ESCUELA DE MEDICINA
San Juan Bautista

IRB STUDY MODIFICATION / AMENDMENT APPLICATION

(Changes to Previously Approved Human Subjects Research) (eCFR)

IRB Use Only (Administrative Tracking)

- IRB Protocol #: _____
- Amendment / Modification #: _____
- Date Received: ____ / ____ / _____
- Review Routing: ☐ Administrative ☐ Expedited ☐ Convened Full Board ☐ Exempt (no IRB review required) ☐ Limited IRB Review
- Reviewer(s) Assigned: _____
- Meeting Date (if convened): ____ / ____ / _____

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1) Study Identification

1. **Study Title:** _____
2. **Principal Investigator (PI):** _____ **Dept/Unit:** _____
3. **PI Email/Phone:** _____
4. **Study Status:**
   ☐ Not yet started (no enrollment)
   ☐ Enrollment ongoing
   ☐ Enrollment closed; study activities ongoing (follow-up/data analysis)
   ☐ Data analysis only (no further interaction/intervention)
   ☐ Closed (if closed, do not use this form; submit Closure/Final Report)
5. **Current IRB Approval Period:** From ____ / ____ / _____ to ____ / ____ / _____
6. **Funding / Support:** ☐ None ☐ Internal ☐ Federal ☐ Industry ☐ Other: _____
   - Sponsor/Prime Award #: _____

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San Juan Bautista

2) Modification Overview

2.1 Type of submission (check all that apply)

☐ Protocol amendment (procedures/visits/interventions)
☐ Informed consent form (ICF) revision
☐ Recruitment/advertising materials change
☐ Study personnel change
☐ Study sites change (add/remove/replace)
☐ Eligibility criteria change
☐ Sample size / enrollment target change
☐ Data/specimen collection change (type/volume/timing)
☐ Data handling / privacy / confidentiality plan change
☐ Compensation / incentives change
☐ Safety monitoring / reporting plan change
☐ Questionnaires/surveys/interview instruments change
☐ Device/drug/biologic information change (IND/IDE implications if applicable)
☐ Other: _____

2.2 Summary of proposed change(s) (plain-language; include "what is changing")

_____

_____

2.3 Rationale / justification for the change(s)

_____

_____

2.4 Requested effective date

- ☐ Upon IRB approval (standard)
- ☐ **Immediate change required to eliminate apparent immediate hazard to subjects** (explain; notify IRB promptly):

  _____

  (Note: Changes to approved research generally require IRB review/approval prior to implementation, except when necessary to eliminate apparent immediate hazards to subjects.) (eCFR)

3) Risk/Benefit Impact Assessment (Required)

3.1 Does this modification change risk level?

☐ No change to risk level
☐ Increases risk (explain) _____
☐ Decreases risk (explain) _____
☐ Unknown/uncertain (explain) _____

3.2 Does this change alter the risk–benefit relationship?

☐ No ☐ Yes → explain: _____

3.3 New information that may affect willingness to participate?

☐ No ☐ Yes → describe and attach revised consent/subject communication:

3.4 Does this change introduce any new procedures that are:

- **More than minimal risk?** ☐ No ☐ Yes (describe) _____
- **Invasive?** ☐ No ☐ Yes (describe) _____
- **Sensitive (behavioral/illegal activity/stigma)?** ☐ No ☐ Yes (describe) _____

(IRB approval criteria require that risks are minimized and reasonable in relation to benefits, among other criteria.) (eCFR)

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4) Detailed Change Checklist (Complete all applicable subsections)

4A) Protocol / Procedures

1. Describe changes to study procedures/visits/interventions (attach tracked-changes and clean protocol):

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2. Does the change affect safety monitoring, stopping rules, or DSMB/monitoring plan?
   ☐ No ☐ Yes → describe:
   _____

4B) Study Personnel

- Add/Remove/Change role: _____
- New personnel human-subjects training completed? ☐ Yes ☐ No ☐ N/A
- New personnel conflict-of-interest disclosure completed? ☐ Yes ☐ No ☐ N/A

4C) Recruitment / Screening

1. Changes to recruitment methods (sites, social media, referrals, etc.):

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2. Attach revised recruitment materials/scripts? ☐ Yes ☐ No ☐ N/A
3. Changes to screening/eligibility determination? ☐ No ☐ Yes → describe: _____

4D) Eligibility Criteria

- Changes to inclusion/exclusion criteria? ☐ No ☐ Yes → list old vs. new or attach:

4E) Consent Process / Documentation

1. Does the modification require changes to the ICF/assent/HIPAA authorization (if applicable)?
   ☐ No ☐ Yes → attach revised documents (tracked + clean).

2. Will currently enrolled subjects be re-consented?
   ☐ No ☐ Yes ☐ Not applicable → rationale/plan: _____
3. Any changes in who obtains consent, where/how consent occurs, or e-consent tools?
   ☐ No ☐ Yes → describe safeguards: _____

4F) Privacy / Confidentiality / Data Security

1. Any change to identifiers collected, coding, or linkage files? ☐ No ☐ Yes → describe
2. Any change to storage location or platform (cloud/vendor/new database)? ☐ No ☐ Yes → describe
3. Any change to access controls, encryption, retention, or destruction? ☐ No ☐ Yes → describe
4. Any change to data sharing (external collaborators, repositories, DUA)? ☐ No ☐ Yes → describe

4G) Data / Specimens (If applicable)

1. New or revised biospecimens to be collected? ☐ No ☐ Yes → type/amount/frequency:
2. Genetic testing/whole genome sequencing introduced? ☐ No ☐ Yes → describe: _____
3. Future unspecified use of specimens/data expanded? ☐ No ☐ Yes → describe: _____

4H) Sites / Reliance / Multi-site

1. Add/remove sites? ☐ No ☐ Yes → list: _____
2. Single IRB / reliance arrangements impacted? ☐ No ☐ Yes → describe: _____

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5) Reportable Events / Noncompliance Screen (Required)

5.1 Does this submission also report any of the following?

☐ Unanticipated problem involving risks to subjects or others (UP)
☐ Serious adverse event that may meet UP criteria
☐ Protocol deviation/violation that increased risk or indicates noncompliance
☐ Suspension/termination by sponsor or site
☐ New safety information from sponsor/DSMB/monitor
If **Yes**, describe event(s), dates, corrective and preventive actions (CAPA), and attach reports.

(OHRP guidance defines "unanticipated problems" and emphasizes meaningful, timely review/reporting when criteria are met.) (HHS.gov)

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6) Attachments Checklist (Required)

Check all that apply and attach:
☐ Revised protocol (clean)
☐ Revised protocol (tracked changes/redline)
☐ Revised consent/assent documents (clean)
☐ Revised consent/assent documents (tracked changes/redline)
☐ Recruitment materials/ads/scripts (clean + tracked as applicable)
☐ Revised instruments/surveys/interview guides
☐ Investigator brochure/device manual/updated safety information (if applicable)
☐ Data security documentation (if new platform/vendor)
☐ Other: _____

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7) PI Assurances and Signature (Required)

By signing below, I attest that:

1. The information in this modification request is accurate and complete.
2. **No changes will be implemented prior to IRB approval**, except when necessary to eliminate apparent immediate hazards to subjects, in which case the IRB will be notified promptly. (eCFR)
3. All study personnel are appropriately trained and will follow the currently IRB-approved protocol and consent process.
4. Any new information that may affect participant safety or willingness to continue will be communicated as required.

PI Name: _____
Signature: _____ **Date:** ____ / ____ / _____

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8) IRB Determination (IRB Use Only)

8.1 Level of review

☐ Administrative (no IRB approval required)
☐ Exempt confirmed (no IRB approval required)
☐ Limited IRB Review (as condition of exemption)
☐ Expedited review (minor changes)
☐ Convened Full Board

(IRBs must review research and have authority to approve, require modifications, or disapprove; expedited review may be used where permissible, including for minor changes in approved research.) (eCFR)

8.2 Action

☐ Approved
☐ Approved with conditions (stipulations required prior to final approval)
☐ Deferred / Modifications required to secure approval
☐ Disapproved

8.3 Required stipulations / reviewer notes

Reviewer/Chair: _____ **Signature:** _____
Date: ____ / ____ / _____

Form: IRB Study Modification / Amendment Application
Version: 2026.01 | **Owner:** IRB Office | **Authority:** 45 CFR 46 (Revised Common Rule) (HHS.gov)
