

The Current Controversy

The current human protection controversy appears to have arisen from clinical experiments to test an artificial blood substitute on accident victims who are unconscious. According to press reports, 31 medical centers in 18 states participated in the trial. Current human protection rules require that the subject must have a life-threatening medical condition **“for which available treatments are unproven or unsatisfactory.”**

Did IRBs Follow the Rules?

We have to question how FDA and IRBs approved the protocol for this experiment when **blood and blood product transfusions are very satisfactory proven treatments** for trauma patients suffering blood loss. The artificial blood experiment offered no benefit to the subjects, but exposed them to considerable risk without their informed consent. Additionally, in a previous clinical study ten people who received the artificial blood suffered heart attacks, but this information was not provided to the public via “community consultation.”

Is “Community Consultation” Sufficient?

The sponsors of the artificial blood experiment did pursue “community consultation.” But instead of asking willing participants to opt-in, they told those who objected to participation that they could opt-out by wearing a blue bracelet during the months and years of the test. Those residents who did not attend or read about the community meetings had no choice. But most disturbing is the fact that people who did not live in the community, and were only passing through on a local highway where they experienced an accident, were not asked for their permission to be exposed to significant risk, nor did they agree to be denied proven standard treatments.

Find Willing Participants

Understanding that development of an artificial blood substitute may have many benefits to society, we have to believe that there are people who would be willing to participate in the blood substitute clinical trial if they were completely informed of all risks and possible benefits. Volunteers should be asked to opt-in instead of asking objectors to opt-out (e.g., people in the military on their way to a war zone, Jehovah’s witnesses, race car drivers and others in careers that often risk trauma, etc., may be willing to participate in this clinical trial).

Community consultation does not suffice for informed consent, especially when interstate drivers do not participate in such discussions. Only those who opt-in by signing an informed consent should participate in a study that will deny them proven satisfactory treatments. This is the basic principle of the human protection system in medical research, and it must not be violated.

FDA Must Enhance Protections

Virtually every instance of improvement in the human protection system arose out of an inhuman research abuse. The artificial blood controversy provides a unique opportunity to FDA to improve its rules for protection of human subjects in emergency research. FDA’s proposed rule is not an improvement over the agency’s current rules, and the proposal would never suffice under the *Common Rule* that all other federal agencies (except for FDA) conform to.

We have to ask why FDA allowed the sponsor and the IRBs to ignore the mandate requiring that informed consent can only be ignored when "available treatments are unproven or unsatisfactory." We have to ask, if you were on vacation with your family, and got into an accident on a distant highway, would you be willing to participate in a risky experiment without your knowledge and consent? Would you agree to deny your spouse or children a blood transfusion in favor of an experimental substitute with unknown risks?

We believe this is a critically important issue that FDA is compelled to address as the guardian of public health in the United States. Any waiver of informed consent is a serious violation of international human protection rules, and cannot be ignored. FDA should improve human protections for research in the private sector, not encourage their erosion.

Very truly yours,



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President

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cc: Diane Dorman, NORD Vice President for Public Policy