KUALI QUICK GUIDE

EXEMPT RESEARCH PROTOCOLS

I. GENERAL INSTRUCTIONS

A. This Quick Guide applies to: Creation of New "Exempt Research" Protocol

B. Navigation:

a. In order to move through the smart form, you must complete all sections within the General Information Page, starting with the Study Identification section. Once you have completed all sections, press "**Next**" to continue with the Exempt Questionnaire Page.

C. Website Guidance: To qualify for exemption, all research activities must fit into one or more of the Exemption Categories 1-6 listed here, present no more than minimal risk to subjects, and not include populations that do not qualify for exemption. Please visit the LSUHSC-NO IRB website for additional information and guidance.

D. Attachment: Protocols and consent/assent/information sheet documents should initially be provided as Word documents; all other documents should be in PDF format. There are no specific document requirements for exempt research; however, there may be some that are needed based on the type of research and activities being conducted, and you will be alerted of these supporting document requirements based on your questionnaire responses.

E. New Protocol Submission Overview: Reference this quick guide found on our Kuali Quickguide webpage for an overview and additional guidance related to each section.

II. GENERAL INFORMATION PAGE

A. Study Identification:

a. **Title:** Enter the title of your study.

b. **Principal Investigator:**

i. Begin typing the first or last name of the PI and candidates will automatically appear from the list of users in Kuali.

ii. Click the PI's name and it will be entered in the field.

c. **Department:** Primary appointment of PI

i. Begin typing the name of the department and candidates will automatically appear from the list of departments stored in Kuali.

ii. Click the department's name and it will be entered in the field.

d. **School:** Select the School from the drop-down list that corresponds to the primary appointment of the PI.

e. **Press "Next"**

B. Protocol Type:

a. **Select the "Protocol Type"** from the drop down menu: **Exempt Research**

b. **Press "Next"**

C. Funding and Sponsor Information Table:

a. Select the Funding Type(s) for the study and provide all requested details based on your selection (e.g., industry sponsor details). *Reference the New Protocol Overview Quick Guide for specific instructions.*

D. Performance Site(s):

a. Follow instructions to select all organizations (sites) that are engaged in the research, i.e., any organization where subject records will be accessed, or where research related interactions and/or interventions occur.
b. If the study will be held outside of LSU Health, you will be required to attach a letter, email, or other correspondence indicating agreement to conduct research at the external facility.

E. Study Population

a. As applicable, indicate the type of participants that may be included in the study, such as children (subjects under the age of 18) and students.
b. **Vulnerable Populations in Exempt Research Considerations:**
    i. Studies that target a prisoner population are not eligible for exemption. In this case, you must submit an expedited application to the IRB. Exemption is allowable for research aimed at involving a broader subject population that only incidentally includes prisoners.
    ii. Studies that include children are eligible for exemption in all categories except for Category 2 (Limitation and Exclusion) and Category 3 (no children allowed).
c. In the count field, enter the total number of subjects to be enrolled in the research.

F. Research Personnel

a. The PI's name will automatically be listed in the Research Personnel Table.
b. Follow instructions in the protocol to list all research personnel, including "Site Administrators" that need to edit the KR Protocol or receive notifications.
c. *Reference the New Protocol Overview Quick Guide for specific instructions on adding personnel to the table.*
a. **Individual Not a User in KR:** *Reference the Accessing Kuali Quick Guide.*

G. Type of Research:

a. Indicate the "Type of Research" being conducted. Based on your response, additional descriptive options for your to select will appear.

Once all required information has been entered on the General Information Page, press "Next" to begin the Exempt specific questionnaire.

III. PROTOCOL TYPE QUESTIONNAIRE PAGE

A. Questionnaire: Exempt Research

a. Complete all general exempt questions.
b. Select ALL categories that apply to the proposed exempt study project and answer all questions that appear.

c. The protocol adapts using built-in logic (smart-form) based on your responses to some questions.
d. If your responses indicate that your project does not qualify for exemption, you will be alerted to revise the type of protocol you selected on the previous page as the study does not qualify as an exempt study.

IV. SUPPORTING DOCUMENTS

A. Relevant Documents

Although you may be prompted to add attachments as you provide responses to questions within the smart form, a supporting documents section will appear at the bottom of the questionnaire page for you to attach any study documents not previously attached but needed based on your research activities.

B. Common Attachment Types for Exempt Research include:

- All Data Collection Instrument (surveys, questionnaires, data collection form).
- All recruitment Materials – flyers, advertisements, emails, letter, phone script, etc.
- Study Information Sheet and/or oral scripts
- Other – for supporting documents that do not meet any of the above criteria (e.g., letters of cooperation from researcher sites)

C. Instructions

a. Click the "+Add Line" button to the right to upload a Supporting Document.
b. In the dialogue box, Drag and Drop a file or Click "+ Choose" and browse for a file:
    i. If browsing, locate the file and click open to attach. Note: all commonly used file types should be compatible except for ".msg" (Outlook messages).
c. Enter a Name that will help you identify the document
d. Select an Attachment Type from the drop-down list.
e. Repeat Steps a-d as many times as necessary to add all necessary documents.

V. PI CERTIFICATION & SUBMISSION

A. PI IDENTIFICATION

a. **The protocol may only be submitted by the PI.**
a. If you are the PI, you will be asked to provide your statement of assurance. If you do not agree with the statement, you can permanently terminate the submission by clicking the "abandon" button.
b. *Reference the New Protocol Overview Quick Guide for Detailed Guidance*.

VI. SUBMISSION INSTRUCTIONS

A. When the Exempt Research application is ready for submission

a. Click "**Submit**" for it to be sent to the HRPP office.
b. If required fields have no entry, error messages will appear
    i. Complete all required fields and click "**Submit**" again.
c. Submission's status will change from "In Progress" to "Submitted for Review"

VII. DEPARTMENT CERTIFICATION

Once the protocol is submitted for review, the HRPP office will assign the Department Head as an ancillary reviewer. The Protocol will not be "approved" until the ancillary review has been approved by the Department Head (*i.e.*, Department certification provided).

VIII. CHECKING THE STATUS OF AN EXEMPT PROTOCOL

Click on "Manage Protocols" to view the submission type and status of your HUD protocol.
Once your Exempt Protocol is Approved, the status will be:

A. Exempt Status Post Approval:

a. **Submission Type:** Initial
b. **Review Type:** Exempt
c. **Status:** Approved
d. **Continuing Review Date:** 3 Years from date of exempt determination date for non-FDA regulated studies.

B. Submission Type Definitions:

a. **New:** an initial (new) protocol submission.
b. **Initial:** "New" submission that is approved by the IRB
c. **Amendment:** submission to request modification of an approved protocol.
d. **Renewal:** submission to request renewal/re-approval of a protocol.
e. **Renewed:** "Renewal" submission that is approved by the IRB.
f. **Close Request:** submission to request closure of an approved protocol.

C. Status Type Definitions:

a. **In Progress:** This is the first version of the Protocol and it has not yet been submitted for review.
b. **Submitted for Review:** This submission has been submitted to the compliance office for review for the first time.
c. **Revisions in Progress:** This is the new version of a protocol created when the Revisions Requested action is taken. This version is sent to the researcher so they can make their changes.
d. **Approved:** This version of the protocol has been approved by the compliance office.
e. **{Submission Type: Amendment} In Progress:** An Amendment is being worked on in this version and has not yet been submitted for review.
f. **{Submission Type: Renewal} In Progress:** A Renewal is being worked on and has not yet been submitted for review.
g. **{Submission Type: Close Request} In Progress:** A request to close the protocol is being worked on and has not yet been submitted for review.
h. **Closed:** This protocol has been closed and is no longer active.
i. **Abandoned:** This submission was abandoned by the researcher.

IX. POST EXEMPTION DETERMINATION REQUIREMENTS

Actions Post Determination

A. RENEWAL: For ongoing studies that are, or have become, exempt from Continuing Review, investigators must submit a Status Update every three years. Status Updates are submitted using the *Renewal* form in KR via the "Renew" button.

B. REPORTABLE EVENTS: Reportable New Information (RNI) refers to any new information or event that may impact on the conduct of an IRB-approved human subjects research study or the safety and welfare of the participants in that study. Please consult the IRB webpage, Reportable New Information, for guidance on RNI types and their submission requirements. Submit RNIs via the "Report an Event" button in KR.

C. AMENDMENTS: Please consult the IRB webpage, Modifications, for guidance about which modifications to Exempt studies need IRB review and approval prior to implementation. Amendments are submitted via the "Amend" action in KR.

D. CLOSURE: Request for closure should be submitted if all research-related interventions or interactions with participants have been completed and collection and analysis of identifiable private data (as described in the IRB-approved protocol) are finished. Close the study via the "Close Request" action in KR.