

CHICKEN SOUP FOR THE BUSY COORDINATOR

<<APRIL 2022>>

Changes to Assent requirements and Documentation – How does it impact your study?

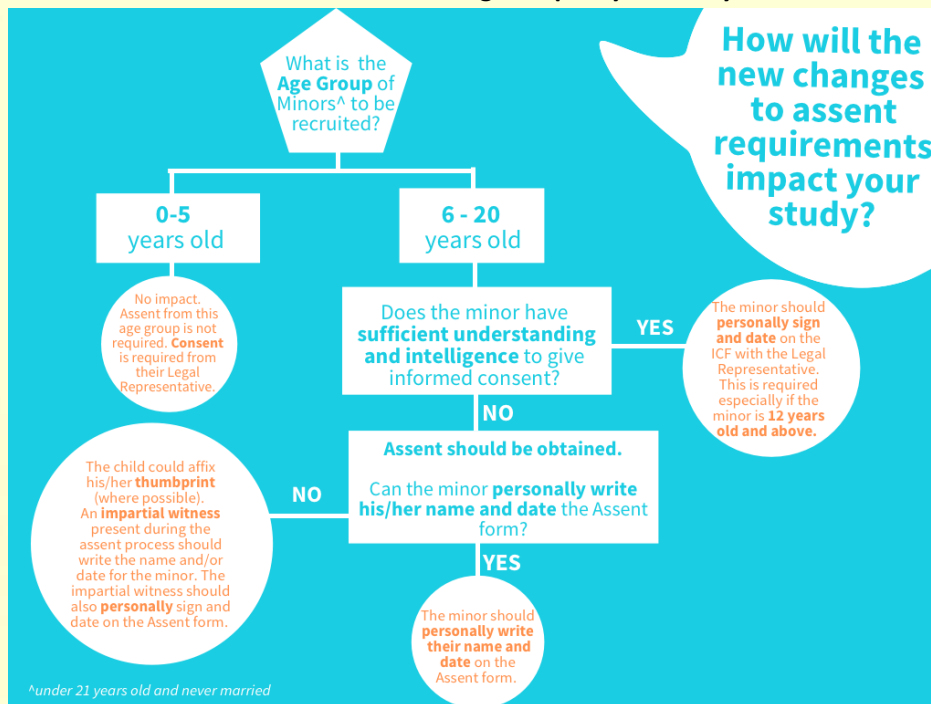
The changes to Assent requirements and Documentation are now in effect (as of **01 Mar 2022**).

In summary,

- Minors who are **12 years old and above**, with sufficient understanding and intelligence should sign the ICF together with consent from their legal representative.
- Assent should be obtained from minors who are **6 years old and above** (including those **12 years old and above** if they lack of sufficient understanding and intelligence) together with consent from their legal representative.
- Where possible, the child should **personally** write his/ her name and assent date in the assent form. If the child is unable to personally write his/ her name and/or date on the assent form, the child could **affix his/her thumbprint** (where possible). The **impartial witness** (i.e. not a member of the study team) should complete the child's name and/or assent date, personally sign and date on the assent form and an explanation should be documented in the source documents (e.g. assent form, medical records).
- It is also recommended that where possible, PIs and study teams should engage an independent assessor to determine whether the child (aged 12 years old and above) has sufficient understanding and intelligence to provide consent.

The above changes apply to all **new studies approved and ongoing studies** requiring assent to be obtained from **01 Mar 2022**. Study teams are not required to retrospectively apply the assent documentation requirements if the minor has provided assent before 1 Mar 2022.

How will the above changes impact your study?



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**Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*

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