



# C I R C A R E

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My name is Michael Susko and I'm President of CIRCARE, the oldest nonprofit advocacy organization dedicated to the protection of human subjects in research. First let me express our appreciation and thanks for the hard work the committee has done over the past three years. A lot of this work is performed selflessly and with great dignity. We would, however, like to call attention to some important gaps in the process of your deliberations. We have requested in writing that research subjects' perspectives be included in your deliberations, but to no avail. We have chosen this public forum as a last resort.

The Secretary's Advisory Committee on Human Research Protection is addressing some of the most important issues concerning human subject protections; the committee's recommendations will have an immense impact on federal policy governing the safety and well-being of human subjects in research. As you know, millions of human subjects participate in research experiments each year. This means that millions of our citizens and their families are affected by the conduct of research. The reason we are able to do research is because of the generosity and altruism of our citizens and their families. The human subjects and their families are the most precious part of this enterprise.

Research participants may pay a price for participation. There are deaths and serious adverse events, some of which are reported, and some of which are not. Any death or significant adverse event is non-trivial; it impacts a real human being and his or her family – potentially changing the course of their individual and family history.

Several months ago the committee appointed a subcommittee to address Sub-part A of the 45 CFR 46. Sub-Part A is the heart and soul of the federal regulations for the protection of human subjects. It bears repeating that your deliberations on this matter will affect millions of Americans and their families.

During the past three years, and especially at recent meetings, you have invited many experts to speak about the research subject from their vantage point. There has been a glaring absence, however, – the absence of the voice of human research subjects, their families, and their advocates. You have invited none of these groups, neither to take part in deliberations as a member of the sub-committee, nor even to speak at a single meeting.

In comparison, however, you have repeatedly invited and heard the perspectives of industry representatives, including academic medical centers, institutional IRBs, commercial IRBs , IRB managers, lawyers, and academic researchers. While it is important to hear from these groups, from our perspective the most important group is first and foremost human subjects, followed by their families, and their advocates. We believe the committee needs to hear from those concerned about human subject protection from those without a vested interest in a particular industry or institution, who nevertheless have a valuable point of view which should be heard.

We are requesting that this committee consider the following:

1. Establishing a subcommittee composed of human subjects, their families and advocates.
2. Inviting the same to be a part of your deliberations on this committee and/or subcommittees which try to improve the regulatory code.

CIRCARE has long advocated for reform which includes:

1. A National Human Research Subject Protection Act so that humans are covered with the same protections that are afforded to animals
2. A national federal registry of comprehensive and mandatory adverse event reporting
3. Effective management and reduction conflicts of interests
4. The inclusion of persons who have been research subjects or their advocates at various points in the decision making process

We thank the committee for their attention to our concerns and we ask that they seriously re-consider our proposal for inclusion of human subjects and/or their advocates.