## 7-2. Special Consideration - Continued

Hide Help

**7-2.1* Will any devices be used, administered, implanted, or applied to the subjects, or will human specimens be used to test in vitro diagnostic devices? [IRBMED Applications Require Section 16]**

Devices can be medical or non-medical and may include software, AI-generated devices, monitoring/alert software, mobile apps, wearable devices, decision support tools, diagnostic software as well as other equipment such as cardiac stents, robots, hospital beds, treadmills, and diagnostic tests (e.g. imaging, specimen collection kits, laboratory tests).

○ Yes ● No Clear

**IRBMED**

A medical device is something that is used for diagnosis, mitigation, cure, prevention, or treatment of disease in humans and that does not work through chemical action for metabolism within the human body.

Medical devices, with certain exceptions, used in association with Michigan Medicine for clinical and/or research purposes MUST be tagged by Clinical Engineering. Please contact the Clinical Engineering Call Center at 734-936-5056 *if you have a question regarding if device(s) must be inspected and tagged.*

See IRBMED Statements of Practice webpage for guidance on how to complete section 16 of the application.

If you are unsure about how to list your device in Section 16 contact the Michigan Institute for Clinical & Health Research (MICHR) IND/IDE Investigation Assistance Program (MIAP) at MICHRMIAP@med.umich.edu.

**IRB-HSBS/Dearborn/Flint**

For most studies under IRB-HSBS/Dearborn/Flint, a device may not meet the FDA definition of a medical device. However, the use of medical devices for data collection purposes only must be documented (e.g., cold-pressor test, BP cuff, galvanic skin response, EEG, etc.). The use of the medical device must be limited to a function for which it was designed and may not be the object of the research (i.e., not testing the device). For IRB-HSBS/Dearborn/Flint, only items 7-2.1 and 7-2.1.1 must be completed.

HSBS only - 'yes' to 7-2.1 triggers 7-2.1.1 and does NOT trigger Section 16.

**7-2.1.1* Describe all devices that are the OBJECT of the study, or ARE RELEVANT to the study. If this study is designed to test the safety or efficacy of any of these devices, then this project is FDA-regulated and must be reviewed by IRBMED.**

**7-2.2* Is the research testing or utilizing a health-related mobile software application that is:**

- Designed for a handheld (e.g., smartphone) or wearable mobile device (e.g., exercise tracking), or
- Tailored to a mobile platform (i.e., a handheld commercial or off-the-shelf computing platform, with or without wireless connectivity) but executed (run) from a server

**and the mobile software application/platform performs any of the following:**

- Uses a built-in feature of a device such as light, vibration, or camera to perform a medical device function.
- Connects or links to an existing device to control its operation, function, or energy source.
- Uses patient-specific data from a connected device including a sensor or electrode to monitor, manipulate, calculate, or analyze information.
- Conveys diagnostic information, or provides education materials or encouragement.
- Performs calculations, conversions, measurements or interpretations.

● Yes ○ No Clear 'Yes' activates highlighted note below, and activates 7-2.2.1.

**Note: If there is intent to introduce the mobile medical app into commercial distribution or to publish via an app store (e.g., Google or Apple), you must contact Innovation Partnerships at 734-763-0614 or um-software@umich.edu to discuss licensure and U-M branding.**

**7-2.2.1* Is the mobile technology intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease)? If so, it is a medical device, regardless of the platform on which it is run. [IRBMED Applications Require Section 16]**

Intended use is shown by how the device is represented or described in the protocol, recruitment materials, informed consent documents, labeling claims, advertising

○ Yes ● No Clear 'No' activates 7-2.2.2.

Exit Save Continue

**7-2.2.2* Describe the health-related mobile software application and its intended use.**

Note for applications routed to IRB HSBS/Dearborn/Flint: If the review determines this to be an FDA-regulated medical device, IRBMED review will be required.

**7-2.3* Will the subjects be exposed to any ionizing radiation during the course of this study? [Require Section 21]**

For example, x-rays, CT-scans, PET-scans, beta-rays, gamma-rays, neutrons, and other high-speed atomic particles. Magnetic Resonance Imaging (MRI) is NOT ionizing radiation.

(●) Yes ( ) No Clear

'Yes' activates 7-2.3.1.

**7-2.3.1* Will radiopharmaceuticals be administered to subjects as part of this study? [Require Section 15]**

( ) Yes (●) No Clear

**7-2.4* Will any organs, tissues, or cells from humans (including fetal tissue) or animals be administered to the subjects for the purposes of this study? [Require Section 22]**

( ) Yes ( ) No Clear

**7-2.5* Does this study involve human gene transfer, which is the deliberate transfer into human subjects of either recombinant or synthetic nucleic acid (DNA or RNA) molecules that meet any one of the following criteria:**

- Contain more than 100 nucleotides
- Possess biological properties that enable introduction of stable genetic modifications into the genome
- Have the potential to replicate in a cell
- Can be translated or transcribed

**Examples of studies that likely involve human gene transfer include:**

- Administration of a recombinant viral vector, regardless of its ability to replicate
- Administration of mRNAs that encode proteins e.g. mRNA vaccines for cancer or infectious agents
- Administration of CRISPR components to participants for gene editing
- Ex vivo genetic modification of patient-derived cells (e.g. CAR-T cells) that are then reintroduced into humans

**[Require Section 23]**

The U-M Institutional Biosafety Committee (IBC) reviews all protocols involving human gene transfer at U-M. The IBC serves in an ancillary role to the IRB and its review is completed before IRB review.

The U-M does not cede IBC review to a central IBC.
Note: IBC review is required for studies using an FDA-approved human gene transfer product if that product is being used for a different disease/condition than that for which it was FDA-approved.

( ) Yes ( ) No Clear