

DEPARTMENT OF DERMATOLOGY

1701 Divisadero Street
Box 0316
San Francisco, California 94143-0316

Tel: (415) 353-7800 Fax: (415) 353-7870

Dear Colleagues:

I have been given the Executive Report of the UCSF Historical Reconciliation Program and appreciate the opportunity to provide a response.

Although the PHR committee has been investigating research practices at CMF since January, 2022, I was not made aware of the committee's investigation until September of this year, and was not given a copy of the committee's report until October. And while the committee has amassed a database of 7,000 documents, I have not been given access to the database (which includes at least one unpublished interview with me). Accordingly, what follows represents my best recollection of events that occurred many decades ago, and may therefore be incomplete.

I believe that the ethical requirements applicable to medical studies in the 1960's and 1970's have changed in the ensuing decades. What I believed to be ethical as a matter of course forty and fifty years ago is not considered ethical today. As explained more fully below, I regret having participated in research that did not comply with contemporary standards.

The Collaboration Between UCSF and CMF: Ethical Evaluations

CMF was intended to use developments in medicine to improve the health of, and possibly rehabilitate, the treated prisoners.

The cooperation between UCSF and CMF predated my recruitment, and its availability was part of my recruitment process. In subsequent years, the collaboration between UCSF and CMF was reviewed and endorsed by leadership at both the campus and school level.

When I first heard a question as to whether these studies at CMF were ethical, UCSF did not have an ethicist. Accordingly, I reached out to the University of San Francisco, whose president was an ethicist. I met with him intermittently before he went to UCSF; numerous times after he was recruited to a full-time position at UCSF, where he established an ethics committee; and several times after he retired from UCSF and shortly before he died about ten years ago.

Based on my frequent conversations with him, I believe that the ethicist believed unequivocally that these volunteers could provide informed consent. In other words, he felt that these

volunteers could say yes or no – in their own judgment. He never wavered in this belief and never encouraged us to stop the collaboration between UCSF and CMF.

Nevertheless, I stopped doing studies at CMF in the mid- or late-1970's when state government started questioning the research.

How We Obtained Informed Consent

When I arrived at CMF, there was no written informed consent requirement in most of the United States. Therefore, I implemented what appeared appropriate to me. Here is what I did:

1. I first explained the procedure (mostly percutaneous penetration and skin tolerance studies) and the research risks.
2. I then performed the procedure on myself, so that the individuals could see what the procedure involved. For the percutaneous penetration studies, I also dosed my collaborator, a senior World War II, 50-mission navigator veteran. This included not only the topical exposures but the tracer doses (now known as mini dosing) of chemicals. The doses were chosen to be miniscule compared to toxicity.
3. After they heard the explanation and saw the demonstration, I then asked small groups of individuals if they had any questions.
4. Participants were then informed that I could be called 24 hours a day/7 days a week if there were any questions.
5. When the IRB system was initiated at UCSF, in addition to the above, the individuals were either one by one or in very small groups walked through the informed consent process. They then signed the informed consent form approved by the IRB before they were allowed to sign and enter the study. We also continued to demonstrate the procedures.

However, informed consent was not routinely mentioned in publications, as would be routine today. In addition, some studies were performed before the IRB requirements existed but the results were published thereafter. Moreover, some publications may have been with collaborators, and approved by their IRB. Accordingly, relying on publications as determinative of whether informed consent procedures were followed is unwarranted.

I would be happy to assist in finding documentation showing IRB approval of the studies conducted at CMF after the requirement was imposed.

The Executive Report states that SIMPR was used to circumvent UCSF's rules for human subject research. I do not believe this is true but, in any event, I was not involved in SIMPR, either as a board or committee member.

The Benefits Provided By The UCSF-CMF Dermatologic Collaboration

As noted, I regret my role in research that did not comply with contemporary standards. While we all now recognize that mere good intent is not a substitute for the good clinical practices framework that we operate under today, our intent was to benefit the prisoners who participated and advance the science. In particular, I believe that the UCSF-CMF collaboration provided several benefits to the prisoners:

1. CMF received extensive (pro bono) dermatologic care not only for those at CMF, but for all referred males in the northern California system (I do not know why women were not included).
2. These relationships eventually led to our being able to bring (at CMF's expense) 2 guards to bring patients to UCSF for specialized dermatologic care that we could not provide at the facility. The most common cause for such assistance was for Mohs chemosurgery. To the best of my knowledge, this arrangement has continued in subsequent years.
3. It is likely that the compensation given to the subjects was of use to the individuals. (I am aware of the early discussions at UCSF about the ethics of compensating volunteers). Today providing appropriate compensation appears well established.
4. Some inmates were aided with help in obtaining positions - at least one person was employed at UCSF and had a fine career here.
5. Several individuals were seen (pro bono) for years after their discharge by me at UCSF.

In addition to providing benefits to the participants, the techniques studied at CMF are now widely used internationally by regulatory bodies and other interested parties.

In contrast, I do not recall any way in which the studies caused medical harm to the participants. Since I was in regular contact with the doctors at CMF, I would have been alerted had adverse consequences occurred.

My Treatment Of Race As A Concept

Regarding race, I have some background in the field, as I was a graduate student of Dr. Loren Easley at Columbia University before starting medical school. Our original nomenclature of Black, White, Caucasian, et cetera, was from the classical medical literature - common in the 1960's and 1970's. Indeed, race was ubiquitously used in patient descriptions, based on the patient's appearance and self-identification. Every medical student and resident would give the age and perceived race of the individual.

Now, with the advancements in science that have led to a much more sophisticated understanding of the genetic diversity of humans, I have come to the understanding that race

has always been a social and not a biological construct, something not appreciated by so many of us in a prior era. This changed perspective appears in several books that I have helped to write:

1. Berardesca, et al: Ethnic Skin and Hair.
2. Vashi Dermatoanthropology of Ethnic Skin and Hair.
3. Li: Ethnic Skin and Hair and Other Cultural Considerations.
4. Monsouri: Clinical Illustrated Dermatology.

On the cover of this last book just released, we have added the sentence "illustrations of skin of color."

Conclusion

The Executive Report states that there is "no documentation" of regret or remorse on my part in connection with the CMF studies. This statement is misleading in light of the fact that at no time from the 1960s to the present has anybody asked me to speak or write on this subject. My first request was from the Provost during our first meeting. But this process has led to a reevaluation and a reckoning.

The work I did with colleagues at CMF was considered by many to be appropriate by the standards of the day, although in retrospect those standards were clearly evolving. I obviously would not work under those circumstances today - as the society in which we live in has unambiguously deemed this inappropriate. Accordingly I have sincere remorse in relationship to these efforts some decades ago.

I hope these reflections help all of us gain a deeper understanding and a reconciliation of our past. I am willing to help the committee search for further relevant documentation. I also believe that meeting with the committee in person would benefit all parties.

Yours sincerely,



12/12/22

Howard I. Maibach, M.D.
Professor of Dermatology