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European Commission
Directorate General for Health and Food Safety
SANTE-B4-GL-Ethics-Minors@ec.europa.eu

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The [REDACTED] response to the EU public consultation on ethical considerations for clinical trials on medicinal products conducted with minors

The [REDACTED] is an apolitical professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 168,000 which continues to grow every year.

The [REDACTED] supports the four main changes to the document:

- Respecting the explicit refusal of a minor to participate in, or continue to participate in, a clinical trial (regardless of age)
- Greater participation of minors in a continual informed consent process
- The use of the term 'agreement' in place of 'assent' to indicate an expression of will by a minor to participate
- Adding 'burden' to 'risk' and including both in the ethical assessment of trials that have no direct benefit to young patients

Comments:

- The importance of avoiding parental separation is stressed at the beginning of the document, but it could have a greater profile along with the importance of another allocated, responsible person if the parent is not with the child – e.g. the parent has to go to care for other children. Siblings also need an explanation.
- It is not clear what is meant by "undue pressure". It is mentioned at a number of points throughout the document that the investigator should not put undue pressure on participants/participants' guardians. In one sense this is tautological - If it were the kind of pressure that's permissible, it wouldn't be undue, and *vice versa* - but it is not obvious that there is a substantial definition of what is undue or permissible. The inclusion of the word "undue" implies that there is an acceptable level of pressure, but it not clear what this would be. For example does this mean encouragement or reassurance? If there isn't

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an acceptable level of pressure, it may be better to not refer to it in the document and use a term more suited to the intended meaning.

- At line 608, it says that researchers should respond to concerns appropriately, but this is uncontentious and arguably is not informative.
- There needs to be recognition of the child's developmental stage in both ability to understand *and* ability to communicate – these may be very different. Also, dissent may be confused with worsening of the condition or with a drug side effect – the communication issues are very important and so children need to be given many opportunities to express their feelings.
- The question of emergency situations is not adequately dealt with; they are incredibly difficult but also incredibly important. Consideration should be given to nation to nation trials, cluster randomisation, time-related alternatives and other ways of ensuring that the best evidence is accrued most rapidly. There are a lot of conditions where such trials may improve outcomes.