**What is the IRB**

* A board of reviewers and committee members looks at proposals to determine if they follow protocol. They ensure the protection of human subjects that are part of research studies.

**Action list**

* Anything that says “APP” needs to be approved
* Anything that says “COM” is an action that needs to be completed
* Anything that says “FYI” shows that the IRB has taken action on your protocol and something needs to be done or needs your attention.

**Information to submit a proposal**

* To submit a proposal, you must have the following information:
  + A description of the details of the protocol
  + Differentiation of the type of protocol
  + Personal ID of lead investigator OR address book ID of lead investigator if not a UNC employee
  + Project title
  + Unit ID of the lead department of the project

**Initiating a proposal**

* Go to Streamlyne
* Use your UNC username and password to log in
* Click main menu
* Click IRB
* Click IRB Protocol
* Click +
* Protocol
  + Document
    - Overview Description
      * Should be short and simple
      * Add your last name
    - Do not need to add an explanation or organization document number
  + Required Fields for Saving Document
    - Protocol type
      * Select correct option from dropdown menu
      * Developmental
        + Used if you need an IRB number to apply for a grant, but are not ready to submit a full protocol for review
        + Cannot get started on project yet
      * Exempt
        + No more than minimal risk
        + Categories

Research looking at normal educational practice within an educational setting

Research using educational tests, survey procedures, interview procedures, or public behavior observation

Research using public data when said data is publicly available

Examination of public benefit/service programs

Research having to do with food quality or consumer acceptance rates

* + - * + Does not require review past the initial approval
      * Expedited
        + No more than minimal risk
        + Does not meet one of the categories for Exempt
        + Annual review
      * Full Board
        + More than minimal risk
        + Research involving minors
        + Research involving special populations
      * *Note: you can go through a questionnaire on the Streamlyne website to find which option is correct for you*
    - Principal Investigator
      * Click the magnifying glass and search
      * *Note: It is best to just use one or two text fields when completing a search*
      * Click return value when you have found the correct individual
    - Title field
      * Type in a descriptive title
    - Lead unit
      * Automatically chooses unit assigned to principal investigator
      * If not correct unit, use dropdown menu to select the correct unit
  + The information below the required fields in the protocol section is not required to complete your protocol
    - If you are completing research with an FDA Investigational New Drug or Investigational Device:
      * Click additional information
      * Go to the additional information subsection
      * Type your numeric identifier in the FDA IND OR IDE # space
      * Type the trial reference number(s) in the reference ID space
      * Type any additional information in the summary/keywords space
    - If you are moving information from IRBNet:
      * Click additional information
      * Click the dropdown menu below “type” under “other identifiers”
      * Click IRBNet
    - If you are completing research at a site off campus:
      * Click organizations
      * Click the magnifying glass to search
      * Do not fill anything in, click search
        + Select your organization from the list
        + Email Nicole Morse (nicole.morse@unco.edu) and ORSP ([orsp@unco.edu](mailto:orsp@unco.edu)) if your organization is not listed
      * Select the organization type
      * Click add
      * Repeat these steps if multiple organizations need to be added
    - If you are receiving grant funding:
      * Click funding sources
      * Select the funding type from the dropdown list
      * Type in the funding number OR click the magnifying glass to search for the funding number
      * Click add
      * Repeat these steps for all funding sources
    - If you have research participants:
      * Click participant types
      * Select the participant type from the dropdown menu
      * Type in a projected number of participants in the count section
      * Click add
      * Repeat these steps for all participant types and amounts
* Personnel
  + Add all people that are engaged in the research project
    - This includes people who...
      * Collect data
      * Have access to data
      * Are involved in the consent process
  + For someone affiliated with UNC: click internal user name
    - Type their UNC email into the blank OR click the magnifying glass if you do not know their email
      * After clicking the magnifying glass you can enter their last name into the blank and click search
  + For someone not affiliated with UNC: click external address book ID
    - If this person has previously used Streamlyne through UNC, they will be listed
      * Click the magnifying glass
      * Type in information (first name, last name) or you can just click search to find a list of everyone
      * Once you find the person you want to add, click return value next to their name
    - If this person has not used Streamlyne through UNC, contact Nicole Morse at [nicole.morse@unco.edu](mailto:nicole.morse@unco.edu)
      * Send their name, email address, and institution/company they are affiliated with
      * Nicole will add them to the address book, and then you will be able to add them to your protocol
  + Select their role from the dropdown menu
    - Click add
  + Repeat these steps for each person that is engaged with the research project
  + After adding all individuals, you must click each of their names to add additional information
    - Person details
      * Click show
      * Choose the affiliation type from the dropdown menu
      * For those that are not affiliated with UNC, click non-affiliate
        + Next to attachments, click show
        + Upload a copy of their human subjects training certificate
    - Click show
      * Ensure that all contact information for each person is up to date
  + To add documents specific to each person:
    - Click show
    - Expand the attachments subsection
    - Select the attachment type from the dropdown list
    - Type a description for the attachment in the description section
    - Click browse to find the file on your computer
    - Click add
  + Click save
  + To delete any added members:
    - Click the checkbox in the section header
    - Click delete selected
  + *Note: you must have a faculty advisor in order to submit this or you will get an error*
* Questionnaire
  + IRB screening questionnaire (optional)
    - Helps to identify if you need IRB approval, and which type of approval is needed if so (exempt, expedited, full board).
  + IRB protocol checklist (optional)
    - Checklist to make sure you have included everything that is needed for the IRB application
  + New IRB protocol (required)
    - Click yes for the first question
    - Read through the rest of the questions and click either yes or no depending on your personal research
      * If you are confused about any question, click the more information button to the right of the question
    - After category 6, fill in boxes will appear
      * Complete each of these questions by typing in the information requested
      * Procedures
        + Who are the participants
        + What the participants will be doing (survey, educational research, etc.,)
      * Recruitment
        + How you will reach out to participants (social media, flyer, etc.,)
        + Attach a copy of the recruitment email/advertisement/etc.,
      * Incentive
        + Extra credit, gift card, etc.,
        + If this does not apply, type “N/A”
      * Process of obtaining consent
        + NOT a copy and paste of your consent form
        + When will consent be completed
        + Type of consent used – form, verbal, consent form as first page of survey, no documentation of consent, etc.,
        + How participants will return consent form to you if applicable
        + Attach a copy of informed consent
      * Recording identifiable information
        + Yes or no
      * Provisions to protect privacy
        + How you will store data
        + Who has access to data
      * Read through last question and click yes or no
  + Click save
  + *Note: The required questionnaire must have a status of complete to submit your protocol*
* Special review
  + Not used often
  + This is for individuals whose research involves sharing data between projects, experimentation on animals, use of biohazardous materials, international programs, requesting additional space on campus, etc.,
  + *If* this section is needed:
    - Click the appropriate option for the dropdown box next to special review type
    - Select the correct approval status from the dropdown menu if it does not auto populate
    - Click the magnifying glass next to protocol number to find the correct number
    - Type in the application date, approval date, and expiration date of the protocol (MM/DD/YYYY format)
    - Type in the exemption number if your protocol is exempt research
    - Click add
    - Repeat these steps until all needed reviews are added
* Permissions
  + Shows who has permissions to view the protocol
  + Under users, you can add more people to give them access
    - Click the magnifying glass next to user name
    - Select the individual’s role from the dropdown menu
    - Click add
    - Repeat these steps for each additional user
    - To remove a user, click delete
    - To change a user’s access, click edit role, then select the correct role from the pop-up window
  + Click save
* Notes and attachments
  + Protocol attachments
    - Select the attachment type from the dropdown menu
    - For status click complete on the dropdown menu
    - Type a short description of the attachment
    - Click choose file and upload the file from your computer
    - Click add
    - Repeat these steps for each attachment that needs to be added
    - To edit any attachments, click show next to whichever attachment you want to edit
      * Type in new information
      * Click replace to change the uploaded attachment
* Protocol actions
  + To validate your protocol
    - Click data validation
    - Click turn on validation
    - If any errors are found, an error message will tell you what they are
      * Click fix next to the listed error
      * Make the corrections that are needed
      * Click save
      * Repeat these steps to correct all errors
  + Request an action
    - To submit protocol
      * Click request an action
      * Click show next to submit for review
      * For submission type select initial protocol submission
      * For submission review type, select whichever type your research is – if you are unsure, you can complete the IRB screening questionnaire on the questionnaire page
      * For the checklist, mark whichever categories you indicated in the questionnaire section of this protocol
      * Click submit
      * *Note: Your faculty advisor will need to click the approve button on the protocol actions page for the protocol to be reviewed*
        + *If you have multiple advisors, each of them will have to do this*

**After your submission**

* To look at the actions that have been taken on your protocol
  + Click protocol actions
  + Click summary and history
  + Scroll to see actions
  + To see questionnaires, click show next to questionnaires
  + When an exempt protocol has been approved, an action will be added with the comment “Exemption granted”
* To see where your protocol is in the process
  + Click protocol actions
  + Click route log
* To recall your protocol
  + This will allow you to make edits to the protocol before it is reviewed
    - *Note: You can only do this if the review process has not already started*
  + Click protocol actions
  + Scroll to the bottom of the page
  + Click recall
  + Type in your explanation as to why you are recalling the protocol
  + Click yes
* To withdraw your protocol
  + This is to withdraw your protocol and no longer have it reviewed
  + Click protocol actions
  + Click request an action
  + Click show next to withdraw protocol
  + Type in your reason for the withdraw
  + Click submit
  + *Note: If you would like to use the same information that was in this protocol in the future, you will need to create a new protocol OR use the copy function*
* To edit a returned protocol
  + A protocol will be returned if:
    - It is incomplete
    - It contains errors
    - It needs revisions
  + Look at your notifications to determine if your protocol has been returned
  + If there is a notification, click the *show* next to it
  + Click the *correspondence link* if there is one
  + Click the *hyperlinked protocol number* to open the protocol
* To access reviews/correspondences
  + Review comments
    - Click *protocol actions*
    - Click *summery and history*
    - Click *show* next to reviews and attachments
    - Read through the comments to see what editing needs to be completed
  + Correspondence
    - Click protocol actions
    - Click summary and history
    - Click show to show the correspondence and access your letter/review
* To resubmit a protocol
  + Complete all needed changes
  + Click protocol actions
  + Click request an action
  + Click on show next to submit for review
  + Select resubmission from the submission type dropdown list
  + Select the correct submission review type from the submission review type dropdown list
  + Click submit
* To close a protocol
  + Click the edit hyperlink for the protocol
  + Click protocol actions
  + Click request an action
  + Click available actions
  + Click show next to request to close
  + Select the correct committee from the dropdown menu next to committee if you know it
    - If this is not known, leave it blank
  + Type in the reason why you would like to close the protocol
  + Attach any needed documents and describe them in the description section
  + Click submit
* To suspend a protocol
  + Click the edit hyperlink for the protocol
  + Click protocol actions
  + Click request an action
  + Click available actions
  + Click show next to request for suspension
  + Select the correct committee from the dropdown menu next to committee if you know it
    - If this is not known, leave it blank
  + Type in the reason why you would like to suspend the protocol
  + Attach any needed documents and describe them in the description section
  + Click submit
* To move into a data analysis phase
  + Click the edit hyperlink for the protocol
  + Click protocol actions
  + Click review an action
  + Click available actions
  + Click show next to request for data analysis only
  + Select the correct committee from the dropdown menu next to committee if you know it
    - If this is not known, leave it blank
  + Type in the reason why you would like to transition the protocol to analysis only
  + Attach any needed documents and describe them in the description section
  + Click submit
* To terminate a protocol
  + Click the edit hyperlink for the protocol
  + Click protocol actions
  + Click request an action
  + Click available actions
  + Click show next to request for termination
  + Select the correct committee from the dropdown menu next to committee if you know it
  + Type in the reason why you would like to terminate the protocol
  + Attach any needed documents and describe them in the description section
  + Click submit

**Link to watch video of this information:** <https://unco.zoom.us/rec/play/LC1B8tv_GaDxw_XDzY74IFJvToqZont5Fz1R5qbKa5i2WTDPLd4ywRJhPLlEi2cpt4vRKsV8JeURJVOl.wJnDopjlKvASwwBR?canPlayFromShare=true&from=share_recording_detail&startTime=1598473763000&componentName=rec-play&originRequestUrl=https%3A%2F%2Funco.zoom.us%2Frec%2Fshare%2F2OkvC7vT7kFOWavy5hvxWowYE6TJaaa80SQeq_MLmRoCuDsYzWrP4jddgokxGALi%3FstartTime%3D1598473763000>

**IRB User Manual**

<https://www.unco.edu/research/research-integrity-and-compliance/institutional-review-board/Streamlyne_ResearcherUserManual_IRB_04202020.pdf>