

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Informed Consent process	Date Effective 9-16-04	Supercedes P&P dated

Waiver of Consent for Planned Research in Emergency Situations

Federal regulations also allow for a waiver of the requirement for obtaining and documenting consent for research subjects who urgently require the intervention being studied but, because of their medical condition, are unable to give consent. One of the following two procedures must be followed:

The intervention may be used provided that the investigator and another physician not connected with the study certify in writing that:

- the subject has a life-threatening condition that requires the intervention being studied, and
- informed consent cannot be obtained because the subject cannot communicate effectively, and
- time is not sufficient to obtain consent from the subject's legal representative, and
- there is no recognized therapy that provides an equal or better chance of saving the subject's life.

If, however, in the investigator's opinion, the above conditions exist, but independent documentation is not possible in the available time, the intervention may be used. The determinations of the investigator must then be reviewed and evaluated in writing by an independent physician within 5 working days.

In either of the above cases, the documentation by the investigator and the independent physician must be provided to CHR for review within 5 working days after the intervention has been used.

Please contact the Office for Research Subjects for additional information on waiver of the informed consent requirements in emergency situations.