CHOPtimize at The Children’s Hospital of Philadelphia received a request for IRB approval of the (Insert Project Name). We are seeking your support in moving forward with the analysis of this project. We are requesting that you provide the following information:

* Product Opportunity
  + Purpose of the product
  + Product brochure
  + Instructions for Use (IFU) & contraindications
* Infection Prevention & Control
  + Is the product single patient use or disposable (one time use)?
  + Can the product be cleaned with a hospital approved disinfectant?
  + Provide cleaning and care instructions if not contained in the IFU.
* Biomedical Engineering
  + Please provide one Operator’s Manual and one Technical Manual (electronic version is acceptable)
  + What are the available options for technical training? Include on-site and factory.
  + How long has the product been available for sale?
  + What is the 510(K) number?
  + Would you be able to provide a device to Biomedical Engineering for evaluation?
  + What service options / warranties available? (if applicable)
* Risk/Legal
  + Is the product MR Safe, MR Conditional or Non-Safe?
    - If Conditional, please list the conditions.
* Information Services
  + Does the product gather Protected Health Information (PHI)?
  + Does the product interface with other systems? If so, please list them & provide compatibility information / systems requirements.
  + Does the product require the use of a cloud-based system?
  + If applicable, please provide MDS2 form.