Studies Involving a Device: INSPiR Submission Instructions

Is the device being used as part of the research FDA approved?

Yes

Per FDA Label

Is the device the focus of the study?

Yes

(E.g. randomizing subjects to 2 FDA approved devices)

No

(e.g. MRI, blood pressure cuff, EKG)

No further device information needed

- Sect. P- Check FDA approved device per indication & manner prescribed
- Sect. S- Attach available device information (i.e. device brochure, marketing materials, and safety information)
- Consider whether signoff by biomedical engineering is needed

No

Not per FDA Label or customizing or combining the FDA approved device with another device/drug

Testing the safety and effectiveness of device?

Yes

Sect. P:
- For FDA approved devices being used off label, check experimental use of an approved device
- For non FDA approved devices, custom or combination devices, check Experimental device

- Sect. S: Attach picture, safety information, device brochure, specifications
- Consider whether signoff by biomedical engineering is needed

- Investigational Device regulations apply [IDE]-see flow chart

No

No

Device not under investigation yet using in research (e.g. eye tracking device)

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