**AIRC Quick Start Guide**

**Artificial Intelligence Review Committee (AIRC)**

**Version:** 2.0 (December 2025)

**Purpose:** This guide provides step-by-step instructions for committee members and administrators on how to select, complete, and communicate results using the AIRC rubrics.

**Step 1: Determine Which Rubric to Use**

The AIRC toolkit includes six rubrics organized into three pathways, with Streamlined and Enhanced versions for each.

**1a. Identify the Pathway (Project Type)**

Select the pathway based on the regulatory classification of your project:

| **Pathway** | **Use When** |
| --- | --- |
| **Human Subjects** | Project involves living individuals OR uses identifiable private information OR is classified as human subjects research (including exempt studies under 45 CFR 46.104) |
| **Animal Research** | Project involves live vertebrate animals AND is reviewed by IACUC or equivalent body |
| **Analytic / Non-Human Subjects** | Project uses fully de-identified data OR anonymous surveys OR is formally determined to be "Not Human Subjects Research" OR involves non-human/non-animal data |

**1b. Select the Version (Streamlined vs. Enhanced)**

After identifying the pathway, determine whether to use the **Streamlined** or **Enhanced** rubric by checking if any of these higher-risk criteria apply:

**Use ENHANCED Rubric if the project has ANY of these characteristics:**

* ☐ The AI tool is **novel, experimental, or unvalidated** (custom model, early-stage, not previously deployed in similar settings)
* ☐ The project involves a **vulnerable population** (as defined locally for human or animal research)
* ☐ The AI will directly influence or make **high-stakes decisions** (clinical diagnosis, treatment planning, safety-critical decisions, legal/financial/employment outcomes, or major welfare impacts)
* ☐ The AI uses **complex or opaque architectures** (e.g., deep learning with limited interpretability) where explanation or auditability is important
* ☐ The AI or analytic output has **potential for significant group-level or societal impact** (affecting policies, resource allocation, or population-level decisions)

**Decision Rule:**

* If **none** of the above apply → Use **STREAMLINED** rubric
* If **one or more** of the above apply → Use **ENHANCED** rubric

**Quick Reference: Rubric Selection**

| **Pathway** | **Streamlined** | **Enhanced** |
| --- | --- | --- |
| **Human Subjects** | Lower-risk, validated tools, simple applications | Novel algorithms, vulnerable populations, high-stakes clinical use |
| **Animal Research** | Standard, validated AI, routine procedures | Novel AI, AI-controlled interventions, high-impact welfare decisions |
| **Analytic / Non-Human** | Routine analytics, validated methods, limited impact | Complex analytics, novel methods, high societal impact |

**Note:** When in doubt about risk level, **default to the Enhanced rubric** for greater scrutiny.

**Step 2: Assign Reviewers**

* Assign **one or more qualified reviewers** with appropriate subject matter expertise and AI/data analytics knowledge
* Ensure reviewers have **no conflicts of interest** with the project or investigator
* **Number of reviewers** and **qualifications** are determined by **local institutional policy**
* Reviewers should have received orientation to the AIRC rubrics and Unified Grading Guide

**Step 3: Complete the Rubric**

Reviewers should follow these steps:

**3.1 Preparation**

* Read all protocol materials carefully, including:
  + Research plan and objectives
  + AI/ML tool description and documentation
  + Data sources and management plan
  + Intended use and clinical/research context
  + Consent, consent waiver, or data governance documentation

**3.2 Score Each Domain**

Use the **1–4 scoring scale** provided in the rubric:

| **Score** | **Label** | **Meaning** |
| --- | --- | --- |
| **4** | Exemplary | Exceeds standards with comprehensive documentation and proactive measures |
| **3** | Proficient | Meets all standards with appropriate documentation |
| **2** | Basic | Minimal compliance; some gaps in documentation or planning |
| **1** | Deficient | Major gaps, unacceptable risk, or inadequate documentation |

**3.3 Use N/A and "Insufficient Documentation" Appropriately**

* **N/A (Not Applicable):** Use when a checklist item genuinely does not apply to the project. Always provide a brief justification.
* **Insufficient Documentation:** Select if required information is missing and you cannot score the domain. Return the rubric to the submitter with a specific checklist of required information.

**3.4 Document Your Reasoning**

* Provide narrative comments in the **Reviewer Notes** section for each domain, explaining:
  + Why you assigned the score you did
  + Strengths in the protocol's approach
  + Concerns or gaps identified
  + Specific recommendations (especially for scores of 1 or 2)

**3.5 Calculate Total Score and Apply Decision Rules**

* Add up all domain scores to calculate the **total score**
* Apply the **Critical Deficiency Rule** (see Step 4)
* Determine the **final recommendation** (see Step 4)

**Step 4: Apply Decision Rules**

**Critical Deficiency Rule**

**Any score of 1 in ANY domain = Automatic "Not Acceptable"**

* A score of 1 ("Deficient") in a single domain constitutes a critical deficiency
* The overall recommendation must be **"Not Acceptable"** until the deficiency is fully corrected
* The protocol must be substantially revised and resubmitted to AIRC for new review

**Final Recommendations**

| **Score/Finding** | **Outcome** | **Action** |
| --- | --- | --- |
| **High scores across all domains (mostly 3s and 4s) AND no domain scored 1** | **ACCEPTABLE** | Forward to IRB/IACUC/designated oversight body with approval recommendation |
| **Moderate scores (mix of 2s and 3s) with specific concerns AND no domain scored 1** | **MODIFICATIONS REQUIRED** | Return to submitter with detailed list of required changes; re-review after revisions |
| **Low scores or any domain scored 1** | **NOT ACCEPTABLE** | Reject and provide comprehensive feedback; major revision required before resubmission |

**Step 5: Communicate Results**

**If Recommendation is ACCEPTABLE:**

* AIRC Chair (or designee) signs the completed rubric
* Forward to the appropriate committee (IRB, IACUC, or designated oversight body) with **approval recommendation**
* Include brief summary of key strengths

**If Recommendation is MODIFICATIONS REQUIRED:**

* Return rubric with **specific, actionable feedback** to whoever submitted the project:
  + The PI, OR
  + The referring committee (IRB staff, IACUC staff, departmental reviewer)
  + Decision depends on **local program design**
* Provide clear list of required modifications
* Indicate that after revisions are made, protocol will be re-reviewed or accepted administratively per local policy

**If Recommendation is NOT ACCEPTABLE:**

* Provide **detailed rationale** explaining why the project is not acceptable in its current form
* Identify the **critical deficiencies** that must be addressed
* Provide guidance for **major revision**
* Indicate that project must be **resubmitted to AIRC after substantial changes**

**Step 6: Documentation and Recordkeeping**

* All completed rubrics must be **stored in accordance with local institutional policy and record retention requirements**
* Records may be maintained:
  + Centrally by AIRC/research operations, and/or
  + Within IRB, IACUC, or departmental project files

**Minimum Documentation Includes:**

* Protocol number and title
* Date of AIRC review
* Rubric pathway and version used (Human/Animal/Analytic; Streamlined/Enhanced)
* Domain scores and final recommendation
* Reviewer comments and notes
* List of required modifications (if applicable)
* Documentation of communication to submitter or referring body

**When is AIRC Review Required?**

**Initial Submission**

All new protocols using **AI/ML tools, data analytics, or decision support systems** require AIRC review before IRB/IACUC approval.

**Protocol Modifications**

AIRC review is **triggered only if** the modification involves:

* Introduction of a **new AI tool** or analytic method
* **Substantial change** to 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

**Minor amendments that DO NOT trigger AIRC re-review:**

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

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

At each IRB continuing review or renewal, the study team must confirm:

* **No changes** to the AI tool, algorithm, analytic pipeline, or how it is used have occurred since last approval
* **No unexpected technical, ethical, or performance risks** related to AI use have emerged

**If either answer is "YES":**

* Protocol is returned to AIRC for reassessment

**If both answers are "NO":**

* Continuing review proceeds without AIRC reassessment (per local IRB policy)

The same principle applies for IACUC and departmental/compliance oversight of animal and analytic projects.

**Additional Resources**

* **Standard Operating Procedure (SOP)** – Complete governance procedures
* **Individual Rubrics** – All six rubrics (Human/Animal/Analytic, Streamlined/Enhanced) with detailed scoring criteria
* **Unified Grading Guide** – In-depth guidance for consistent scoring and calibration
* **Rubric Pathways Table** – Decision matrix for rubric selection (Appendix A of SOP)
* **Reviewer Feedback Tool** – For evaluating rubric usability and reviewer experience
* **Approving Official Feedback Tool** – For evaluating AIRC outputs from committee perspective

**Questions or Support?**

Contact your institutional:

* **AIRC Coordinator:** [Insert local contact]
* **Research Compliance / IRB Office:** [Insert local contact]
* **IACUC Office:** [Insert local contact]

For guidance on:

* Rubric selection and pathway classification
* Scoring decisions and domain questions
* AIRC process and workflow questions