So…what if clinical decision software is defined as a device?

P. Pearl O'Rourke, MD
C-chair, Ethics and Regulatory Core

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

FDA Device Regulations

- Category of device
  - Regarding need for an IDE
    - Investigational Device Exemption
      - Exempt from laws prohibiting unapproved products in interstate commerce
  - Determines oversight and review
- Informed consent requirements

Categories

For research assessing safety or efficacy of a medical device

21 CFR 812

- Exempt from IDE Requirements
- Subject to IDE Requirements
  - Significant Risk
  - Non-significant Risk

Device Studies

- Studies subject to IDE requirements
  - Significant Risk → **FDA & IRB Approval**
  - Non-significant Risk → **IRB Approval****
- Studies exempt from IDE requirements* → **IRB Approval**

* 7 specific categories
  - 3rd category re: diagnostic device:
    - Noninvasive
    - Has confirmation by another established product or procedure

** IRB is surrogate for FDA

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Informed Consent

- Before July 25, 2017
  - Informed consent (almost) always required
    - Limited exceptions (e.g., life-threatening situations and emergency research) 21CFR50.23 and 24
- 21st Century Cures Act – Dec. 13, 2016
  - Provided authority for FDA to permit an exception from IC requirements, allowing a waiver when research determined to be minimal risk. Pub.L. 114-255. Title III.3024

FDA Guidance: July 25, 2017 (82 FR 34535)

For immediate implementation

- Institutional Review Board Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects (82 FR 34535)
- Minimal risk requirements:

1. The clinical investigation involves no more than minimal risk;
2. The waiver or alteration will not adversely affect rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Summary

- If clinical decision software is defined as a device…
  - FDA regulations apply
  - Determination of device category will inform the review
  - Since July 25, 2017, for minimal risk research, a waiver of consent is allowed