Nancy Moody, J.D., M.A.
Director, Research Integrity

775 327 2367

nmoody@unr.edu

Political Regulation of Research

- Historically, governments have had to put serious restrictions on researchers. In fact, the origin of codes of research ethics can be traced to the NUREMBERG CODE, a list of rules established by a military tribunal on Nazi war crimes during World War II.

The principles outlined in the Nuremberg Code include:

- Voluntary consent
- Avoidance of unnecessary suffering
- Avoidance of accidental death or disability
- Termination of research if harm is likely
- Experiments should be conducted by highly qualified people
- Results should be for the good of society and unattainable by any other means

National Research Act (Pub. L. 93-348)

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.

The Commission was directed to consider:

- **the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine,**
- **the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects,**
- **appropriate guidelines for the selection of human subjects for participation in such research and the nature and definition of informed consent in various research settings.**

What is Institutional Review Board?

- An Institutional Review Board (IRB), according to federal law, must evaluate the potential physical or psychological risk of research involving human subjects.
- All proposed human research must be reviewed and approved by an IRB before experimentation begins.
- This includes any surveys or questionnaires to be used in a project.

Participant's Perspective

- Who are the participants?
- How are they recruited?
- Coerced to participate?
- Will they understand, in advance, what they are agreeing to participate in?
- Could the participant be compromised or embarrassed if information collected leaked out?
- Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful?
- Long-term consequences?
- IRB's role is to look at the study from this perspective and to ensure that proper precautions are taken to protect individuals when they agree to participate in research.

Historical Overview:
The Belmont Report – April 18, 1979

Ethical Principles and Guidelines for the Protection of Human Subjects of Research	
Respect for Persons	Informed Consent Capacity to Consent
Beneficence	Do no harm Maximize Benefit
Justice	Equitable Selection of Subjects Equitable Burdens and Benefits

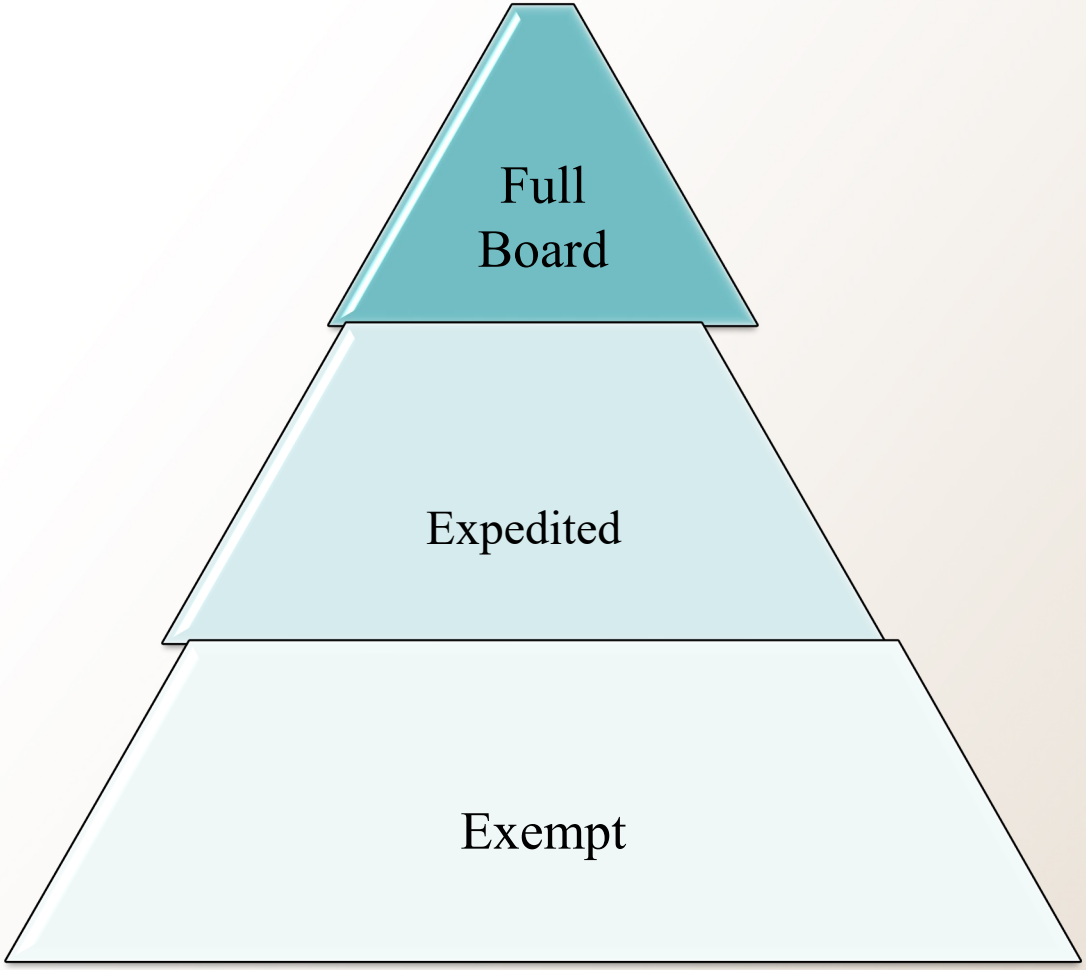
Institutional Review Board (IRB): Mission, Duties, Authorities

- **Mission** ~ To protect the rights and welfare of individuals participating in research involving human subjects
- **Duties** ~ To approve, disapprove, modify, suspend research as necessary to ensure protections for human subjects in research
- **Authority** ~ To exercise final authority within the institution for ensuring adequate protections for subjects. Officials of the institution may not approve research if it has not been approved by an IRB.

Criteria for IRB Approval

- **Risks are Minimized** (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable** in Relation to Benefits
- Selection of Subjects is **Equitable**
- Informed Consent will be Sought for Each Prospective Subject
- Informed Consent will Be Documented
- Research Plan Adequately Provides for **Monitoring the Data Collected to Ensure Safety** of the Subjects
- Research Plan **Adequately Protects the Privacy of Subjects and Maintains Confidentiality**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards need to be included in the protocol to protect the rights and welfare of these subjects.

Levels of IRB review for research with humans



- More than minimal risk to participants
- Not covered under other review categories
- Example: Interventions involving physical or emotional discomfort or sensitive data

- Not greater than minimal risk
- Fits one of the 9 Expedited Review Categories
- Examples: Collection of biospecimens by noninvasive means, research with existing documents or records collected for non-research purposes where participants are identifiable

- Less than minimal risk
- Fits one of the 6 Exempt categories
- Fits additional Flex exemption*
- Example: Research with de-identified records, anonymous surveys

Exemption

- Under Federal regulations, certain categories of activity are considered research, but can be declared exempt from further review by the IRB.

- This determination is made by the IRB itself, not the researcher. To qualify for an exemption, the study may not pose more than minimal risk to human subjects

Investigator's Concern

- The primary concern of the investigator should be the safety of the research participant.
- Harm to research participants must be avoided.
- The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

Informed Consent

- Competent individuals are entitled to choose freely whether to participate in research, and they are able to do so only if they adequately understand what the research entails.

- The informed consent process is described thoroughly in the protocol;
- Sharing appropriate information in a culturally sensitive manner, addressing questions and concerns that arise, and ensuring that decisions about participation are made freely;

- The process provides appropriate information, and supports comprehension of the information and voluntary participation.

- The informed consent form itself is clear and complete;

Informed Consent - graphic

Modified from www.citiprogram.com

Informed Consent - cont

- ***2018 Federal Common Rule IRB Regulations require that potential participants be presented with, "a concise and focused presentation of the key information." This part of the informed consent must be organized and presented in a way that facilitates comprehension.***
- ***Include Key Information that is most likely to assist a participant in understanding the reasons why one might or might not want to participate in the research. The Key Information may be the most critical risks & benefits, but could also be other pros and cons that a reasonable person would want to consider.***
- ***For all consent documents that are more than 4 pages in length, you need to offer Key Information face sheet followed by the detailed informed consent document. Also, you may use an appendix for specific instructions, diagrams or graphics presented in a way that facilitates comprehension.***

Privacy and Confidentiality

- Unauthorized invasions of privacy and breaches of confidentiality are disrespectful to participants and can lead to feelings of loss of control or embarrassment, as well as tangible harms such as social stigma, rejection by families or communities, or lost opportunities such as employment or housing.
- Research protocols should also include clear procedures about how research participants' privacy will be maintained throughout the course of the research.
- Confidentiality is a duty of all members of the research team.

What is Privacy and Confidentiality?

- **What is the difference between privacy and confidentiality?**
  - Privacy is about people and setting
  - Having control over the extent, timing, and circumstances of sharing oneself with others.
  - Privacy is an individual right.
- **Confidentiality is about data**
  - Disclosed private information, given in a relationship of trust, will not be divulged to others in ways not originally agreed upon.
  - It is the obligation of the researcher to keep collected private information from being shared with others.

Training for human subjects research

- **Training for Human Research Oversight Responsibilities (THOR)**

  - Go to WebCampus and log in as you normally do to access courses with your NetID/Password.
  - While logged into WebCampus, open the IRB training course at unr.canvaslms.com/enroll/X3B4LC in a new tab or window in the same browser.
  - You should then see a link to complete the enrollment without having to re-enter your username and password.

- **Collaborative Institutional Training Initiative (CITI)**

  - Go to the Collaborative Institutional Training Initiative
    Be sure to locate University of Nevada, Reno in the drop down options
  - When you get to the options for which training you would like to take, scroll down to Question 1: Human Subject Research (Basic Course) choose either Group 1 or Group 2, whichever most closely matches your discipline

Determine if Human Research

- Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- (2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- (3) Interaction includes communication or interpersonal contact between investigator and subject.
- (4) 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- (5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Research

- **Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.**

Deemed not to be research

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

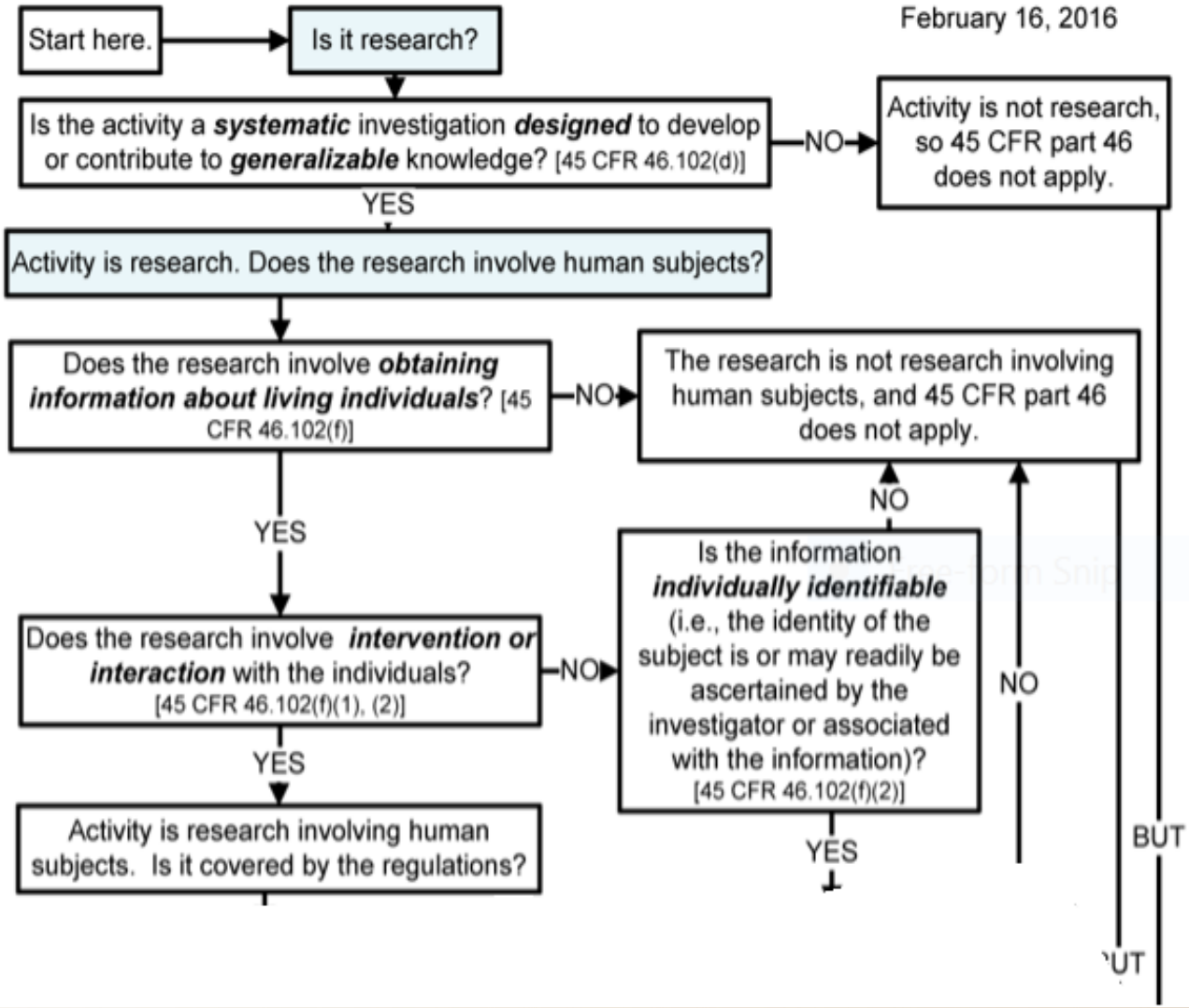
EXAMPLES OF STUDIES THAT ARE HUMAN SUBJECTS RESEARCH

- Studies that collect data through intervention or interaction with individuals. Examples of this type of research include, internet surveys, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews that contribute to generalizable knowledge.
- Studies using private information that can be readily linked to individuals, even if the information was not collected specifically for the study in question.
- Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
- Studies that use human beings to evaluate environmental alterations. For example, making changes to a living or working space (e.g. changing the temperature); studies with pretest, education on alteration and post test.

Determine If Your Project Is Human Subjects Research

- Before you begin a study, you should first determine whether your project meets the definition of human subjects research. The U.S. Department of Health and Human Services (HHS) Office for Human Research Protections provides guides.
- If your study does not qualify as human subjects research, your sponsor or a publication may require certification.

Is it Research?



Evaluative studies

- Systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program (or processes, products, systems, organizations, personnel, or policies), improve effectiveness, and/or inform decisions about future program development.

Intent

- **Answer a research question**
- **Go external**
  - Peer Journal request Ethics approval letter
- **Existing Data – on-the-shelf**
  - Collect internal surveys from students for 3 years
  - Determine data merit to answer research question

IRBNet access

- All protocols must be submitted through IRBNet. Use our instructional materials to help you navigate through your submission process.
- Step-by-step guides with images

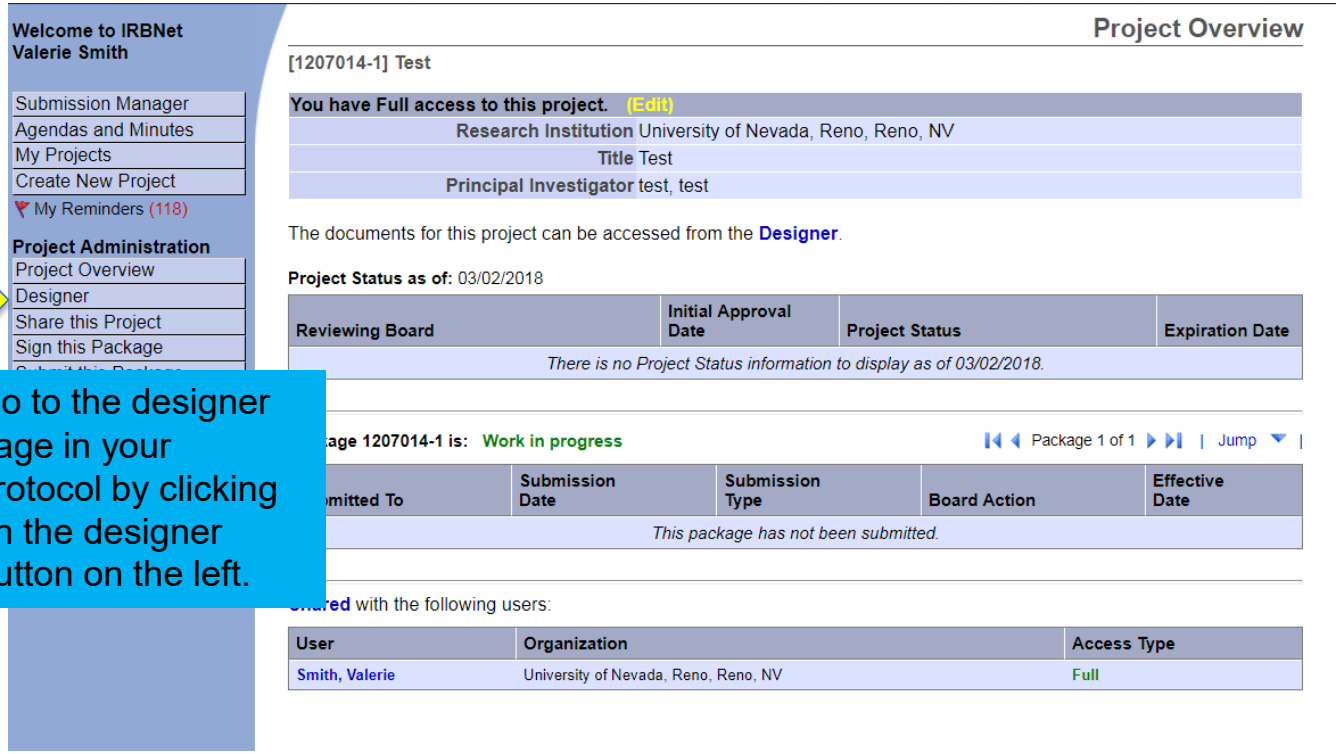
https://www.unr.edu/research-integrity/training/irbnet

How do I select and prepare the correct IRB application?

- **Exemption**
- **Part II Social Behavior**
  - Start with Part 1 Coversheet

- **The Part I cover sheet collects basic information:**
- **PI, contact person, Co-I, research team list**
- **Type of research**
- **Type of review**
- **Funding information**
- **Risk level**
- **Vulnerable populations as participants**
- **When completed, you can print this form, and the form and your answers will prompt you as to additional forms or other documents you need to prepare and upload to complete your submission.**

How to locate the Part I cover sheet IRBNet



Go to the designer page in your protocol by clicking on the designer button on the left.

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Protocol

Study Protocol Title:
Be consistent with the title throughout your application, protocol and the regulatory documents

Table of Contents:

List of Abbreviations:
Use commonly used abbreviations and acronyms.

Principal Investigator, Research Team, and Study Site:
Principal investigator:
Co-Investigators:
Research team and contact Information:
Study site:

Research Synopsis

Study Title
Enter the full title

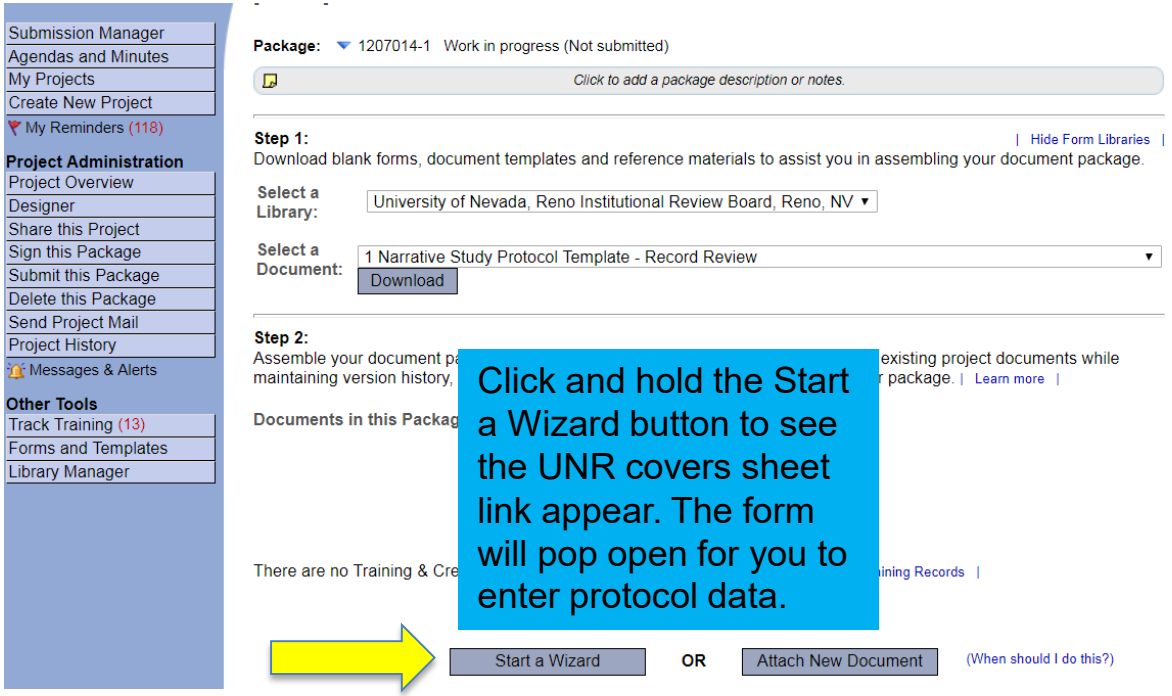
Study Population
Include a brief description of the population such as health status, gender, age, etc.

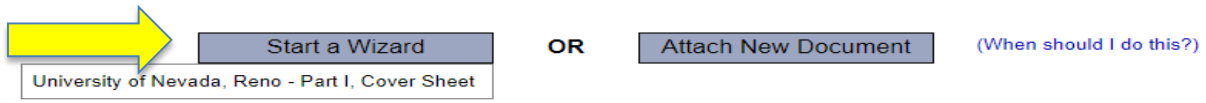
Study Design
Present an overview of the study design for example, retrospective chart review, data or specimen collection, etc.

Sample Size
Include total number of patients or charts for the study including other sites.

Study Duration
Length of time to review charts, data collection, and analysis till the completion of the study

How to locate the Part I cover sheet IRBNet





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Form Complete

IRBNet Document Wizard

University of Nevada, Reno - Part I, Cover Sheet - [1167658-2] Accessibility Test

Jump To: Form Complete ▼ Jump

Form Complete

You have completed Part I of the application process. **Preview** Part I and correct if needed. Print the last page so you have the list of the researcher forms required for this research. Click **Save and Exit.** Log-in to IRBNet, go to My Projects, select the new project, and **Add** the remaining required documents (listed below or referenced in the researcher forms/applications), and electronically **Sign** and **Submit** the project.
If you have any questions, refer to the **IRBNet pages of the RI website**.

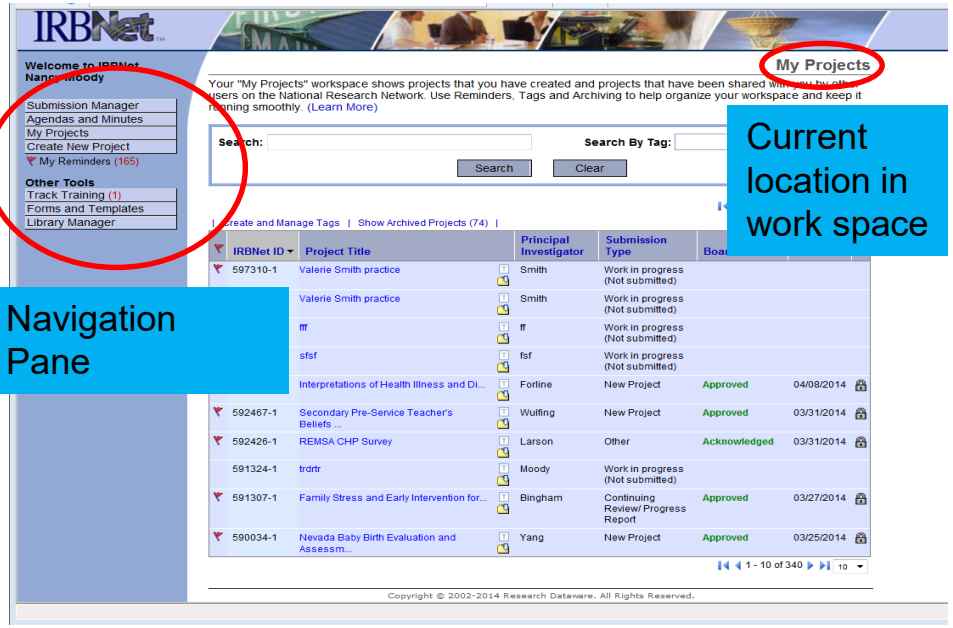
Additional required researcher forms:

- Complete *Request for Human Research Determination*

Save and Exit | Preview | Previous

How to create a submission in IRBNet 4 of 32

The navigation pane is on the left, and your current location in work space appears in the upper right.



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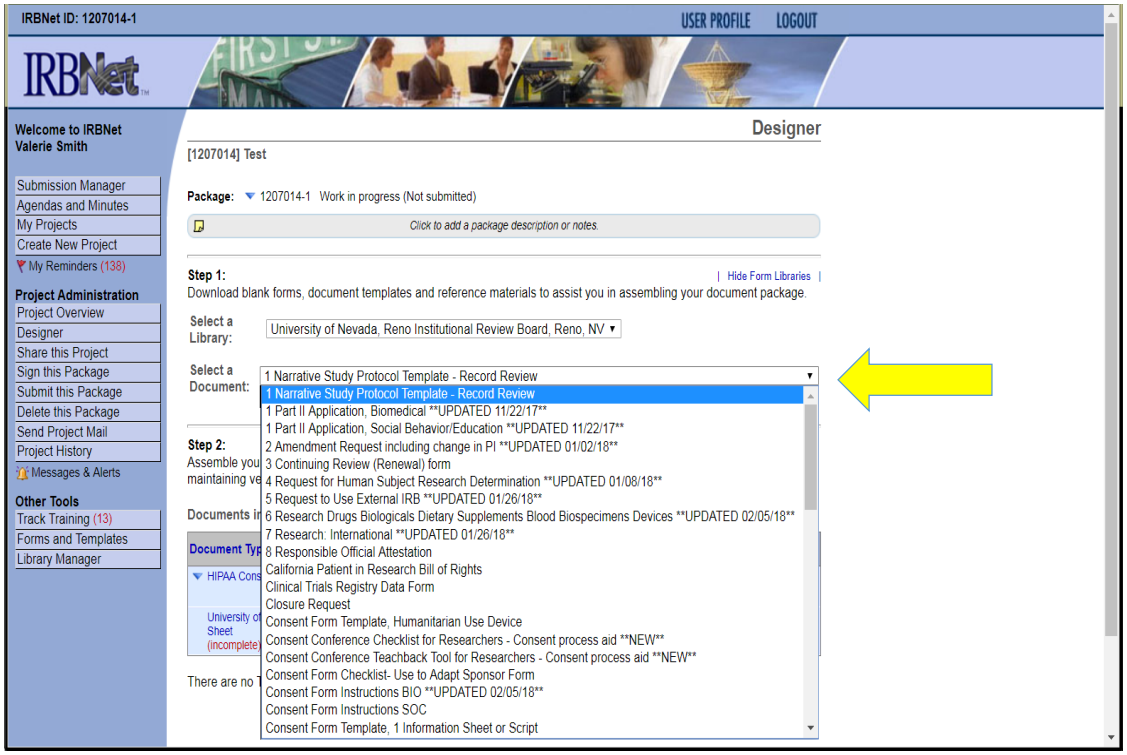
How to create a submission in IRBNet 18 of 32

Click the arrow to view the forms library list; select and download all forms needed for your submission as guided by the wizard form.



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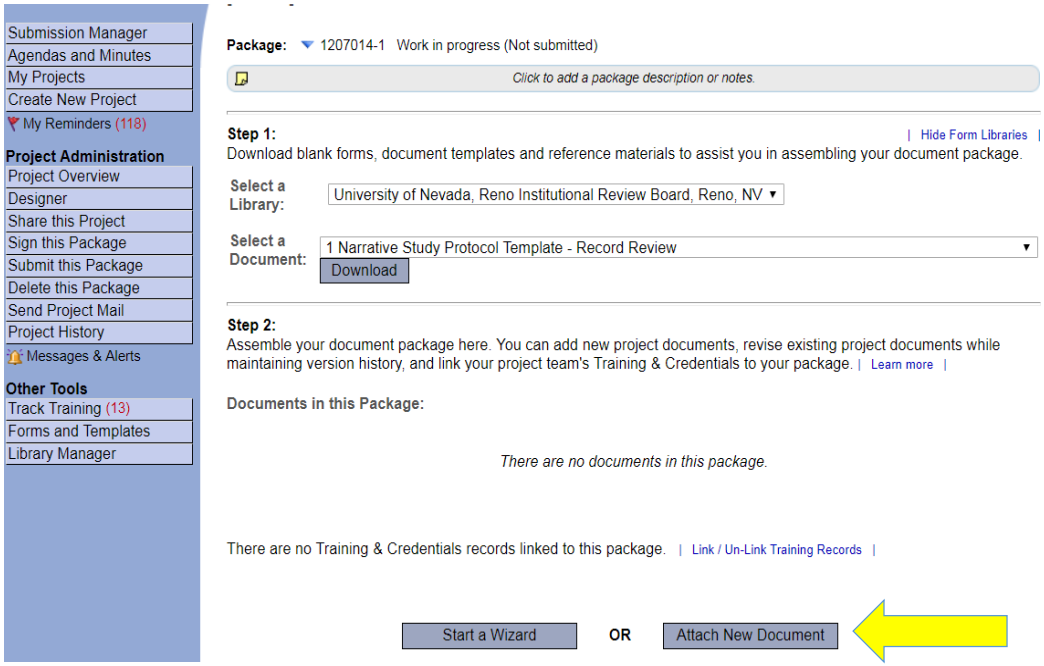
Complete all application forms and gather all other study materials to upload them into your project. Other materials may include recruitment ads, data instruments, consent forms, training records, conflict of interest reports, CVs, and other committee approvals. Click attach new document to browse and find the study documents.

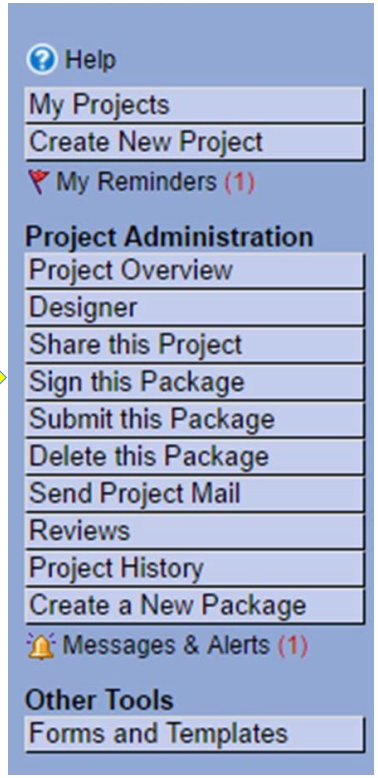


Recruitment Settings and Procedures

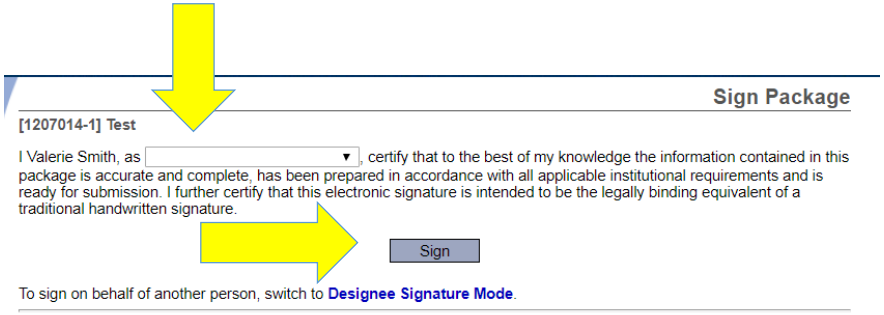
Common Recruitment Venues

- Flyers or advertisements
- Emails or letters
- Scripted presentations
- Direct Person-to-person contact with prospective participants
- SONA (for University researchers)
- Third party assistance and snowball sampling
- Recruitment lists, databases, and repositories

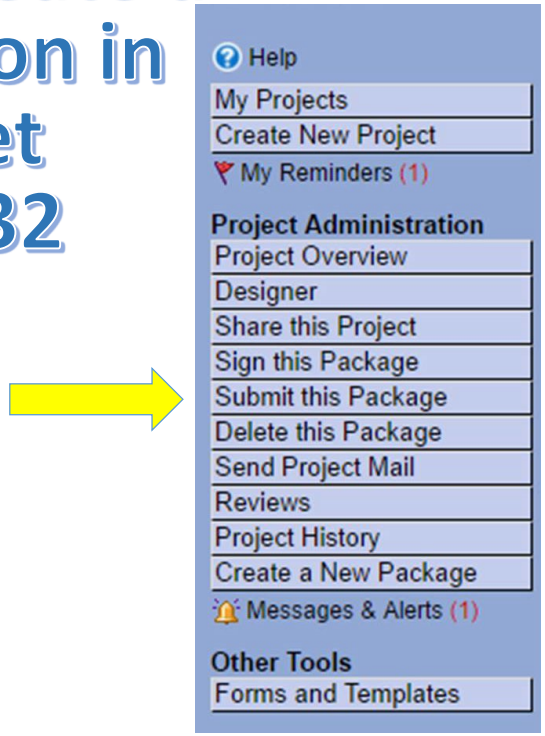
How to create a submission in IRBNet



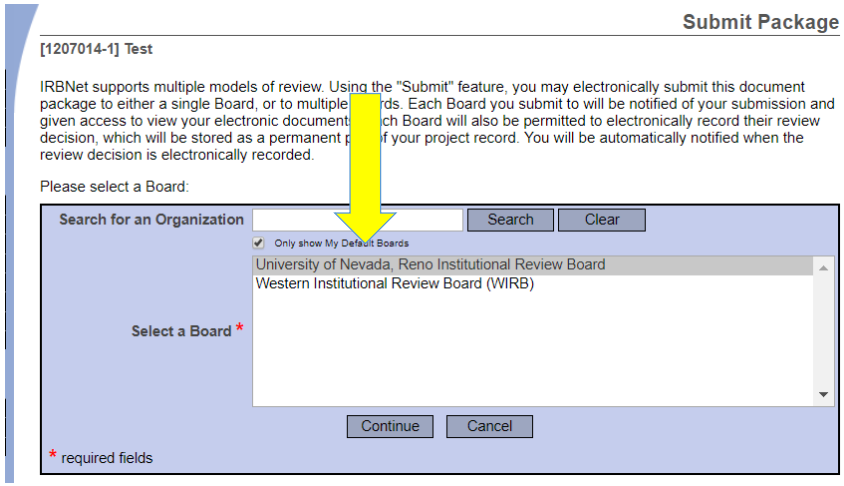
Next, click the sign this package button. Click the drop down arrow to select Principal Investigator for the role and click sign. PIs are required to review and sign off on all new projects, renewals, and amendments. Responsible Officials (RO) need to sign only on new projects that require expedited or full board review, not exemptions. These signatures may not be delegated to someone else. You will need to request RO signature by email when the submission is complete and ready for his/her review.



How to create a submission in IRBNet



The most important step is to **submit** the package. Click submit and select UNR in the pop-up window. This is a separate step in the process.



How to create a submission in IRBNet
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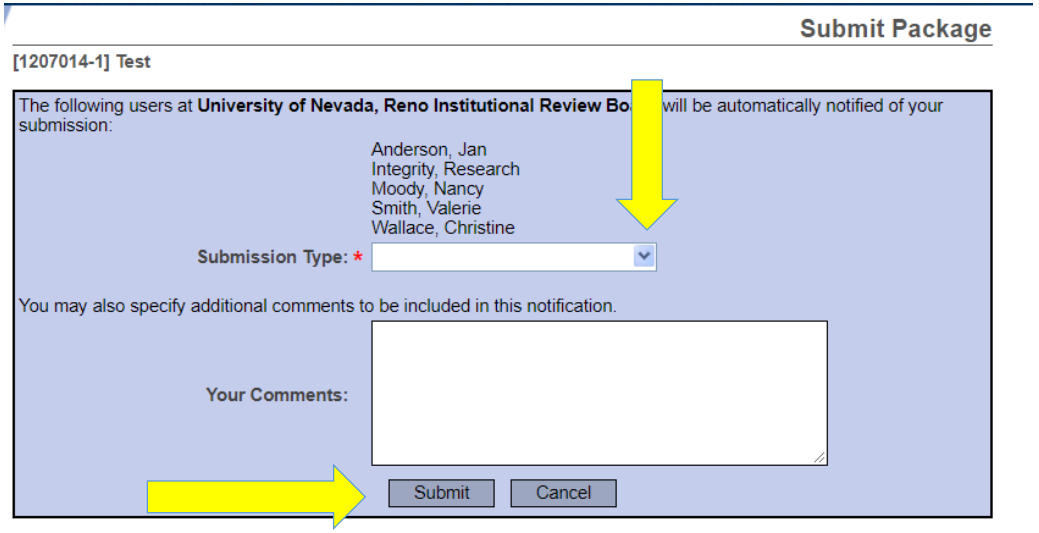
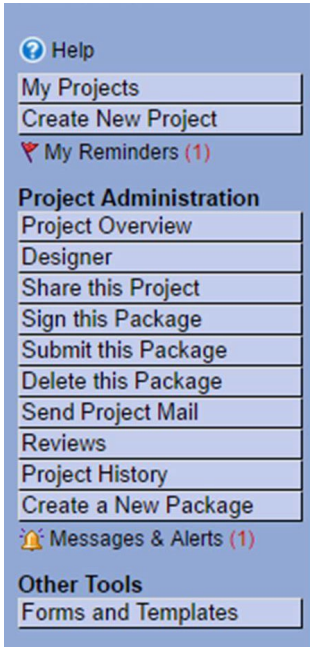
In the next window, select the submission type, add any important comments for the recipients, and click **submit**.

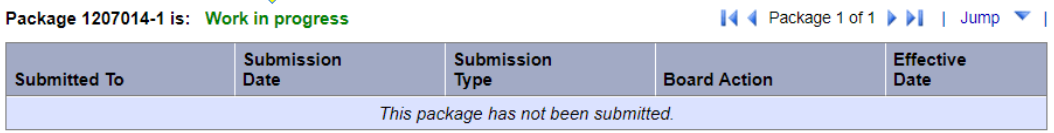
The IRB will not see the submission for processing until this step is complete.



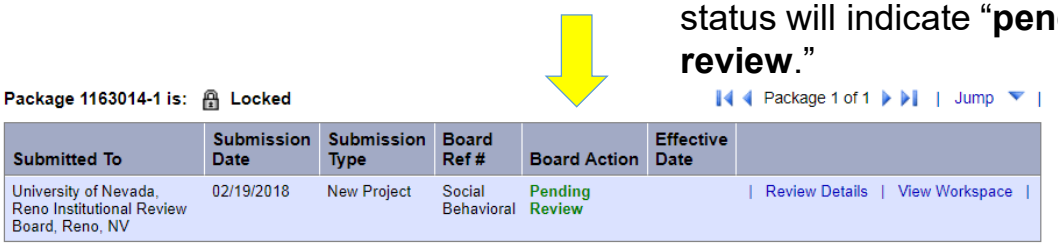
How to create a submission in IRBNet 31 of 32



Confirm that your project has been submitted by clicking the project overview button to return to this screen. Before submission, your project status will indicate "**work in progress**."



After submission, your project status will indicate "**pending review**."



How to create a submission in IRBNet
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Steps:

1. Create the project record
2. Complete Part I core form/cover sheet first (very important), and complete and upload protocol documents
3. Share the package with research team and administrators
4. Sign the submission (new protocol, modification, renewal)
5. Submit your project to the IRB

Internet Studies

- Recruitment of subjects online--whether by email, chat room, discussion board, or other means-- must be guided by the level of privacy expected by participants.
- Some sites are “fully public” whereas others require user login or invitation by a site administrator.
- Researchers must ensure they obtain appropriate permission from a website or discussion board administrator and include a copy of that approval in his/her IRB submission.
-

Internet Studies cont

- Electronic mail E-mails are not “public information” simply because they are posted on a website. The websites of many professional societies often have guidelines for contacting (or not contacting) its members to participate in research, even if the members’ names/emails appear on that organization’s website.
- People under the age of 18 cannot legally consent to participate in a research study. However, researchers recruiting from the internet cannot know the exact age of respondents. For this reason, it is best to limit online research studies to minimal risk research that would typically qualify for waiver of parental consent under federal regulations.

Right to Withdrawal

- Online survey instruments must explain at the outset what options are available, if any, for retrieving and discarding responses, and for some studies it may be appropriate to provide a “no response” option for questions subjects may consider to be sensitive or intrusive.

Mechanical Turk - Amazon

- Recent research shows that MTurk worker IDs can easily be linked to individual Amazon profiles including individuals wish lists and previous product reviews. This means that researchers must be careful in deciding what information to collect from participants. The default should be that participants MTurk worker IDs not be collected. If it is necessary to collect worker IDs, then the researchers should ensure that worker IDs are kept confidential and secure, are not linked back to survey data, and are deleted after use.

Consent Transparency

Your participation is voluntary. You may withdraw at any time, and you may choose not to answer any question, but you must proceed to the final screen of the study in order to receive your completion code which you must submit in order to be paid.

Anytime you share information online there are risks. We're using a secure system to collect this data, but we can't completely eliminate this risk. Amazon could link your worker ID (and associated personal information) with your survey responses. Make sure you have read Amazon's MTurk participant and privacy agreements to understand how your personal information may be used or disclosed.

In accordance with Mechanical Turk policies, we may reject your work if the HIT was not completed correctly or the instructions were not followed.

How IRB's Got Started