Protocol Review

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Disclaimer

The opinions expressed are those of the presenters and do not necessarily reflect the policy of the U.S. Department of Health and Human Services
What is your role in the research enterprise? (Select most suitable answer)

A. Investigator
B. IRB member
C. Both investigator and IRB member
D. IRB administrator
E. Both IRB administrator and IRB member
F. Other

[Bar chart showing percentages: Investigator 17%, IRB member 17%, Both investigator and IRB member 17%, IRB administrator 17%, Both IRB administrator and IRB member 17%, Other 17%]
PROTOCOL 1
Research Proposal

• Randomized controlled trial to compare the use of a machine learning-based sepsis prediction algorithm (MLA) to the use of SIRS criteria from patients’ electronic health records, a method used in usual care to manage patients at risk of developing severe sepsis.

• The hypothesis is that the MLA predicts the development of severe sepsis with a higher sensitivity and specificity.
You are on the IRB that has been asked to review and approve this research.

Please review the protocol and discuss with your colleagues some of your considerations and concerns.
Is this non-exempt human subjects research under the regulations?

A. Yes
B. No
C. Unsure
Protocol Approval Criteria

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is sought from each subject
- Informed consent is properly documented

- And, when appropriate:
  - Data collection is monitored to ensure subject safety
  - Subject privacy and data confidentiality protected
  - Additional safeguards for vulnerable populations

§46.111

Note: Additional findings – Subparts B, C, & D
Is the current research *minimal risk research*?

A. Yes
B. No
C. Unsure
Making a Minimal Risk Determination

“The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (§46.102(i))

1. Identify risks that could reasonably result from the study procedures
2. Estimate the **probability** (how likely) and **magnitude** (how severe), and
3. Compare to risk:
   a. In daily life, or
   b. In routine physical or psychological examinations or tests
Risks

What are the risks?

Have the risks been minimized?
  • If not, how might they be further minimized?

Is the risk-benefit ratio reasonable?
Consider the Study Design ...

Patients >18yrs admitted to ICU

MLA
(experimental)

Monitoring for SIRS criteria
(standard care)
Consider the Study Design ...

Patients >18yrs admitted to ICU

- MLA (experimental)
  - Monitoring for SIRS criteria (standard care)

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Note: Additional findings – Subparts B, C, & D
Other Relevant Considerations

Data collection monitored for safety?

Additional safeguards for vulnerable populations?
• Consideration of involvement of LARs, if needed

What about informed consent?
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Note: Additional findings – Subparts B, C, & D
PROTOCOL 2
Research Proposal

Phase II single arm trial to study the effectiveness of giving chemoradiation treatment (CRT) followed by local excision (LE) for the treatment of early T2N0 distal rectal cancer
Total mesorectal excision (TME) +/- Adjuvant chemotherapy and/or radiation therapy

Current standard

Patient with T2N0 distal rectal cancer

Proposed research

Neoadjuvant chemoradiation treatment 6-8 weeks later Local excision
You are on the IRB that has been asked to review and approve this research

Please review the protocol
Survey: What is your familiarity with informed consent for biomedical research?
(Select the response that best fit your situation)

A. I review informed consent documents regularly
B. I write or help write informed consent documents regularly
C. I work with informed consent documents to obtain consent regularly
D. I have some familiarity with informed consent documents
E. I am not familiar with them at all

20% 20% 20% 20% 20%
Required Elements of Informed Consent

1) Research Description:
   • Purpose
   • Duration
   • Research procedures

2) Risks, discomorts (if any)

3) Benefits (if any)

4) Alternatives (if any)

5) Confidentiality (extent, if any)

6) Compensation for injury

7) Whom to contact

8) Voluntariness and right to refuse or withdraw without penalty

§46.116(a)
• Discussion points
Have you ever been asked for your consent to participate in a biomedical research study with a treatment intervention?

A. Yes
B. No
Research Protocol on Rectal Cancer Treatment

• Who is the target population?
• What do you think may be the key concerns for this target population?
  • If you were the patient, what would be the crucial piece of information that you would need to make a decision about participation?
You have early stage cancer in the rectum and you need treatment

**Standard treatment**

- Involves an operation through the abdomen to remove the rectum and the surrounding tissues. This may be the only treatment needed and gives very good control of the disease with a high cure rate (90% of patients remain disease free in 5 years).
- But the operation can lead to complications and even deaths in up to 6% of patients, possibility of a permanent colostomy, and long term problems including sexual and urinary dysfunctions and fecal incontinence in as many as 30% of the patients.

So if what is *most* important to you is to avoid recurrence, then this may be your preferred choice.
This research study

- Offers possibility of a smaller operation without entering the abdomen, and minimizes chances of needing a colostomy. It may also reduce the chance of problems of sexual and urinary dysfunctions and fecal incontinence.
- But everyone gets chemoradiation treatment before surgery. There are notable side effects with chemoradiation.
- It is not known if the research treatment will treat the disease and prevent recurrence as well as standard treatment.

So if what is *most* important to you is to have less major operation, or to increase chances of preserving current functions, then this may be your preferred choice.
Do you think that the information in the last 2 slides was clearly conveyed in the informed consent document we “developed” earlier?

A. Yes
B. No
If you were the patient asked about joining the clinical trial, would this be information that you would want to help you make a decision about participating in the research?

A. Yes
B. Possibly
C. No
D. Not sure
THANK YOU FOR PARTICIPATING IN TODAY’S DISCUSSION