

Researchers must ensure woman didn't die in vain

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THE DEATH of Ellen Roche, a 24-year-old employee and experimental subject at the Johns Hopkins University need not be in vain.

The severity of the case led the federal government, in a surprise, to suspend all human research studies at a prestigious institution that was just ranked the No. 1 hospital in the country. The suspension recently was lifted except for studies that are "greater than minimal risk." The chair of the review panel at Hopkins took "full institutional responsibility" for Ms. Roche's death and suggested that her life was given for the cause of science.

But we who are active in the human rights movement suggest that her death can serve the cause of protecting human subjects in medical experiments. Indeed, Hopkins, to its credit, has voluntarily initiated a number of reforms. We believe that many lives could be saved by reforms that go even further.

There were two main ethical lapses in this particular experiment.

One is that Ms. Roche was not informed of the full risks involved - risks published in the scientific literature but of which the researcher claimed he was not aware.

The second was that Ms. Roche was an employee of Hopkins and worked in the same general field as the researcher. This meant that the subject had a false presumption of safety - that your employer won't harm you - as well as a potential, implicit coercion to participate.

These two lapses are particularly egregious since this was a high-risk experiment - known as a "challenge study" - in which illness is purposely induced. Asthma research is but one of many fields that make use of such a method.

In Ms. Roche's case, hexamethonium, which constricts a human's respiratory system, is a high-risk chemical known

to have potentially lethal effects. Not only was it withdrawn from human use in the 1970s, but it was never approved for use for asthma by the Food and Drug Administration or any other entity.

How do such lapses occur?

First, there is institutional pressure to come up with new drugs and discoveries, not only for relief from suffering but for recognition and big profits.

Second, there was a lack of truly independent review since the university basically polices itself by what are called institutional review boards.

Other research institutions nationwide have similar boards.

But all employees, as we know, tend to have a vested interest in not running up against their employer.

Such lapses have been routine because the federal government does not pay sufficient attention to protecting human research subjects.

Perhaps scrutiny is changing, as evidenced by the recent federal action against Hopkins.

In the past 10 years, only eight deaths and 386 adverse events have been reported in federally supported research nationwide. Given the millions of people enrolled in experiments nationwide, those low figures lead to speculation that researchers may not be reporting all of the data gathered in the course of their research. The public may be deceived.

This problem occurs throughout the country. It is deep-rooted, systematic and requires a solution that puts more fundamental protections in place, measures that are basically common sense. These should include:

The initiation of independent review boards by people not employed by the research institution.

Forbidding employees from participating in high-risk

experiments that are overseen by their employers.

Closer scrutiny of "challenge studies." These types of studies should be undertaken only in cases of clear need, with a full appreciation of risks from the entire history of research and truly informed consent to all the known risks.

Federal oversight as a final safety net with clear uniform standards.

Good science is not unharmonious with treating people with dignity and respect and ensuring their well being.

The failure to fully provide protection leaves us with science that becomes distorted and a population afraid of potentially helpful benefits of research. We urge that our institutional soul-searching go deeper, that full reform be initiated so that Ellen Roche's death will not have been in vain.

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