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

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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
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.
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