



# Connected Sensors

## Introduction

Connected sensors include technology products such as wearables, sensors, and other connected devices (e.g., spirometers and continuous real-time glucose monitors) that can be connected to the internet. These mobile sensors capture and process data using algorithms to generate measures of behavioral and /or physiological function.

Note: this section should be used in conjunction with the section on Devices (smartphones and tablets).

## Questions for IRBs/ECs to Consider

- Is an investigational testing authorization by the health regulatory authority required for the sensor? (In the US: is the study exempt from investigational device exception (IDE) regulations?)
- What is the purpose of the sensor being used?
  - How is the device classified?
  - Is the sensor an investigational medical device in the study?
    - For instance, in the US, is it a Significant Risk (SR) or Nonsignificant Risk Medical (NSR) device?
  - Is the sensor validated for the purpose and population for which it is being used?
  - What data is the sensor collecting?
  - If the sensor is being used to monitor an at-risk participant group, consider:
    - How often will the study team review sensor data?
    - Will the study team be able to intervene in a timely way if abnormal vital signs or findings are detected by the sensor?
    - Note: data that may trigger the need for timely intervention may relate to blood pressure, heart rate or rhythm, or other vital functions, but may also relate to other types of data such as suicidality, depression, etc
- Where is sensor data stored?
  - If a third-party vendor is involved in studies using connected sensors, does the vendor have access to the data?
  - Is any potential re-use by the vendor defined and clearly stated in the informed consent document?
    - Is such re-use compliant with relevant legislation and requirements for ethical approval?
  - Is the third-party vendor a business associate or contracting party required to maintain privacy and confidentiality? If not, what provisions are in place for protecting participant privacy and confidentiality?
  - Are there additional applicable contractual agreements that should be considered?



- What, if any, burden does the sensor impose on the participant?
  - If the sensor is required for trial participation, are participants provided with appropriately administered and documented instructions to properly use the sensor?
  - Do trial participants need access to a 24/7 call center to troubleshoot issues with the sensor as they arise? If not, how likely will the lack of assistance cause meaningful risks to patient safety or data quality?
- Will the sensor be collected at the end of the study?
  - Optimally, the value of the sensor will be depreciated over the course of the study, and sensor return will not be required. If return is not required, will the sensor be cleaned or wiped to remove personal research data?
  - Are there processes in place that make sensor return as simple as possible for participants?
  - While rare exceptions are possible, there should be no financial or other penalties for lost or broken sensors.