Office of Research, Grants and Contracts
Guidance

Guidance Title	Use of Artificial Intelligence for Human Subjects Research				
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Applicability	☐ RGC Internal	☒Researcher		☐Institutional	
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 GUIDANCE

Generative Artificial Intelligence (AI) systems, such as ChatGPT, have emerged from several technologies like machine learning and can produce images, text, and other outputs in reaction to prompts and requests. Consequently, generative AI has emerged as a valuable resource for academic studies and research. Tools such as ChatGPT may be tailored for specific tasks and can grow and adapt through input from users and external resources.

This guidance document should be referred to throughout the proposal lifecycle. However, it is ultimately the researcher's responsibility to ensure they are using artificial intelligence ethically and within the bounds of the compliance standards.

A. INFORMED CONSENTS

- **Transparency**: Researchers must disclose when and how AI will be used in the study, including any data analysis, predictive modeling, or automated decision-making processes.
- **Explanation of AI**: Provide a clear, understandable explanation of AI's role in the research, especially for participants with limited technical knowledge.
- **Participant Rights**: Inform participants of their right to opt out of AI-based processes if possible and the potential consequences of opting out (e.g., limited participation or exclusion from certain analyses).
- **Dynamic Consent**: Consider implementing dynamic consent models, where participants can update or withdraw their consent for AI usage as new research phases develop.

B. DATA COLLECTION AND PRIVACY

- **Minimization of Data**: Only collect data that is necessary for the study, ensuring compliance with relevant privacy laws.
- **De-identification**: Personal data must be de-identified before being used in AI systems to minimize risks of privacy violations.
- **Sensitive Data**: Special considerations should be taken when AI processes sensitive data (e.g., health information, racial or ethnic data), including additional layers of protection or explicit consent for its use.
- **Anonymization**: Ensure that AI models cannot re-identify anonymized data when used in research.

C. BIAS AND FAIRNESS

- **Bias Identification**: Researchers must assess and document any biases in AI algorithms, especially when they affect vulnerable or minority populations. This includes biases in training datasets or in the way AI models are applied.
- **Mitigation**: Implement strategies to mitigate bias, such as diversifying training data, adjusting algorithmic weighting, or adopting fairness-aware algorithms.
- **Ongoing Review**: Regularly review AI models for evolving biases as new data or societal trends emerge.

D. ACCOUNTABILITY AND OVERSIGHT

- **Human Oversight**: AI should not replace human decision-making in critical aspects of research. Ensure human oversight is in place for any AI-driven recommendations or outcomes, especially where there are ethical concerns.
- **Audits and Transparency**: AI systems should be transparent, with clear documentation on how algorithms work, the data they use, and how they were trained. Independent audits should be considered for high-stakes research.
- **Responsible Parties**: Define clear accountability within the research team for the ethical use of AI, including regular reviews by the university's Institutional Review Board (IRB).

E. ETHICAL USE OF AI

- **Non-exploitation**: AI should be used to enhance research outcomes, not to exploit participants or exacerbate inequalities. Researchers must avoid using AI in ways that may cause harm or discrimination.
- **Proportionality**: The use of AI should be proportional to the benefits of the research. If AI adds unnecessary risk or complexity, it should be reconsidered.
- **Involvement of AI Ethics Experts**: Researchers should consult with AI ethics experts or committees to evaluate the implications of AI usage, especially in sensitive or complex areas of study.

F. SECURITY OF AI MODELS AND DATA

- **Data Security**: Implement robust cybersecurity measures for both data and AI models, including encryption, access controls, and regular security audits.
- **Model Security**: AI models themselves should be protected against adversarial attacks, model theft, or manipulation that could affect research integrity.
- **Risk Assessment**: Conduct thorough risk assessments before deploying AI systems in research, evaluating vulnerabilities in the data, AI model, and external influences.

E. REGULATORY COMPLIANCE

- **Legal and Ethical Compliance**: Ensure that all AI-related research complies with local, national, and international laws governing data protection, AI usage, and human subjects research.
- **Institutional Guidelines**: Align AI research protocols with university-specific policies on AI usage, human subjects research, and ethical standards.

E. POST SECONDARY USE OF DATA

- **Secondary Use**: If the AI models or data collected during research may be reused in future studies, participants must be informed during the consent process, and IRB approval should be sought for future studies.
- **Data Retention and Deletion**: Establish clear guidelines for how long data used in AI models will be retained and under what conditions it will be deleted or archived.

E. TRAINING AND EDUCATION FOR RESEARCHERS

- **AI Literacy**: Ensure that all researchers involved in the project are trained in AI ethics, data security, and responsible AI practices. This includes understanding the limitations and risks of AI models.
- **Continuous Learning**: Researchers should stay informed about the evolving legal, ethical, and technological landscape of AI in research through ongoing education and professional development.

E. PARTICIPANT FEEDBACK AND INTERACTION WITH AI

- **Participant Access to AI**: Provide participants with the option to review how AI analyzed their data if relevant to the study. This could include the provision of AI-generated insights or predictions.
Debriefing on AI Usage: Offer post-study debriefings where participants can learn more about how AI was used in the study, including any significant findings or decisions made by AI systems.

2.0 REFERENCES

3.0 FORMS OR ATTACHMENTS

4.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	02/10/2025	☐
IRB Chair	☒	02/10/2025	☐
Institutional Official	☐		☒

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☐		☐	
IRB Chair	☐		☐	
Institutional Official	☐		☐	