I. Introduction

All IRB applications must be submitted through Kuali Research Protocols (KR). This guidance document describes protocol types available for selection in the KR IRB application.

This guidance is intended for all IRB submissions, including potential and actual human subjects research (HSR) under the oversight of HSC Human Research Protection Program (HRPP) and HSR for which HSC or its affiliates are relying on an external IRB for oversight.

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II. Definitions

Protocol: An IRB study in KR, independent of study status or submission type.

Submission: Refers to the type of application being submitted for the protocol.

> *Submissions are broken down into two main categories: new and post-approval submissions. New submissions are described in terms of "Protocol Type", which is a field in the initial application that corresponds to the level of review required.*

Protocol Type: A field in the IRB application that the end user selects to populate the appropriate application for the protocol. It corresponds with the level of review required.

Review Type: Hard coded options available for HRPP staff when indicating the level of review required for the protocol.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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III. Protocol Type Guidance

This document emphasizes new submission protocol type selection criteria; however, once the study is approved or determined to be exempt, the protocol type listed in the initial application should be selected for all post-approval submission (e.g., amendments and renewals). Post-approval submissions are not applicable for NHSR projects.

Please contact the HRPP Office by email @IRBOffice@lsuhsc.edu if you need additional guidance with the protocol type selection process.

A. Not Human Subjects Research (NHSR)

Select this protocol type if you are requesting that HRPP staff determine if your project meets the regulatory definition of HSR:

- **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, **AND**
- **Human Subjects:** Involves living individuals about whom an investigator (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.

Click the above "NHSR" link for specific details and to access the NHSR Activities guidance document.

Any project that does not meet the regulatory definition of human subjects or research, is not human subjects research (NHSR) and therefore does not require IRB and HRPP review.

If your project includes only activities listed in the NHSR Activities guidance document, you do not need to submit a NHSR protocol for the project. However, if documentation of a NHSR determination has been requested by a sponsor, a journal or a collaborator, or if you are unsure if your project meets the regulatory definition of HSR, a NHSR submission can be created in KR for HRPP review. If the project is NHSR, you will receive a formal email notification from KR as documentation of the determination that IRB review is not required.

B. Exempt Research

Select this protocol type if your research study presents no more than minimal risk to human participants and meets the criteria for exemption as defined by federal regulations; HSC currently recognizes only Exempt Categories 1-6. **Click the above "Exempt Research" link for specific details.**

Below are additional exempt requirements:

- The research **DOES NOT** involve prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- If the study will be recording identifiable information, adequate provisions are in place to maintain confidentiality of the data.
- Adequate provisions are in place to maintain the privacy interests of participants.
- For studies with participant interaction (e.g., survey studies), participants should receive verbal or written information about the study including the purpose and procedures of the research project, a statement that participation is voluntary, and contact information for the principal

investigator. **Go to Section IV ("Related Information") to access HSC Forms and Templates – Exempt Research Information Sheet.**

Projects eligible for exemption may include:

- **Exempt 1**: Research conducted in established or commonly accepted educational settings;
- **Exempt 2**: Research using tests, surveys, or observations:
- **Exempt 3**: Research utilizing painless, brief behavioral interventions subjects would not find offensive or embarrassing;
- **Exempt 4: Secondary*** research uses of identifiable private information or identifiable biospecimens for which consent is not required;
- **Exempt 5**: Research involving public benefit or service programs; and
- **Exempt 6**: Taste and food quality evaluation and consumer acceptance studies.

***NOTE: Secondary** means the re-use of identifiable information and identifiable biospecimens that were collected during some other "primary" or "initial" activity. In other words, data/specimens were not collected for your specific study.

Studies that involve ONLY secondary data are eligible for exemption under Category 4; for example:

- Research involving only the collection and analysis of data from medical records;
- Analysis of biospecimens from an IRB-approved biorepository, given that researchers do not record identifiers or link them to the specimens.

Studies that involve collection of new identifiable data in addition to secondary data or require consent are NOT exempt under Category 4; for example:

- Research involving the collection of an extra biopsy sample for evaluation for research purposes. This research involves direct data collection and will also require consent.

C. Expedited

Select this protocol type if your project is minimal risk but is not eligible for exempt review and falls into one or more of the expedited categories listed in the federal regulations.

Click the above "Expedited" link for specific details and also go to Section IV ("Related Information") below for links to additional resources.

The IRB may NOT use an expedited review procedure for any of the following:

- Research in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- Classified research involving human subjects.
- Research involving interaction with prisoners.*
- Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product.
- Research on medical devices that require an Investigational Device Exemption regardless of whether they are classified as Significant Risk or Non-significant Risk by the Sponsor or FDA.

***NOTE**: Research that does not involve interaction with prisoners (e.g., medical chart reviews that intentionally include prisoners as the study population), may be reviewed via the expedited procedure, unless subject to Department of Defense requirements, if:
- The primary IRB reviewer and the prisoner representative determine the research is minimal risk for the prison population being studied or included.

Projects eligible for expedited review may include:

- **Expedited 1 – Drugs**: Research on drugs for which an investigational new drug (IND) application (21 CFR 312) is not required, such as:
    - Clinical investigation of a drug product that is lawfully marketed in the US and all of the criteria for IND exemption in §312.2(b)(1) is met;
    - Clinical investigation involving the use of a placebo AND the investigation does not otherwise require submission of an IND §312.2(b)(5); and
    - Clinical investigation that has been submitted to the FDA and the FDA documented in writing that an IND is not required for investigation §312.2(e)
- **Expedited 1 – Medical Devices**: Research on medical **devices** for which 1) an investigational device exemption (IDE) application (21 CFR 812) is not required; or 2) the device is cleared/approved for marketing for the study indication, such as:
    - A legally marketed device when used in accordance with its labeling §812.2(c)(1,2);
    - A diagnostic device, with all of the applicable shipping requirements in § 809.10(c) met and all testing conditions in § 812.2(c)(3) satisfied; and
    - A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, *if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk* §812.2(c)(4).
- **Expedited 2**: Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
- **Expedited 3**: Prospective collection of biological specimens for research purposes by noninvasive means. Some examples include:
    - Mucosal/skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
    - Sputum collected after saline mist nebulization; and
    - Permanent teeth if routine patient care indicates a need for extraction.
- **Expedited 4**: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays/microwaves. When medical devices are used, they must be cleared/approved for marketing.
- **Expedited 5**: Research involving materials that have been collected, or will be collected solely for nonresearch purposes (e.g., medical treatment or diagnosis). This listing refers only to research that is not exempt.
- **Expedited 6**: Collection of data from voice, video, digital or image recordings made for research purposes
- **Expedited 7**: Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. This listing refers only to research that is not exempt.

D. Full Board

Select this protocol type if the study is not eligible for an exempt or expedited review either because it is greater than minimal risk or because the study procedures are outside the exempt and expedited

categories. Because of the nature of the full board review process, you should allow ample time to obtain full board approval. **Click the above "Full Board" link for specific details and go to Section IV ("Related Information") below for additional resources.**

NOTE: If your study involves a device classified as ***Significant Risk*** or ***Non-significant Risk*** by the FDA or sponsor, select **Full Board** as the **Protocol Type**. Only devices for which an Investigational Device Exemption application to the FDA is not required or the medical device is cleared/approved for marketing by the FDA as may be eligible for expedited review.

E. **Reliance Request**

Select this protocol type if are requesting to rely on the determination of an external IRB for your research study. As a general rule, reliance is not applicable for studies that were determined to be exempt. **Click the above "Reliance Request" link for specific details and go to Section IV ("Related Information") below for links to additional resources.**

F. **Humanitarian Use Device (HUD)**

Select this protocol type if your research involves the use of a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects, or is manifested in, not more than 8,000 individuals in the United States per year. **Click the above "HUD" link for specific details and go to Section IV ("Related Information") below for links to additional resources.**

G. **Expanded Access to a Test Article (EATA)**

Select this protocol type if you intend to use an unapproved medical product (drug, biologic, or medical device) on one or a few patients who have a serious or immediately life-threatening condition; there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; and enrollment in a clinical trial is not possible. **Click the above "EATA" link for specific details and go to Section IV ("Related Information") below for links to additional resources.**

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IV. Related Information

Related Policy Documents

A. **HSC Policies**

1. NHSR –P & P # 1.02 (Definition of Human Subjects Research)
2. Reliance Request – P & P # 8.01 (IRB Reliance)

Related Guidance Documents

B. **HSC Guidance Materials**

1. NHSR - HRP-2600 (Activities That are Not Human Subjects Research)
2. NHSR – HRPP – 2300 (Certification of Research on Decedent information)
3. Exempt - HRP-2650 (Exempt Research Categories)
4. Expedited - HRP-2651 (Expedited Categories)

5. EATA - HRP-2602 (Expanded Access to a Test Article)
6. EATA - HRP-2301-03 (Certification Letters)

Related HSC Forms and Templates

C. HSC Forms and Templates

1. Exempt - HRP-2259 (Exempt Research Information Sheet)
2. Exempt/Expedited - HRP-2264 (Verbal Consenting Script Template)
3. Expedited/Full Board – HRP-2251 (Standard Consent Template – Minimal Instructions)
4. Expedited/Full Board – HRPP 2265-66 (Assent Templates, Ages 7-12 and 13-17, respectively), when CHNOLA is not a Site.
5. HUD - HRP-2258 (HUD Treatment Consent Template)
6. Expedited/Full Board/Reliance Requests – HIPAA Forms

D. HRPP Kuali Quick Guides

1. NHSR - HRP-2810
2. Exempt - HRP-2812
3. Expedited/Full Board - HRP-2813
4. HUD - HRP-2816
5. EATA - HRP-2815

E. Regulatory References

NHSR/Exempt: 45 CFR 46

Exempt: 28 CFR 46: Exempt Research that may undergo Expedited Review

Expedited/Full Board: 21 CFR 56; Expedited Review Procedure (OHRP)

Full Board: 21 CFR 812 (Food, Drugs, Devices).

HUD: Humanitarian Device Exemption (FDA)

EATA: Expanded Access Introduction (FDA)

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V. Protocol Type Corrections

If an incorrect protocol type is selected for the study, it will be returned to the submitter for protocol type revision. The protocol type update will also entail completion of additional form fields as the application displayed is linked to the protocol type selected.

To avoid incorrect protocol type selection, please review the protocol type information provided in the document and reach out to HRPP Staff for guidance as needed at IRBOffice@lsuhsc.edu.

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VI. History

Version Number	Version Date	Summary of Changes
1.0	6.13.2022	N/A
1.1	7.26.22	Exempt Criteria Clarity