

## Sections 15 and 16 of IRB Application

**Effective:**        **May 26, 2017**

### **What Agents/Articles must be listed in Sections 15 and 16 of the IRBMED eResearch application?**

**Note:** This document outlines IRBMED recommendations for completing the eResearch application. Other committees may make additional requirements.

**Note:** Agents/articles which are standard of care procedures or assessments utilized as part of the research study should not be listed in Sections 15 or 16.

#### **I.        STATEMENT OF PRACTICE**

The primary purpose of eResearch Sections 15 (Drugs, Biologics) and 16 (Devices) is to capture information about investigational agents/articles that may be governed by an IND or IDE and to collect appropriate documentation which allows the IRB to determine regulatory decisions with respect to submissions utilizing investigational drugs, biologics, or devices. It is IRBMED's expectation that all investigational agents/articles will be appropriately listed in these sections.

#### **II.        PROCESS**

Sections 15 and 16 of the IRB application are mainly divided into three categories:

- 1) Not approved by FDA, Investigational (may require an IND for drugs or an IDE or SR/NSR determination for devices)
- 2) FDA Approved On-label
- 3) FDA Approved Off-label (may be exempt or require an IND for drugs or IDE or SR/NSR determination for devices)

#### **Section 15, Drugs/Biologics/Other Materials:**

Agents/articles that are the OBJECT of the study are listed into Section 15 of the IRB application with the appropriate FDA approval designation. This includes biologics, nutritional products, or other materials not traditionally considered to be a drug that will be used as the object of the study. For example, if a food product is the object of the study, it should still be listed in Section 15 even though it does not meet the FDA definition of a drug.

Agents/articles that are NOT the OBJECT of the study should be described and referenced in the protocol document, the risk section of the application, and in the informed consent document (ICD) as appropriate. For example, a 'research-only' biopsy using a local or topical anesthetic does not require listing the anesthetic in Section 15, but information about the use of the anesthetic must be included in the protocol, and associated risks of the anesthetic should be described in the protocol, the application, and in the ICD.

### Sections 15 and 16 of IRB Application

#### **Section 16, Medical Devices:**

Medical Devices that are the OBJECT of the study are listed in Section 16 of the IRB application with the appropriate FDA approval designation.

Devices that are NOT the OBJECT of the study should be described and referenced in the protocol document, the risk section of the application, and in the informed consent document, as appropriate. For example, if an ultrasound is performed as part of a research protocol, and is not the object of the study, but rather a procedure used for the research, it should be described in the protocol, risk section, and consent as necessary, but should not be included in Section 16.

If an “approved medical device used on label” is included in Section 16 of the IRB application, this section of the application itself provides questions which specifically ask if the medical device is the object of the study. As long as the study team indicates it is NOT the Object of the study, the medical device may remain in the application, but the IRBMED preference is that these types of devices not be listed in Section 16. We will not require its removal as long as it is appropriately designated.