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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.

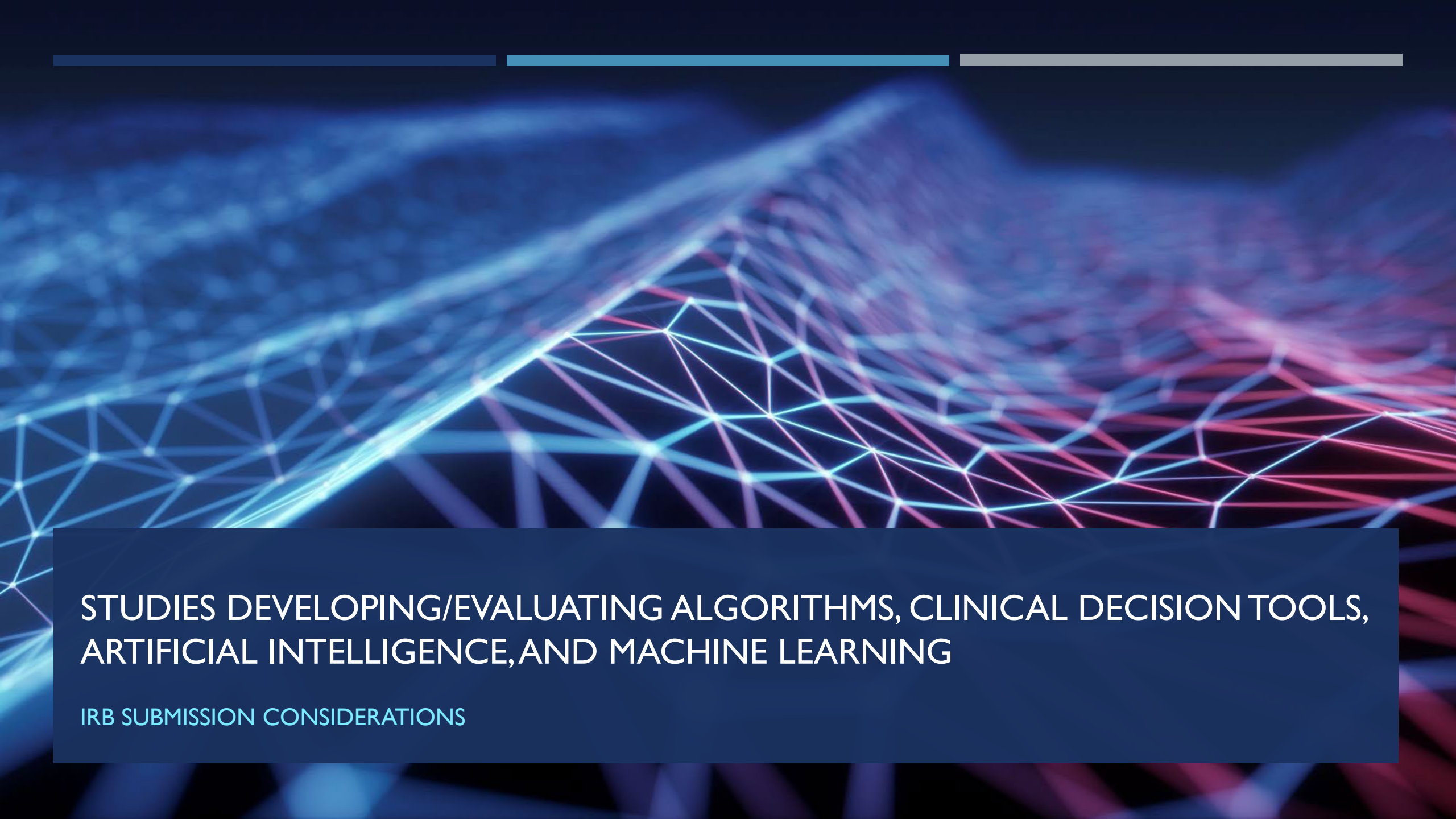
Today's session will cover IRB submission considerations when your study is developing and/or evaluating an algorithm, clinical decision tool, artificial intelligence, and/or machine learning tool

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.

Just a reminder, in order to experience the best audio quality, please make sure to adjust your volume settings.



STUDIES DEVELOPING/EVALUATING ALGORITHMS, CLINICAL DECISION TOOLS, ARTIFICIAL INTELLIGENCE, AND MACHINE LEARNING

IRB SUBMISSION CONSIDERATIONS

TOPICS

- FDA DEFINITIONS AND RESOURCES
- PROTOCOL REQUIREMENTS
- FDA REGULATIONS
- SUBMISSION REQUIREMENTS IF FDA REGULATIONS APPLY
- EMORY OIT SECURITY REVIEW REMINDER
- WHAT'S NEXT?

TERMS AND DEFINITIONS

- **Artificial Intelligence (AI)*** a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions
- **Machine Learning (ML)*** A subset of AI that allows ML models to be developed by ML training algorithms through analysis of data, without models being explicitly programmed

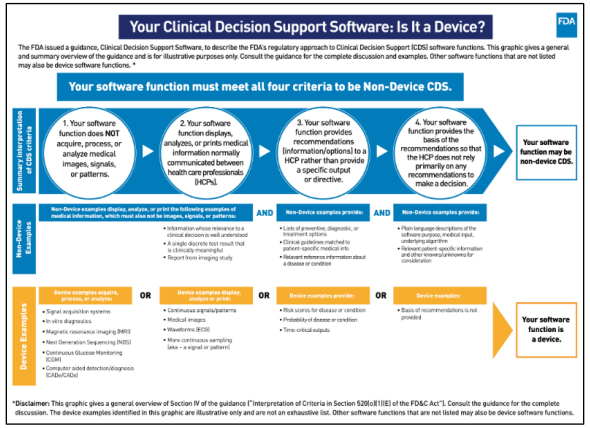
Some real-world examples of artificial intelligence and machine learning technologies include:

- An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
- A smart sensor device that estimates the probability of a heart attack.

- **AI/ML in SaMD**: Artificial Intelligence and Machine Learning in Software as a Medical Device

FDA Resources

- Is your clinical decision support software a medical device?
- Digital Health Policy Navigator
- Artificial Intelligence and Machine Learning (AI/ML) - Enabled Medical Devices
- Artificial Intelligence and Machine Learning in Software as a Medical Device
- FDA Center for Drug Evaluation and Research Artificial Intelligence in Drug Manufacturing



*AI and MLD definitions are from IMDRF (International Medical Device Regulators Forum)

CLINICAL DECISION SUPPORT SOFTWARE – FDA DEVICE EVALUATION

Software Function:

1. does **NOT acquire**, **process**, or **analyze** medical **images**, **signals**, or **patterns**
2. displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs)
    - Information whose relevance to a clinical decision is well understood
    - A single discrete test result that is clinically meaningful
    - Report from imaging study
3. provides **recommendations** (information/**options**) to an HCP **rather than** provide a **specific output** or **directive**
    - Lists of preventive, diagnostic, or treatment options
    - Clinical guidance matched to patient-specific medical info
    - Relevant reference information about a disease or condition
4. provides the **basis of the recommendations** so that the HCP does not rely primarily on any recommendations to make a decision
    - Plain language descriptions of the software purpose, medical input, underlying algorithm
    - Relevant patient-specific information and other knowns/unknowns for consideration

If **all four criteria are met**, your software function **may** be **non-device** CDS.

If **any** one **of the 4** criteria **is not** met, your **software function is a device**.

FDA'S LIST OF CLINICAL DECISION SUPPORT SOFTWARE DEVICE EXAMPLES

According to criterion 1: Device examples acquire, process, or analyze:

- Signal acquisition systems, In vitro diagnostics, Magnetic resonance imaging (MRI), Next Generation Sequencing (NGS), Continuous Glucose Monitoring (CGM), Computer aided detection/diagnosis (CADe/CADx)

According to criterion 2: Device examples display, analyze, or print:

- Continuous signals/patterns, Medical images, Waveforms (ECG), More continuous sampling (aka – a signal or pattern)

According to criterion 3: Device examples provide:

- **Risk scores** for disease or condition, **Probability** of disease or condition, **Time-critical** outputs

According to criterion 4: Device examples:

- **Basis of recommendations** is **not provided**

FDA ACTION PLAN FOR AI/ML IN SAMD

- **Tailored Regulatory Framework for AI/ML-based SaMD - Predetermined Change Control Plan**
- **Good Machine Learning Practice (GMLP)**: a set of AI/ML best practices (e.g., data management, feature extraction, training, interpretability, evaluation and documentation) that are akin to **good software engineering practices or quality system practices**.
- **Patient-Centered Approach Incorporating Transparency to Users**: promotion of the transparency of these devices to users, and to patients more broadly, about the devices' functioning
- **Regulatory Science Methods Related to Algorithm Bias & Robustness**: develop methodology for the evaluation and improvement of machine learning algorithms, including for the identification and elimination of bias, and for the evaluation and promotion of algorithm robustness
- **Real-World Performance (RWP)**: a framework that can be used for seamless gathering and validation of relevant RWP parameters and metrics for AI/ML-based SaMD in the real-world.

FDA AI/ML in SaMD Action Plan

GOOD MACHINE LEARNING PRACTICE FOR MEDICAL DEVICE DEVELOPMENT: GUIDING PRINCIPALS

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP)

1. **Multi-Disciplinary Expertise** Is **Leveraged** Throughout the **Total Product Life Cycle**
2. Good **Software Engineering** and **Security** Practices Are Implemented
3. Clinical Study **Participants** and **Data** Sets Are **Representative** of the Intended **Patient Population**
4. **Training Data** Sets Are **Independent** of **Test Sets**
5. Selected **Reference Datasets** Are Based Upon **Best Available Methods**
6. Model **Design** Is **Tailored** to the **Available Data** and **Reflects** the **Intended Use** of the Device
7. Focus Is Placed on the Performance of the Human-AI Team: "**Human in the loop**"
8. **Testing Demonstrates** Device **Performance** during **Clinically Relevant Conditions**
9. **Users** (healthcare providers or patients) Are **Provided Clear, Essential Information**
10. Deployed Models Are **Monitored** for **Performance** and Re-training **Risks** are **Managed**

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?

FDA REGULATIONS

FDA regulations may apply if:

- If the **research data** will or may be **submitted to FDA**
- There is a **plan to test the model clinically** such as providing output to healthcare provider(s) or patients at the stage of the research in the submission
- The AI/ML in your study is functioning as a **mobile medical device** or **clinical decision tool** that meets the FDA definition of device

SUBMISSION REQUIREMENTS IF FDA REGULATIONS APPLY

- FDA-regulated mobile medical device or clinical decision points tool - **Mobile Medical apps worksheet**
- Standard FDA-regulated research requirements apply

Emory IRB Medical Device Guidance

Emory IRB Device Checklist

WHEN FDA REGULATIONS MAY NOT APPLY (AT THIS TIME)

Based on the guidance we have at this time, **FDA-regulations may not apply** in the following scenarios until we find out otherwise through updated regulations, guidance, or other information:

- The IRB protocol solely describes developing and testing the algorithm in a data set, and **NOT providing any output to healthcare provider(s) or patients at this stage**
- The study team has confirmed they **do not plan to submit the research data from this protocol to the FDA**

WHAT TO DO WHEN THE RESEARCH MOVES TO A STAGE THAT BECOMES FDA-REGULATED?

Once the work proceeds to the stage of **using the algorithm in the actual clinical workflow** such that it may have some impact on patient care (even if the output is presented alongside standard of care information), it will meet the definition of "clinical investigation" and the Emory IRB would consider the study to be "**FDA Regulated**"

A **new IRB submission is required** for this stage of the research.

EXISTING ACTIVE STUDIES WITH THESE TOOLS

If you have an approved IRB submission that involves developing/evaluating an algorithm/ clinical decision tool/artificial intelligence/machine learning tool(s) and you think these elements were **not considered during the review process**, please **reach out to the IRB analyst** assigned to your study, so any additional considerations can be reviewed.

EMORY OIT SECURITY REVIEW REMINDER

Studies that include artificial intelligence and machine learning may meet the criteria requiring a security review.

Review the Data Security section on our study submissions guidance page and submit a ticket for a security review if needed.

- **When is a OIT security review needed?** Guidance to help you determine if you need an OIT security review when using a software or app for research
- **OIT approved apps for research**: Find a complete and updated list on the OIT website
  - Emory Zoom Account Type (PDF): HIPAA-compliant vs. General **(also on the OIT website)**

You can find further information in the Emory OIT webinar from January on our webinar page

For studies taking place at Children's Healthcare, please log in to their intranet (Careforce) and access this CareforceConnection document for information on how to submit for security review. Please refer all questions to BISRA@choa.org.

For studies taking place at Grady: email the device and data use information to the Grady privacy officer, D'Andrea Morning, at djmorning@GMH.EDU for her review and approval. Upload the email in the study history for our records.

WHAT'S NEXT

Please note that FDA, OHRP, and other regulatory bodies are **continuing to release new guidance** in these areas, so **expect updates** as any new relevant regulations are released.

We appreciate your patience while **we continue to navigate the regulations** in this space **as they continue to evolve**.

We may be asking **new questions** since the guidance and regulations on these topics are new and continuing to develop and change.

Please note there are some **additional identifiability and data security considerations** that continue to develop in this space as well.

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.

Q&A SESSION

PLEASE ENTER YOUR QUESTIONS IN THE Q&A WINDOW

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!