IRBManager Quick Start Guide

INITIAL APPLICATION - OVERVIEW

GENERAL INFORMATION

Initial Application Types: The IRBManager initial application form (xForm) is available for specific types of initial submissions. The list of application types will continue to expand over time. If the options listed are not applicable to your proposed study, do not continue with the xForm. You must submit a standard application to the IRB office using a traditional application (not IRBManager), found here.

Study Team Members:
Someone is engaged in human subjects research if he/she obtains:
1. Data through intervention or interaction with an individual;
2. Identifiable private information about the study subjects; or
3. Informed consent of human subjects for the research.

If someone is NOT engaged in research by the above definition, his/her participation in the research does not need to be reviewed by the IRB and he/she does not need to be listed as a study team member.

Principal Investigator’s (PIs): PIs must be LSUHSC-NO employees, faculty, or staff. Those in training (students, fellows, residents, and others in training without a faculty appointment) are not permitted to serve as the PI but can be listed as a study team member.

Training Requirements:
Click here for research training requirements for internal and external study team members. LSUHSC-NO IRB will review training once the form has been submitted and request additional training/assignments and/or provide instructions as appropriate.

Contact Not Found: If you receive the error message “Contact not found” when entering an e-mail address in the xForm, this means that the individual is not a contact in the IRBManager System. There will be links (red arrow below) provided throughout the xForm (on the first page when listing the PI and the Department Head and on the study personnel pages) for you to click to add the contacts to the system as needed. Once the contact is added to the system, you may then re-enter the e-mail address to continue the initial application submission process. For more instructions on this process, click here.

ONLY click here if you received an error when entering an e-mail address below
**Show Help:** On certain sections, you will see a “Show Help” tool that you can click on for additional guidance related to that section to appear.

**Add Note:** Certain sections have the “Add Note” option. This option is available for you to provide additional clarification, if necessary, but does not substitute for listing the information in the provided fields.

If you do not answer the required questions in the appropriate fields, you will receive an error message (like the one pictured below) that will prevent you from moving forward with the application.

**Incorrect Information:** If the information listed in the application is deemed insufficient or incorrect, the form will be sent back to the study team for revisions prior to IRB review. Please review the guidance provided in the xForm and below to ensure that the application is accepted for review.

**IRBManager System Compatibility:** the IRBManager system is **NOT** compatible with Internet Explorer (IE) and Microsoft EDGE browsers at this time. You must use Google Chrome or Mozilla Firefox (with Windows and iOS operating systems) or Safari (with Apple devices). [Click here](#) for instructions on how to set Chrome as your default browser.
STEP BY STEP INSTRUCTIONS FOR INITIAL APPLICATIONS

Starting an Initial Application xForm Procedure:

**Step 1:** Log into IRB manager: [https://lsuhsc-no.my.irbmanager.com/](https://lsuhsc-no.my.irbmanager.com/)

  a. Follow login instructions as listed in the quick start guide found [here](#).

**Step 2a:** Click on **Start xForm** on the left side of your screen under "Actions."

**Step 2b:** Select the Initial Application xForm by clicking on the form's title:

Once you click on the Initial Application link, a screen similar to the image below will appear:

**Step 3:** Select the appropriate application type and click “Show Help” when available for specific details related to each section.

**Step 4:** Once you have selected the application type, begin to answer the questions that populate on the first page, following the instructions listed in the application (shown on next page).
Step 4a: Enter the full title of the research protocol and sponsor protocol number (if applicable)

Step 4b: Enter the e-mail address of the Principal Investigator. When you enter the e-mail address of the PI, the training and annual COI disclosure expiration dates will automatically populate next to the e-mail address if the person is in the LSUHSC-NO compliance system as shown on the image below.

Step 4c: If necessary, click “Add Attachment” and upload the necessary training document(s).

If comparable training was completed through a different institution or if applicable training done through LSUHSC-NO CITI or KDS did not populate, please add the training completion certificates in the attachment section.

Step 4d: Select the school associated with the study from the drop down lists.

Step 4e: Select the department associated with the study from the drop down lists.
**Step 4f:** Enter the e-mail address of the Department Head/Center Director. He/she will receive an email notification of this initial application to provide a signature for department review certification.

Department Head/Center Director Information:
Enter the e-mail address of the Department Head/Center Director:

(Required)
test@lsuhsc.edu
Email: test@lsuhsc.edu

If you received an error indicating "Contact not found" when entering e-mail addresses, reference submission instructions at the top of this page.

**Step 5:** Select the existing, planned, or pending support that will be used for the study, selecting “Show Help” for specific definitions, as listed below.

**Funding Information Definitions:**

- External - Governmental (funded in any way by federal, state, or local government of the US or other country)
- External - Industry (funded in any way by a company)
- External - Other (funded in any way by entities other than a government agency or company such as a foundation grant/contract, subcontract from a different institution or a private donor)
- Internal (funded by LSUHSC-NO or other internal resources, including: Department/Institutional Funds; Intramural/Internal Grant/Residual Funds; or unfunded but LSUHSC-NO is providing space and other resources for infrastructure).

Based on your response, additional information will be required.

**Step 6:** Select the type of research applicable to the study, selecting all that apply and press "Show Help" for specific definitions as listed on the next page.
Type of Research Definitions:

- **Social/Behavioral/Education Research**: This category is defined by topic areas, not methodology. This includes research involving human behavior and social functioning and the social and biological contexts of behavior (e.g. sociology, psychology, anthropology, human ecology, history, and communications). Education is also included in this category.
- **Biomedical/Clinical - General**: Includes research involving human biological function, pathology, or clinical issues, diagnosis or treatment. Health research, including public health, health services research, and epidemiology should be included in this category.
- **Biomedical/Clinical - Investigational Drugs**
- **Biomedical/Clinical - Investigational Devices**
- **Biomedical/Clinical - Other**: Includes other biomedical research not included in the categories above
- **Other**: Includes research that does not fit into the categories above.

**Step 7**: Select the study population. Additional information will be requested based on your response. If your study includes a vulnerable population(s) - vulnerable to coercion or undue influence, specifically in regards to the ability to make an informed decisions about participating in research – do not select pregnant women, which are no longer included in this definition with the revised Common Rule.

**Step 8a**: Select the study performance sites. If your response includes sites other than LSUHSC-NO or CTRC, a site permission letter attachment section will appear.

**Step 8b**: If necessary, click “Add Attachment” and upload site permission letters. Attach letters documenting each site’s permission to conduct the study if outside of LSUHSC-NO, if available. Ultimately, you will have to obtain the site’s permission to conduct the study prior to initiating research activities. If it is a community-based site, a site permission letter is required at the time of submission.
**Step 9:** Press “Next.” You will be directed to a page that provides instructions for listing study team members.

**Step 10:** Indicate if there will be other study team members in addition to the PI. **NOTE:** This question will only appear if you, the submitter of the xForm, listed yourself as the PI of the study on the previous page.

Select “No” if you are the PI and will be the only person on the study. Then click “next” at the bottom of the page to continue with the application.

**Additional Study Team Members**

If you select “Yes” at step 10, or if you are not the PI of the study, a question will appear, prompting you to indicate the affiliation (either internal or external) of the additional study team members. **Note:** This section is applicable to study team members besides the PI. Do not list the PI in this section.

**Step 11:** Select “Internal,” “External” or both. Follow Steps 12a-f for adding Internal personnel and Steps 13a-e for External personnel steps.

**Internal Investigators**

**Step 12a:** Enter the e-mail address of the internal study team member in the Internal Personnel Training Table.

**Step 12b:** Click “save”. Repeat this process for as many internal investigators as needed.
For an individual in the IRBManager system, after entry of the email address, the training and annual COI disclosure expiration dates will automatically populate next to the e-mail address if the person is in the LSUHSC-NO compliance system as shown on the image below:

If you received an error indicating “contact not found” when entering an e-mail address, click the link below to add the user(s) IRBManager System. Once added to the system, you can re-enter the email and proceed without error. More instructions on this process can be found here.

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### Internal Personnel Training Table: (Required)

<table>
<thead>
<tr>
<th>E-mail address</th>
<th>BBP HR</th>
<th>BBP LR</th>
<th>HIPAA</th>
<th>COI Research</th>
<th>Bio</th>
<th>SBR</th>
<th>GCP</th>
<th>Annual</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rome, Kacie</td>
<td>01/02/2013</td>
<td>11/22/2022</td>
<td>05/01/2019</td>
<td>04/23/2022</td>
<td>05/31/2010</td>
<td>10/25/2014</td>
<td>06/03/2010</td>
<td>08/02/2018</td>
<td></td>
</tr>
<tr>
<td>Email: <a href="mailto:krome@lsuhsc.edu">krome@lsuhsc.edu</a></td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>Missing</td>
<td>✔</td>
</tr>
</tbody>
</table>

If you received an error indicating “contact not found,” reference instructions and the link at the top of this page.

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**The column headings in the table are abbreviations for the following training courses:**

- **BBP HR** - Bloodborne Pathogene High-Risk, KDS Training
- **BBP LR** - Bloodborne Pathogene Low-Risk, KDS Training
- **HIPAA** - HIPAA in Research, KDS Training
- **COI Research** - Conflict of Interest in Research, KDS Training
- **Bio** - Biomedical Research - Basic/Refresher, CITI
- **SBR** - Social & Behavioral Research - Basic/Refresher, CITI
- **GCP** - Good Clinical Practice, CITI
- **Annual** - Conflict of Interest in Research Disclosure, COI Risk Manager

If “Missing” is listed in a column, that means that the course is not required, not assigned, incomplete, or not done through LSUHSC-NO. Dates that are red, indicate that the training has expired. [Click here](#) for internal training requirements.

If comparable training was completed through a different institution (for example: documentation of human subjects research (HSR) CITI training) or if applicable training done through LSUHSC-NO did not populate in the table, please add the training completion certificates by clicking the “Add Attachments” button (orange arrow) directly below the training table.

LSUHSC-NO IRB will review training once the form has been submitted and request additional training/assignments and/or provide instructions as appropriate.

Clicking “Save” at Step 12b creates a new email entry line in the Internal Personnel Training Table. Repeat Steps 12a-b for all internal personnel being added.

**Step 12c:** Once the Internal Personnel Training Table is complete, re-enter the e-mail address of the first study team member into the Internal Personnel Details Table (see image on the next page). Select the individual’s role and duties for the study.
Step 12d: Click “save”. The table will look similar to the image below. A new email entry line will appear. Repeat for all email addresses inserted in the Internal Personnel Training Table. **All of the e-mail addresses listed in the first table must be listed in the second table.**

![Internal Personnel Details Table]

**Step 12e:** Add any additional information/clarifications regarding the internal study team members in the text box below the Internal Personnel Details Table (optional).

![Text box for additional information]

**Step 12f:** Press “Next.” If “External” personnel was checked at Step 11, you will be directed to the “External Investigator” page (Step 13)
**External Investigators**

**Step 13a:** Enter the e-mail address of the external study team member (someone who is not a LSUHSC-NO employee, faculty or student)

Unlike internal people, you can only list one external e-mail at a time. If the study will include more than one external study team member, you can click the “add another external investigator” button at the bottom of the page.

If you received an error indicating “contact not found” when entering an e-mail address, click the link in the form (green arrow) to add the contact to the IRBManager system. For more details regarding this process, click here.

**Step 13b:** Select the Study Role of the external person.

**Step 13c:** Indicate the person’s duties, selecting all that apply, and listing details in the text box if “Other” is selected.

**Step 13d:** List the external’s person home institution (their affiliation).

**Step 13e:** Indicate if LSUHSC-NO will be the IRB of Record for this investigator.

Based on this response, you will be asked a series of questions, which will determine which training modules and documents are needed for processing this request. For more guidance on required documents and agreements to serve as the IRB of Record, click here.
LSUHSC IRB is NOT the IRB of Record

If you respond “No” at step 13e, you will be prompted to provide the following documents in the attachments section:

A. Documentation of the Human Subjects Research (HSR) training completion (CITI or comparable HSR training report), and
B. IRB approval of the study from the external investigator's IRB of record (e.g., home institution).

Click “Add Attachment” to provide the required attachments.
Then press the “Add Another External Investigator” button to repeat the process if you want to add another person.
When finished adding external personnel, press “Next” to move forward.

LSUHSC IRB is the IRB of Record

If you respond “Yes” at step 13e, you will be asked a series of questions and the person will be required to meet specific training and documentation requirements depending on your responses.

A. Conducting Research on LSUHSC-NO Campus? - If, yes, additional training modules are required (KDS – HIPAA Privacy and KDS- Bloodborne Pathogen or comparable training if done through a different institution).
B. Gratis Appointment? - If the external investigator has a gratis appointment with LSUHSC-NO, then no additional agreements will be required. For external investigators that do not have a gratis appointment, an agreement (either an IRB Authorization Agreement or an Individual Investigator Agreement) will need to be in place prior to moving forward with this amendment application (see next page).
LSUHSC IRB is the IRB of Record for those without a Gratis Appointment:

Does the external investigator have a gratis appointment with LSUHSC-NO? (Required)
- Yes
- No

Is either an IRB authorization agreement (IAA) or an Individual Investigator Agreement (IIA) in place for LSUHSC-NO to serve as the IRB of record? (Required)
- Yes
- No

- If you indicate that the agreement is **not** in place, you can either click “save for later” and return to completing this form once agreements are complete or remove this person from the application to move forward and submit the request to add him/her at a later time. Click here to access template IAA and IIA documents and instructions for executing the agreements.

- Enter the training **expiration dates** for applicable modules, based on external investigator requirements, found here.

**Enter Training Expiration Dates** - Press "Show Help" for additional guidance

- CTA Biomedical Research Basic/Refresher or Comparable Training
- CTA Social & Behavioral Research Basic/Refresher or Comparable Training
- CTA Good Clinical Practice or Comparable Training
- COT Risk Manager: Annual Conflict of Interest in Research Disclosure
- KDS Conflict of Interest in Research
- KDS HIPAA Privacy - Research or Comparable Training
- KDS Bloodborne Pathogen or Comparable Training

Attach documentation of training as needed - click "Show Help" for guidance.

- Attach copies of completion reports if done through a different institution (Not LSUHSC-NO KDS or LSUHSC-NO CITI).

LSUHSC-NO IRB will review training once the form has been submitted and request additional training/documentation and provide further instructions as needed.

- After providing required attachments, press the “Add Another External Investigator” button if you want to add another person.

**To add another external investigator, click the “Add Another External Investigator” button. If you are done adding external personnel, click the “Next” button.**

- When you are done listing external personnel, press “Next” to move forward.

**Application Type Specific Questions**

**Step 14:** After entering the general study information and investigator details, you will be directed to pages that list questions specific to the application you selected in **step 3**. Follow the instructions listed in the form and list all required information, pressing “Next” at the bottom of each page to move forward. Ultimately, you will be directed to an attachments page (see next page).
Step 15a: After listing all of the study-specific information, you will be directed to a final attachments page. Attach the required forms (not previously attached within the application) based on the submission type (for instance: the data collection sheet is required for medical chart reviews). Be sure to name the document appropriately and select the correct document type so you can easily be identified in the future.

Step 15b: Press “Next” when you are finished adding attachments. You will be directed to the final screen as shown on the next page.

SPECIAL NOTE: If the form is sent back to the study team and requires revisions to the attachments submitted with the application, be sure to click the green arrows to replace the obsolete version with the one reflecting the IRB’s requested revisions.

A “Replace Attachment” screen will appear for you (as shown below) to replace the prior document with the corrected version.
Submitting the Application

PI not original Submitter: Press “Next” when you are finished adding attachments. If you are not the PI of the study, you will be brought to the last screen as pictured below. Click “Submit” for the form to be sent to the PI for signature.

The PI will then be sent an email requesting review and signature of the application with a link to the form. The PI will review the application, clicking “Next” at the bottom of each page until he/she reaches a page, prompting him/her to select if the initial application is ready for department head and IRB Review or if it needs to be sent back to the original submitter for revisions prior to submission. If the PI selects “Ready for Submission”, he/she will be brought to the PI Signature page which looks like the one pictured in the next section.

PI Sign-Off: Press “Next” when you are finished adding attachments. If you are the PI and the original submitter, you will be brought directly to the page below to provide your signature. If you are not the original submitter, you will be sent an email, as listed above, with a link for you to review the application, pressing “Next” at the bottom of each page until you lead to the PI Signature Page (below):

Click “Sign,” entering the prompted information. Once the application is signed, it will look similar to the picture below. Then click “Next”. The form will not be submitted unless you click “Next” and then “Submit”.

Please click "Next" to move forward with the application. Ultimately, you will need to click “Submit” for the application to be processed.
Finally, click “Submit” on the last screen.

Once you submit the form you will get the following message:

Department Head Signature

After the application has been signed by the PI, an e-mail will be sent to the Department Head/Center Director (DH/CD) (listed in step 4f) requesting review and certification of the application with a link to the form. He/she will review the application, clicking “Next” at the bottom of each and will be prompted to provide his/her recommendation for the submission. If the DH/CD does not recommend the application for submission, an e-mail will be sent to the study team with details regarding this decision. If the DH/CD is ready to provide his/her certification and recommends the application for submission to the IRB, he/she will be brought to the signature section which looks like the one pictured below.

DH/CD: Click “Sign,” entering the prompted information. Then click “Next”. The form will not be submitted unless you click “Next” and then “Submit” on the final screen (shown on next page).
Finally, click “Submit” on the last screen.

Once you submit the form you will get the following message:

IRB Review Stage

After all electronic certifications (by the PI and Department Head) have been completed, the application will be routed to the IRB Office for administrative pre-review.

You can check on the status of the xform after you have submitted it by visiting your dashboard and referencing the xFrom section. The current stage the form is in will be listed under the “Stage” column. Click here for instructions on navigating your dashboard.

If you have any questions about IRBManager please contact the LSUHSC-NO Office of Research Services at: IRBOffice@lsuhsc.edu