CHICKEN SOUP FOR THE BUSY COORDINATOR

JULY 2018

REMINDER: RECONSENTING FOR HBR STUDIES EXTENDING PAST 31 OCTOBER 2018 INVOLVING THE USE OF INDIVIDUALLY IDENTIFIABLE DATA/ MATERIALS

In view of the HBRA regulation enforcement date from 1 Nov 2018, investigators with Human Biomedical Research (HBR) studies which will extend past 31 Oct 2018; will need to ensure that appropriate consent had been obtained for the use of individually identifiable data/ materials.

Disclaimer: This article is intended for all NHG Researchers conducting HBR studies. Recipients should adhere to their respective Research Institutions' guideline and/or policy for compliance to the HBRA regulation.

Will your HBR study:

End by 31 Oct 2018 - YES

Investigator(s) are required to: a) Submit their study completion report using the Study Status Report Form (SRF) to DSRB as soon as possible to close their study.
b) Re-consent is not required.

Extend past 31 Oct 2018 - YES

Will your study involve :

a. Subjecting an individual to further *intervention(s) **or**
b. Using **individually identifiable data/ materials**

**intervention(s) is defined as "Subjecting an individual to any intervention (including any willful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual". HBRA 2015, Part 1, Section 3(2)(i)*

Note: If your study was given a waiver of consent and will extend past 31 Oct 2018, no further action is required.

YES

Investigator(s) are required to:

a) Check if existing study ICF used is HBRA compliant.
b) Obtain re-consent by 31 Oct 2018 if existing ICF does not meet the requirements specified in HBRA.

Note: ICF amendment **must** be approved by the NHG DSRB/IRB prior to re-consenting.

NO

Investigator(s) are:

a) Not required to obtain re-consent.
b) No further actions required.

Note: Investigator(s) are to ensure that only **de-identified** data/materials are used.

Tools to assist

Investigator(s) are encouraged to use the Guidance to Determine if ICF Amendment is Required:

- ✓ Check whether your study is HBR
- ✓ Check whether your study ICF requires an amendment
- ✓ Check whether your study ICF is compliant to HBRA

Contraventions

With the enactment of the **Human Biomedical Research Act** and its **subsidiary legislations**, researchers and research staff conducting HBR are reminded to ensure that their research study complies with the regulatory requirements as stipulated in the applicable Acts. **Contraventions under any of these Acts are criminal offences and would result in fines or imprisonment or both, subject to the nature of the offence.**

For queries pertaining to HBRA, please consult your respective Research Institute. For NHG Researchers please write to NHG Research Compliance Unit (RCU) at NHGRISecretariat@nhg.com.sg.

Reference:

- Ministry of Health, Human Biomedical Research Act
- www.research.nhg.com.sg, HBRA
- NHG DSRB ICF Template v10, date 16 Jul 2018

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