Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Article 32
Clinical trials in emergency situations

(a) due to the urgency of the situation, it is impossible to obtain prior informed consent from the subject and it is impossible to supply prior information to the subject;

(b) no legal representative is available;

(c) the subject has not previously expressed objections known to the investigator;

(d) the research relates directly to a medical condition which causes the impossibility to obtain prior informed consent and to supply prior information;

(e) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject.

Ernst Singer, EC Med. Univ. Vienna Oct 16, 2012; Barcelona