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WELCOME TO THIS IRB WEBINAR SESSION!

Welcome to this IRB webinar session. My name is Briana Rotterman, and I am with the Education and QA team here at the IRB.

Today's session will cover IRB Initiatives in the use of Artificial Intelligence (AI), Machine Learning (ML), and Big Data in Human Subjects Research(HSR)

If you have a **question**, please feel free to enter it at any time in the **Q&A window**.

We will **answer** all **questions at the end of the webinar**.

Also, the recording of this webinar will be available on our website shortly after this presentation.

Please make sure to adjust your volume settings in order to experience the best audio quality.

IRB Initiatives in the use of Artificial Intelligence (AI), Machine Learning (ML), and Big Data in Human Subjects Research(HSR)

IRB Webinar

11/9/2023

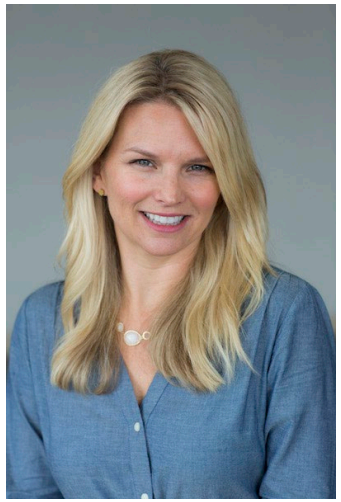
Presentation Topics

1. IRB AI/ML/Big Data Working Group
   - Goals and Topics of Concern
   - Meetings with researchers (internal and external) and other institutional offices
   - Lunch time series
2. Study Submission Considerations
3. Resources

Emory IRB AI/ML/Big Data Working Group

Rebecca Rousselle, BA, CIP

Assistant Vice-President for the Human Research Protection Program



Shara Karlebach, WHNP-BC, CIP

Associate Director, QA/Education Team

Briana Rotterman, MA, MS, CIP

QA and Education Research Protocol Analyst

Michelle Kalbeitzer, MSIOP

Research Protocol Analyst

Project Highlights

Goal:

Development of useful guidance and reasonable requirements which maximize participant safety, rights, and welfare while facilitating research.

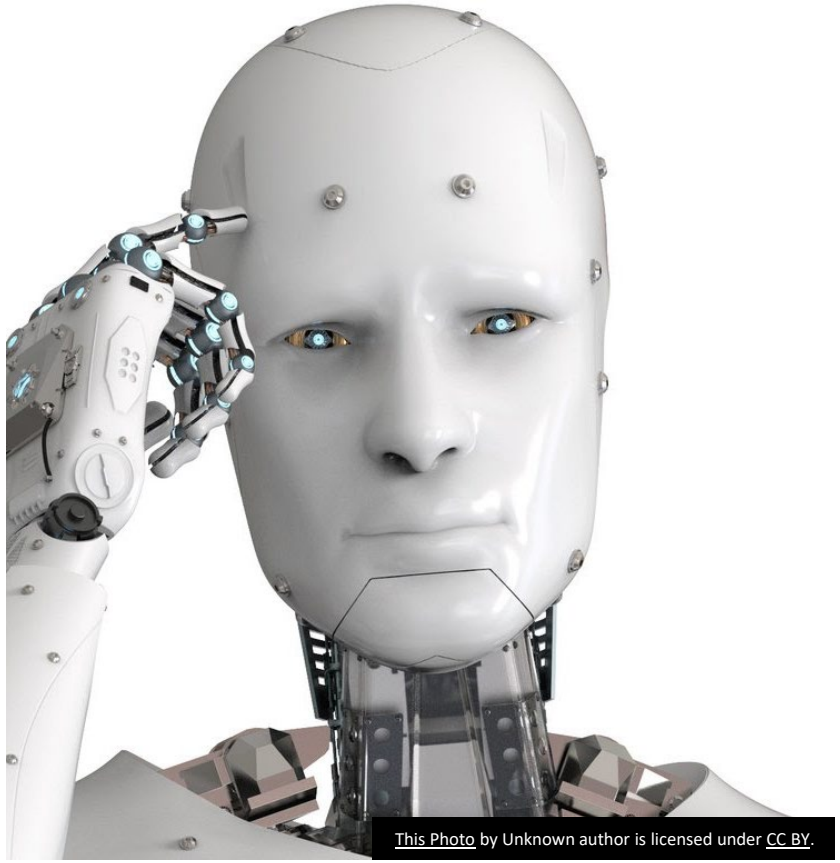
Topics of Concern:

- Data: Data quality, bias, security, monitoring in secondary use, development, training, testing, deploying in research
- Blackbox Considerations: transparency, explainability
- Identifiability: ease/risk of reidentification, best practices to avoid re-identifiability, transparency to participants
- IRB Oversight: IRB manual oversight for the life cycle of AI/ML protocols

Consulting Key Stakeholders

The Working Group has held meetings with the following groups:

- Data science experts
- IRB Members
- Emory and External Researchers who are working with and have expertise in AI/ML/Big Data
- Internal Emory Offices working on institutional, compliance, and ethical guidance and best practices in this space



Nationwide IRB Working Group

1. Dartmouth-Hitchcock Medical Center
2. Emory University
3. Georgia Institute of Technology
4. Harvard University
5. Johns Hopkins University School of Medicine
6. Mass General Brigham
7. Mayo Clinic
8. PRIM&R
9. Stanford University
10. The University of Texas at Austin
11. University of California San Francisco
12. University of Florida
13. University of Washington
14. Vanderbilt University Medical Center
15. Washington University in St. Louis

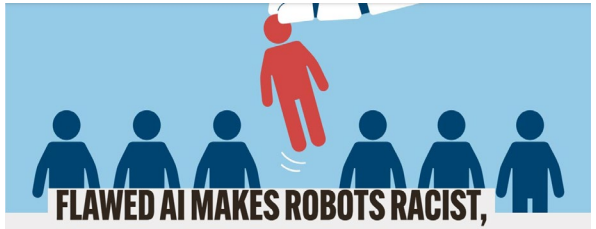
What does this mean for research teams?

- Additional sections in IRB templates
- New questions from IRB analysts
- Potentially new Policies inside and outside of the IRB office
- Improved Website Resources

PROTOCOL REQUIREMENTS

When your study involves developing/evaluating an algorithm/clinical decision tool/artificial intelligence/machine learning tool(s), the protocol **must** address:

- Whether **data** will or *may* be **submitted to FDA**
- Whether there is a plan to **test the model clinically** (i.e., providing any **output to healthcare provider**(s) or **patients** at this stage) in the current submission.
  - If there are no plans to test the model clinically in this protocol, note that a **new IRB submission** will be required **if it will be tested clinically** in the future
- Whether the Algorithm/Product/Software is intended to become proprietary, and can/will it be commercialized outside of Emory?



FLAWED AI MAKES ROBOTS RACIST, SEXIST

New work led by several universities, including Johns Hopkins, shows that neural networks built from biased Internet data teach robots to enact toxic stereotypes

Machine Bias

There's software used across the country to predict future criminals. And it's biased against blacks.

by Julia Angwin, Jeff Larson, Surya Mattu and Lauren Kirchner, ProPublica
May 23, 2016

KHARI JOHNSON BUSINESS MAY 19, 2021 4:23 PM

Twitter's Photo Crop Algorithm Favors White Faces and Women

A study of 10,000 images found bias in what the system chooses to highlight. Twitter has stopped using it on mobile, and will consider ditching it on the web.

COMPUTING

Racial Bias Found in a Major Health Care Risk Algorithm

Black patients lose out on critical care when systems equate health needs with costs

By Starre Vartan on October 24, 2019

REUTERS World Business Markets Breakingviews Video

RETAIL OCTOBER 10, 2018 / 7:04 PM / UPDATED 5 YEARS AGO

Amazon scraps secret AI recruiting tool that showed bias against women

Social Behavioral Research and AI/ML/Big Data

Please note the AI/ML/Big Data concerns are not unique to biomedical research.

For projects that are not under IRB oversight, please consider the downstream impacts when designing your project even if the data is publicly available or does not contain identifiers.

FDA – AI/ML in SaMD

FDA Resources on Artificial Intelligence and Machine Learning in Software as a Medical Device

- Is your clinical decision support software a medical device?
- Digital Health Policy Navigator: A tool to help in determining whether your product's software functions are potentially the focus of the FDA's oversight.
- Artificial Intelligence and Machine Learning (AI/ML) - Enabled Medical Devices (692 devices listed)
- FDA Center for Drug Evaluation and Research Artificial Intelligence in Drug Manufacturing
- FDA's Predetermined Change Control Plans for Machine Learning –Enabled Medical Devices: Guiding Principles

Other Resources

Federal:

- White House: Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence
- https://ai.gov/
- U.S. Department of Health and Human Services Trustworthy AI (TAI) Playbook
- SACHRP (The Secretary's Advisory Committee on Human Research Protections): Considerations for IRB Review of Research Involving Artificial Intelligence
- NIH and Artificial Intelligence

Emory:

AI.Humanity

Center for AI Learning

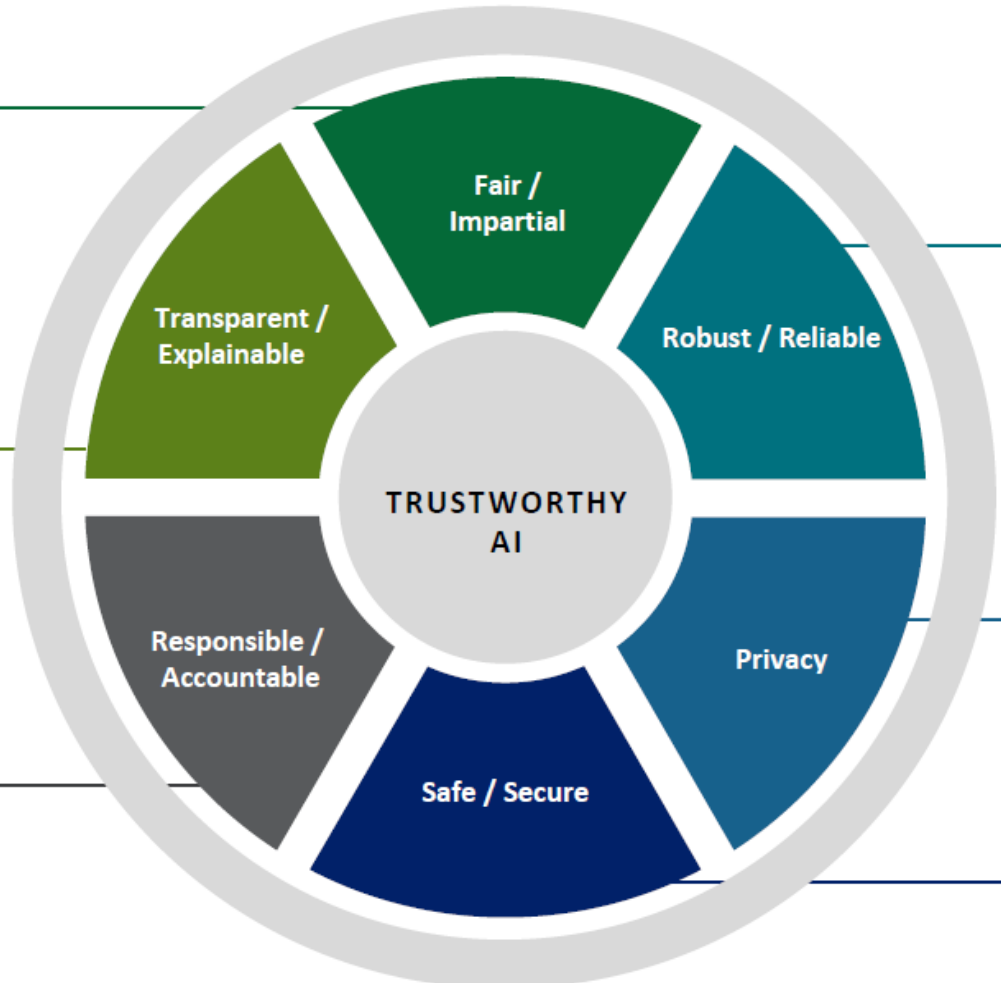
Overview of TAI Principles [12]

By applying these six TAI principles across all phases of an AI project, OpDivs and StaffDivs can promote ethical AI and achieve the full operational and strategic benefits of AI solutions.

Fair / Impartial
AI applications should include checks from internal and external stakeholders to help ensure equitable application across all participants

Transparent / Explainable
All relevant individuals should understand how their data is being used and how AI systems make decisions; algorithms, attributes, and correlations should be open to inspection

Responsible / Accountable
Policies should outline governance and who is held responsible for all aspects of the AI solution (e.g., initiation, development, outputs, decommissioning)



Robust / Reliable
AI systems should have the ability to learn from humans and other systems and produce accurate and reliable outputs consistent with the original design

Privacy
Individual, group, or entity privacy should be respected, and their data should not be used beyond its intended and stated use; data used has been approved by the data owner or steward

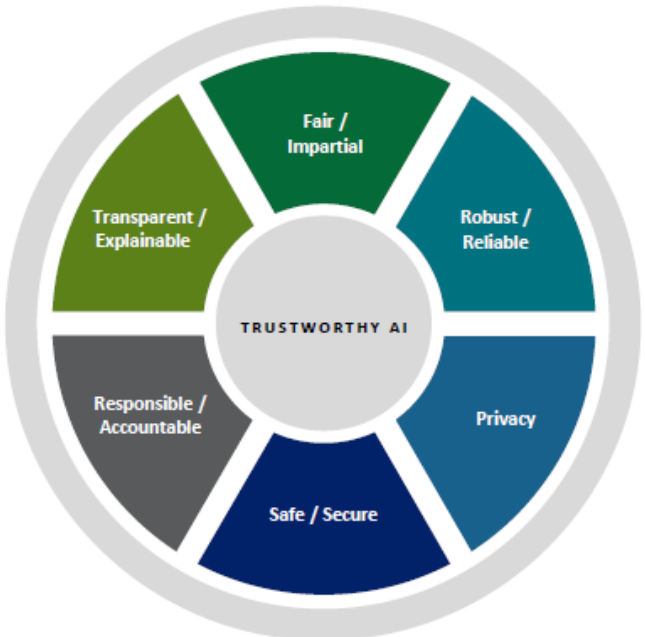
Safe / Secure
AI systems should be protected from risks (including Cyber) that may directly or indirectly cause physical and/or digital harm to any individual, group, or entity

TAI principles are not mutually exclusive, and tradeoffs often exist when applying them.

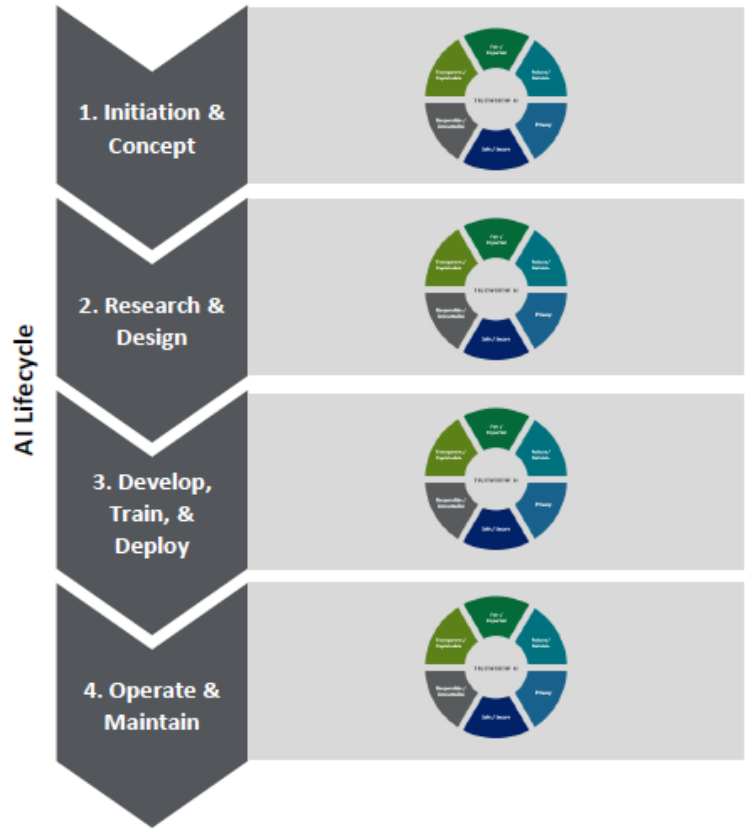
Application of TAI Principles Across the AI Lifecycle

Reviewing TAI principles during each phase of the AI lifecycle is critical to effectively creating TAI solutions.

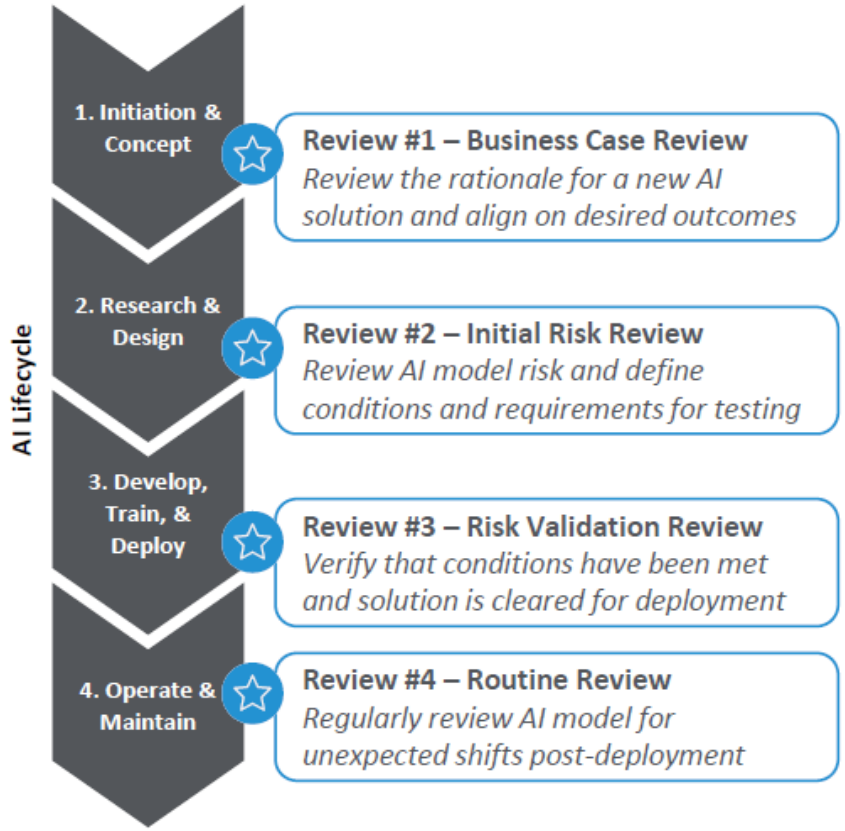
The TAI principles serve as a framework for understanding AI risk.



The TAI principles are applied during every stage of the AI lifecycle.



AI models should undergo reviews during each stage of the AI lifecycle to ensure TAI principles and risks are balanced.



*Using the principles to **understand and mitigate AI risk throughout the lifecycle** supports TAI solutions.*

FEEDBACK

Thank you for taking the time to listen to this presentation.

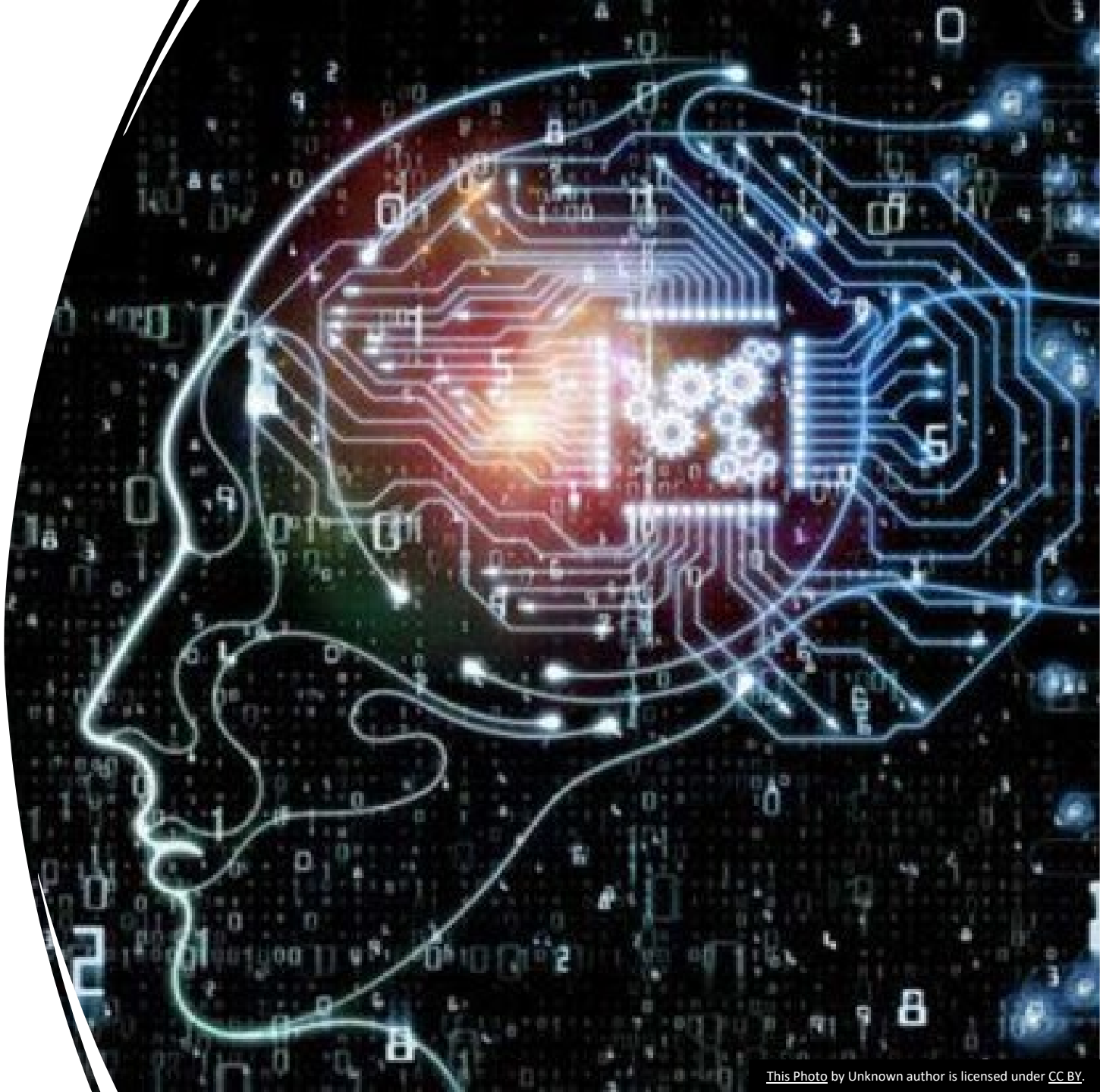
Before we open it up for questions, we want to ask you to help us by providing your feedback on today's webinar.

Your feedback will help us by pointing out areas we could improve and by providing ideas for future topics.

A survey will be available along with the webinar on the IRB website.

Questions?

If you have questions after this webinar, please reach out to the IRB analyst on your study. For general questions, please reach out to the IRB listserv, IRB@emory.edu.



THANK YOU!

We will now conclude this presentation, but if you have additional questions, please visit our website at www.irb.emory.edu, or call the main IRB line at 404-712-0720. Our contact information is available on the website as well as within the current presentation. Thank you for your attention to this webinar, we hope it was helpful. See you next time!