AI & IRB Administration:

A Use Case

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COI Disclosure

I have no actual or potential conflict of interest in relation to this presentation.

Background – UTA's Institutional Review Board

- ~700 submissions per year
- 3 FTE Specialists + ½ FTE Coordinator
- Electronic submission system – "Mentis" (homegrown)
- Mix of biomedical and social/behavioral studies including clinical trials, Common Rule, and FDA regulated
- Conducts "flex reviews" for non-federally funded/non-FDA regulated protocols

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How can we leverage AI for efficiency?

- “Proof of concept” project – keep it small and expand later if successful
- Test on *internal* administrative process to minimize disruption to researchers
- Partnered with Microsoft and Infused Innovations, initiated December 2023
- Pulled in UTA IT personnel with understanding of research/IRB to handle technical components (developer access, technical implementation)
- Landed on an idea to combine new automation features with AI capabilities:

The Workflow

UTA IRB's "Workflow"

- "Workflow" tracking mechanism - spreadsheet of pending submissions with protocol details, funding, review status
- Initial protocol entry made by Coordinator (5 – 10 minutes per entry, average 10 – 20 entries per day)
- Specialists use Workflow spreadsheet to self-assign submissions and keep track of potential Full Board items
- Review category (Exempt, Expedited, Full Board, Flex-MR, Flex-GMR) determined by Specialists during their review

UTA IRB's "Workflow"

Flex Reviews

Protocol number	Submission type	Expiration Date	Rules	Review Category	PI	Funding Source(s)	BlueSheet #	HSP Done?	COI Req'd?	Other Training Req'd? (GCP, RCR)	Assigned Reviewer	Current Study Status	Date of Last Action
2023-0349	Initial Review		UTA SOPs	Risk	M	Funds		Yes			LA	Review	2/27/2024
2024-0112	Initial Review		UTA SOPs	Minimal Risk	Al	Internal UTA Account		yes			LA	Resubmission Waiting for Coordinator Review	3/6/2024
2024-0242	Initial Review			Reliance	G			yes			SP	Waiting on Other Institution	3/22/2024
2024-0088	Initial Review		FDA Only	Greater than Minimal Risk	Fa	Other		Yes	COI - yes	GCP- yes	SP	Resubmission Waiting for Coordinator Review	3/14/2024
2024-0042.1	Modification		Revised Common Rule	Exempt	Sa	NIH		Yes			LA	Waiting for Initial IRB Coordinator Review	3/18/2024
2024-0087	Initial Review		UTA SOPs	Minimal Risk	He	Industry Sponsored		yes			SP	Waiting for Initial IRB Coordinator Review	3/20/2024
				Greater than								Sent to IRB	

+ ≡ Inbox ▾ Returned to PI ▾ Approved/Closed/Reclass ▾ Full Board Prep ▾ 2024 CR tracking ▾ COVID Research

Project Plan – Proof of Concept

1. Automate entries into the Workflow spreadsheet as protocols are submitted to the electronic system
2. Automate AI decision-making by combining data from electronic system + AI scan of protocol to predict the review category (Exempt, Expedited, Full Board, Flex-MR, Flex-GMR)

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Potential Benefits / Rationale

AI Protocol Predictions

- Efficiency: Specialists can self-assign based on expertise *and* time available
- Planning: earlier identification of potential Full Board items
- Accuracy: may reduce potential for human error

Automating Workflow Entries

- Eliminate dependency: entries maintained even if Coordinator is absent or position vacant
- Shorter lead time: entries made in real time, Specialists can act on them sooner
- Significant time savings:
  10 – 20 submissions/day x
  5 – 10 minutes/entry =

50 minutes to 3+ hours of time saved per day!!

Development Process

- Provided specific sources and fields to pull data for Workflow auto entries
- Wrote rules/conditions for AI to predict review category

EXAMPLE (AI scans for funding source then predicts based on conditions):

- Regulations: FDA Only = Non-Federal Funded + “IRB Form: Devices in Human Subject Research” and/or “IRB Form: Drugs, Food, Dietary Supplements”
- Review Category: Full Board = If “Greater than Minimal Risk” is checked yes in #4 of Primary Research Application Form + Revised Common Rule, FDA, or Both FDA and Common Rule is the Regulation applied

Challenges from UTA IRB Team's Perspective

- Limited PoC scope – 69% accuracy after three iterations
- Time-consuming – translating IRB process for AI development team, writing conditions for AI predictions, testing/assessing multiple iterations, providing feedback after each iteration
- IT components – beyond our (IRB) technical expertise
- Cost (both for development and monthly) – luckily UTA has a high level of interest in leveraging innovative technology
- How to transition from test environment to real environment
- How to manage future "training" of AI to improve accuracy

Conclusions / Impact

- Too early to say? As of April 2024, proof of concept project completed; still planning implementation/transition
- Need time to analyze its performance and impact
- Need help from our IT team or other partners for continued AI training

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