

# Sections 12(1) and (2) HBRA appropriate consent elements

❖ 15 consent elements applicable to HBR research participants under Section 12(1)

❖ 17 consent elements applicable to tissue donors under Section 12(2)

12(1)(a) **Investigational nature** of the HBR

12(1)(b) **Purpose** of the HBR

12(2)(a) **Specific research purpose** if available, otherwise general research purpose

12(2)(b) Whether the tissue will be **used for any purpose other than research** and if so, the specific purpose for which the tissue will be used

12(1)(c) **Reasonably foreseeable risks, discomforts or inconveniences** to the living research subject

12(2)(d)

12(1)(d) **Benefits** which subject may reasonably expect

12(1)(h) Extent to which information identifying the research subject will be kept **confidential**

12(2)(i)

12(1)(k) Whether **individually-identifiable information** of the research subject is involved

12(2)(m)

12(1)(n) Research subject or authorised person's **right to withdraw** consent to further participation in the research

12(2)(f) Similar right for tissue donors, provided tissue is individually-identifiable and has not been used yet/has been used but practicable to discontinue further use

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**12(1)(e)** Where applicable, any available **alternative procedures or treatments** and the potential benefits and risks of such alternatives

**12(1)(f)** Any **compensation and treatment** available to the research subject **in the event of injury** from participation in the research

**12(2)(g)** Similar right to be informed if any compensation and treatment is available for injury, in relation to tissue donation process

**12(1)(g)** Any **anticipated expenses** the research subject is likely to incur as a consequence of participating in the research

**12(2)(h)**

**12(1)(i)** Whether individually-identifiable information obtained from the research subject will be **used for future biomedical research**

**12(2)(j)**

**12(1)(j)** Where applicable, whether **biological material** taken from the research subject will be **destroyed, discarded or stored for future biomedical research**

**12(2)(k)**

**12(1)(l)** The circumstances, if any, under which the research subject or authorised person will be **contacted for further consent** e.g. SAE, change in proposed research

**12(2)(l)**

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**12(1)(m)** Whether the research subject would wish to be **re-identified** in the case of an **incidental finding** if the research expressly provides for such re-identification

**12(2)(o)**

**12(1)(o)** The **person or persons to contact** to obtain further information on the research and to provide feedback in relation to the research

**12(2)(p)**

**12(2)(c)** The proposed areas of research approved by the institutional review board in a case where it has **waived the requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose** under section 37(3)

**12(2)(e)** **Voluntary donation** of the tissue and the **renunciation of the donor's rights to the tissue and any intellectual property rights** that may be derived from the use of the tissue

**12(2)(n)** Whether the tissue will be used in **restricted human biomedical research** involving human-animal combinations

**12(2)(q)** Whether the tissue will be **exported or removed** from Singapore to a place outside Singapore