Executive Report

Introduction
In January 2022, the UCSF Program for Historical Reconciliation (PHR) began addressing a request from EVCP Dr. Lowenstein to investigate past research practices conducted by certain UCSF faculty at the California Medical Facility (CMF), a state prison medical facility located in Vacaville, CA. Upon learning that two doctors at UCSF, Dr. Howard Maibach and Dr. William Epstein, had earlier trained with Dr. Albert Kligman, whose unethical experiments on prisoners in the 1950s-1970s at Holmesburg Prison in Philadelphia have been well documented, concerns were raised about possible unethical research in the 1960s and 1970s at CMF.

Aware that federal, state, and institutional policies were then being developed to protect vulnerable populations from medical experimentation, the PHR sought to establish whether human subjects research review protocols were followed and whether the research methodologies used were justified and appropriate. The PHR research team have identified, digitized, and assessed approximately 7,000 archival documents, medical journal articles, interviews, documentaries, and books. The file titled “Maibach_database” serves as a database of our findings. This database features three spreadsheets: (1) journal articles featuring human subjects research conducted in prisons, 1960-1980; (2) journal articles on race; (3) archival research.

As of November 2022, the findings presented in this report are limited by the amount of material the PHR team has been able to assess. Further analysis of primary documents is necessary to provide a more comprehensive picture of the scope of medical research that was conducted at CMF, to determine the extent of medical harm done to incarcerated individuals, and for the institution to ascertain the steps that should be taken toward full historical reconciliation.

Knowing that Drs. Kligman and Epstein (both now deceased) went on record to defend their research, and being aware that Dr. Maibach is currently still an active member of the UCSF faculty, the PHR welcomed the opportunity to include Dr. Maibach’s replies to the PHR’s findings in this report.

Howard I. Maibach has had a prolific career in the field of dermatology. He has been involved in human research for over 60 years, has published over 2500 journal articles, has served on the editorial board of more than 30 scientific journals, and has won numerous awards. Maibach has had leadership roles in scientific societies including President of the San Francisco Dermatological Society (1970-71). The American Contact Dermatitis Society has a travel grant named in his honor. He has served as a consultant to various entities including the State of California Department of Public Health, Sonoma State Hospital, and the International Society for Bioengineering and the Skin Standardization Committee. Maibach has been a faculty member in UCSF’s Dermatology Department since 1961, a position he currently still holds.

While Maibach has had an accomplished career, aspects of his research raise ethical concerns. Maibach was involved in human subjects research of incarcerated individuals until it was halted by the state of California in 1977. He began conducting human subjects research on incarcerated individuals during his fellowship at the University of Pennsylvania, under the supervision of Albert Kligman. When Maibach joined UCSF in 1961, he took Kligman’s model and adapted it for his use at the California Medical Facility (CMF), a prison hospital located in

Content warning: This report contains disturbing details related to human subject research conducted on incarcerated individuals by UCSF faculty and may be harmful and/or traumatizing, particularly for individuals who have personal experiences with oppression.
Vacaville, California. Throughout his tenure at UCSF, Maibach experimented on at least 2600 individuals who were incarcerated at CMF. His research was nontherapeutic, meaning incarcerated individuals were not suffering from any diseases or conditions that the research was intended to treat. Research conducted ranged in invasiveness and purpose. The use of CMF as a site for human subjects research predates Maibach’s arrival to UCSF and, according to Maibach, “its availability was part of the recruitment process.”

Publications on Human Subjects Research Conducted at CMF

To best document the involvement of incarcerated individuals in human subjects research, the PHR reviewed 222 publications from 1960-1980 and identified thirty-four articles featuring human subjects research. Twenty-four of these articles are believed to be referencing research conducted at CMF.

Fourteen publications specifically referenced CMF either by name or names of collaborators, Drs. William C. Keating, Jr and Lester A. Pope. Out of these fourteen articles, one article references a study that predates the establishment of the first internal review board (1966). Only one of the remaining thirteen publications indicated that informed consent was obtained from its seven human subjects and that the study had been approved by UCSF’s Committee for Human Research (CHR).

Published articles referencing human subjects research conducted at CMF and mention of UCSF internal review board reference

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<tr>
<th>Article</th>
<th>CMF Reference</th>
<th>UCSF Internal Review Board Reference</th>
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<tr>
<td>A. A Khan et al., &quot;Increased Attractiveness of Man to Mosquitoes with Induced Eccrine Sweating,&quot; <em>Nature</em> 223, no. 5206 (1969): 859–860.</td>
<td>&quot;We thank Drs. Lester Pope and Eugene Prout and the inmates of the California Medical Facility, Vacaville, California, for assistance.&quot;</td>
<td>None</td>
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<td>Howard I Maibach, Robert J Feldmann, Thomas H Milby, and William F Serat, &quot;Regional Variation in Percutaneous Penetration in Man,&quot; <em>Archives of Environmental Health: An International Journal</em> 23:3 (1971): 208-211.</td>
<td>&quot;Drs. Lester Pope and Eugene Prout, California Department of Corrections, made the arrangements, provided medical consultation, and contributed to the project design for this study.&quot;</td>
<td>None</td>
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<td>Howard L Johnson and Howard I Maibach, &quot;Drug Excretion in Human Eccrine Sweat.&quot; <em>J Invest Dermatol</em> 56, no. 3 (1971):182–188.</td>
<td>&quot;We wish to express our appreciation to Drs. Lester Pope and Eugene Prout of the State Department of Corrections&quot;</td>
<td>None</td>
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There were also ten articles that we believe referenced studies conducted at CMF, though they did not mention prison collaborators by name. Three articles reference studies predating the establishment of the first review board at UCSF. An additional article based on research conducted at CMF is published the same year the first board was established. Only one of these articles reported on a study receiving consent by subjects and/or CHR. The search for documentation of CHR approval for the other studies is ongoing.

### Published articles possibly referencing human subjects research conducted at CMF and mention of UCSF internal review board

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<th>Article</th>
<th>Human Subjects Reference</th>
<th>UCSF Internal Review Board Reference</th>
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<tr>
<td>William L Epstein and Howard I Maibach, &quot;Immunologic Competence of Patients With Psoriasis Receiving Cytotoxic Drug Therapy.&quot; Arch Dermatol 91, no. 6 (1965): 599–606.</td>
<td>30 patients with psoriasis being treated; 11 &quot;healthy untreated male volunteers varying in age from 22 to 55 years&quot;; 11 &quot;healthy nonpsoriatic male subjects&quot; being treated; and 6 untreated psoriatic patients - (believed healthy nonpsoriatic males could be from CMF).</td>
<td>Predates establishment of first board</td>
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<td>Robert J Feldmann and Howard I Maibach, &quot;Percutaneous Penetration of 14C Hydrocortisone Through Normal Skin: The Effect of Stripping and Occlusion.&quot; Arch Dermatol 91, no. 6 (1965): 661–666.</td>
<td>&quot;hydrocortisone alcohol with diluted acetone given intravenously or intradermally. Urine was tracked.&quot; Study similar to those conducted at CMF based on our research.</td>
<td>Predates establishment of first board</td>
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<tr>
<td>Robert J Feldmann and Howard I Maibach, &quot;Percutaneous Penetration of 14C Hydrocortisone in Man: II. Effect of 2 steroids - hydrocortisone and testosterone was applied in 5 chemicals used as vehicles - mineral oil, propylene glycol (PG), dimethyl</td>
<td>Same year as the establishment of first board and announcement to</td>
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sulfoxide (DMSO), dimethyl formamide (DMF), and dimethyl acetamide (DMAC). CMF was a site for UCSF-conducted DMSO research during the 1960s.


Hydrocortisone applied to skin. Subjects requested not to wash the area for one day; site was not protected. Urine collected for 5 days. Similar to research as being identified as taking place at CMF. Also, subjects were described as “normal male volunteers.”


Similar research conducted at CMF based on our research.


Building on their work with hydrocortisone, they tested 14 steroids on subjects. Steroids - hydrocortisone, hydrocortisone acetate, cortisone, corticosterone, 17-OH Progesterone, Progesterone, Fluocinolone acetonide, Desamethosone, estradiol, testosterone, testosterone acetate, testosterone propionate, dehydroepiandrosterone, androstenedione.


“Healthy adult male volunteers.” This wording is similar to description of volunteers who reside at CMF.


Type of research typical of CMF. No location identified. 4-C-hydrocortisone acetate preparation deposited on forearm. Area was covered and measured. Urine collected.


Similar research conducted at CMF based on our findings.

Ten additional articles mention human subjects research, but do not provide enough information to determine if the research was conducted at CMF. We also found one publication based on a case study from the prison hospital. Three articles were published (1978–1980) after California halted human subjects research in prisons which do not reference CMF directly; however, we believe these articles are possibly discussing findings from research conducted at the prison hospital given the description of the human subjects. Our research is ongoing.

Our findings show that Maibach practiced questionable research methods. Archival records and published articles have failed to show any protocols that were adopted regarding informed consent and communicating research risks to participants who were incarcerated. Publications detail experimental methods which included the topical application and intravenous dosing of pesticides and herbicides, placing small cages with mosquitoes “1 cm from the arms” of human subjects to observe “host attractiveness of humans to mosquitoes,” other mosquito studies placing the cages directly on the skin and observing direct penetration of the proboscis by the appearance of blood, and experimenting with medications to determine their therapeutic effectiveness.

Informed Consent Practices
Based on our archival research of internal human subjects research review board(s) records and state of California hearings proceedings, PHR has concluded that Maibach and others engaged in questionable informed consent practices at the prison, especially before 1969.
demonstrated above, it was not until 1975 that consent and/or acknowledgement of approval by a review board was indicated in any article referencing research conducted at CMF.

While the search for documentation of UCSF internal reviews of Maibach’s human subjects research at CMF is ongoing, we have discovered several records documenting a lapse in obtaining approval from UCSF’s Committee on Human Experimentation (CHE) for several studies, including “Selenium-Tocopherol Blood Levels Study” (1969-1970) and “DMSO-Drug Interaction Study” (1969). These studies began three years after UCSF faculty were informed that all research involving human subjects was required to go through review regardless of the source of funding and even under circumstance with which “no funding at all was required.” In addition, we did find records pertaining to the CHE disapproving Maibach’s “Study of Cutaneous Penetration of Pesticides in Man…insofar as the use of prisoners as experimental subjects are concerned” in late 1971. In February 1972, CHE approved the study but only for one year.

Maibach’s relaxed approach to UCSF internal review was made possible by the use of the Solano Institute for Medical and Psychiatric Research (SIMPR) at CMF. Founded in 1963, SIMPR was a non-profit organization that coordinated human subjects research at CMF, including conducting peer review of studies. However, solely seeking approval through SIMPR was in direct violation of the mandate communicated to all UCSF faculty in 1966. Maibach and his colleague, Chair of the Department of Dermatology of UCSF, William Epstein, were such frequent users of SIMPR that the organization referred to them as a “continuously active research team” in one of their publications.

Reflection on past practices
We found no documentation of regret or remorse by Maibach or Epstein regarding their human subjects research on incarcerated individuals at CMF. In fact, Epstein testified at the 1977 state hearings in support of biomedical experimentation in California prisons. Epstein died in 2006 and we found no documentation of him changing his opinion on biomedical experimentation. In an unpublished interview, Maibach defended human subjects research on those who are incarcerated as a catalyst for knowledge. In addition, He voiced support for Albert Kligman’s human subjects research on those incarcerated at Holmesberg prison. To our knowledge, he has yet to discuss the research he conducted at CMF in public.

Race and Dermatological Research
As Maibach’s human subjects research in prisons came to an end, his interest in racial, ethnic, and national skin differences grew. In 1979, he co-authored the article “Black and White Human Skin Differences” with Klaus E. Anderson. They argued that while “color is the most striking racial skin difference, it is but one piece of a biologic mosaic.” A sampling of Maibach’s work on racial skin differences stretching 45-years of scholarship demonstrates his curiosity with the topic and how race might play a role in differences in dermatological conditions including contact dermatitis, sodium lauryl sulphate induced cutaneous irritation, skin responses to topical methyl nicotinate, (1989) and other biological skin processes such as transepidermal water loss (TEWL).

In many of Maibach’s publications on racial skin differences, he uses language that further perpetuates the biologization of race. Names for racial groups are employed but not defined and there is slippage between nationalities, ethnicities, and racial identifications. While one of his recent articles hints at a possible reconsideration of the biology of race, we believe the long
history of his research of skin differences along racial lines, with race as a possible biological factor, perpetuated the continuance of racial science in dermatology and has yet to be publicly addressed.

**PHR Recommendations**

1. A restorative justice-informed public dissemination of our findings
2. Development and dissemination of relevant educational materials to all schools at UCSF and UCSF Health, including a formal lecture in the Department of Dermatology
3. The development of an oral history project to identify and interview those who were subjected to research at CMF, 1955-1977
4. An official institutional statement of remorse
5. The establishment of a reconciliation process which is co-created with community organizations and the Office for Restorative Justice
6. Further research in this area, including but not limited to:
   a. All research conducted through SIMPR, the non-profit organization established at the California Medical Facility (CMF) by UCSF faculty.
   b. UCSF faculty-led human subjects research conducted on vulnerable populations. Beginning with but not limited to:
      i. Individuals seeking care at UCSF free healthcare clinics
      ii. Sonoma State Hospital
      iii. San Quentin Prison
   c. Contributions by UCSF faculty in the development, endorsement, and perpetuation of racial science

**Appendix: UCSF Policies and Procedures for Research Involving Human Subjects**

(https://ucsf.box.com/s/yt87wrp405ydq8b6abfjmxpfu4csbzo8, 106-108)

On September 1, 1966, Dr. Harold Harper, Vice Chancellor for Graduate Studies and Research sent a memo to all Deans, Department Chairs, Principal Investigators and all others concerned. It set forth the guiding policy statements and indicated that these are the requirements which must be considered by investigators when seeking approval for experimental protocols involving human subjects.

In September 1966, Vice-Chancellor for Graduate Studies and Research created a Committee on Human Welfare and Experimentation and delegated to this committee the responsibility for establishing and administering a policy that met the Surgeon General's requirements for protecting individual rights in human experimentation. The members of the Committee were selected by committee action of the Academic Senate (Emerging assets and liabilities of a committee on human welfare and experimentation. New Eng J Med 282:427–431, 1970, DOI: 10.1056/NEJM197002192820806). R. Curtis Morris, Jr., M.D., served as the Chairman of Subcommittee on Human experimentation of the Academic Senate Committee on Research
On September 26, 1966 another directive was sent by Dr. Harold Harper, Vice Chancellor for Graduate Studies and Research. A memo was sent to all Deans, Department Chairs, Principal Investigators and all others concerned. It contained same research procedures as before and also indicated that responsibility for review was assigned to the Academic Senate Committee on Research.

On December 5, 1969 a directive was sent by Dr. L. Bennett, Vice Chancellor for Academic Affairs to Deans, Department Chairs, Principal Investigators and others. It was intended to re-emphasize two prior directives from November 17, 1967, and June 4, 1969, that all research involving human subjects required review regardless of the source of funding and even under circumstance with which no funding at all was required.

On June 25, 1970 the UCOP issued a memorandum on Research Involving Human Subjects (President Hitch), paragraph 2. This UC presidential policy required review committees to approve "all investigations involving human subjects for which the University is responsible," regardless of the source of funding. (https://www.osti.gov/opennet/servlets/purl/904683.pdf)

On September 20th, 1971, Vice Chancellor for Academic Affairs Dr. Dallas Tuck appointed the Committee on Human Experimentation (CHE) to review research protocols where human beings are involved as experimental subjects.

Federal-Level Oversight - The United States Department of Health, Education and Welfare (DHEW), now called the Department of Health and Human Services (DHHS), has required prior review and approval of human subjects research funded by federal agencies since 1966. In December 1971 DHEW issued its “Institutional Guide to DHEW Policy on Protection of Human Subjects.” In 1974, these “guidelines were revised and made regulation in 1974.”51

Works Cited

3 The Federal Bureau of Corrections had halted all human subjects research at prisons in 1976. California was only one of only seven states in the nation that allowed for the continuation of human subjects research in prisons. According to Shae Goldstein, "Abuses told: Experiments on Prisoners," Synapse – The UCSF Student Newspaper, February 17, 1977, CMF was where the majority of human subjects research in California prisons took place at that time.
5 Karen Konoske, on behalf of Howard Maibach, email message to Daniel Lowenstein, October 19, 2022.
31 Maibach_Database_Human Subjects Research.
33 Raza Aly and Howard I. Maibach, "A Comparison of the Antimicrobial Effect of 0.5% Chlorhexidine (Hibistat®) and 70% Isopropyl Alcohol on Hands Contaminated with Serratia Marcescens," Clin Exp Dermatol 5, no. 2 (1980): 197–201.
41 Leslie L Bennett, Chair, CHE, Letter to Howard I Maibach, January 31, 1972, Box 1, ar86-23_001_009, 88-89.
44 The Assembly Select Committee on Corrections, The Status of Biomedical Experimentation in California's State Prisons, January 28, 1977 (testimony of William Epstein), 14-27.


51 see [https://irb.ucsf.edu/irb-review](https://irb.ucsf.edu/irb-review).