**Artificial Intelligence Review Committee (AIRC)**

**Human Subjects Research - Enhanced Rubric**

Version: 2.0 (December 2025)

Use this rubric for: High-risk, novel, or complex human subjects research using experimental or unvalidated AI tools, or studies involving vulnerable populations.

**Administrative Information**

| **Field** | **Information** |
| --- | --- |
| Protocol Number | [blank line] |
| Principal Investigator | [blank line] |
| Project Title | [blank line] |
| Date of Review | [blank line] |
| AIRC Reviewer(s) | [blank line] |
| AI Tool/Model Name and Version | [blank line] |
| Intended Use/Clinical Context | [blank line] |
| IRB Status | ☐ Exempt ☐ Expedited ☐ Full Board |
| Risk Level | ☐ High ☐ Novel Algorithm ☐ Vulnerable Population |

**Instructions for Reviewers**

* Complete all applicable domains using 1-4 scale
* Use N/A with justification if item does not apply
* Select "Insufficient Documentation" if unable to score
* Critical Rule: Score of 1 in any domain = "Not Acceptable"

**Domain 1: Data Quality & Provenance**

Purpose: Ensure AI is built on high-quality, representative, ethically sourced data.

Checklist Items

1.1 Is the source/lineage of all datasets clearly documented?

1.2 Does data accurately represent the target population?

1.3 Are inclusion/exclusion criteria defined?

1.4 Are data cleaning and preprocessing documented?

1.5 Are de-identification methods appropriate with risk assessment?

Scoring Criteria

| **Score** | **Description** |
| --- | --- |
| 4 - Exemplary | Comprehensive provenance with lineage tracking, thorough representativeness analysis, robust preprocessing fully documented, advanced de-identification with formal risk assessment |
| 3 - Proficient | Clear documentation of sources, demographics match population with acknowledged limitations, standard preprocessing documented, appropriate de-identification |
| 2 - Basic | Data source identified but limited documentation, some representativeness info but gaps, limited preprocessing details, basic de-identification |
| 1 - Deficient | Missing data documentation, no representativeness analysis, insufficient preprocessing, inadequate privacy protections |

Reviewer Assessment

| **Item** | **Rating** | **Comments** |
| --- | --- | --- |
| Domain 1 Score (1-4) | [blank] | [blank area for detailed comments] |
| ☐ N/A - Justification: |  |  |
| ☐ Insufficient Documentation |  |  |

**Domain 2: Privacy & Informed Consent**

Purpose: Ensure participant privacy and consent processes are appropriate for AI use.

Checklist Items

2.1 Are privacy protections adequate for data sensitivity?

2.2 Is informed consent (or waiver) appropriate for AI application?

2.3 Are participants informed about AI use in the research?

2.4 Are data security measures adequate?

2.5 Is there a secure data storage and retention/destruction plan?

Scoring Criteria

| **Score** | **Description** |
| --- | --- |
| 4 - Exemplary | Enterprise-grade security with encryption, detailed participant-friendly consent explaining AI risks/benefits, multi-layered access controls with audit trails, formal data management plan |
| 3 - Proficient | Security meeting HIPAA or equivalent, consent appropriately addresses AI use, access controls in place, data management plan documented |
| 2 - Basic | Basic security with incomplete documentation, consent mentions AI but lacks detail, limited access controls, basic data management |
| 1 - Deficient | Security insufficient, consent does not adequately address AI, no access controls, no data management plan |

Reviewer Assessment

| **Item** | **Rating** | **Comments** |
| --- | --- | --- |
| Domain 2 Score (1-4) | [blank] | [blank area for detailed comments] |
| ☐ N/A - Justification: |  |  |
| ☐ Insufficient Documentation |  |  |

**Domain 3: Bias & Fairness (Including Group Harms)**

Purpose: Ensure AI performs equitably and does not perpetuate bias.

Checklist Items

3.1 Has model performance been evaluated across demographic subgroups?

3.2 Is there evidence of fairness in AI outputs across populations?

3.3 Is there a documented plan to mitigate bias and monitor emergent bias?

3.4 Have potential group harms or societal impacts been assessed?

3.5 Were stakeholders or community representatives consulted?

Scoring Criteria

| **Score** | **Description** |
| --- | --- |
| 4 - Exemplary | Comprehensive performance evaluation across multiple demographic dimensions with quantitative fairness metrics, proactive bias mitigation with continuous monitoring, meaningful stakeholder engagement, group harm assessment with mitigation |
| 3 - Proficient | Performance evaluated across major demographic groups, fairness definition with rationale, documented mitigation plan, basic stakeholder consultation, group harms considered |
| 2 - Basic | Limited subgroup analysis (1-2 dimensions), fairness acknowledged but not formally assessed, vague mitigation plan, minimal stakeholder engagement |
| 1 - Deficient | No subgroup analysis, fairness not considered, no mitigation plan, no stakeholder involvement, no group harm consideration |

Reviewer Assessment

| **Item** | **Rating** | **Comments** |
| --- | --- | --- |
| Domain 3 Score (1-4) | [blank] | [blank area for detailed comments] |
| ☐ N/A - Justification: |  |  |
| ☐ Insufficient Documentation |  |  |

**Domain 4: Risk & Vulnerable Populations**

Purpose: Assess risks and ensure appropriate safeguards for vulnerable populations.

Checklist Items

4.1 Are risks associated with AI use clearly identified?

4.2 Are safeguards in place to protect participants from AI-related harms?

4.3 Are additional protections appropriate for vulnerable populations?

4.4 Is there a plan for monitoring and responding to adverse events?

4.5 Are risks balanced appropriately against benefits?

Scoring Criteria

| **Score** | **Description** |
| --- | --- |
| 4 - Exemplary | Detailed risk analysis covering technical, ethical, clinical dimensions; multi-layered safeguards; enhanced protections for vulnerable populations; formal adverse event monitoring with escalation; favorable risk-benefit balance |
| 3 - Proficient | Major risks identified and assessed, safeguards appropriate to risk level, vulnerable population protections in place, adverse event plan documented, reasonable risk-benefit balance |
| 2 - Basic | Some risks identified but assessment incomplete, basic safeguards, limited vulnerable population considerations, vague monitoring plan, unclear risk-benefit balance |
| 1 - Deficient | Risks not identified or underestimated, no safeguards, no vulnerable population considerations, no adverse event plan, risks outweigh benefits |

Reviewer Assessment

| **Item** | **Rating** | **Comments** |
| --- | --- | --- |
| Domain 4 Score (1-4) | [blank] | [blank area for detailed comments] |
| ☐ N/A - Justification: |  |  |
| ☐ Insufficient Documentation |  |  |

**Domain 5: Transparency & Documentation**

Purpose: Ensure AI is appropriately documented and transparent.

Checklist Items

5.1 Is the AI algorithm type, version, and rationale clearly stated?

5.2 Are model performance metrics reported and appropriate?

5.3 Is there documentation of validation studies or prior testing?

5.4 Are human oversight roles and decision authority clearly defined?

5.5 Is there a plan for version control and algorithm updates?

Scoring Criteria

| **Score** | **Description** |
| --- | --- |
| 4 - Exemplary | Algorithm type, architecture, version with unique identifiers; multiple performance metrics with confidence intervals and subgroup analysis; external validation or published evidence; clear human oversight protocols; formal version control |
| 3 - Proficient | Algorithm and version clearly stated with rationale, relevant performance metrics meeting standards, validation documented, human oversight roles defined, version tracking in place |
| 2 - Basic | Algorithm identified with limited detail, performance metrics incomplete, limited validation information, vague oversight description, minimal version control |
| 1 - Deficient | Algorithm unclear, missing performance metrics, no validation evidence, no human oversight defined, no version control |

Reviewer Assessment

| **Item** | **Rating** | **Comments** |
| --- | --- | --- |
| Domain 5 Score (1-4) | [blank] | [blank area for detailed comments] |
| ☐ N/A - Justification: |  |  |
| ☐ Insufficient Documentation |  |  |

**Final Score Calculation and Recommendation**

Score Summary

| **Domain** | **Score (1-4)** |
| --- | --- |
| Domain 1: Data Quality & Provenance | [blank] |
| Domain 2: Privacy & Informed Consent | [blank] |
| Domain 3: Bias & Fairness | [blank] |
| Domain 4: Risk & Vulnerable Populations | [blank] |
| Domain 5: Transparency & Documentation | [blank] |
| Total Score (Range: 5-20) | [blank] |

**Critical Deficiency Rule**

| **Check if applicable** |  |
| --- | --- |
| ☐ One or more domains scored 1 | *(If checked, Final Recommendation MUST be "NOT ACCEPTABLE")* |

Final Recommendation

Select One:

☐ ACCEPTABLE - Forward to IRB with approval recommendation

☐ MODIFICATIONS REQUIRED - Return to submitter with feedback below

☐ NOT ACCEPTABLE - Reject; major revision required

Required Modifications (if applicable):

1. [blank line]
2. [blank line]
3. [blank line]

Overall Summary

Strengths:

[Large blank area]

Concerns:

[Large blank area]

Additional Comments:

[Large blank area]

**Signatures**

| **Role** | **Signature** | **Date** |
| --- | --- | --- |
| Reviewer | [blank line] | [blank line] |
| AIRC Chair/Designee | [blank line] | [blank line] |