**AIRC Rubric Selection Tool**

**December 2025**

**1. Purpose**

This tool helps committees and AIRC coordinators determine which AIRC rubric to use for a given protocol and whether to apply the Streamlined or Enhanced version.

It is designed to be:

* Simple for new users
* Consistent across programs
* Flexible for local policy decisions

**2. Step 1 – Identify the Regulatory Pathway**

Question 1: What is the primary subject of this research protocol?

Select one:

1. Human Subjects
   * Involves living individuals, OR
   * Uses identifiable private information or biospecimens, OR
   * Is classified by the institution as human subjects research (including exempt under 45 CFR 46.104).

→ Use a Human Subjects Rubric (Streamlined or Enhanced – determined in Step 2)

1. Animals
   * Involves live vertebrate animals, AND
   * Is overseen by an IACUC or equivalent animal care and use committee.

→ Use an Animal Research Rubric (Streamlined or Enhanced – determined in Step 2)

1. Analytic / Non-Human Subjects
   * Uses fully de-identified data, OR
   * Uses anonymous surveys with no identifiers, OR
   * Has been formally determined to be Not Human Subjects Research, OR
   * Involves simulations, synthetic data, or non-animal, non-human data.

→ Use an Analytic / Non-Human Subjects Rubric (Streamlined or Enhanced – determined in Step 2)

If you are unsure whether the protocol is Human, Animal, or Analytic, follow local research policies to classify it first; then return to this tool.

**3. Step 2 – Determine Streamlined vs. Enhanced**

After identifying the pathway (Human / Animal / Analytic), answer the following:

Question 2: Does the AI tool or its application meet ANY of the following “higher‑risk” criteria?

Check all that apply:

* ☐ The AI tool is novel, experimental, or unvalidated (e.g., custom model, early-stage tool, or not previously deployed in similar settings).
* ☐ The protocol involves a vulnerable population (as defined locally for human or animal research).
* ☐ The AI will directly influence or make high‑stakes decisions, such as:
  + Clinical diagnosis or treatment
  + Safety‑critical decisions
  + Legal, financial, or employment outcomes
  + Major welfare-impacting decisions (for animals)
* ☐ The AI uses complex or opaque architectures (e.g., deep learning with limited interpretability) in a context where explanation or auditability is important.
* ☐ The AI or analytic output has potential for significant group‑level or societal impact (e.g., affecting policies, resource allocation, or population-level decisions).

Decision Rule:

* If you checked NONE of the boxes above →  
  → Use the STREAMLINED rubric for the identified pathway.
* If you checked ONE or MORE boxes above →  
  → Use the ENHANCED rubric for the identified pathway.

**4. Putting It Together – Quick Selection Table**

Use this table after answering Questions 1 and 2.

| **Step 1 Answer (Pathway)** | **Step 2 Answer (Risk)** | **Rubric to Use** |
| --- | --- | --- |
| Human Subjects | No high‑risk criteria checked | Human Subjects – Streamlined |
| Human Subjects | One or more high‑risk criteria checked | Human Subjects – Enhanced |
| Animals | No high‑risk criteria checked | Animal Research – Streamlined |
| Animals | One or more high‑risk criteria checked | Animal Research – Enhanced |
| Analytic / Non-Human Subjects | No high‑risk criteria checked | Analytic/Non-Human – Streamlined |
| Analytic / Non-Human Subjects | One or more high‑risk criteria checked | Analytic/Non-Human – Enhanced |