ORahs 2.0 Quick User Guide

For Investigators

This quick user guide was created to assist investigators with creating and submitting a protocol application using ORahs 2.0 for review of research applications involving human subjects by the UCSB Human Subjects Committee.

Questions?

Please contact the Human Subjects Coordinator (hsc@research.ucsb.edu or 805-893-3807).

A. Getting Started

1. First time users

If you are a first time user, review section A.3 below information to determine which ORahs role you should be assigned.

2. Requesting Access

If you are a post-doc or a student (graduate or undergraduate), you will need to contact your faculty advisor to give you an associate role under their account. Once you have been added to their account, you will be able to use your UCSB Net ID and password to log in and create a protocol.

If you are a faculty member or a researcher and need access, you will need to contact the HSC at orahshelp@research.ucsb.edu to request a researcher role.

If you are a faculty member or researcher and need to add an associate or proxy role to your account, log into ORahs and click on the "My Info" button on the right hand side of the page, then select either "add associate" or "add proxy" and enter the last name if the person who needs the account. Find the person you want to add and click "select". They now have an account and can access ORahs.

3. ORahs User Roles

Administrative: UCSB personnel (staff only). Role has read-only access to ORahs, can view all ORahs submissions associated with their department, and are authorized to receive all automated email communications on behalf of their department.

Associate: Post-docs or students (graduate, and undergraduate); may also include other individuals who are required to have a faculty advisor on the project (e.g., extra campus users). Associates cannot directly submit protocols to the HSC. The faculty advisor (i.e., "researcher" role) assigns the role of the "associate" to the individual under their faculty advisor's researcher account.

Proxy: UCSB personnel (staff only). A "proxy" is authorized to draft and submit human subjects protocols on behalf of a faculty advisor (i.e., "researcher" role). "Proxy" is assigned under the "researcher" role account. The "proxy" role must be added to each individual protocol. The "researcher" is responsible for all "proxy" actions and the HSC considers any action taken by the "proxy" to be taken and approved by the "researcher". The "proxy" is able to access only specific protocols they have been assigned to.

Researcher: Only faculty, professional researchers, or certain staff may be assigned this role. HSC assists with assigning this role.

For all other questions, or if you are unsure which role you should be assigned to, contact orahshelp@research.ucsb.edu.

4. Returning Users

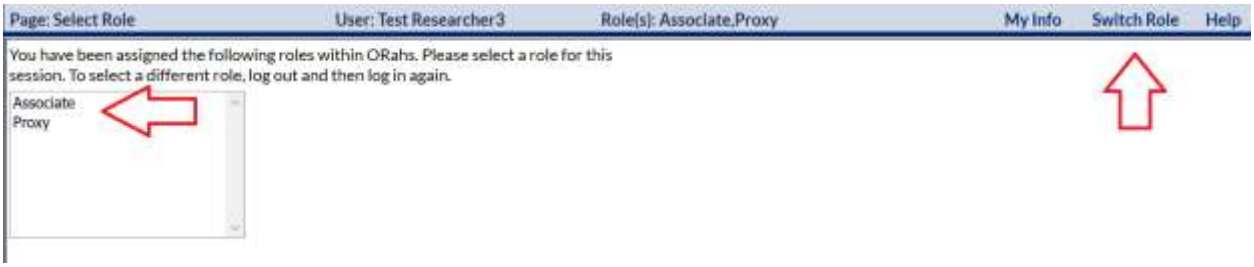
If you are a returning user, use your UCSB Net ID and password to access the online application system.

5. Submission Deadlines

Please review the submission deadlines on the login page to facilitate planning your project accordingly. It is recommended to submit your application *at least* one month prior to the anticipated start date.

6. User profile

Once you are logged in, if you have been assigned multiple user roles you will need to select the user role you would like to use for this session. If you need to switch your role while you are in ORahs, you may do so by clicking on "Switch Role" next to the "My Info" button. This button will bring you back to the main log in screen where you initially select the user role preference.



Depending on the role you are logged in as, you will have different access levels and have access to different menus. For more information on user roles, see section A.3 on ORahs User Roles.

7. ORahs Queues

After you login, you will be routed to the home page where you will have access to all submissions in which you are listed as investigator. ORahs submissions are saved in one of the following queues, depending on the status of the submission. Below is a brief summary of each queue:

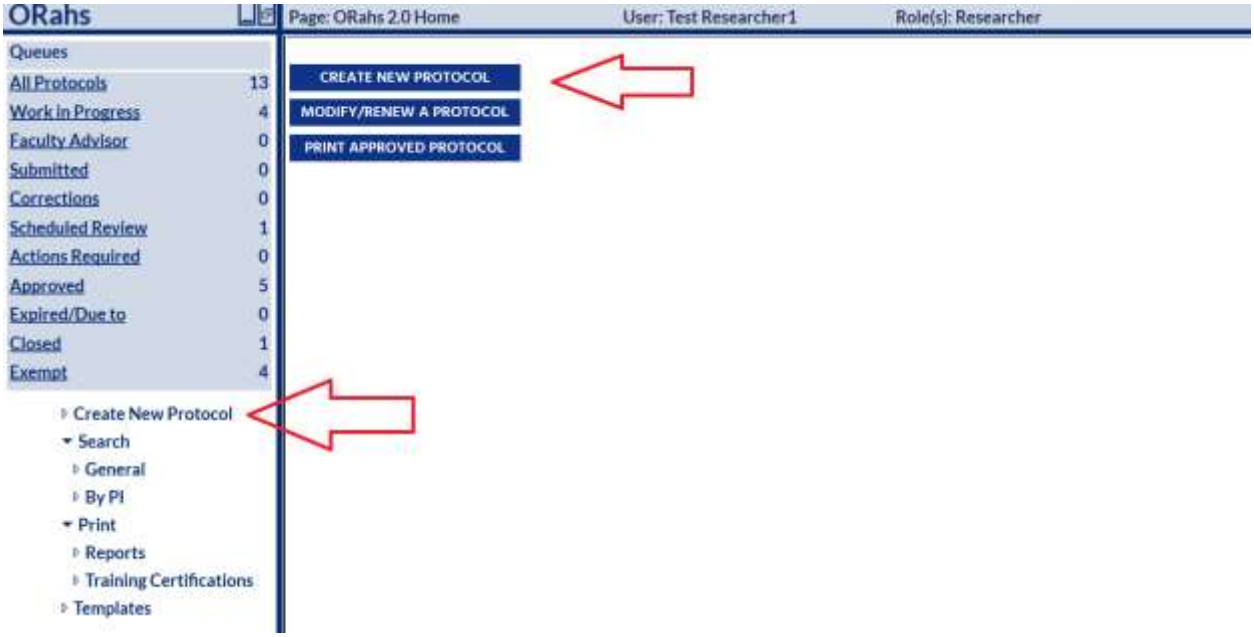
- All Protocols (queue will show all protocols, regardless of the status of their submission)
- Work in Progress (previously known as WIP, protocols that have not yet been submitted to the HSC are in this queue)
- Faculty Advisor (protocols submitted to the faculty advisor, are awaiting review by the advisor, and submission to the HSC)
- Submitted (submitted to the HSC for review)
- Corrections (corrections following administrative pre-review or committee review)

- Scheduled Review (protocols that have been set-up for review)
- Actions Required (protocols that either require human subjects training or Conflict of Interest release before final approval)
- Approved (approved protocols)
- Expired/Due to (protocols that are expired or will be expiring)
- Closed (protocols that have been closed, either voluntary or automatic following the protocol's expiration)
- Exempt (exempt protocols that do not expire)

B. The Protocol Application

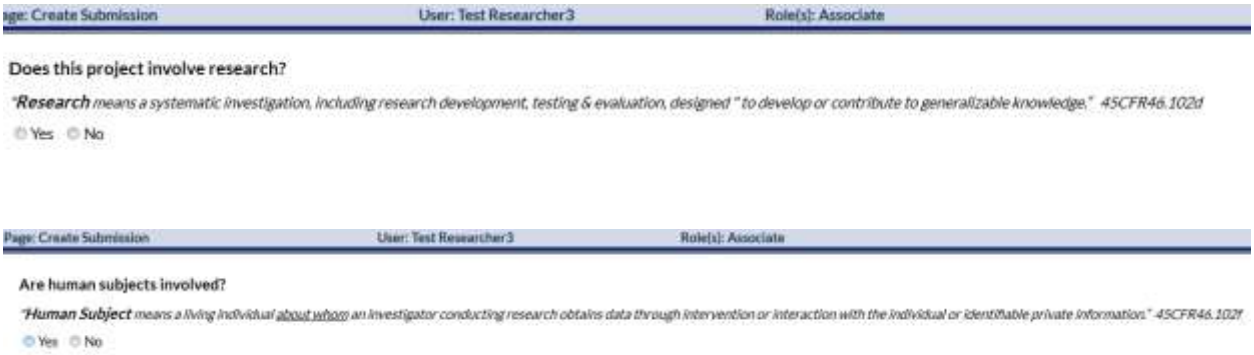
1. Creating an application

There are a few options for creating a new application. You can select the "Create New Protocol" button from the side bar menu on the main menu page or on the main screen.



After you select "Create New Protocol" you will be asked to confirm if your project is "research" involving "human subjects".

Please carefully review the definitions of "research" and "human subjects" in these two questions.



See definitions below:

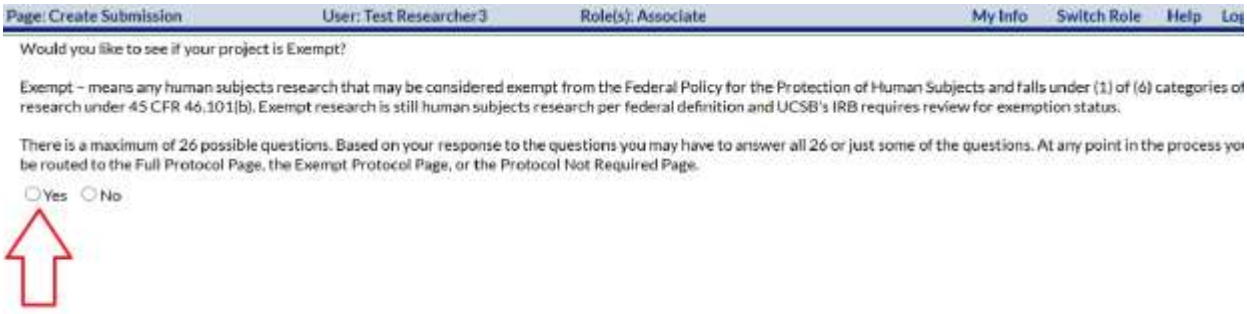
> ***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
>
> ***Human subject*** means a living individual *about whom* an investigator (whether professional or student) conducting research obtains: 1) Data through ***intervention*** or ***interaction*** with the individual, or 2) Identifiable private information.
>
> ***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
>
> ***Interaction*** includes communication or interpersonal contact between investigator and subject.
>
> ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

2. Not Human Subjects Research

If you think your project may not qualify as human subjects research after you have reviewed the definitions and would like a letter of determination of "Not Human Subjects Research" from the Human Subjects Committee, please download and complete this form, then email to hsc@research.ucsb.edu for review.

3. Exempt Research

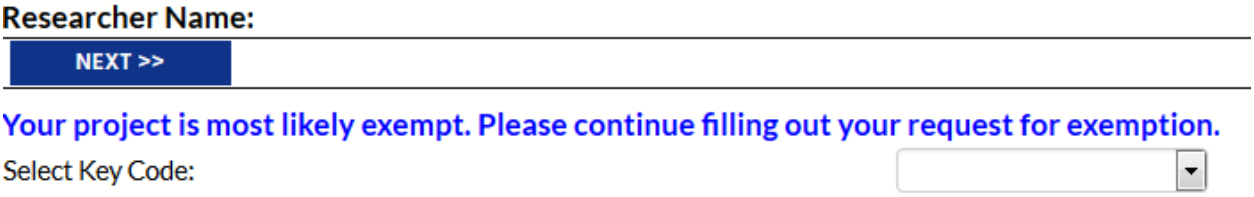
If your project is research involving human subjects, then the next step is to see if your project qualifies as "exempt" under one (1) of six (6) categories of research. It is recommended to complete the exemption decision tree to see if your project may qualify as "exempt".



The exemption decision tree was designed to assist investigators with determining whether a project qualifies as "exempt". There are 26 possible questions you may be asked to respond to. Review the questions carefully before responding "yes" or "no" and think about your subject population in the context of the questions.

Depending upon your answers, you will be routed directly to the full application to submit your non-exempt research for review or you will be prompted to answer the exemption tree questions to determine if your research is eligible for exemption. Please note that depending upon your responses, ORahs may automatically **skip** over some of the exemption tree questions.

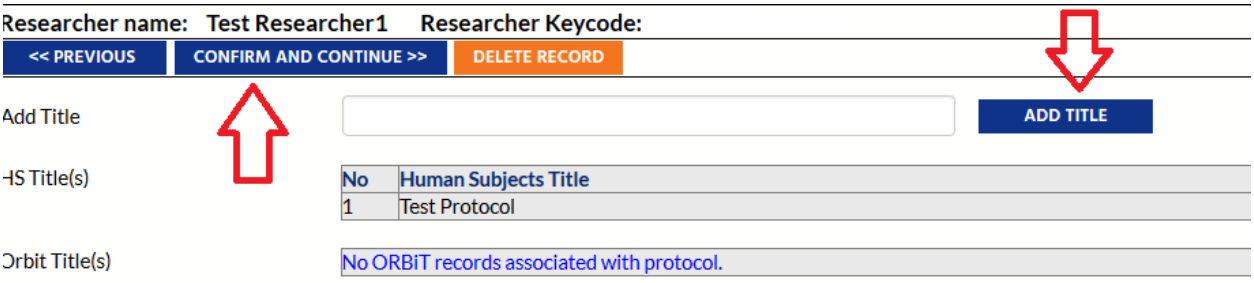
After you have completed the decision tree, select the appropriate key code from the drop down menu that you wish to have your project associated with.



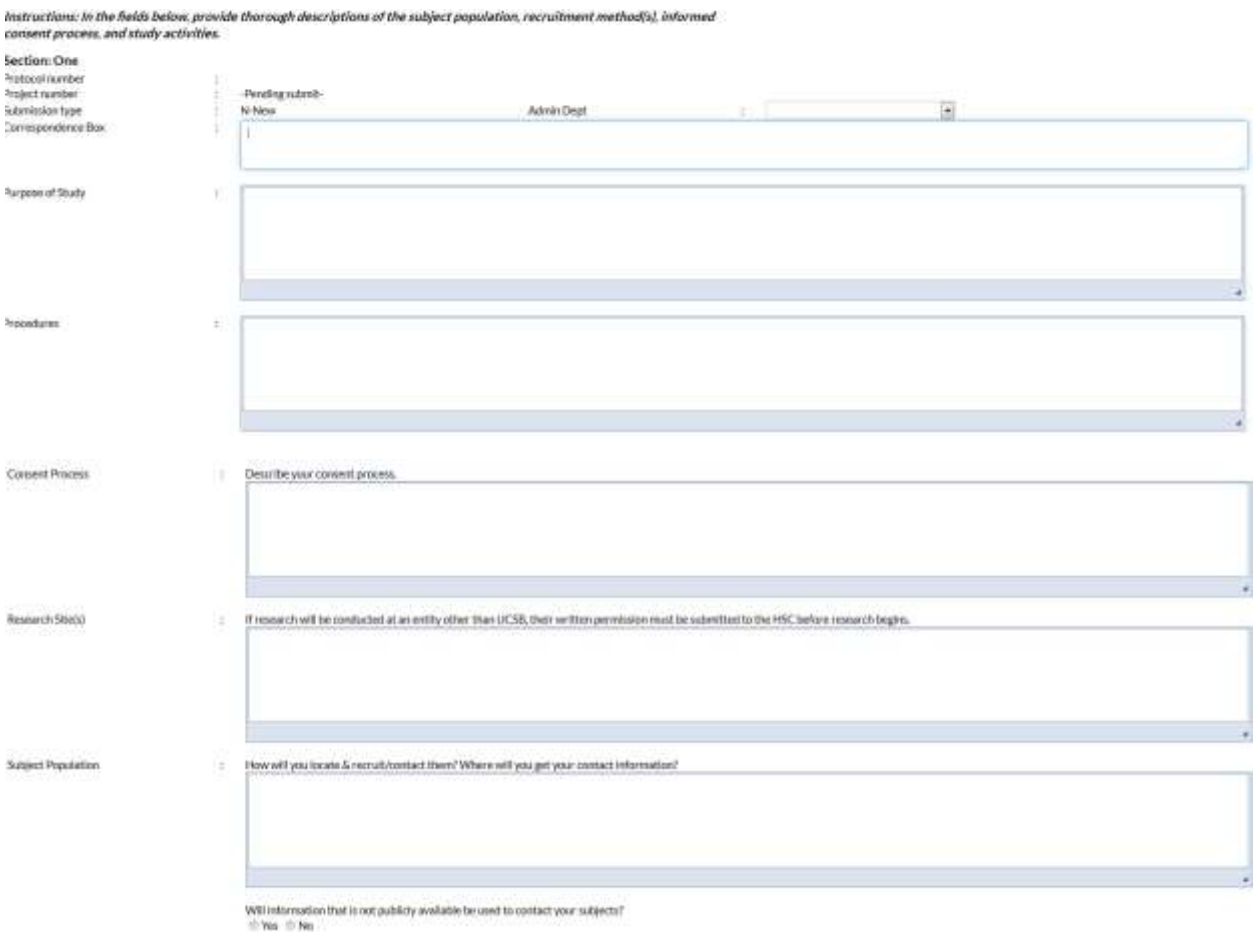
On the following page you will be asked about how the project will be funded.

Note: If you are a student investigator, funding should only be added by your faculty advisor. If the project is funded by the Department of Defense, then additional requirements may be applicable. Please see UCSB's guidance on Department of Defense human subjects research.

On the following page, add the title of your project and click "Confirm and Continue".



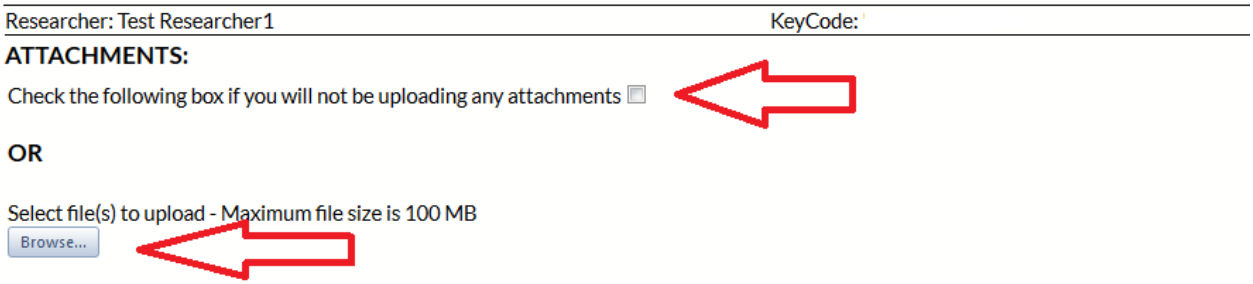
The next screen will bring you to the Exempt application. Review and complete all the sections within the application.



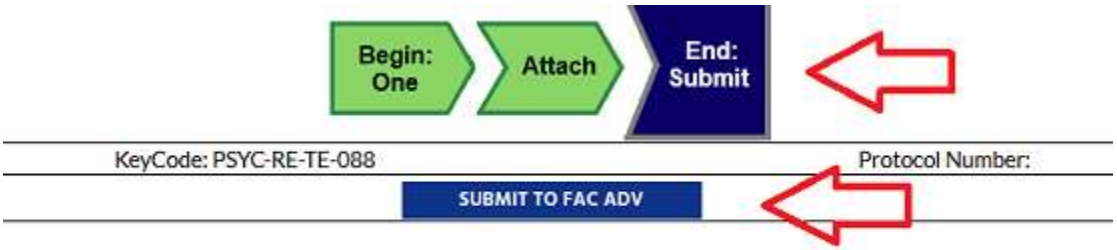
Click on “save and continue” to move to the Attachments tab. Upload all research related materials to the Attachments tab. Materials may include, but are not limited to:

- Surveys, questionnaires, interview guides and other research tools;
- Advertisements, invitations, and other recruitment documents;
- Any other study specific documents.

If you do not have any materials to upload, check the corresponding box.



Next click on "Save and Continue" and depending on which role you are logged in as, you may submit the application to your Faculty Advisor or to the HSC for review.



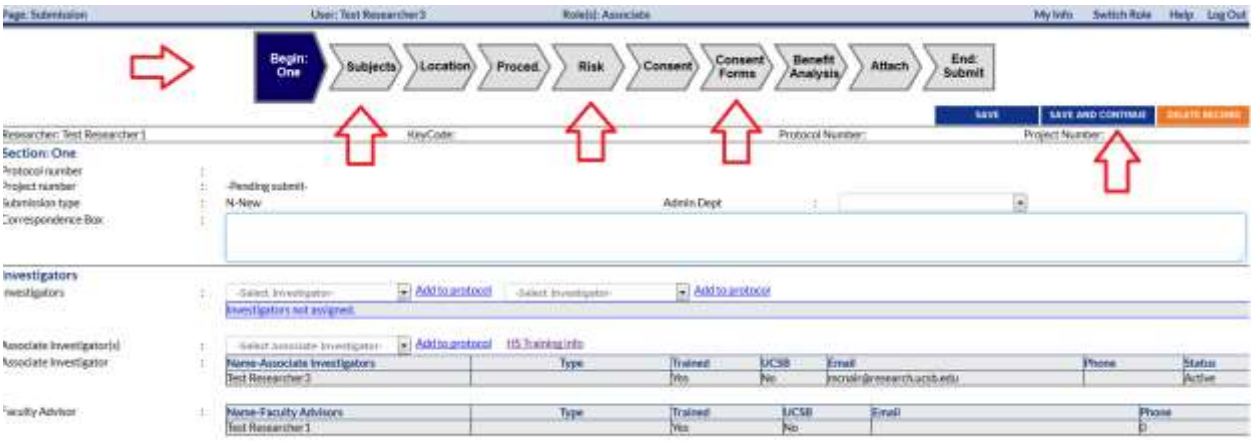
4. Non-Exempt Research

If you completed the decision tree and were routed to the non-exempt application or if you know your proposed research is not "exempt", then click "No" and you will need to complete a full application.

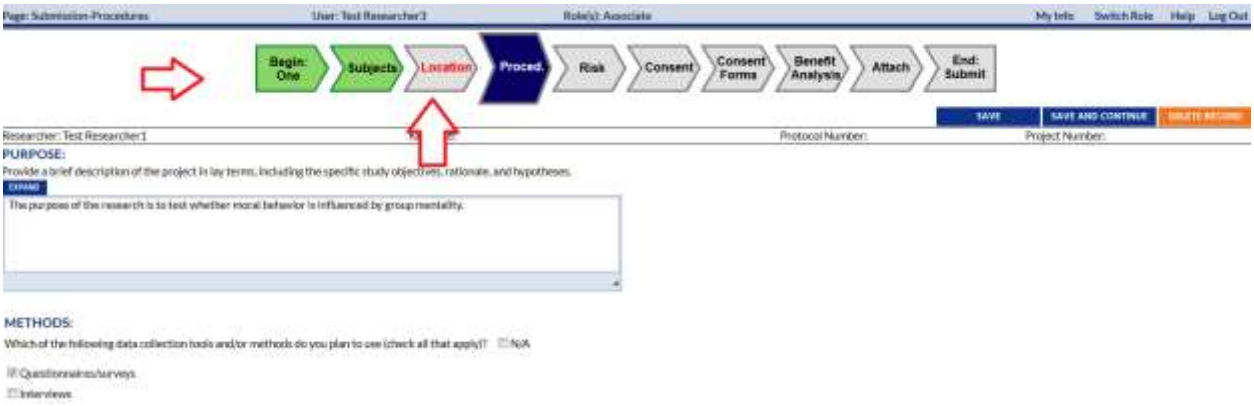
Research that is considered greater than minimal risk cannot be considered "exempt" and requires a full application submission. Some minimal risk studies may not qualify for exemption. Examples are studies that may involve non-educational surveys or interviews involving minors, collection of biological specimens, and some non-invasive procedures (physiologic measures such as fMRI). In addition, greater than minimal risk means research procedures that may include risk beyond those ordinarily encountered in daily life. For example, research involving vulnerable populations (prisoners, minors, undocumented immigrants, etc.), using deception, and collecting identifiable private information, are typically not exempt research projects.

Follow the instructions under Section B.1 to create a new non-exempt application for HSC review.

You will be routed to the main non-exempt protocol application page. Complete all the required fields within each tab and click on “save and continue” before moving to the next tab.



When moving to another tab, the Navigation Bar at the top of the protocol application will turn green to indicate all required fields have been answered. If a tab is missing information, the Navigation Bar will turn red indicating that a required field still needs to be answered before the protocol application can be submitted to the HSC for review.



Once you have completed the protocol application, all tabs should be green indicating the protocol is complete and can be submitted to the HSC. Depending on your user role, you will be able to submit it your faculty advisor for review or directly to the HSC for review.

C. Submitting the Application

1. Submit to HSC or Faculty Advisor

After your new application (exempt or non-exempt) has been created, it will remain in the Work In Progress queue until you submit the application to your Faculty Advisor queue for review and input or approval.

If you are a faculty member submitting the application, you may either sub it directly to HSC or send it back to your research team for revision.

2. HS Administrative Pre-review

The HS staff conducts an administrative pre-review of all proposed research activities. The administrative review includes, but is not limited to, the following:

- Risk level assessment to determine if the application qualifies as Exempt, Expedited, or Full Board;
- Checking the protocol for completeness (e.g., are the survey materials, questionnaires, recruitment flyers attached, are there consent forms, etc.);
- Review of the elements of informed consent and any requests for waivers;
- Review of the protocol procedures (e.g., recruitment methods, data collection methods, etc.);
- Review of the proposed study population and any exclusion/inclusion criteria.

Any requests for revisions or clarifications will be communicated to you on the “One” tab of the protocol application in the “Correspondence” box. Each tab that needs corrections will be identified in red.

After you have made the revisions, depending on your role, resubmit the protocol directly to the HSC or your faculty advisor.

Note: The administrative pre-review helps evaluate the content of each ORahs tab to determine if sufficient information about the proposed research is included for review. Items that are missing or not fully described require additional HSC time for pre-review and review (e.g., multiple reviews).

3. Scheduled Review

After the pre-review is complete, the protocol will be set-up for Expedited or Full Board Review, depending on the level of risk to subjects identified during the pre-review process. ***Note***: Exempt application are reviewed during Expedited review.

4. Following Scheduled Review

After the protocol has been reviewed by the Committee during Expedited or Full Board Review, the protocol may be approved or there may be revisions requested before final approval. You will receive an email notification of the status of the protocol submitted.

5. Approval

Once the protocol has been approved, you will receive an email notification and you may now begin your human subjects research.

Research activities, including recruitment, enrollment, and analyzing data may not commence until FINAL HSC approval has been received.

D. Miscellaneous

For information on how to modify, renew, add or change personnel, close a protocol, change faculty advisors, etc., see the ORahs 2.0 tutorials on the Office of Research website.

If you would like specific training on how to use each tab within ORahs 2.0, contact the HSC at hsc@research.ucsb.edu to set-up a time for a one-on-one training session.