



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

12 January 2023

Memorandum

To: Trialists

Fr: Curtis Meinert

Re: On the risks of researching on human beings

I am an accidental trialist. My involvement in trials commenced when Chris Klimt joined the faculty at the University of Minnesota and was looking for someone to help organize what was to become the University Group Diabetes Project (UGDP). The trial started in 1960, before IRBs.

As a budding trialist, I was blissfully ignorant of the risks inherent in trials, surrounded by experienced investigators and studying approved drugs for type II diabetics. But everybody here at Hopkins got a wake up call in mid 2001 with the death of Ellen Roche enrolled in an hexamethonium asthma study. Ms Roche was a technician at the Johns Hopkins Asthma and Allergy Center. She volunteered for a study with the aim of learning about reflexes that protect lungs against asthma attacks. She was the 3rd person enrolled in a small observational study.

After inhaling hexamethonium Ms Roche became ill with her condition progressively worsening. She died 2 June 2001 about a month after entering the study. The death shut down 100s of research projects at the IRBs serving medical institutions at Hopkins.

Though I was not involved in the study, nor did I know Dr. Togias (PI of the study), it seemed to me he was tossed to the wolves with everybody running for cover with the death. My feeling was, "there but for the grace of God go I".

It was an awakening. My reaction was akin to that of the Buffalo Bills football team kneeling around Damar Hamlin after collapsing.

Had Ellen Roche died at the beginning of my career, I might well have opted for another career path.

* * * * *

We need trials and a populace willing to accept the reality that there is no such thing as risk free human research. Even research not involving the administration of anything, as in studies to assess the benefit of prayer in the healing process, carry risks.

The reality is that most home remedies or treatments perscribed are not tested. A fair number are the result of fortuitous observations, for example, as made by Ambroise Paré during the battle to capture the castle of Villaine in 1537 (Packard, 1921).

Then the battlefield practice was pouring boiling oil on gun shot wounds. But the battle was so intense as to cause Paré to run out of oil. As a result he resorted to a digestive made of egg yolks, oil of roses, and turpentine.

Paré, on visiting his battlefield victims the next day, wrote:

I raised myself very early to visit them, when beyond my hope I found those to whom I had applied the digestive medicament, feeling but little pain, their wounds neither swollen nor inflamed, and having slept through the night. The others to whom I had applied the boiling oil were feverish with much pain and swelling about their wounds. Then I determined never again to burn thus so cruelly the poor wounded by arquebuses (Packard, 1921).