

Research without Prior Consent in Children and Young People

The Human Research Ethics Committee (HREC) has various roles and functions. A fundamental role is to protect the safety of children and young people in research studies. Another role is to facilitate research activity that may benefit children and young people in the future. There can be a tension between these two functions.

The National Statement of Ethical Conduct of Research makes provision for a waiver of consent in certain limited conditions. Integral to the waiver of consent process is the concept that consent will not be sought after the initial intervention. The HREC is unlikely to approve a waiver of consent process for emergency research.

In some extenuating circumstances, the HREC will consider approving an arrangement where consent may be obtained after the intervention has occurred, with the proviso that the intervention carries the same or only slightly more risk than standard care. This is referred to as 'agreement to continue participation' in the National Statement, however is most often referred to as deferred consent, delayed consent, consent to continue, or research without prior consent.

The HREC will consider approval of research without prior consent in emergency situations. Such approval must be obtained when a study is first submitted to the HREC for consideration. The HREC would, firstly, need to be convinced that the research objectives could not be achieved in non-emergency situations and the application must meet the following criteria:

The broad requirements for research without consent that the HREC would consider include:

- The study is lawful and consistent with the National Statement on The Ethical Conduct of Research on Human Subjects and meets with all relevant sections, including 4.5.22
- The treatment or intervention needs to be given urgently to meet the needs of the child / young person
- It is not reasonably practicable to obtain consent from a legal representative. Such situations include:
 - where no parent guardian is in immediate attendance
 - the emergency situation which surrounds the child or young person's situation is sufficiently distressing to the parent / guardian that it is considered inappropriate to approach the parent/guardian acutely

If deferred consent is approved by the HREC, the following conditions must be met:

- Written consent is sought from a parent or a legal guardian as soon as possible thereafter.
- The parent or guardian must be informed about the research as soon as possible after it commences and their consent for continuing involvement sought. It must also be made clear that if the parent/ guardian withdraws at that point or anytime thereafter, they must be given the option of having any data collected destroyed.

- The gold standard for consent is prospective informed consent. There is no universal guidance in the literature as to the definition of “as soon as possible”. This could be as short as a few hours but must not exceed 24 hours. Research to that time point is research without consent. This must be remedied as soon as possible by obtaining consent.

HREC approval for the option of research without prior consent [deferred consent] for a trial does not automatically mean that every child / young person can be enrolled in this way. It is still necessary to meet the criteria stated above.

Researchers with approval to use research without prior consent [deferred consent] must give careful consideration as to how enrolment will occur after-hours and on weekends. Experience to date suggests that many patients are enrolled and then not consented before discharge. The HREC will look for advice from applicants as to how this will be managed.

Researchers bringing forward a proposal for research without prior consent must address two specific issues:

1. What steps will be followed if a child/young person is discharged from DEM / hospital before consent is obtained?
2. What steps will be followed if a child/young person dies after the treatment / intervention and before consent is obtained. As a general principle, parents have a right to know that a research intervention occurred. Some useful guidance can be found at:-

<https://www.liverpool.ac.uk/media/livacuk/iphs/Research,without,prior,consent,in,trials,investigating,the,emergency,treatment,of,critically,ill,children,CONNECT,guidance,July,2015.pdf>

Researchers will be required to include information about the use of deferred consent in the annual HREC report. This information must include:

- Number of participants recruited using prospective consent.
- Number of participants recruited using deferred consent.
- Reason why deferred consent was used eg: Parents not present; parent too distressed; unexpected deterioration of patient etc.
- Time from intervention to written informed consent.
- Number of participants who refused consent.
- All parental complaints relating to the consenting process.

It may be helpful to build this information into data collection from the commencement to the study.

Document history

Version	Date	Changed by	Nature of amendment
1	16/10/19	Amanda Smith	Creation of document.
2	17/09/25	Amanda Smith	Minor update to document.

Previous versions are recorded and are available for audit.