Tab and upload the edited version(s) using the same title.

Be sure to include the version number in the document title.

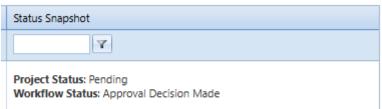
### Your Application – Resubmitting after Revisions

Once the application is re-submitted, it appears in the Research Portal as back "Under Review" with no options to make changes.

The application reassigned for review is moved to the "Post-Review" folder.



You can follow the status of review under: Status Snapchat (**Project Status**).



#### Your Application - Approval

Once the application has been approved, the PI receives a formal approval letter through email. A copy of the approval letter will be kept in the ROMEO application.

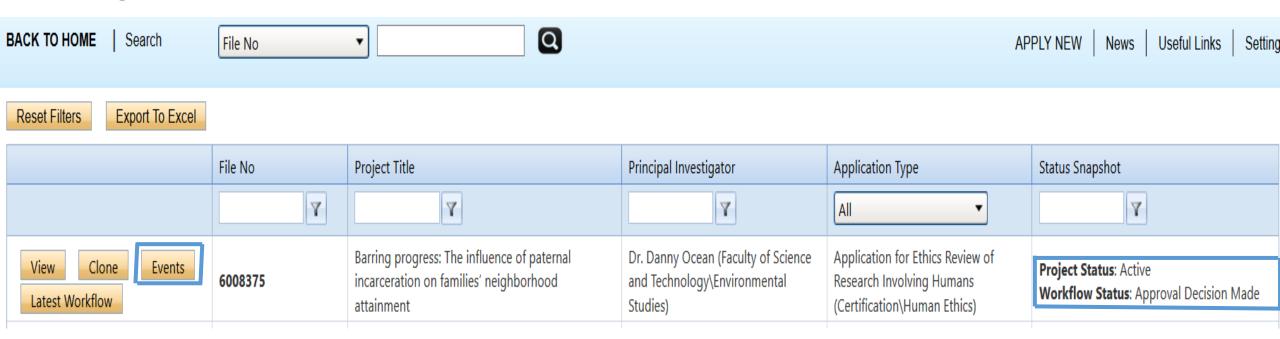
An approved application can no longer be modified but is available for viewing under "Applications – Post Review".

Role: Principal Investigator		
Applications: Drafts	(5)	
<u>Applications: Requiring Attention*</u>		
Applications: Under Review	(9)	
<u>Applications: Post-Review</u>	(20)	
Applications: Withdrawn	(1)	
Events: Drafts	(6)	
Events: Requiring Attention*		
Reminders*		

#### Your Application — Post-Approval

An approved human or animal ethics application can be modified by submitting the Events forms in ROMEO.

"Active" project status opens the ability to submit Events like project renewals, annual progress reports, study amendments, incident and closure forms, and adding new team members.



#### Your Application – Post Approval

Amendments to the approved ethics certifications can be created and submitted by **all** Team members.



#### File No: 28632

Principal Investigator: Dr. Anna Kisiala Project Title: Title - test application



The submission and approval procedures for Event forms are the same as for full ethics applications.