CHICKEN SOUP FOR THE BUSY COORDINATOR

MAY 2020

TRANSLATED INFORMED CONSENT FORMS NO LONGER REQUIRED TO BE SUBMITTED TO DSRB

With effect from 1 June 2020, for new study applications and new study amendments (involving informed consent form changes), translated informed consent documents will not need to be submitted to DSRB for acknowledgment / approval.

The NHG Proper Conduct of Research (PCR) Standard Operating Procedure (SOP) on Informed Consent Form and Process (PCR SOP 501-C01) has been updated as follows:

[PREVIOUS] "The Investigator must submit all fully translated informed consent forms, and language versions of the Short Form Consent appended to the English language informed consent form, to DSRB for approval prior to the use of these documents. Separate sets of documents should be submitted for each translated language."

[UPDATED] "Submission of translated informed consent documents and all language versions of Short Consent Form (SCF) appended to the English ICF are not required to be submitted to the DSRB for acknowledgment / approval. The PI/Designee should ensure the accuracy of the translations and ensure that correct versions of the translated documents are used. All versions of the translated consent forms (i.e. fully translated or SCF) to be used should be tracked in the investigator file."

IMPORTANT REMINDERS for RESEARCHERS & STUDY TEAM MEMBERS

i. Researchers and study team members using translated consent documents should keep track of the various versions created and used throughout their research study. All translated documents should be verified for accuracy and completeness before it is used for subject recruitment.

   It is recommended to use an ICF tracking log (e.g. **PCR 509-017 Informed Consent Form Tracking Log**) to track information such as the version no. and date of the approved English ICF from which the translated consent document was developed, the translated document version no. and date, and the translated document verification process (e.g. verification completion date, name of individual who completed the verification).

ii. The translated consent document name (e.g. document type, version no. & date) should be consistent and included on every page of the translated documents (i.e. same document name in every page). Page no. should also be included (i.e. Page X of Y). **Example of document name: [Healthy Volunteer_ICF with Chinese SCF_V1.0_01 May 2020]**

iii. When using a translated Short Consent Form (SCF), the SCF should be appended to the DSRB approved English language ICF as a single set of document used to consent subjects. All relevant parties (i.e. subject/legal representative, consenter and impartial witness) should personally sign and date on both the English ICF and translated SCF.

NOTE: NHG staff are advised to refer to NHG SharePoint (https://mynhg.nhg.com.sg) for the latest SOPs.

Reference (via Sharepoint):

- NHG Proper Conduct of Research (PCR) 501-C01 Informed Consent Form and Process (https://mynhg.com.sg/ > Home Group Research > OHRPP > Research Quality Management (RQM) > PCR SOP and Templates)

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**Disclaimer: IRB practices or requirements for informed consent form and process may differ between different clusters/ institutions. Readers are encouraged to follow their approving IRB's policies/ guidelines relating to the above scenario/ case study.*

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