# Devices in Research

*Instructions: Please submit this supplemental form if your research procedures involve the use of a device product. A device product might be any of the following: instrument, machine, implant, software application, algorithm, in-vitro diagnostic, lab developed test, in vitro reagent, assay, or other similar or related article or component, part, or accessory.* ***ALL SECTIONS OF THIS FORM SHOULD BE COMPLETED.***

*For additional guidance, please see:* <https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research> *under Research with Device Products*

# SECTION A: DEVICE PRODUCT BACKGROUND INFORMATION

1. What is the name of the device product?
2. What type of device product is being used? (e.g., MRI, fitness tracker, software, etc.)
3. Device Manufacturer/Developer:
4. Where or from whom is the device being obtained?

*Please explain if this device is a clinical device being used for research purposes, a device borrowed from another Penn Faculty, a device being purchased directly from the manufacturer, a device on loan from the manufacturer, etc.*

1. **Please upload device manuals and/or instructions for use from the device manufacturer into HSERA for IRB review.** If these are available online, you may include weblinks here as an alternative to uploading:

*Note: This document should outline indications for device use, any instructions for the investigator administering the product, and/or any instructions for subject, as well as any applicable warnings/contraindications.*

# SECTION B: MARKETING

1. Is the device product legally marketed in some way?
   1. The device is commercially marketed *(e.g., Fitbit or other general wellness devices).*
   2. Marketed as a **medical device**\* in the U.S. ([510K exempt](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm), [510K cleared](http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda), [PMA](http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda), [HDE](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm)).

**Please upload marketing documentation into HSERA, or provide a weblink to the documentation here:**

\*A [medical device](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm) is:

* recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, OR
* **intended** **for** use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment, or prevention of disease**, in man or other animals, OR
* **intended to affect the structure or any function of the body** of man or other animals."
  1. Not yet marketed in the U.S.
     1. If not marketed: is the device product a novel device with no predicate*?*

*A predicate is a medical device that may be legally marketed in the U.S. and is used as a point of comparison for new medical devices.*

No  Yes

* 1. Are there any plans to market the device product or update the marketing of the device product?

No  Yes

# SECTION C: USE OF THE DEVICE PRODUCT

1. Is the device product the subject\* of the investigation? In essence, are any of the primary or secondary objectives outlined in the protocol investigating the device product? *\*Note: If a device product* *is being validated, this question should be answered Yes. If the purpose of the protocol is to evaluate the safety and/or effectiveness (or predictive ability) of a device product, the question should be answered Yes.*

No  Yes

1. Intended Use
   1. What is the intended use of the device product in general? *(Note: this can be found in the product manual, brochure, and/or the marketing documentation. If not marketed, please refer to the investigator’s brochure or consult with the manufacturer.)*
   2. What is the intended use of this device product **on the current protocol?**
      1. Is the device product being used for an indication not previously evaluated by the research team, FDA, or in peer reviewed research literature?

No  Yes

1. Is the device product undergoing any of the following?
   1. consumer preference testing,
   2. testing of a modification,
   3. testing of a combination of 2 or more commercially available devices
2. Is the device product a custom device?

*Guidance: A custom device is created or modified in order to comply with the order of an individual physician or dentist (or other specially qualified person). It is not generally available in finished form through labeling or advertising by the manufacturer. It is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat. It is intended to either meet the special needs of a physician or dentist in the course of their professional practice OR* ***intended for use by an individual patient*** *named in the order of a physician or dentist.*

No  Yes

1. Is the device product a diagnostic device? (e.g., MRI, In vitro diagnostic, lab developed test, genetic testing, assay, ultrasound, etc.)

No  Yes

1. Are ALL of the following TRUE? The device product and/or the testing…

* Is noninvasive, and
* Does not require an invasive\* sampling procedure that presents significant risk, and *(\*e.g., a biopsy for research purposes)*
* Does not by design or intention introduce energy\* into a subject, and *(\*e.g., sound, light, magnetism, radiation, biofields)*
* Is not used as a diagnostic procedure\*\* without confirmation of the diagnosis by another, medically established diagnostic product or procedure (*\*\*Diagnostic procedure means that either the results are returned to participants, OR the results are placed in the medical record, OR their care will change based on the results of the test/device.)*

No

Yes 🡪 Please describe the medically established product or procedure used to confirm the diagnosis:

# SECTION D: DEVICE PRODUCT RISK ASSESSMENT

*The risk assessment is based on the* ***proposed use of a device product on a protocol****, and* ***not on the device product alone****. Identify device product**hazards and potential risks associated with exposure to those hazards. Consider the likelihood (probability) of the risk as well as the consequences and severity of the risk. Consider the potential harm caused by any* ***device product related procedures as well as the device****.*

1. Is the device product an implant*?*

No  Yes

1. Will the device product be used to support or sustain human life?

No  Yes

1. Will the device product be used to diagnose, cure, mitigate, or treat disease, or otherwise prevent impairment of human health?

No  Yes

1. Does the device product present a potential for serious risk\* to the subject?

*\*Serious risk is defined as: Any risk associated with the device product that adversely affects the health or safety of a participant that could be life-threatening, or cause death, hospitalization, disability or permanent damage, congenital anomaly/birth defect, or require a medical / surgical intervention to prevent permanent impairment or damage, or any other serious medical event that may adversely affect the safety or welfare of subjects. For more details, please reference the FDA definitions of a serious adverse event.*

*Devices that may be considered to present serious risk could include but are not limited to:*

* ***A novel device product with no predicate*** *(a predicate is a medical device that may be legally marketed in the U.S. and is used as a point of comparison for new medical devices)*
* *A device product* ***used for an indication not previously evaluated*** *by the research team, the FDA, or peer review, without medical and or scientific rational justifying the safety of the device(s)*

***Rationale is required if the response to this question is no.***

No, please explain and discuss the risks of the proposed use of the device product(s) in this protocol. Please do not re-state what is in HSERA or the protocol. This assessment should be specific to the device product, AND should explain how the device product does not meet the definition of serious risk outlined above:

Yes

*If this study is not determined to be exempt from IDE regulations by the IRB, Penn Medicine Office of Clinical Research, or the FDA,* who will hold the IDE (i.e., who will be the IDE sponsor and be responsible for study oversight)?

Device Manufacturer/Developer:      . *If the protocol is investigator-initiated (drafted by a Penn faculty), please upload confirmation of manufacturer sponsorship from the manufacturer in HSERA.*

Penn Principal Investigator

Other (e.g., another Penn Faculty or individual at another institution):

1. If this is a significant risk device, please provide the IDE number issued by the FDA (if pending, indicate this):

**If questions 13 through 16 are ALL answered No, and the IRB agrees with the rationale provided, the use of the device on the protocol qualifies as a non-significant risk device. This means that abbreviated IDE regulations apply if the study has not been determined to be exempt from IDE regulations by the IRB, Penn Medicine Office of Clinical Research, or the FDA.** An application to the FDA is probably not required. A guidance document on abbreviated IDE requirements is available online [here](https://irb.upenn.edu/sites/default/files/Abbreviated%20IDE%20Requirements%2002Feb2020clean.pdf).

**If you answered YES to at least one question in Section D: This means that IDE regulations apply, and an application to the FDA may be required.** If you need guidance or assistance on submitting to the FDA, please contact the Penn Medicine Office of Clinical Research Sponsor Support Unit: [www.med.upenn.edu/ocr/sponsor-support-unit.html](http://www.med.upenn.edu/ocr/sponsor-support-unit.html)