Investigational Device Study: Significant Risk or Non Significant Risk?

The sponsor or sponsor-investigator first determines whether the study involves a **Non Significant Risk (NSR)** or **Significant Risk (SR)** device.

- **No, NSR**
  - Sect. P-Describe how the device meets all 4 criteria for **NSR**
  - Sect. S- Provide any supporting documentation (e.g. summary report of previous investigations, an independent source verifying that the device operates within safe guidelines, safety data, pictures, FDA determination if applicable, etc.)
  - Consider whether signoff by biomedical engineering is needed
  - Submit for IRB review

- **Yes, SR**
  - IDE# assigned by FDA
    - Sect. P- IDE #
    - Section S- Attach investigational device brochure, safety information, pictures
    - Consider whether signoff by biomedical engineering is needed
    - Submit for IRB review

- **No IDE #**
  - Convened IRB makes a Non Significant Risk Determination or acknowledges FDA NSR determination if applicable
    - **Abbreviated IDE Regulations Apply**
  - Convened IRB Determines that PI needs to contact the FDA to see if IDE indicated
  - Submit IDE application to FDA to see if IDE indicated
    - May simultaneously submit for IRB Review (investigational device brochure, safety information, pictures); however the FDA IDE approval letter is needed prior to IRB approval for SR studies.

- **NSR device**
  - No IDE
    - Sect. P- Complete justification for NSR
    - Sect. S-attach FDA letter indicating NSR determination
      --provide any supporting documentation (summary report of previous investigations, an independent source verifying that the device operates within safe guidelines, safety data, pictures, etc.)
    - Consider whether signoff by biomedical engineering is needed
    - Submit for IRB review

- **FDA determines**
  - IDE required
    - PI receives IDE #
      - Sect. P- IDE #
      - Sect. S- Attach FDA IDE approval letter
      - Consider whether signoff by biomedical engineering is needed
      - Submit for IRB review

3-8-2007