ESCUELA DE MEDICINA
San Juan Bautista

APPLICATION FOR DETERMINATION OF NON-HUMAN SUBJECTS RESEARCH (NHSR)

SAN JUAN BAUTISTA SCHOOL OF MEDICINE
Institutional Review Board (IRB) / Human Research Protection Program (HRPP)

Form Number: IRB-NHSR-001
Version: 1.0 | October 22, 2026
Regulatory Basis: 45 CFR 46.102(e), 45 CFR 46.102(l), and applicable OHRP guidance

PURPOSE

This application is intended for investigators requesting an institutional determination that their proposed activity does not constitute research involving human subjects as defined by the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR Part 46.

Submission of this application does not constitute IRB approval, exemption, or authorization to initiate an activity requiring regulatory review. A written determination must be issued by the IRB Office or another institutionally authorized official under applicable institutional procedures.

SECTION I. INVESTIGATOR AND PROJECT INFORMATION

1. Project Title:

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2. Principal Investigator (PI):

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3. Academic Degree(s) and Position:

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4. Department / Academic Program:

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5. Institutional Affiliation:

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6. Institutional Email:

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7. Telephone:

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8. Co-Investigators / Research Personnel:

Investigator Institutional affiliation Project responsibilities

9. Type of Project (select all that apply):

- ☐ Retrospective analysis of existing data
- ☐ Analysis of publicly available data
- ☐ Analysis of de-identified datasets
- ☐ Secondary analysis of existing research data
- ☐ Quality improvement / quality assurance
- ☐ Program or educational evaluation
- ☐ Medical education curriculum assessment
- ☐ Institutional operational assessment
- ☐ Literature review / systematic review / meta-analysis
- ☐ Case report or case series
- ☐ Research involving only deceased individuals
- ☐ Laboratory analysis of non-identifiable biospecimens
- ☐ Public health surveillance
- ☐ Other: _____

10. Anticipated Project Start Date: _____

11. Anticipated Project Completion Date: _____

12. Funding Source:

- ☐ No external funding
- ☐ Institutional funding
- ☐ Federal funding

- ☐ Private / Foundation funding
- ☐ Other: _____

Funding Agency / Sponsor: _____

13. Is an outside institution, hospital, clinic, government agency, or data repository participating?

☐ Yes ☐ No

If yes, identify the organization and describe its role, including data collection, extraction, coding, transfer, or analysis.

SECTION II. PROJECT DESCRIPTION

14. Background and Rationale

Provide a brief description of the problem or institutional need addressed by the proposed activity.

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15. Project Objectives

State the primary and secondary objectives.

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16. Project Methodology

Describe the study design or operational approach, including:

- Data sources and collection procedures.
- Population or records represented in the data.
- Inclusion and exclusion criteria, when applicable.
- Variables to be collected.
- Proposed statistical or qualitative analysis.
- Any anticipated publication or external dissemination.

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17. Intended Use of Results

Select all that apply:

- ☐ Internal institutional improvement
- ☐ Educational or administrative evaluation
- ☐ Scientific publication
- ☐ Conference presentation
- ☐ Institutional report
- ☐ Development or contribution to generalizable knowledge
- ☐ Other: _____

Explain how the findings will be used and whether the project was designed to generate generalizable knowledge.

Note: An intention to publish or present results does not, by itself, establish that an activity constitutes research under 45 CFR 46.102(l). The project's design and purpose must be evaluated.

SECTION III. REGULATORY SCREENING: DOES THE ACTIVITY CONSTITUTE RESEARCH?

Under 45 CFR 46.102(l), research generally means a systematic investigation designed to develop or contribute to generalizable knowledge. Certain activities are expressly excluded from this regulatory definition.

18. Is the activity a systematic investigation involving a predefined methodology for collecting, analyzing, or evaluating information?

☐ Yes ☐ No ☐ Uncertain

Explanation: _____

19. Is the activity designed to develop or contribute to generalizable knowledge beyond the specific institution, program, or operational setting?

☐ Yes ☐ No ☐ Uncertain

Explanation: _____

20. Is the primary purpose of the activity limited to internal program evaluation, quality assurance, quality improvement, or institutional operations?

☐ Yes ☐ No ☐ Uncertain

If yes, explain the operational objective and whether the activity includes research-specific procedures.

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21. Does the activity fall into one of the following categories expressly deemed not to be research under 45 CFR 46.102(l)?

- ☐ Scholarly or journalistic activity focused directly on specific individuals, as described in §46.102(l)(1)
- ☐ Qualifying public health surveillance activity conducted, supported, requested, ordered, required, or authorized by a public health authority under §46.102(l)(2)
- ☐ Qualifying criminal justice or investigative activity under §46.102(l)(3)
- ☐ Qualifying national security operational activity under §46.102(l)(4)
- ☐ None of the above
- ☐ Uncertain

If applicable, provide a regulatory justification and supporting documentation.

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22. Investigator's Preliminary Assessment

☐ The activity does not meet the regulatory definition of research.

☐ The activity constitutes research; evaluation of human-subject involvement is required.

☐ The classification is uncertain and requires institutional review.

Justification:

SECTION IV. REGULATORY SCREENING: DOES THE PROJECT INVOLVE HUMAN SUBJECTS?

Under 45 CFR 46.102(e)(1), human-subject involvement includes research in which an investigator obtains information or biospecimens through intervention or interaction with a living individual and uses, studies, or analyzes them, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

For Questions 23–31, answer based on the activities of all investigators, including students and collaborating personnel.

Question	Yes	No	Uncertain
23. Will investigators interact or communicate with living individuals to obtain research information?	☐	☐	☐
24. Will investigators perform interventions, examinations, tests, interviews, surveys, or research procedures involving living individuals?	☐	☐	☐
25. Will investigators obtain, use, study, analyze, or generate identifiable private information about living individuals?	☐	☐	☐
26. Will investigators access identifiable medical records, educational records, personnel records, or other private information for research?	☐	☐	☐
27. Will investigators obtain or analyze identifiable human biospecimens?	☐	☐	☐
28. Will investigators have access to codes, re-identification keys, or other means by which identities may readily be ascertained?	☐	☐	☐
29. Will investigators obtain data containing direct personal identifiers?	☐	☐	☐
30. Will investigators obtain data containing indirect identifiers that could reasonably permit identification, alone or in combination with other information?	☐	☐	☐
31. Will identifiable information be shared with any research collaborator or external investigator?	☐	☐	☐

32. If any response is Yes or Uncertain, explain the circumstances and whether identifiable information or biospecimens will be used for research.

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33. Does the project exclusively involve deceased individuals?

☐ Yes ☐ No

If yes, explain how the absence of living individuals was established.

34. Does the project use only publicly available information?

☐ Yes ☐ No

If yes, provide the source and describe whether the information is publicly accessible without special authorization.

SECTION V. DATA SOURCES AND IDENTIFIABILITY

35. Source of Data / Information

Identify all applicable sources:

- ☐ Publicly accessible database
- ☐ Government or public health database
- ☐ Previously collected institutional administrative data
- ☐ Existing clinical database / Electronic Health Record
- ☐ Existing educational records
- ☐ Previously collected research dataset
- ☐ Existing biospecimen repository
- ☐ Published literature
- ☐ Other: _____

36. Name of Dataset / Repository / Institution:

37. Is data collection prospective or retrospective?

☐ Entirely retrospective

☐ Prospective use of routinely generated information

☐ Prospective research-specific collection

☐ Other: _____

38. Data Identifiability Classification

- ☐ Publicly available information
- ☐ Aggregate data without individual-level records
- ☐ Individual-level data without identifiers
- ☐ Coded individual-level data
- ☐ Data containing direct identifiers
- ☐ Data potentially identifiable through combinations of variables
- ☐ Uncertain

39. If data are coded, answer the following:

a. Who maintains the code or re-identification key?

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b. Can the PI or any research team member access the key?

☐ Yes ☐ No

c. Can a collaborator release the key to the research team?

☐ Yes ☐ No

d. Is there a documented agreement, policy, or legal restriction prohibiting release of the key to investigators?

☐ Yes ☐ No

e. Attach applicable data-use agreements, certification of restrictions, or repository policies.

40. If human biospecimens will be analyzed, describe:

- Source and method of collection.
- Whether the specimens were originally collected for clinical care or research.
- Whether specimens are identifiable or coded.
- Who can access the code or identification key.
- Whether any new specimens will be collected from living individuals for the proposed project.

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41. Describe Data Security Measures

Explain storage location, access restrictions, institutional cybersecurity safeguards, data transfer arrangements, retention schedule, and destruction procedures, as applicable.

42. HIPAA and Other Privacy Considerations

Does the activity involve individually identifiable health information or information subject to HIPAA or other applicable confidentiality requirements?

☐ Yes ☐ No ☐ Uncertain

If yes, explain what authorization or lawful basis permits the proposed activity, including access, disclosure, or use.

Important: A determination that an activity is not human subjects research under the Common Rule does not independently waive HIPAA, contractual confidentiality obligations, institutional policies, or other applicable legal requirements.

SECTION VI. JUSTIFICATION FOR NON-HUMAN SUBJECTS RESEARCH DETERMINATION

43. Identify the primary basis for requesting NHSR classification.

- ☐ The project is not research as defined under 45 CFR 46.102(l).
- ☐ The project falls within an activity expressly deemed not to be research under 45 CFR 46.102(l)(1)–(4).
- ☐ The project constitutes research but does not involve human subjects under 45 CFR 46.102(e)(1).
- ☐ The project involves only deceased individuals and no living human subjects.
- ☐ The research uses existing information or biospecimens for which individuals' identities cannot readily be ascertained by investigators, and no intervention or interaction with living individuals occurs.
- ☐ Other regulatory justification: _____

44. Investigator's Regulatory Justification

Provide a concise explanation demonstrating why the proposed activity does not meet the applicable regulatory definition of human subjects research.

Specifically address:

1. Whether the project meets the definition of research.

2. Whether any living individuals will be involved.
3. Whether investigators will obtain information through intervention or interaction.
4. Whether investigators will obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens.
5. Whether identities could readily be ascertained by any investigator.
6. Why the proposed classification is consistent with 45 CFR 46.102.

Investigator's Statement:

SECTION VII. REQUIRED SUPPORTING DOCUMENTATION

Attach applicable documents to support institutional review.

- ☐ Complete project protocol or methodological summary
- ☐ Project objectives and analytical plan
- ☐ Complete list of proposed variables / data dictionary
- ☐ Description of data sources
- ☐ Data collection instrument or abstraction form, if applicable
- ☐ Documentation that data are publicly available
- ☐ Documentation supporting non-identifiability or coding restrictions
- ☐ Data Use Agreement, if applicable
- ☐ Written authorization from data owner or institution, if applicable
- ☐ HIPAA/privacy compliance documentation, if applicable
- ☐ Institutional quality improvement or program evaluation authorization, if applicable
- ☐ Public health authority authorization, when claiming a qualifying surveillance exclusion
- ☐ Other supporting documentation requested by the IRB Office

The IRB Office may request additional documentation to determine whether the proposed project meets applicable regulatory definitions.

SECTION VIII. PRINCIPAL INVESTIGATOR CERTIFICATION

I certify that:

1. The information presented in this application and its attachments is accurate and complete to the best of my knowledge.
2. The activities described in the application accurately represent the proposed project and all planned data collection, data access, analysis, and dissemination procedures.
3. I understand that a determination of Non-Human Subjects Research is distinct from IRB approval or exempt human subjects research.
4. I will not undertake research procedures involving living individuals or identifiable private information or identifiable biospecimens outside the scope of the activities reviewed without obtaining any required prospective institutional review.
5. I will notify the IRB Office or designated HRPP official before implementing material modifications that could affect the project's regulatory classification.
6. I will comply with applicable institutional policies, confidentiality requirements, privacy laws, data-use agreements, and other relevant legal or contractual obligations.
7. I understand that an NHSR determination does not constitute a general authorization to access medical records, personnel files, educational records, clinical databases, or other restricted information.
8. I acknowledge that the institution may reconsider or withdraw the determination if relevant information is incomplete, inaccurate, or changes materially.

Principal Investigator: _____

Signature: _____

Date: _____

Department Chair / Faculty Supervisor (if required): _____

Signature: _____

Date: _____

SECTION IX. IRB OFFICE / HRPP ADMINISTRATIVE REVIEW

FOR AUTHORIZED INSTITUTIONAL USE ONLY

Application Tracking Number: _____

Date Received: _____

Date of Administrative Review: _____

Reviewer Name / Title: _____

A. Completeness Review

- ☐ Complete application submitted
- ☐ Adequate project description
- ☐ Data sources adequately identified
- ☐ Identifiability adequately addressed
- ☐ Applicable supporting documents provided
- ☐ Additional information required

Reviewer Comments:

B. Regulatory Determination Worksheet

Regulatory assessment	Yes	No	Uncertain
Activity meets the definition of research under §46.102(l), accounting for specified exclusions	☐	☐	☐
Activity involves intervention or interaction with living individuals and use, study, or analysis of resulting information or biospecimens under §46.102(e)(1)(i)	☐	☐	☐
Activity involves obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens under §46.102(e)(1)(ii)	☐	☐	☐
Adequate evidence supports the proposed non-identifiability of the information or biospecimens	☐	☐	☐
Additional regulatory or institutional review is indicated	☐	☐	☐

C. Final Institutional Classification

Select one determination:

- ☐ **NOT RESEARCH:** The activity does not constitute research under 45 CFR 46.102(l).
- ☐ **NOT HUMAN SUBJECTS RESEARCH:** The activity constitutes research but does not involve human subjects as defined under 45 CFR 46.102(e)(1).
- ☐ **HUMAN SUBJECTS RESEARCH:** The activity meets the applicable definitions of research and human-subject involvement. The investigator must submit the appropriate IRB application for further review and classification.
- ☐ **DETERMINATION DEFERRED:** Additional information or clarification is necessary.
- ☐ **OTHER:** Additional jurisdictional analysis is required, including possible FDA or other agency-specific regulations.

D. Regulatory Rationale

Provide a written explanation supporting the institutional determination, including the applicable regulatory provision and relevant project-specific findings.

E. Conditions or Limitations

Identify project-specific restrictions or conditions associated with the determination.

F. Authorized Institutional Determination

Determination Issued By: _____

Title: ☐ IRB Chair ☐ HRPP Director ☐ Authorized Institutional Designee ☐ Other: _____

Signature: _____

Date of Determination: _____

Determination Effective Date: _____

Institutional Tracking Number: _____

G. Institutional Notification

☐ Written determination letter issued to the PI.

☐ Additional submission required.

☐ Referral to Privacy Officer / Compliance Office.

☐ Referral for FDA regulatory evaluation, if applicable.

☐ Other: _____

SECTION X. STANDARD CONDITIONS OF AN NHSR DETERMINATION

If the project is determined to be Not Human Subjects Research or Not Research, the investigator must observe the following conditions:

1. **Scope:** The determination applies only to the project activities, data sources, methods, and institutional arrangements described in the submitted documentation.
2. **Modifications:** Material changes that could affect the project's human-subject status must be submitted for institutional reassessment before implementation.
3. **Identifiability:** Investigators must not obtain access to identifiable private information, identifiable biospecimens, or re-identification keys beyond the scope evaluated in the determination.
4. **Privacy:** All applicable confidentiality, privacy, cybersecurity, and data governance requirements remain in effect.
5. **Other approvals:** Authorization from the appropriate data owner, hospital, repository, educational institution, privacy office, or other regulatory authority must be obtained independently when required.
6. **Documentation:** Investigators should retain the official institutional determination, submitted application, and supporting documentation according to applicable institutional retention policies.
7. **Reclassification:** If subsequent activities meet the definition of human subjects research, the appropriate IRB review or exemption determination must be obtained before those activities begin.
8. **External requirements:** Investigators remain responsible for compliance with funding, sponsor, journal, institutional, and other regulatory requirements applicable to the project.

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