DSRB-140222: Updated DSRB Informed Consent Form Template and Assent Form Template

The DSRB Informed Consent Form (ICF) Template (207-001) and Assent Form Template (207-008) have been updated.

A summary of the changes is as follows:

Informed Consent Form Template (Version 13, dated 31 Jan 2022)

A new paragraph has been added at the end of the document to provide for the use of e-consent (i.e. use of electronic signatures). Please refer to Page 11 of the ICF Template for the statement (bolded, below the Investigator Statement). This is a generic statement and can be used in all ICFs.

Study Teams of existing studies which are using e-consent are strongly encouraged to update their ICFs to include this new paragraph.

Assent Form Template (Version 2, dated 14 Feb 2022)

Changes are made to align with the latest assent requirements and documentation. There is now a provision for impartial witness which is required if the child is unable to personally write his/her name and date in the Assent Form. Please refer to the latest Proper Conduct of Research (PCR) SOPs here for more information.

Study Teams which anticipate the use of an impartial witness are strongly encouraged to update their Assent Forms to include this new section.

With effect from **01 March 2022**, all new studies submitted to DSRB should use the latest versions of the DSRB ICF and Assent Form Template which can be downloaded from here.