IRBnet.org

Before conducting any formal research, students must secure UNLV Institutional Research Board (IRB) approval following the instructions outlined on the linked webpages below. Students are encouraged to review the Quick Start Guide and the Research Proposal Protocol Form (see subsequent pages, below; students should access the Word version of the protocol form from within the IRBnet.org system when they are ready to begin working on it for their proposed study/studies).

Home Page:
https://www.irbnet.org/release/index.html

New User Registration Page:
https://www.irbnet.org/release/public/register.jsp

UNLV
Office of Research Integrity

IRBNet

Researcher Submission Quick Start Guide

Important Terms

Project = An entire study. When you create a new project you are submitting an application for a completely new study.
Package = A package is a document or set of documents that are submitted as part of a project. For example, protocol forms, amendments, revised documents, continuing reviews, consent forms, etc.
IRBNet ID# = (Format is ######-#) The digits before the dash are the project number, the digit after the dash is the package number. When referencing a project number only include the first set of digits.

Tips

Tip 1: After login, click [Forms and Templates] to download all of the necessary forms for a complete submission. Complete the forms and assemble any other documents and save them in one folder location on your computer before creating a new project. There is also a submission checklist in the library.

Tip 2: Upload your training documents to your user profile after you register. Click [User Profile] at the top right corner of the page, next to [Logout]. Scroll down to the bottom of the User Profile screen to find the link to upload training. This will allow you to link your training records to your projects once you enter the Designer screen.

Tip 3: Once you start the process of creating a new project or package your progress will be saved in IRBNet as you move from step to step. If you logout and come back later you will find the project or package you started in [My Projects] and it will have "Work in Progress" as the submission type. You can pick up where you left off at any time.

IRBNet Instructional Videos

IRBNet offers two instructional videos to show new users how to work with the system: New Project Submissions and Post-submission Advanced Topics. These videos can be accessed at http://www.irbnetresources.org/tresources/training.html. When prompted, enter Username (UNLV) and Password (training).

Additional Help

If you are having trouble with a submission after watching the videos and reading the guidance below you can contact a board administrator for assistance.

- For IRB submissions contact Christa Esparza at (702) 895-4225
- For IBC & IACUC submissions contact Kevin Bergeron at (702) 895-5453

Part A. Creating a New Project

1. Login at www.IRBnet.org, the default screen after login is the My Projects screen.
2. Create a new project (i.e. new study) by clicking [Create New Project] in the left menu. Do not create a new project to manage an existing project. Amendments, continuing reviews, revisions, adding missing documents, etc. to an existing project will be discussed in Part B. Managing Existing Projects.
3. Enter the project information and click [Continue]
4. The Designer screen opens. [Step 1.] Download forms. Select the correct board (IRB Biomedical, IRB Social/Behavioral, IACUC, or IBC) from the drop down list as each board has its own library. The second drop down list contains the forms available for the library selected. *If you followed tip 1 above all of your documents should be prepared to upload and therefore you can skip this step.* [Step 2.] Add your documents to the project [Add New Document], select the Document type, enter a description, choose the file to upload, then [Attach]. For example, select "Protocol" as the document type, type " Protocol" as the description, then choose the protocol file saved on your computer, then click [attach]. Repeat this process for each document, if the document type is not listed, use "Other" then use the description field to describe the type of document. Finally once all documents are attached link your training documents to this project (see tip 2 above).
5. Select [Share this Project] from the left navigation menu.
6. From the Share Project screen select one of the three options, Share, Multi-site, or Transfer. If you are the PI on the project you may want to share the project with other team members who are also registered with IRBNet. You can select the type of access they have to the project, again there are three options, Full, Write, Read. If you are not the PI on this project you are required to share the project with the PI and grant them Full access.
7. After the project is shared (if applicable) it is time to sign your Project/Package. All projects and packages must be signed by the PI. Select [Sign this Package] from the left menu. If you are not the PI, once you have shared the project/package with the PI, you must notify them to login to IRBNet and sign the project/package. You can message other team members from within IRBNet by clicking [Send Project Mail].
8. Once the Project/Package is signed by the PI select [Submit this Package] from the left menu. The Submit Package screen will open, type "UNLV" in the search box and click [Search]. **Carefully select the correct Review Board** from the list and click [Continue]. Select the submission type from the drop down list. Enter any comments that you would like the board Administrators to read. Click [Submit].
9. Your submission is now locked  and the Board Action is Pending Review. Your submission will first receive an administrative pre-review. If edits or additional information is needed, the administrator will unlock the package and notify you why the package was unlocked. See Part B. for instructions on how to respond to an unlocked package. Do not create any new packages for this project unless requested by the board. If you accidentally submitted a project/package contact an IRBNet Administrator (irb@unlv.edu for IRB submissions, kevin.bergeron@unlv.edu for IACUC and IBC submissions).

Part B. Managing Existing Projects

Scenario 1. During pre-review the board administrators have requested revisions to a document, additional documents, training records, or other missing information.

In this scenario an administrator will send you a notification with details about the corrections needed and they will unlock the package. There are three ways to view the message from the board. 1) From the My Projects screen, click on the red unlocked icon , which opens the Designer screen, then click "View History" at the top of the screen next to the red unlocked icon. 2) Click [My Reminders] on the left navigation menu, a list of notifications will be displayed, click Package Unlocked, the message will be displayed in a pop out window. 3) Email, you will receive a copy of the notification message via email.

Respond to an unlocked package: Do not create a new package to make edits to an unlocked package. From [My Projects], click on the title of the project. To make the necessary changes open the [Designer]. All of the documents are located in the table. To revise/update an existing document, click the paper icon to download the current document. Edit the document as necessary and remember the location of the saved file. Next click the pencil icon in the table next to the document, this opens a file upload window. Upload the updated document. If you need to remove a document completely, click the delete icon. To add missing documents, click [Add New Document] and follow the steps used before to upload a new document. The final step to "re-submit" the updated package is to "Mark Revisions Complete."

By marking your revisions complete it locks the package and notifies the board that you have made the necessary edits. Failure to mark revisions complete will delay the review process. You can confirm that your revisions have been marked complete and the package has been locked by the presence of the green locked icon.

Scenario 2. Revisions-Modifications Required Letters, Amendments, Continuing Reviews (IRB), Annual Reviews (IACUC), Renewals (IACUC, IBC), or other submissions during or after board review.

In this scenario, the project is under review by the board and they have requested modifications to a submission or the project has already been approved and you need to submit an amendment, continuing review, annual review, etc. The process is very similar to editing an unlocked package only this time you will submit the documents as a new package rather than editing the original package.

Respond to a revisions request or submit amendments, continuing reviews, annual reviews, renewals, etc: Open the project from [My Projects] by clicking on the project title. Select [Project History] from the left navigation menu. Click [Create New Package] under the table. You will notice that the IRBNet ID# will now read (######-2). The -2 identifies this as the second package created for this project. Each subsequent package is identified this way. Next open the [Designer]. To submit a revised version of an existing document, click the paper icon to download the current document. Edit the document as necessary and remember the location of the saved file. Next click the pencil icon in the table next to the document, this opens a file upload window. Upload the updated document. Repeat this process for only those documents that need to be updated. To add a new document like an amendment form, continuing review form, annual review form, etc., click the [Add New Document] button located above the table. After the new document is uploaded you will see the new document has been added to the table. You will notice that the first column in the table is "pkg#" (package number), any new documents or documents that have been updated will now have a "2" in this column. Any documents that have not been revised will still have a "1" in this column, thereby distinguishing what documents are being submitted as part of the new package (in this example second package). You then Share, Sign, and Submit the package.

Research Protocol Proposal Form
For Research Involving Human Subjects

Instructions:
1. CITI certification (www.citiprogram.org) must be current at the time of protocol submission.
2. Complete all sections. Do not reference other sections as a response (e.g., "see section…" or "see attached…")
3. Projects with funding/proposed funding must include copy of the application or proposal.
4. You must proofread your document for spelling and grammar before submitting to assure timely IRB review.

Note:
1. Research may not begin until you have received notification of IRB approval.
2. For your records, it is important that you keep a copy of this completed form.

1. Research Protocol Title (Research Protocol Title must match the funding/proposed funding application or proposal):

2. Investigator(s) Contact Information
(The PI must be UNLV faculty in all cases involving studies carried out by students or fellows.)

A. Principal Investigator (*Name and Credentials*):

☐ Faculty ☐ Faculty Advisor

Department: Mail Stop: Phone Number:

E-Mail Address:

B. Student/Fellow Investigator (*Name and Credentials*):

☐ Undergraduate ☐ Master's Student ☐ Doctorate Student ☐ Fellow

Department: Mail Stop: Phone Number:

E-Mail Address:

C. Please complete (if applicable).

Protocol Coordinator (*Name and Credentials*):

Phone Number:

E-Mail Address:

Co-Principal Investigator (*Name and Credentials*):

☐ Faculty

Department: Mail Stop: Phone Number:

E-Mail Address:

3. Research Team Members: *List all research team members (including PI) who will have contact with subjects, have contact with subjects' data or biological samples, or use subjects' personal information. If additional members will be included, submit Appendix "Additional Research Team Members."*

NAME and DEPARTMENT	ROLE IN PROTOCOL	SPECIFIC EXPERIENCE WITH ROLE IN PROTOCOL	ROLE IN CONSENT PROCESS
EXAMPLE: Dr. Chris Researcher, Research Department	**EXAMPLE:** Developed protocol, collecting data, analyzing data, writing report	**EXAMPLE:** Has had 7 years of conducting and publishing human subjects research at a university	**EXAMPLE:** Recruiting subjects, writing the consent form, consenting subjects, answering questions

Hit tab in last available cell to add additional rows.

4. Duration of Study

Anticipated Start Date: MM/DD/YEAR Anticipated Termination Date: MM/DD/YEAR

5. Research Subjects

5.1 Describe the sampling strategy used to select subjects.

5.2 Maximum number of subjects:

5.3 Describe the targeted population (e.g. healthy adults age 18-45), including age range. Delineate between the various subject groups:

5.4 Summarize the inclusion criteria for each subject group that must be met in order for the subject to participate in the study.

5.5 Are there any enrollment restrictions based on gender, pregnancy, race or ethnic origins? ☐ Yes ☐ No
If yes, specify and explain the nature of the restriction(s) and provide justification for each population.

5.6 Will you be recruiting any of these specific populations?

☐ Children 17 and under
☐ Prisoners, Parolees and/or Probationers
☐ College Students
☐ Pregnant Women, Fetuses and Neonates
☐ Wards of the State
☐ I will be using biological specimens
☐ CCSD Employees and/or students

5.7 Would your population be considered decisional/cognitively impaired? ☐ Yes ☐ No
5.7.1 Will the subjects be able to provide consent/assent on their own? ☐ Yes ☐ No

6. Recruitment Procedures

6.1 Describe the methods of recruitment including use of letters and/or advertising. Include when, how and by whom the subjects will be recruited.

6.2 Indicate the types of recruitment materials to be used below (check all that apply). Attach copies of all recruitment materials to this application.

☐ Internet/Email ☐ Television/Radio/Newspaper ☐ Flyers/Posters/Brochures
☐ Letter of Contact ☐ Subject Pool Description ☐ Telephone Script
☐ Word of Mouth ☐ Social Media ☐ Other (Describe):
☐ This research study will not be using any recruitment materials.

7. Purpose and Procedures

7.1 State the purpose of the study:

7.2 Lay language summary (Please use non-technical language to summarize your research study):

7.3 Describe all research procedures (sequentially). Include required screening procedures performed before enrollment and while on study. Describe the types, frequency and duration of tests, observations, interviews, questionnaires, etc. Please provide a list or outline format/flow chart for ease of review.

7.4 List and attach all instruments associated with this research study:

7.5 Will subjects be recorded? ☐ No ☐ Yes, audio ☐ Yes, video

8. Consent

8.1 Describe the consent process(es) for enrolling each subject population into the study.

8.2 Describe where the consent process(es) take place.

8.3 Will any information about the research purpose and/or design be withheld from potential or participating subjects at any time during the study? ☐ Yes ☐ No

8.3.1 Explain and justify the non-disclosure and describe plans for post-study debriefing.

8.4 Is a waiver of the signature requirement on the informed consent being requested? ☐ Yes ☐ No

8.4.1 Explain why the waiver of signature is being requested.

9. Project Site(s) *(Check all that apply)*

☐ University of Nevada, Las Vegas (UNLV) – Please check the specific campus.
☐ Maryland Campus (main) ☐ Shadow Lane Campus

☐ Online only ☐ Other: (Specify and Explain all):

NOTE: If the project site is other than UNLV or online, Facility Authorization Letter must be submitted.

10. Privacy and Confidentiality

Privacy *refers to a person's desire to control the access of others to themselves. Privacy relates to the subject.*
Confidentiality *refers to the researcher's agreement with the subject about how the subject's identifiable private information will be handled, managed, and disseminated. Confidentiality relates to a subject's information.*

10.1 In regards to the above definition, how will you protect the privacy of the participants?

10.2 In regards to the above definition, how will you ensure confidentiality of the data obtained?

10.3 Where will all data be stored? (for review/audit purposes, a copy of all records must be kept in a location accessible by the PI on UNLV property):
☐ PI's office (bldg/room): ☐ PI's laboratory (bldg/room): ☐ Other (bldg/room):

10.4 How long will identifiable AND de-identified data be stored?

10.5 What are the plans for the final disposition or destruction of identifiable and de-identified data?

11. Medical Devices

Are you using a medical device? ☐ Yes ☐ No (If yes, please complete the supplement "Medical Device.")

12. Risks

12.1 Summarize the nature and amount of risk (including side effects, stress, and discomfort). Examples of risk include physical risks, psychological risks (such as stress, discomfort, or invasion of privacy) and social risks (such as jeopardy to insurability or employability).

12.2 Estimate the probability (e.g. not likely, likely, etc.) that a given harm may/will occur, its severity, and its potential reversibility.

12.3 What procedure(s) will be utilized to prevent/minimize any potential risks?

13. Benefits

13.1 Describe any probable benefits of the research for the individual subject(s). (Do not address compensation)

13.2 Describe the probable benefits of the research for society.

14. Cost/Compensation

14.1 Describe the total amount of participation time, followed by breakdowns of this time (if necessary):

14.2 Are there financial costs to the subject? ☐ Yes ☐ No If yes, explain:

14.3 Will subjects be paid or otherwise compensated for research participation? This may be monetary OR non-monetary.
☐ Yes ☐ No

14.3.1 If yes, please respond to the following questions:
a) Describe the nature of any compensation to subjects. Include cash, gifts, research credit, etc.
b) Provide a dollar amount, if applicable, and indicate method of payment. $
☐ Cash ☐ Check ☐ Research Credit ☐ Other:
c) Explain when and how the compensation is provided to the subject.
d) Describe the alternative option offered to subjects if the potential subject does not wish to participate in the research.

15. Funding

15.1 Is there any internal or external funding (e.g., grants, contracts, gifts, etc.) ☐ Yes ☐ No

15.1.1 If yes, Name of Sponsor or UNLV Grant Program
Attach a copy of the proposal and/or award document (the budget must be included).

16. Conflict of Interest

16.1 Does a conflict of interest exist with this study? ☐ No ☐ Yes, explain:
16.2 Do you or any member of the research team have an authoritative role over the research subjects? ☐ Yes ☐ No
16.2.1 If yes, please explain:

17. Signatures of Assurance

A. Investigator's Assurance:
I certify that the information provided in this application is complete and accurate. As Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations designated by the IRB. I agree to comply with all UNLV policies and procedures, as well as with all applicable Federal, State and local laws regarding the protection of human subjects in research including, but not limited to the following:

- Performing the project by qualified personnel according to the approved protocol.

- Not changing the approved protocol or consent form without prior IRB approval (except in an emergency, if necessary, to safeguard the well-being of human subjects).
- Obtaining proper informed consent from human subjects or their legally responsible representative, using only the currently approved, stamped consent form.
- Promptly reporting adverse events to the ORI – Human Subjects in writing according to IRB guidelines.
- Arranging for a co-investigator to assume direct responsibility, if the PI will be unavailable to direct this research personally, as when on sabbatical leave or vacation.

***FACULTY ADVISOR** (IF APPLICABLE)**:** By my signature as Principal Investigator on this research application, I certify that the student/fellow investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the approved protocol. In addition:

- I agree to act as the liaison between the IRB and the student/fellow investigator with all written and verbal communications.
- I agree to meet with the student/fellow investigator on a regular basis to monitor the progress of the study.
- I agree to be available and to personally supervise the student/fellow investigator in solving problems, as they arise.
- I assure that the student/fellow investigator will promptly report adverse events to the ORI – Human Subjects according to IRB guidelines.
- I will arrange for an alternate faculty advisor to assume responsibility if I become unavailable, as when on sabbatical leave or vacation.
- I assure that the student/fellow investigator will follow through with the storage and destruction of data as outlined in the protocol.
- By submitting this form electronically, I agree to the assurance as stated above.