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IRBNet Instructions for Investigators

Lifespan's Research Protection Office (RPO) uses IRBNet for the electronic administration and management of its IRB's.

Below is a 'How to' tutorial on IRBNet.

Departmental Chairs should also review the - Instructions for Department Chairs

Index:

I. How do you register with IRBNet?

- Go to www.irbnet.org and register with IRBNet**.**
- Follow the directions for *New User Registration.*
- Note: When you choose your affiliation, be sure you select Lifespan, Providence, RI.
- To complete the registration process, you will need to authenticate your registration via your e-mail account.

- You will need to share your study with department chairs, co-investigators, coordinators, etc., (i.e., allowing them to electronically review your submission), as well as other individuals (see section IV). Make sure they are aware of the need to register as well, or else you will not be able to share with them. When you "share" your study with someone you may grant them levels of access. "Full access" means this person can create projects, change documents and submit to the IRB. Full access people will receive all emails. "Write access" means this person can change documents and create projects but cannot submit to the IRB. "Read only access" means this person can read only all documents for that study. Any level of access can "electronically sign" the package for submission. The PI must electronically sign all submissions. The department chair must sign the initial IRB submission package. Remember, Read Only Access still allows that person to "sign" the package.

II. How do you create a new (first time) project submission in IRBNet?

Depending on an individual's access level, the PI can delegate (through sharing) to a co-investigator, or a study coordinator, the task of helping to create the study. **Higher levels of sharing (ability to submit a study, as an example) should be granted to as few individuals as possible (e.g., PI and study coordinator).**

- To begin, log on, choose *'Create New Project'* (on the left), and fill out all *required* and non-required initial fields, including *Keywords* (include whatever you like, but inclusion of any drugs, biologics, devices, and disease state being studied are **required**) and *sponsor*.

- Next, you will go into the *Project Designer* to complete the **Research Application Part 1** form, and to upload all the materials you want to provide to the IRB in support of your submission. See section III for details on creating your new project, including doing all this, as well as information on what materials need to be submitted to ensure a complete package.

III. What materials have to be submitted to the IRB for a new or continuing review project, and how do you get them "into" IRBNet?

- For new, first time submissions, you will first need to **create a new PROJECT** (see section II).
- For continuing review submissions you will first need to **create a new PACKAGE (notice this is different from creating a new PROJECT)** to your previously approved project (see section X for instructions on how to do this).
- Note that consent forms **should** be submitted in Microsoft word, and **should not** be submitted on letterhead.
- For instructions on **how to terminate a study**, see section XIII

- **If you are constructing a new project in IRBNet:**
  - Create a **new (first time) project** for this activity (see Section II for instructions on how to do this).
  - Complete the **Research Application Part 1 for Expedited or Full Review**: This is a short 'smart' or 'wizard' or 'core' form that quickly captures critical, searchable data pertaining to your study. **To access this document:**

- Go to your project's Designer
- Select 'Add New Document'
- In the **lower shaded** 'On-Line Document' box, select 'Research Application 1 Form' for Expedited or Full Committee Review', then hit the 'Add' button Begin completing the Application 1 Form. You do not need to complete the whole form in one sitting; you can 'save and exit', and then go back and update the document by clicking the pencil icon next to the document listed in the designer.
- When you are done completing the Application 1 Form, click **"Preview"** to see what the completed form looks like, and confirm that all the information provided is accurate. Once you are satisfied in this regard, **Click "Save and Exit", and then continue constructing your project package to completion:**

- Download and complete the "Research Application Part **2**" for Expedited or Full Review. Select Application for Chart Review if your study is a Chart Review. All documents are downloadable and are located in the Document Library (found on the Designer page). Select a library. You can select RIH library or TMH library. Download the document to your computer and save it for completion. Once you have completed the document save it again for uploading to IRBNet.
- Continue adding documents (click 'Add a Document' in the Designer) for your submission, in accordance with the requirements outlined in the Application Checklist also available in the Designer library. Keep in mind appendix forms may be required if your study is proposing inclusion of vulnerable populations. During uploading your forms, you are asked for *'document type'*, select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called *'description'*. Then browse and find the document for uploading from your computer.
- Share with your project team members (see section IV).
- Obtain appropriate signatures, always the PI and for new projects the Department Chair, and submit the package in accordance with this IRBNet instructions (see section V).

- **If you are submitting a Continuing Review, Revision, AE, or Deviation Report package into IRBNet you would first go to the project that was forwarded to you by the Research Protection Office. If you cannot locate this project in your "My Projects" please contact the Research Protection Office.**
  - If this is the first IRBNet submission for this study you must complete the Research Application Part 1, as detailed above, (if not done in any prior packages). This document need only be filled out once but it is essential so the IRB can get detailed searchable information into the system on each study.
  - **Click "Save and Exit", and then continue constructing your project package to completion:**
  - Continue adding documents (click 'Add a Document' in the Designer) for your submission. During uploading your forms, you are asked for *'document type'*, select the descriptor that best describes what you are uploading. If unsure, select 'other' and provide the description you want in the field called *'description'*. Then browse and find the document for uploading from your computer.
- You can also take a document from a previous package of the project in IRBNet, revise it, and submit with the current continuing review package. See Section X for instructions.
- Obtain appropriate signatures as instructed above and submit the package.

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IV. Sharing your submission package:

- **How do you share your submission with other researchers?**
- **What level of access should the members of your study team have?**
- **With whom must you share your submission?**

How do you share your submission with other researchers?

- Press the 'Share this Project' button on the left.
- You will first need to select the name of the organization where the individual is affiliated. Select Lifespan (this is why you should have all key personnel register as Lifespan so you can locate them easily for sharing).
- Click 'select organization'.
- On this next screen, you can search by last name (type it in and hit 'search') or if you don't know the exact spelling, enter a space and then hit 'search', and a listing of all registered users for that organization will pop up. **If the individual is not listed, it most likely means that the person has not yet registered on IRBNet or they did not select Lifespan.** You must contact the individual and tell him/her to do so before you can share the project with him/her.
- Only the principal investigator and maybe one other (a study coordinator) should have full access to edit and submit the project to the IRB. **Those with full access will receive e-mails when the RPO or IRB posts an action or decision.**

What level of access should the members of your study team have?

- It is up to you to decide what kind of access shared individuals should have. It bears repeating: only the principal investigator and maybe one other (a study coordinator) should have full access to edit and submit the project to the RPO. Those with full access will receive e-mails when the RPO or IRB post an action or decision.

With whom must you share your submission?

- All **co-investigators, including**
  - Your **study coordinator**
  - **Your department chair/dep't review committee chair (the department chair may be granted read only access during the signing process. Once he/she has signed the project you may remove their access by now granting them No access. This will avoid their having a large number of projects in their "My Project"**
  - **If the project involves a grant or contract,** please give read –only access to your Sponsored Programs Administrator and/or Coordinator.

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When you share your project, the individuals you select will get an e-mail notification that you have done so.

V. Obtaining necessary electronic signatures for your package

Once you are done uploading all your documents and have given access (shared) your submission with all relevant individuals, be sure to sign your project. If the coordinator is completing this project/package for submission email your PI and tell him/her to go on to the system to review the submission and sign the project. To sign the project (click the button 'Sign this Package' on the left side margin of your screen). Make sure your department chair (with whom you also shared the project) also electronically signs your project. **Chair should only sign when your documents are finalized for submission, i.e., just before you are ready to submit to the RPO.**

For any interim submissions (Revisions, Deviations, SAEs)

- The PI must provide electronic signature before the project is submitted to the RPO. This process has not changed from how the submissions were submitted before IRBNet.

VI. What does your electronic signature mean?

Good question.
If you are the Principal Investigator, your electronic signature that is associated with a given project means that the research described in the application and supporting materials will be conducted in full compliance with Lifespan's Policies and Federal and State regulations governing human subject research. Furthermore, you will:

- Ensure that all aspects of the project will be conducted by the study team as approved by the IRB,
- Promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- Promptly report any unanticipated problems or serious adverse events affecting risk to subjects or others,
- Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Use only IRB-approved, stamped consent forms for studies in which consent form(s) have been approved for the research activity, and
- Ensure that all personnel involved with human subjects, or identifiable human data/records and/or biological specimens during the course of this research activity are trained in the Protection of Human Subjects (HSP) and HIPAA in Research, in full accordance with Lifespan's policy on this matter. For HSP and HIPAA courses log on to www.citiprogram.org and again select Lifespan as your affiliate.

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VII. How do you submit the package/project to the RPO Office? What 'submission type' should you use?

- Hit the '*Submit this Project'* button on the left. You will be submitting to the either the RIH or TMH Lifespan IRB Office. Please be sure to select the appropriate IRB. The selection of the Library in the beginning did not "select" the IRB of choice.

- You will then need to identify the submission type.

The submission type you choose should make sense, and identify what it is you are submitting:

- The first time you submit a brand new project, you will choose the submission type **'New Project'**.
- For a continuing review, choose "**Continuing Review/ Renewal"**
- If the IRB issues a modifications required or deferral letter, and you now wish to submit a response to their concerns, select **'Response/Follow-up'**
- If you are submitting an amendment or revisions on an approved study, choose **'Modification/Amendment'**
- And so on…

VIII. What is the administrative routing once you submit a package to the RPO Office? What's with all the e-mails?

- You (and anyone else to whom you have granted full access on the study) will receive e-mails at various steps of the review process for your package. They are meant to be informative, and to make the IRB process more transparent. *(It is important you consider this when assigning access level. Remember all full access people will receive all these emails where write and read only access will not).*
- The Research Protection Office does a preliminary review of your submission to confirm that all obvious components are present, critical individuals have been granted access where applicable and PI and department chair e-signatures have been provided. If any such components are missing, the PI, study coordinator, and anyone else having full access will be notified by e-mail to address the issue.
- **Once a complete submission is received by the RPO Office, it will take one of two routes.**
    - **Exemption Submissions:** If your study is determined to meet the requirement for exemption, the study will remain in the 'virtual' RPO office and be assigned both an IRBNet number and a local IRB number (see section XII for more on the various #'s in IRBNet). The RPO Director and coordinators will then review the submission on behalf of the institution. You will receive an **e-mail** notifying you when the review is completed, and a decision is rendered. You will then log on to IRBNet, click on the study title, go into your project designer and review the decision letter from the office.
    - **Non-Exempt Submissions (expedited or full committee reviews of new studies, continuing reviews, amendments, AEs, Deviations etc):** If you have submitted something that requires review by one of our IRB's, the submission will be assigned a number (see section XII for more on the various #'s in IRBNet) and will then be reviewed by the IRB administrators for either prior to forwarding the project to the IRB reviewer. **Any investigator with full access on the**

study will receive an e-mail notifying them that the study has been forwarded to an IRB for either immediate review assignment (expedited review materials) or to be placed in queue for full committee review (full review materials). This e-mail does not require action from you. It is just an 'FYI'.

- If your package is determined to be expedited, IRB administrators will 'share' the submission with 1 or more IRB members of the relevant committee member(s) for their review. When all reviews are in, the IRB administrators will change the status on the study from 'pending review' to either approved, modifications required, or deferred to full committee. **Any investigator will full access on the study will receive an e-mail notifying them of the change in status**, with instructions to log on to IRBNet and see the review details in your Project's Designer, under Board Documents.

- If your package requires full review, **you will receive an e-mail, usually immediately following the 'forwarded' e-mail** indicating that the project has been 'Referred to Full Board', along with the date of the meeting at which it will be reviewed. This e-mail does not require action from you. It is just an 'FYI'. The IRB Administrators will prepare the meeting agenda approximately one week prior to the particular IRB meeting. Once the meeting has occurred, any investigator will full access on the study will receive an **e-mail** notifying them of the IRB's decision regarding their submission.

NOTE: Documents listed in your Project designer are sorted in alphabetical order by document title.

IX. How do you respond to the RPO, post-review (i.e., for modifications required, deferrals etc)?

Answer: You respond by submitting to the RPO office a revised project package with updated information. The following steps will help ensure a smooth submission.

Create a New Package for an Existing Project in IRBNet

1. In your Study Manager click on the title of the project to go to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page.
4. Click the Designer button to work on documents for the new package via two methods (described in detail below):

- **METHOD #1:** Revise a previously submitted document;

OR,

- **METHOD #2:** Attach a new document to the package.

METHOD #1: Revise or Submit a Previously Submitted Document for Review (Designer page)
Refer to the 'Documents from Previous Packages' section at the bottom of the Designer page.
1. To revise **the Research Application Part 1 Form** from a previous package for committee review:

- Click on the pencil icon for the Research Application Part 1 Form. This will open up the Form.
- Make any necessary changes to previously entered information and save. The document will move to the 'New and Revised Documents in this Package'section. Submit this revised Research Application Part1 Form with a revision to Protocol form.

2. To revise an **uploaded document** (.doc, .xls, .pdf, etc.) from a previous package:

- First download the document by clicking on its Document Type or the paper icon.
- Make necessary changes and save the revised document to your computer.
- Click on the pencil icon for that document in the Designer.
- Browse your computer, select your revised document to upload, make necessary changes to Document Type and Description (below), and click the Update button.
- When you click Update, the revised document will appear in the current document package ('New and Revised Documents in this Package') with a revision history (the 'stack of paper' icon) that reflects versions from previous packages (see below).

METHOD #2: Attach a New Document to the Package (Designer)
1. Complete applicable forms downloaded from the Library, or create applicable documents on your computer.

2. Use the Add New Document button to upload the document into the current package. The document will not have a revision history (stack of paper icon) at this time as it is new.

Points to Remember
When you have attached all the required documents, submit the revised package, **complete with PI e-signature**, to the RPO office in IRBNet. Be sure to indicate the appropriate Submission Type ('response/follow-up').

X. OK. Your project is approved. Now what? How do you submit amendments, Unanticipated Problems (including SAE's) etc.?

Answer: You will create, and submit **a new package** for the project. The following steps will help ensure a smooth submission.
Create a New Package for an Existing Project in IRBNet
1. In you're my Projects click on the title of the project to go to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page.
4. Click the Designer button to work on documents for the new package via two methods (described in detail below):

- **METHOD #1:** Revise a previously submitted document **(e.g. for amendments etc.)**

OR,

- **METHOD #2:** Attach a new document to the package **(e.g., continuing review application, Unanticipated Problem Form, etc).**

METHOD #1: Revise or Submit a Previously Submitted Document for Review (Designer page)

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer page.

1. To revise **the Research Application Part 1 Form** from a previous package for committee review:
   - Click on the pencil icon for the Research Application Part 1 Form. This will open up the Form.
   - Make any necessary changes to previously entered information and save. The document will move to the 'New and Revised Documents in this Package'section.

2. To revise an **uploaded document** (.doc, .xls, .pdf, etc.) from a previous package:
   - First download the document by clicking on its Document Type or the paper icon. **If you will be revising a consent document, be careful to ensure that the document in your designer that you will be downloading and revising is identical to the most current, stamped, IRB-approved version that sits in the Board Documents.**
   - Make necessary changes and save the revised document to your computer.
   - Click on the pencil icon for that document in the Designer.
   - Browse your computer, select your revised document to upload, make necessary changes to Document Type and Description (below), and click the Update button.

   - When you click Update, the revised document will appear in the current document package ('New and Revised Documents in this Package') with a revision history (the 'stack of paper' icon) that reflects versions from previous packages (see below).

METHOD #2: Attach a New Document to the Package (Designer)

1. Complete applicable forms downloaded from the Library, or create applicable documents on your computer.
2. Use the Add New Document button to upload the document into the current package. The document will not have a revision history (stack of paper icon) at this time as it is new.

Points to Remember

When you have attached all the required documents, **submit** the revised package, **complete with required signatures** (see section V), to the RPO office in IRBNet. Be sure to indicate the appropriate Submission Type (e.g., 'Continuing Review/Renewal', or 'Modification/Amendment', 'Reportable Event' etc.).

XI. Locked vs. Unlocked Status

Once a study is submitted to RPO, it will be **LOCKED**.

VERY IMPORTANT: You can continue to obtain investigator signatures on a locked package. Under no circumstances should you create a new package just for the purpose of obtaining signatures.

Packages can only be unlocked by RPO Staff. This can be done if you let us know that you've made an error in something that you just submitted, or if we let you know that we see something that is missing or needs to be fixed before forwarding to the RPO.

When you need to respond to an IRB review, or if you want to submit an amendment, or continuing review, you will **create a new package** for the project by adding documents in the designer for that project. See sections IX and X for details.

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XII. The numbering system in IRBNet (What happened to the old IRB #'s?)

1. You will note 2 different #'s in the IRBNet system, **IRBNet #,** and **Local Board Reference #:**
    a. **The IRBNet # is not your IRB #,** but is an important 'internal tracker' provided through IRBNet which is assigned to all studies that you create (new and continuing).
    b. The root # (first six digits) stays the same from creation of a project to termination thereof. The suffix of the IRBNet # (e.g., -1, -2. -3 etc) is the 'package #' with which you are dealing for a single project, i.e., each new package will change the suffix of the IRBNet #.
    - Example: So if your original submission is given the IRBNet # 123456-1, and the IRB reviews the submission and requires changes, you will submit your response as a new package to the original, and it will be given the IRBNet # 123456-2. If it's then approved, and you want to add an amendment, you will submit it as a new package, it will be given the IRBNet #123456-3. And so on. If you click on 'project history' for IRBNet #123456-3, you will see all the packages for the study.
2. **The local board reference # is the IRB# for your project. Once a project is assigned An IRB# in IRBNet*, that # will remain exactly the same throughout the life of the study.***

XIII. Continuing Reviews /Termination Reports

Once your project is approved by the IRB, IRBNet will send those with full project access an e-mail notification 90 and 60 days prior to the expiration of the approval period. You should respond to the first notice as soon as possible, to ensure that there is no lapse in your study approval. If your approval **does** lapse before you have been re-approved (even if you submitted the continuing review materials), the research activity (including data analysis) must be halted immediately.

Once you receive your e-mailed notice to renew your study:
A. If you do not want to continue the study (including data analysis) past the study expiration date:

- Go into your project manager
- Click on the exact IRBNet package (including same suffix) referenced in the e-mail you received
- Go into project designer, and select 'add new documents'. **You will be creating a new package for this study.**
- Go into the Library, and download the Termination Report. Complete the document and upload it back into IRBNet.
- Obtain e-signatures of PI.
- Submit the package as a 'Closed/Final' report.
- You will receive acknowledgement of the closure by the RPO.

B. If you do want to continue the study (including data analysis) past the study expiration date:

- Directions for continuing reviews are available in Section III above.