CHICKEN SOUP FOR THE BUSY COORDINATOR

Nov 2018

HUMAN BIOMEDICAL RESEARCH (EXEMPTION) REGULATIONS 2018 & APPROPRIATE CONSENT REQUIREMENTS

YOU ARE STRONGLY ADVISED TO READ THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA) 2015, THE HBR REGULATIONS 2017 AND HBR (EXEMPTION) REGULATIONS 2018 IN FULL TO OBTAIN A BETTER UNDERSTANDING OF THE REGULATORY REQUIREMENTS

The Human Biomedical Research Act (HBRA) savings and transition period has ended on 31 Oct 2018. Today, all human biomedical research must comply to HBRA and its Regulations. Here are the salient points from the HBR (Exemption) Regulations 2018.

1) **HBR Exemption Regulations 2018 – Exemption from appropriate consent if biological material or health information obtained before 1 November 2018**
   This new Regulation provides an exemption for studies that had obtained individually identifiable biological material or health information before 1 Nov 2018 AND are no longer obtaining new individually identifiable biological material or health information from 1 Nov 2018, from the need to obtain appropriate consent. The waiver ends 31 Oct 2019.

2) **HBR Exemption Regulations 2018 – Exemption from appropriate consent if the ethics committee waived consent before 1 November 2017**
   HBR studies granted a waiver of consent by the IRB before 1 Nov 2017 are exempted from appropriate consent. However, if the study continues beyond 31 Oct 2019, researchers will need to (1) Seek waiver of consent again from the IRB, (2) Obtain appropriate consent in accordance with HBRA, or (3) De-identify human biological material (HBM)/ health information (HI).

3) **HBR Informed Consent Elements for "Appropriate Consent" (HBRA 2015, Part 3, Section 12)**
   All elements (except for 12(1e) and 12(1j) which may be applicable to some studies and can be omitted if not applicable) of the HBRA consent requirements must be present in the informed consent form (ICF) to make it "Appropriate Consent". This means that an element such as 12 (1m) "*whether the research subject would wish to be re-identified in the case of an incidental finding if the proposed biomedical research expressly provides for such re-identification*" MUST be included as a point in the ICF. For all HBR (including questionnaire studies), there must also be a statement on available compensation and treatment to the subject in the event of injury (Element 12(1f)).

IMPLICATIONS:

If you are conducting HBR studies, you are strongly advised to:

1) Review your informed consent form (ICF) [*Refer to www.research.nhg.com.sg > Home > Resources > Ethics Forms and Template for the updated NHG DSRB ICF Template]*
2) Submit the ICF to the IRB for approval (if needed)
3) Use "Appropriate Consent" ICF to consent subject before the next subject intervention and/or obtaining individually identifiable subject HBM/HI
4) Ensure a witness is present during consent taking

Note: According to the HBRA (HBRA 2015 Part 3, HBR Regulations 2017, Part 4 Sections 25 & 26), "Appropriate Consent" must be obtained:

✓ *In writing;*
✓ *from the research subject personally or his/ her legal representative (as applicable);*
✓ *full explanation provided to the research or persons authorized to give consent on behalf and,*
✓ *in the presence of a witness.*

CONTRAVENTIONS

Researchers and research staff who conduct HBR must ensure that they comply with the applicable regulatory requirements. Contraventions under the HBRA and its applicable regulations are criminal offences and would result in fines or imprisonment or both, subject to the nature of the offence.

For queries pertaining to HBRA, readers are encouraged to write to their Research Institution (RI) point- of- contact.

Reference:

- Human Biomedical Research (Exemption) Regulations 2018 (https://sso.agc.gov.sg/Act/HBRA2015)
- NHG Research Website (http://www.research.nhg.com.sg > Home > Who can be a Principal Investigator > Human Biomedical Research Act
- Human Biomedical Research (Exemption) Regulations – Frequently Asked Questions (FAQs) (http://www.research.nhg.com.sg > Home > Who can be a Principal Investigator > Human Biomedical Research Act

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