**AIRC Standard Operating Procedure (SOP) v3**

**With Integrated Rubric Selection and Local Adaptation Notes**

Below is the fully updated SOP text, with the rubric selection logic and local adaptation notes incorporated. You can copy and paste this into Word and format in Times New Roman 12 pt.

**Artificial Intelligence Review Committee (AIRC)**

**Standard Operating Procedure (SOP)**

Document Owner: [To be determined by local institution]  
Effective Date: [To be determined by local institution]  
Applies To: All research programs and projects involving artificial intelligence, machine learning, data analytics, or AI-driven decision support tools

**1. Purpose**

This Standard Operating Procedure (SOP) establishes a uniform, risk-based framework for the review of AI-enabled research protocols across all project types, ensuring ethical, technical, and regulatory alignment.

The AIRC rubrics and processes support:

* Consistent evaluation of AI tools and methodologies
* Risk identification and mitigation planning
* Transparency and accountability in AI research governance
* Compliance with federal regulations and institutional policies

**2. Scope**

This SOP governs the use of AIRC rubrics for:

* Human subjects research
  + Studies that meet the Common Rule definition of human subjects research under 45 CFR 46
  + Includes protocols that are exempt under 45 CFR 46.104 and those requiring expedited or full IRB review
* Animal research
  + Studies involving live vertebrate animals
  + Reviewed and overseen by an Institutional Animal Care and Use Committee (IACUC) or equivalent body
* Analytic / non-human subjects projects
  + De-identified data analytics
  + Anonymous surveys
  + Projects formally determined to be Not Human Subjects Research
  + Projects involving non-human, non-animal data (e.g., simulations, synthetic datasets)

All projects using AI/ML tools, predictive analytics, or AI-driven decision support—regardless of regulatory pathway—are subject to AIRC review as specified in this SOP.

Recordkeeping and exact operationalization of this SOP are subject to local institutional policy and must align with existing IRB and IACUC procedures.

**3. Definitions**

* AI/ML Tool: Any artificial intelligence, machine learning algorithm, predictive model, natural language processing system, or automated decision support tool used in research.
* AIRC: Artificial Intelligence Review Committee, a designated body responsible for evaluating AI tools and methods in research protocols.
* AIRC Chair: The institutional official (or designee) responsible for overseeing AIRC operations, reviewer assignments, and final sign-off on rubric determinations.
* Rubric: A structured evaluation tool with defined domains, scoring criteria, and decision rules used to review AI-related aspects of research protocols.
* Streamlined Rubric: A shorter rubric intended for lower-risk, validated, or standard AI use cases.
* Enhanced Rubric: A more detailed rubric intended for novel, high-risk, complex, or high-impact AI use cases.
* Modifications Required: A determination that the project has merit but requires specific changes before approval.
* Not Acceptable: A determination that a project has significant deficiencies that must be addressed through major revision and resubmission.

**4. Roles and Responsibilities**

| **Role** | **Responsibility** |
| --- | --- |
| Principal Investigator (PI) | Submits complete protocol and AI-related documentation; responds to AIRC feedback; reports changes to AI use over the life of the project |
| AIRC Coordinator | Receives protocols for AIRC review; applies the Rubric Selection Tool; assigns appropriate rubric type and reviewers; tracks workflow and timelines |
| AIRC Reviewer | Completes the assigned rubric thoroughly and objectively; uses grading guide for consistent scoring; documents reasoning and recommendations |
| AIRC Chair (or Designee) | Reviews completed rubrics for completeness and consistency; confirms final determinations; signs off and forwards outputs to appropriate committees |
| IRB | Uses AIRC outputs for human subjects research to inform ethical and regulatory decision-making; determines whether attestations or additional conditions are required |
| IACUC | Uses AIRC outputs for animal research to inform welfare, 3Rs, and ethical decision-making; determines any additional conditions |
| Department/Compliance/Other Oversight Bodies | Use AIRC outputs for analytic/non-human subjects projects to guide local governance decisions |
| Research Operations/Compliance | Maintains records per institutional policy; oversees adherence to this SOP; coordinates training, calibration, and periodic review |

Note: The composition, qualifications, and number of AIRC members and reviewers are determined by each institution in accordance with local governance, IRB, and IACUC policies.

**5. AIRC Rubrics**

The AIRC toolkit includes six primary rubrics, grouped into three pathways:

**5.1 Human Subjects Research Rubrics**

Used for protocols involving human participants or identifiable private information, whether exempt or requiring full IRB review:

* Human Subjects – Streamlined Rubric
  + For lower-risk, validated or commercial AI tools, or relatively simple applications
* Human Subjects – Enhanced Rubric
  + For novel, experimental, high-risk, or complex AI uses, or involving vulnerable populations

The IRB determines whether a protocol is human subjects research and whether it is exempt or requires board review, following local policy.

**5.2 Animal Research Rubrics**

Used for protocols involving animals, overseen by IACUC:

* Animal Research – Streamlined Rubric
  + For standard, validated AI uses or lower-risk applications
* Animal Research – Enhanced Rubric
  + For novel AI tools, AI-controlled interventions, or higher-risk applications impacting animal welfare

IACUC policies and local institutional animal care guidelines govern classification and use of these rubrics.

**5.3 Analytic / Non-Human Subjects Rubrics**

Used for de-identified data analytics, anonymous surveys, or projects classified as Not Human Subjects Research:

* Analytic / Non-Human Subjects – Streamlined Rubric
  + For routine analytic projects using validated methods with limited impact
* Analytic / Non-Human Subjects – Enhanced Rubric
  + For complex, high-impact, or novel analytic uses with potential group or societal risk

Classification of a project as Not Human Subjects Research or as purely analytic is governed by local IRB, compliance, or data governance policy.

**6. Procedure**

**6.1 Initial Submission**

Step 1: Protocol Submission

* The PI submits the protocol and all required materials (e.g., research plan, AI/ML tool description, data management plan, consent/assent materials, IACUC forms) to the appropriate institutional office or committee (IRB, IACUC, or designated oversight body), following local procedures.

Step 2: Rubric Assignment (Pathway and Version Selection)

* The AIRC Coordinator (or designated committee member) determines the appropriate rubric pathway (Human, Animal, or Analytic/Non-Human Subjects) using the institution’s classification (IRB/IACUC/compliance determination).
* The Coordinator then determines whether to use the Streamlined or Enhanced rubric for that pathway using the AIRC Rubric Selection Tool.

Rubric Selection Tool (Summary Logic):

1. Identify Pathway – Project Type
   * Human Subjects → Use Human Subjects rubric set
   * Animals → Use Animal rubric set
   * Analytic / Not Human Subjects → Use Analytic rubric set
2. Determine Risk Level – Streamlined vs. Enhanced  
   The Enhanced rubric is recommended when any of the following higher‑risk criteria apply:
   * Novel, experimental, or unvalidated AI algorithm
   * Vulnerable population involvement (as defined locally)
   * High‑stakes decisions (e.g., clinical care, safety-critical, major social/financial/legal impact)
   * Complex or low‑interpretable AI architecture where transparency is important
   * Potential for significant group-level or societal impact
   * If no higher‑risk criteria are present → Streamlined rubric is used.
   * If one or more higher‑risk criteria are present → Enhanced rubric is used.

Notes for Local Adaptation:

* Institutions may add additional high‑risk triggers for requiring the Enhanced rubric (e.g., particular data types, specific clinical domains, sensitive populations, or regulatory flags).
* This selection tool is intended to be used by committees, coordinators, or designated reviewers, not by investigators.
* When there is uncertainty about risk level or complexity, committees may default to the Enhanced rubric for greater scrutiny.
* Local policy should specify:
  + Who has authority to classify the project as Human/Animal/Analytic
  + Who decides whether high‑risk criteria are met
  + Who may override rubric assignment in exceptional cases

Step 3: Reviewer Assignment

* The AIRC Coordinator assigns one or more reviewers with appropriate expertise and without conflicts of interest.
* The number of reviewers (single vs. multiple) is determined by local institutional policy and may vary by rubric type or risk level.
* Reviewer orientation to the rubrics and grading guide is required; specific training requirements beyond orientation are determined locally.

**6.2 Conducting the AIRC Review**

Step 1: Pre-Review

* Reviewers must:
  + Read the complete protocol and all relevant materials
  + Review the applicable rubric and the Unified Grading Guide
  + Confirm absence of conflicts of interest

Step 2: Completing the Rubric

* Reviewers evaluate each domain using the 1–4 scoring scale:
  + 4 – Exemplary
  + 3 – Proficient
  + 2 – Basic
  + 1 – Deficient
* Reviewers may mark items as:
  + N/A (Not Applicable) with brief justification; or
  + Insufficient Documentation: If scoring is not possible due to missing information, trigger a request for additional information before final scoring.

Step 3: Critical Deficiency Rule

* Any domain scored 1 (Deficient) constitutes a critical deficiency, and the overall recommendation must be Not Acceptable until the issues are corrected.

Step 4: Reviewer Notes and Recommendations

* Reviewers provide narrative comments describing:
  + Strengths
  + Concerns and risks
  + Specific, actionable recommendations (for Modifications Required)

Step 5: AIRC Chair/Designee Review

* The AIRC Chair or designee:
  + Reviews the completed rubric(s) for completeness and consistency
  + Confirms or adjusts the final recommendation if necessary
  + Signs off and prepares a brief summary for the IRB, IACUC, or oversight body

**6.3 AIRC Recommendations**

Possible Outcomes:

1. Acceptable
   * All domains score 3 or 4
   * No critical deficiencies identified
   * The protocol is ready for IRB/IACUC/oversight review with favorable AIRC recommendation
2. Modifications Required
   * Most domains score 2 or above; no domain scores 1
   * Specific improvements are needed to meet standards
   * A detailed list of required modifications is provided
   * After modification by the PI, the rubric may be re-reviewed or accepted administratively, per local policy
3. Not Acceptable
   * One or more domains score 1 (critical deficiency)
   * Or numerous significant concerns across domains
   * The project is not acceptable in its current form
   * Major revisions and resubmission to AIRC are required

Communication of Results:

* The AIRC recommendation is communicated to:
  + The party that submitted the project to AIRC, which may be:
    - The PI, or
    - Another committee (e.g., IRB staff, IACUC staff, departmental reviewer), depending on local program design
* Local IRB and IACUC policies determine:
  + Whether and how AIRC recommendations are integrated into deliberations
  + Whether they are advisory or required
  + Any additional documentation or attestations needed

**6.4 Protocol Modifications**

AIRC review is only triggered by modifications that change AI use.

Triggers for AIRC Review of Modifications:

* Introduction of a new AI tool or analytic method
* Substantial change to the existing AI methodology, algorithm, training data, or implementation
* Change in how AI outputs are used or interpreted (e.g., moving from advisory to decision-making use)
* New data integration that meaningfully changes AI performance or risk (e.g., adding sensitive variables)

Modifications That Do NOT Trigger AIRC Re-Review:

* Administrative changes (e.g., personnel updates, minor wording edits)
* Amendments unrelated to AI or analytics (e.g., small sample size changes without AI methodology changes)
* Typos or minor clarifications that do not alter AI risk or use

Process:

* At the time a modification is submitted, local IRB/IACUC or research operations staff determine if there is a change in AI use.
* If yes, the modification is referred to AIRC for focused review using the existing rubric type (Streamlined or Enhanced) or an upgraded rubric (e.g., Streamlined → Enhanced) if risk has increased.
* AIRC issues an updated recommendation and returns it to the referring body.

**6.5 Continuing Review (IRB-Approved Protocols)**

At each IRB continuing review or renewal:

* The study team must provide information (or attest, if required by IRB policy) on:
  + Whether the AI tool, algorithm, analytic pipeline, or its use has changed since the last approval
  + Whether any new risks, incidents, or harms related to AI use have been observed

If Changes or New Risks Are Reported:

* The IRB (per local policy) may refer the protocol back to AIRC for updated review.
* AIRC conducts a focused review of:
  + The change in AI use, and/or
  + The newly identified risks or harms

If No Changes or New Risks Are Reported:

* IRB may proceed with continuing review without AIRC reassessment, consistent with local policy.

Local IRB policies determine:

* Whether formal PI attestations are required at continuing review
* Whether AIRC review is mandatory for all continuing reviews or only when AI-related changes occur

The same principle may be applied by IACUC or departmental/compliance bodies for animal or analytic projects, as determined locally.

**7. Recordkeeping and Documentation**

* All completed AIRC rubrics, reviewer notes, and recommendation summaries must be stored in accordance with local institutional policy and record retention requirements.
* Records may be:
  + Maintained centrally by AIRC or research operations, and/or
  + Integrated into IRB, IACUC, or departmental project files

At minimum, records should include:

* Protocol identifier and title
* Date of AIRC review
* Rubric pathway and version used (Human/Animal/Analytic; Streamlined/Enhanced)
* Domain scores and final recommendations
* Reviewer comments and required modifications (if any)
* Communication of AIRC decision to the submitter or referring body

**8. Training and Reviewer Orientation**

* Each institution determines qualification requirements for AIRC reviewers (e.g., expertise in AI/ML, ethics, subject matter domain).
* At a minimum, all AIRC reviewers must receive:
  + Orientation to each applicable rubric
  + Orientation to the Unified Grading Guide
  + Orientation to this SOP and local AIRC workflow
* Additional training (e.g., annual calibration sessions, specialized AI ethics modules) is recommended but not mandated by this SOP; the decision is left to local policy.

**9. Compliance, Oversight, and Local Determination**

* This SOP must be implemented in alignment with:
  + Local IRB policies for human subjects research
  + Local IACUC policies for animal research
  + Local data governance and compliance policies for analytic/non-human subjects projects
* Final decisions about:
  + Who serves as AIRC Chair and members
  + How many reviewers are needed for each type of protocol
  + Which committees must see AIRC outputs and in what format
  + Whether attestations at continuing review are required

are determined by each institution, in accordance with existing IRB, IACUC, and governance frameworks.

* Non-adherence to this SOP may be referred to institutional research compliance or quality oversight bodies for follow-up.

**10. References**

* 45 CFR 46 (Common Rule)
* 45 CFR 46.104 (Exempt research categories)
* Applicable IRB policies and guidance (local)
* Animal Welfare Act and IACUC regulations
* SPIRIT-AI Guidelines
* CONSORT-AI Guidelines
* WHO Guidance: Ethics and Governance of AI in Health
* FDA guidance on AI/ML-enabled medical devices
* Local institutional research, animal care, and data governance policies

**11. Contact Information**

For questions regarding AIRC processes, rubric use, or this SOP:

AIRC Coordinator:  
[Insert local contact]

Research Compliance / IRB Office:  
[Insert local contact]

IACUC Office:  
[Insert local contact]