

**Human Biomedical Research (Requirements for Appropriate Consent —  
Exemption) Regulations 2019**

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**No. S 703**

**HUMAN BIOMEDICAL RESEARCH ACT 2015  
(ACT 29 OF 2015)**

**HUMAN BIOMEDICAL RESEARCH  
(REQUIREMENTS FOR APPROPRIATE CONSENT —  
EXEMPTION) REGULATIONS 2019**

In exercise of the powers conferred by section 63 of the Human Biomedical Research

Act 2015, the Minister for Health makes the following Regulations:

### **Citation and commencement**

1. These Regulations are the Human Biomedical Research (Requirements for Appropriate Consent — Exemption) Regulations 2019 and come into operation on 1 November 2019.

### **Exemption from need for witness to research subject's consent**

2.—(1) The requirement in section 6(*d*) of the Act that appropriate consent must be obtained in the presence of a prescribed witness does not apply to the appropriate consent of a research subject where the research —

- (a) is not invasive;
- (b) is not interventional; and
- (c) is not restricted human biomedical research.

(2) For the purposes of paragraph (1), research that comprises solely of a survey or collection of information from the research subjects is treated as not invasive and not interventional.

(3) Despite paragraph (1), the requirement in section 6(*d*) of the Act that appropriate consent must be obtained in the presence of a prescribed witness does not apply to the appropriate consent of a research subject where —

- (a) the research is interventional but the intervention involves no more than minimal risk to the research subject;
- (b) the research subject is able to read and sign the appropriate consent form; and
- (c) the research is not restricted human biomedical research.

(4) The requirement in section 6(*d*) of the Act does not apply to any consent to human biomedical research given by a research subject before 1 November 2017.

(5) In this regulation, research is interventional if the research involves subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual.

### **Exemption from need for witness to tissue donor's consent**

3.—(1) The requirement in section 6(*d*) of the Act that appropriate consent must be obtained in the presence of a prescribed witness does not apply to the appropriate