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## A Study Of Factors That Influence Individual Opinions On Research Involving Waiver Of Informed Consent In The Emergency Department.

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The Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) require prospective informed consent to be obtained from potential human subjects before they can enroll in a research study. This principle is the core of the Nuremberg code (1949), the Declaration of Helsinki (WMA, 1964) and the Belmont Report (1974). However, in emergency medical research, an individual's ability to give informed consent before enrolling study becomes questionable either due to critical illness, serious injury or unconsciousness. Under these circumstances, the FDA permits research to proceed with a waiver of informed consent, when known risks of the research are minimal and provided the following conditions are adequately addressed: (1) Consultation with representatives of the communities in which the research study will be conducted and from which research subjects are drawn. (2) Public disclosure to the communities in which the research study will be conducted and from which research subjects will be drawn, prior to the initiation of the study, of plans for the investigation and its risks and expected benefits. (3) Public disclosure of sufficient information following completion of the research study to appraise the community and researchers of the study, including demographic characteristic of the research population, and its results. The objectives of this study were: (1) to assess the opinions of emergency department (ED) patients and visitors about the waiver of informed consent requirement in emergency research (2) to inform ED patients and visitors about an on-going research study (the Polyheme study) that met the FDA criteria for waiver of informed consent and (3) to assess the opinions and awareness of ED patients and visitors about the Polyheme study (4) to determine the demographic and background factors that influence individual opinions about waiver of informed consent and (5) to evaluate the effectiveness of a community consultation and public disclosure effort about the Polyheme study. In order to accomplish the objectives of this study, a self-administered survey was conducted at a level 1 trauma center ED in Upstate NY, one of the sites of the Polyheme study. Patients and visitors in the ED were randomly approached and handed the questionnaires. A total of 204 individuals (patients and visitors) participated in the survey, while 43 individuals declined to participate. Completed questionnaires were tallied and data analysis was carried out using SAS 8.0.