

Breakout Session 2: Track B

A Synopsis of the PREMIERE Ethics Supplement

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- **Parent Award:** “PREMIERE: A PREdictive Model Index and Exchange Repository”; PI: Alex Bui; R01EB027650
- **Supplement Award:** “PREMIERE: A PREdictive Model Index and Exchange Repository”; PIs: Alex Bui and Jennifer Kristin Wagner; 3R01EB027650-03S1

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PennState

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- The content of this presentation is solely my responsibility and does not necessarily represent the official views of the National Institutes of Health, Rock Ethics Institute, Penn State University, or any other person or entity.

The Research Team



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Principal Investigator,
PREMIERE



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Principal Investigator,
PREMIERE Ethics Supplement

Co-Investigators



Anders Garlid, PhD



Daniel Susser, PhD



Laura Cabrera, PhD



Sara Gerke, Dipl.-Jur Univ.

The Working Group Convened

I. Glenn Cohen, JD, Professor of Law at Harvard Law School

Megan Doerr, MS, LGC, Director Applied ELSI Research at Sage Bionetworks

Jordan Harrod, PhD Candidate, Harvard-MIT Health Sciences and Technology Program

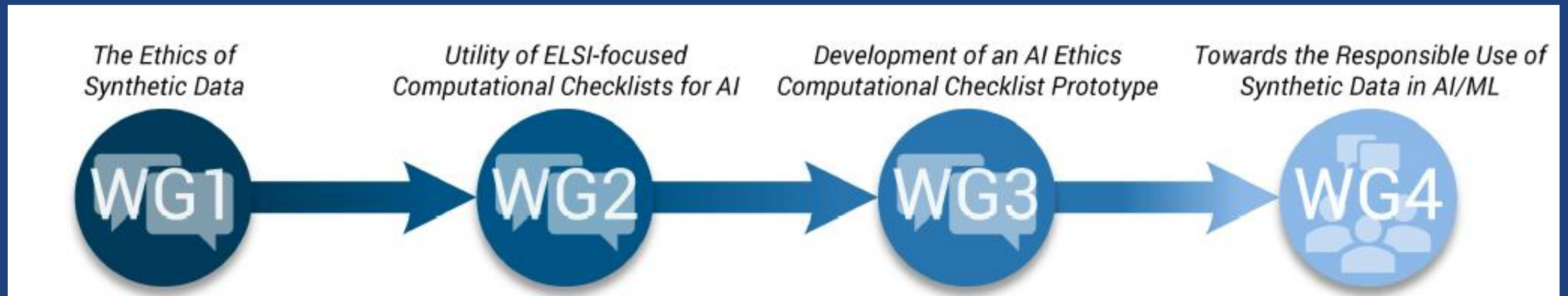
Kristin Kostick-Quenet, PhD, Assistant Professor in the Center for Medical Ethics and Health Policy at Baylor College of Medicine

Jasmine McNealy, JD, PhD, Associate Professor at the University of Florida

W. Nicholson Price, II, JD, PhD, Professor of Law at University of Michigan

Michelle Meyer, PhD, JD, Chief Bioethics Officer and Associate Professor and Chair of the Dept of Bioethics and Decision Sciences at Geisinger

Daniel Schiff, MS, PhD, Assistant Professor of Technology Policy at Purdue University



PREMIERE: A PReDICTive Model Index and Exchange REpository

- **Aim 1:** To develop standards for describing a predictive model and its evaluation, establishing a modeling representation that provides full scientific reproducibility of a model and its results
- **Aim 2:** To provide a means of comparing and contrasting predictive models, with tools that provide insight into differences in performance and methods to adapt models
- **Aim 3:** To engage a community of stakeholders to evaluate the developed standard and tools for comparing predictive models, initially targeting models that utilize diagnostic images as a primary input.
- **Supplement Aim 1:** To critically examine the ethics of synthetic data in AI/ML through key informant interviews
- **Supplement Aim 2:** To explore the utility of ELSI-focused computational checklists for AI/ML through a survey of medical professionals (AI developers and users as well as ethics professionals)
- **Supplement Aim 3:** To develop a prototype ELSI-focused AI/ML computational checklist that can be integrated into PREMIERE

Key Informant Interviews

- Research Approach
 - IRB Exemption Determination from PSU IRB (STUDY00020918) on Aug. 30, 2022
 - Recruited informants Nov 2022-Jan 2023
 - AI → 50% (n=7)
 - AI Ethics → 43% (n=6)
 - Both → 7% (n=1)
 - Performed Semi-Structured Interviews via Zoom
 - Questions about the informants
 - Questions about synthetic data
 - Questions about computational checklists
 - Qualitative content analysis of interview transcripts performed via Dedoose

Informant Characteristics

- Gender
 - Female → 57% (n=8)
 - Male → 43% (n=8)
- Race/Ethnicity
 - Latino, White → 7% (n=1)
 - Non-Latino, White → 57% (n=8)
 - African American → 7% (n=1)
 - Middle Eastern or North African → 7% (n=1)
 - Other → 21% (n=3)
- Workplace
 - Medical School → 50% (n=7)
 - College or University → 36% (n=5)
 - Teaching Hospital/Health System → 14% (n=2)
- Experience in Role
 - Less than 10 years → 36% (n=5)
 - More than 10 years → 64% (n=9)
- Familiarity with Synthetic Data
 - Substantial → 35.71% (n=5)
 - Moderate → 28.58% (n=4)
 - Minimal → 35.71% (n=5)
- Familiarity with Computational Checklists
 - Substantial → 21.43% (n=3)
 - Moderate → 7.14% (n=1)
 - Minimal → 35.71% (n=5)
 - None → 35.71% (n=5)

Regarding Synthetic Data

[AI expert]: "Synthetic data is not a solution for everything, [...] I believe there are a lot of use cases where you still will need the source data. [...] It is a tool in our toolbox. It's not the tool. It's a tool."

[AI expert]: "It's not going to fix like whatever is wrong with real data, [...] So it's not some magic tool to fix, for example, small sample sizes or rare diseases."

Generally favorable views, but cautionary

Privacy

[AI ethics]: "I think that a big part of the attractiveness of data mining in general is profiling, and [...] this is the part that I'm not sure that [synthetic data] can mitigate."

Bias

[AI expert]: "I think it's a mistake to think of simulated data as inherently promoting or averting bias. But it could be used to do either. Bad uses could certainly exacerbate them. Good uses could diminish them."

Opportunities

[AI expert]: "I think there's tons of educational opportunities for it, [...] being able to generate some kind of synthetic dataset which accurately reflects some of the challenges [of real datasets] That's super helpful."

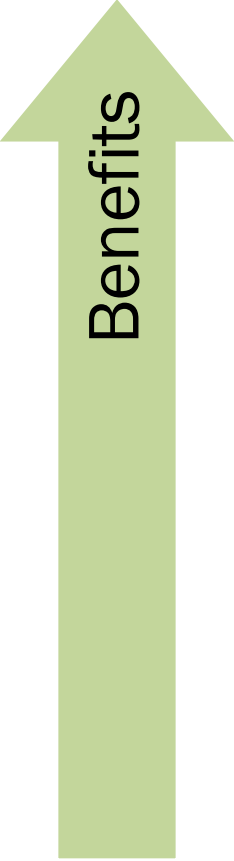
[both]: "I think there's an opportunity for providing people with the look and feel of real data before they start working with it."

Challenges

[AI expert]: "One of the biggest challenges, might be how do we know when a synthetic dataset is good? What are the metrics for success there?"

Policy

[AI expert]: "I think that by and large the people that serve on institutional review boards as well as sort of the regulatory climate in which the IRBs operate are completely unable to cope with sort of modern data science methods, including synthetic data. [...] Maybe we need a data science IRB for projects that are primarily data science where we actually have experts that understand sort of the risk benefit."



Benefits

ELSI-Focused Computational Checklists

- establish a baseline to have those types considerations
 - explain the choices in a way that humans can understand
 - facilitate review of models/grants
 - educate the next generation
- can be biased
 - hard to make a comprehensible, compact, scalable and adaptable checklist
 - several already available
 - too abstract to implement
 - ethics washing



Challenges



Regarding ELSI-focused Computational Checklists

[AI ethics expert]: “Ethics checklist for computation *could be useful*, but there's a part of me that also feels like a big part of ethics is different from surgery in that the ethical issues or like the *ethics don't stop at the checklist*, right? Ethics is something that's sort of ongoing. And the checklist almost sort of like circumscribes it in a way that I think can be a little bit limiting. So [...] they could be good for establishing a baseline, but *they shouldn't be where discussions of ethics stops.*”

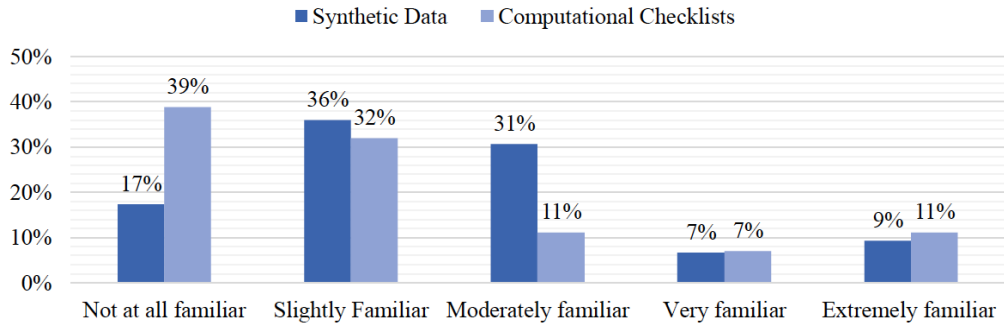


Survey of Professionals

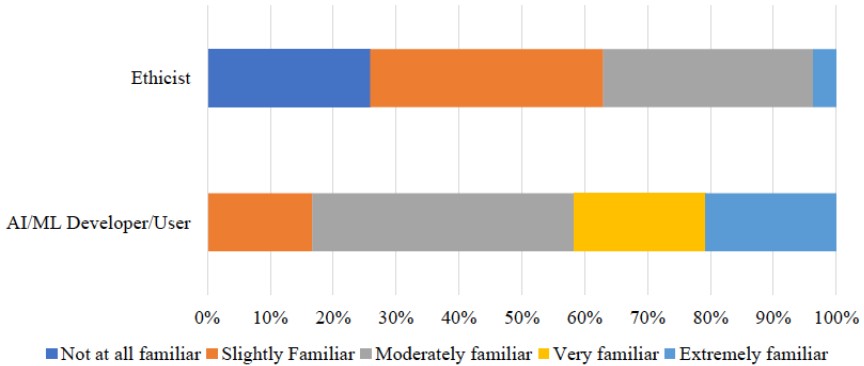
- Research Approach
 - IRB Exemption Determination from PSU IRB (STUDY00020918) on Aug. 30, 2022
 - Recruitment using a modified Dillman approach
 - Random sample of AAMC member organizations
 - Identification of professionals at those sampled organizations in relevant roles (AI or AI ethics)
 - Attempted recruitment of N=771
 - Survey administration via Qualtrics
 - Data collected June – August 2023
 - Overall survey response rate = 10.4%
 - N=75
 - AI developer/user → 32% (n=24)
 - Ethics → 32% (n=27)
 - Other → 32% (n=24)

		Count* (N)	Frequency (%)
Age	18-25 years	2	2.7
	26-35 years	13	17.3
	36-45 years	24	32.0
	46-55 years	17	22.7
	56-65 years	14	18.7
	66-75 years	5	6.7
Gender	Male	34	45.3
	Female	40	53.3
	Non-binary	1	1.3
Race/Ethnicity	Asian	12	16.4
	Hispanic, Latino, or Spanish	2	2.7
	White	52	71.2
	More than one selection	7	9.6
Educational Attainment	College 4 years or more	3	4.0
	Advanced degree	73	96.0
Workplace	Medical School	25	35.2
	Teaching Hospital or Healthcare System	26	36.6
	College or University	20	28.2
Experience in Role	0-5 years	23	30.7
	6-10 years	8	10.7
	More than 10 years	44	58.7
Geographic Region	Northeast	20	27.4
	South	21	28.8
	Midwest	23	31.5
	West	9	12.3

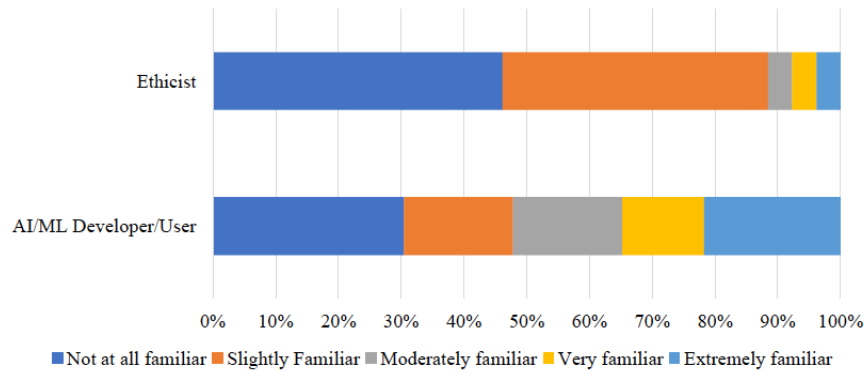
Familiarity with Synthetic Data and/or Computational Checklists



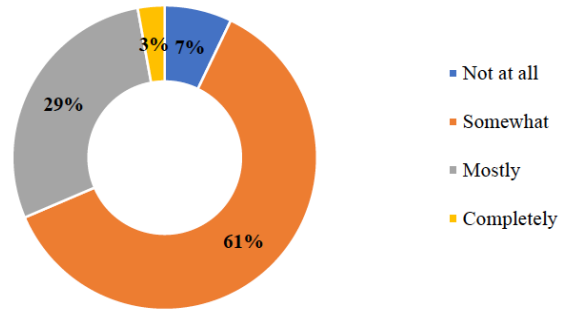
Familiarity with Synthetic Data (By Professional Role)



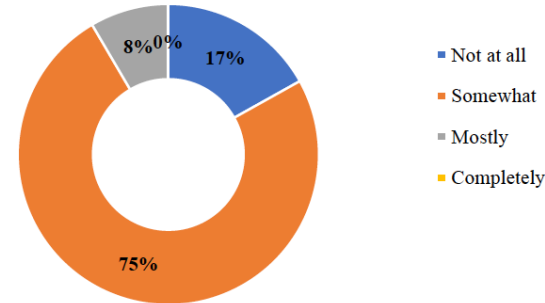
Familiarity with Computational Checklists (By Professional Role)



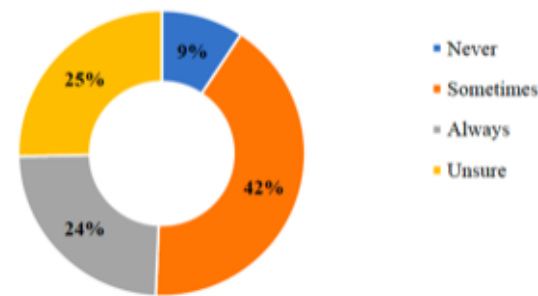
Whether Synthetic Data Addresses Privacy Concerns



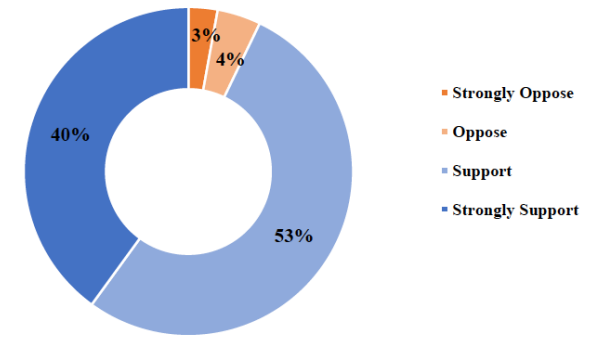
Whether Synthetic Data Addresses Bias Concerns



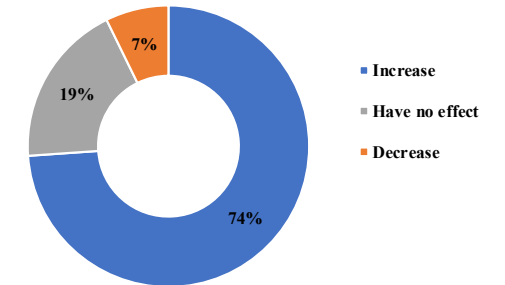
Whether IRBs should oversee the use of synthetic data in biomedical contexts



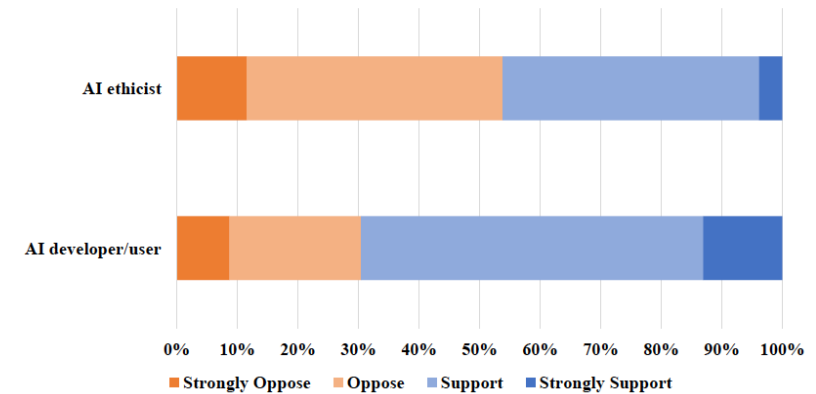
Initial Opinion of ELSI-Focused Computational Checklists



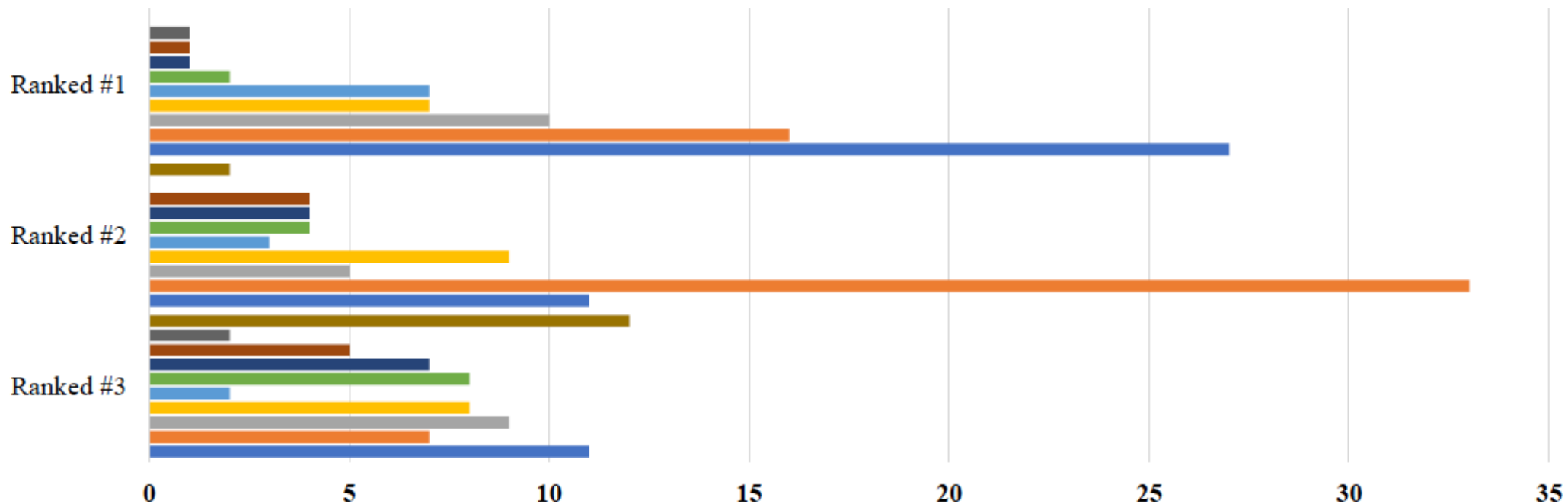
Perceived effect of ELSI-focused computational checklist on the quality of attention given to ELSI-related issues for AI models and datasets.



Support for Automated Processes to Validate ELSI-Focused Features of AI Models and Datasets



Ranking items (by importance) for inclusion in an ELSI-focused computational checklist



- Sources of funding that supported the development of the AI model or dataset
- Reputation of the institution or organization that developed the AI model or dataset
- Diversity of expertise among members of the team who developed the AI model or dataset
- Details regarding any conditions or restrictions on future uses of the AI model or dataset
- Details regarding patient and community engagement during the development of the AI model or dataset
- Informed consent documentation
- Steps taken to ensure that access to the AI model or dataset is equitable
- Steps taken to preserve information privacy and security in the design of the AI model or dataset
- Steps taken to reduce bias in the AI model or dataset
- Characteristics of the individuals or groups used to train the AI model or dataset



Symposium Towards Responsible Biomedical AI



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- **Opening Remarks** by Jennifer Wagner
- **Keynote Address**
 - Neil Richards, “Responsible Biomedical AI: From Half-Measures to Loyalty”
- **Session 1** with discussion moderated by Laura Cabrera
 - Michelle Meyer, “Health AI aversion or appreciation? Four randomized field trials of personalized risk-communication nudges to encourage flu vaccination”
 - Kristin Kostick-Quenet, “Computer perception meets AI: Ethical implications for healthcare”
 - I. Glenn Cohen, “Legal and Ethical Issues with Generative AI; Issues of Enterprise Liability”
- **Session 2** with discussion moderated by Sara Gerke
 - Jasmine McNealy, “Constructive (Data) Trusts”
 - Megan Doerr, “Big Health Data Research and Group Harm: a tool for researchers, access boards, and ethics boards”
 - Nicholson Price, “Toward Collaborative Local Governance of Medical AI”
- **Session 3** with discussion moderated by Daniel Susser
 - Daniel Schiff, “What Can We Learn from Research and Discourse on Deepfakes?”
 - Jordan Harrod, “What happens when AI fails in the clinic”
 - Laura Cabrera, “‘Not some magic tool’: Views around synthetic data and ELSI-focused computational checklists for artificial intelligence in medicine”
- **Closing Remarks** by Jennifer Wagner



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View the playlist of video recordings of the Symposium on the Rock Ethics Institute's YouTube page at

<https://www.youtube.com/playlist?list=PLs5jqQzJBAYsl6jD28bEbfyW35T1Mrckw>

The screenshot shows a YouTube playlist page for "A Symposium Towards Responsible Biomedical AI" by Rock Ethics Institute. The page is viewed on a desktop browser. The address bar shows the URL: <https://www.youtube.com/playlist?list=PLs5jqQzJBAYsl6jD28bEbfyW35T1Mrckw>. The YouTube navigation menu is visible on the left, including Home, Shorts, Subscriptions, You, and History. The main content area features a video player for the first video, "A Symposium Towards Responsible Biomedical AI", with a duration of 54:18. Below the player, the video title "A Symposium Towards Responsible Biomedical AI" is displayed, along with the channel name "Rock Ethics Institute" and the number of videos (13). The video description includes the date "Friday, October 20, 2023" and the location "Penn State University Park". It lists the organizers: Laura Y. Cabrera, Dorothy Foehr Huck, J. Lloyd Huck, Sara Gerke, Daniel Susser, and Jennifer K. Wagner. The description also mentions sponsors: the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Institutes of Health Office of the Director (NIH OD). The video description concludes with an acknowledgement of collaborators: Dr. Alex Bui, Dr. Anders Garlid, Morgan Schnars, Samiksha Kature, Pingxu Hao, and Khalid Smith. The right side of the page shows a list of 13 videos in the playlist, each with a thumbnail, title, and view count. The titles of the videos are: "Opening remarks, Jennifer Wagner, and keynote address, Neil Richards: 'Beyond AI half-measures'", "Michelle Meyer, 'Health AI aversion or appreciation?'", "Kristin Kostick-Quenet, 'Computer perception meets AI: Ethical implications for healthcare'", "I. Glenn Cohen, 'Legal and ethical issues with generative AI; issues of enterprise liability'", "Session one moderated discussion led by Laura Cabrera", "Jasmine McNealy, 'Constructive (data) trusts'", "Megan Doerr, 'Big health data research and group harm'", "Nicholson Price, 'Toward collaborative local governance of medical AI'", "Session two moderated discussion led by Sara Gerke", "Daniel Schiff, 'What can we learn from research and discourse on deepfakes?'", "Jordan Harrod, 'What happens when AI fails in the clinic'", "Laura Cabrera, 'Not some magic tool'", and "Session three moderated discussion led by Daniel Susser, and closing remarks by Jennifer Wagner".

Discussion & Questions

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