HOW TO APPLY THE MULTIPHASE OPTIMIZATION STRATEGY (MOST) IN YOUR INTERVENTION DEVELOPMENT RESEARCH

Module 5

Responsible conduct of intervention optimization research

Lesson 4: Informed consent in a factorial optimization trial

NYU SCHOOL OF GLOBAL PUBLIC HEALTH

Intervention Optimization Initiative

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In the previous lesson you learned how to:

- Plan an optimization trial when the outcome of interest is far in the future

In this lesson you will learn how to:

- Develop appropriate informed consent procedures for a factorial optimization trial

The Institutional Review Board (IRB)

- An institutional body responsible for:
  - Ensuring ethical conduct of research
  - Mitigating potential risks to participants,
    - Physical and psychological well-being
    - Confidentiality, privacy, and autonomy
- Protects the rights and welfare of human research subjects
- May also be known as: independent ethics committee, ethical review board, research ethics board, etc.

IRB approval for a factorial experiment…

- Is not dissimilar to what one would encounter in a standard 2-arm RCT
  - Designated as human subjects research
  - Informed consent

- Careful consideration of the comparison condition
  - Where experimental design meets consent
  - Participant burden (i.e., time of participation)

Everything you know about IRBs from your basic research methods training holds true.

The IRB & the factorial experiment

- May require educating the institutional review board to some degree
  - Provide details about the experimental design to justify experimental procedure

- By default, more experimental conditions to explain

Informed Consent in a Factorial Experiment: Participant

- Participants need to know what they can expect
  - "You may receive a combination of components …"

- Your IRB may require more detail
  - For example, you may be asked to describe all of your experimental conditions (even if its 32!)

Informed Consent Example 1

- Suppose you are enrolling participants in an intervention based upon a clinical diagnosis
  - Randomization occurs once consented (or after baseline)

- In this case, you'll explain all of the experimental conditions to some degree:
  - *"All participants will receive weight loss treatment, and will be randomized assigned to receive a different combination of the following factors..."*

Informed Consent Example 2

- itMatters study (R01 AA022931; PI Collins)
- All first year college students were randomized into the 32 experimental conditions
  - Access to the intervention was available regardless of participation in the research
  - Access to all content after research
- Participants gave informed consent to participate in the surveys

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Informed Consent Example 2

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- "Your university is implementing itMatters with all the freshman on your campus. itMatters is a web-based program aimed at the relationship between alcohol use and sexual behaviors of college students. ItMatters includes lessons that address normative perceptions, expectancies, knowledge, perceived benefits, and self-efficacy related to alcohol use and sexual activity by first-year college students. In addition to itMatters, you will be invited to voluntarily complete three, 10-15 minute web-based surveys."

Best practices

- Provide participants (and those responsible for recruitment) with a handout to help explain the technical elements of the informed consent document

- Really not that different from how you would acquire informed consent in an RCT

In this lesson you learned how to:

- Develop appropriate informed consent procedures for a factorial optimization trial

In the next lesson you will learn how to:

- Enter an optimization trial into a clinical trials registry (such as ClinicalTrials.gov in the US)