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Application Number: 1 R21 HD086419-01

Principal Investigator

STERN, ALEXANDRA M PHD

Applicant Organization: UNIVERSITY OF MICHIGAN

Review Group: **SEIR**
Societal and Ethical Issues in Research Study Section

Meeting Date: 06/17/2015	*RFA/PA:*	PA14-278
Council: OCT 2015	*PCC:*	PDB -RK
Requested Start: 09/01/2015		

Project Title: Demographic Patterns of Eugenic Sterilization in California: Quantitative and Qualitative Analysis of Reproductive Control of the "Unfit"

SRG Action: Impact Score: Priority Score Percentile: Percentile

Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: Evaluative Info
Animal Subjects:
Gender:
Minority:
Children:

Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	125,000	Estimated Costs
2	150,000	
TOTAL	275,000	

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R21HD086419-01 STERN, ALEXANDRA

RESUME AND SUMMARY OF DISCUSSION: This project will evaluate the history of eugenic sterilization in California where approximately one third of all known eugenic sterilizations occurred. The investigator discovered microfilms containing documents on the sterilization recommendations in nine California hospitals and have created a de-identified HIPAA compliant data set. This project is significant because it will provide an in-depth understanding of the factors associated with recommendations to sterilize an institutionalized person. Few historical studies of eugenics have involved such a large data set for analysis. The investigator is an outstanding historian of medicine and has gathered a strong team of interdisciplinary collaborators. The project is innovative with the interdisciplinary collaboration between history and epidemiology and the combination of qualitative and quantitative methods. A minor concern is that the project does not discuss how California may be atypical and as a result, generalizations may be limited. In addition, the qualitative methods needed greater description but this concern is mitigated by the investigator's expertise. The reviewers all agreed that this project will have a significant impact as it will provide a more fine-grained analysis of eugenic practices and although we are in a different era, this project may provide lessons that can be important for current issues of risk factors for unethical behavior.

DESCRIPTION (provided by applicant): From the passage of the country's first sterilization law in Indiana in 1907 until the 1960s approximately 60,000 people were sterilized based on eugenic criteria that sought to regulate the reproduction of the "unfit" and mentally deficient. California performed about 20,000, or one-third, of all documented sterilizations nationwide. Few empirical historical analyses of this practice are available. In 2007, while conducting historical research at the Department of Mental Health (now Department of State Hospitals) in Sacramento, Dr. Stern located 19 microfilm reels from this era that contain 15,000 sterilization recommendations along with supplemental letters and forms from nine state hospitals (in total, over 30,000 individual documents). Over the past two years Dr. Stern and her team have created a de-identified HIPAA-compliant data set of these recommendations, which date from 1921 to 1952. We now propose to conduct quantitative analyses with the eugenic sterilization dataset, which contains 212 coded variables, to describe trends in sterilization over time and to describe patterns of sterilization according to gender, age, ethnicity, nationality, diagnosis, institutional home, and many other variables. We propose to link the eugenic sterilization dataset to individual-level census microdata and tract-level census reports, which will allow us to calculate population-based estimates of sterilization rates and test hypotheses about the associations of gender, age, ethnicity, nationality, and diagnosis with the risk of sterilization. For example, we hypothesize that teenagers and Spanish-surnamed patients were disproportionately sterilized in California institutions. In addition, we will analyze qualitative patterns in the data with respect to familial resistance to sterilization, patient refusal, and experiences of institutionalization and sterilization. This study is relevant to contemporary ethical, legal, and social issues in human genomics, as it will provide an empirically-based, richer understanding of how medical paternalism and a particular variant of genetic determinism operated during the eugenics era in the United States, and how eugenic stereotypes about ethnicity, gender, sexual behavior, and intellectual disability influenced the state's intervention into the reproductive lives of institutionalized persons. Furthermore, our findings can inform contemporary conversations about the extent to which societal values of "fitness" and "unfitness," abnormality and normality, can insinuate themselves into the norms of disease prevention and human improvement that guide some genetic technologies and tests.

PUBLIC HEALTH RELEVANCE: We will conduct quantitative and qualitative analysis of 15,000 eugenic sterilization recommendations processed by the state of California from 1921 to 1952. Working with a de-identified HIPAA-compliant dataset we created during the pilot phase of this project, we will describe patterns of sterilization according to over 200 coded variables such as gender, age, ethnicity, nationality, parental status, and diagnosis. We will expand this analysis by linking the eugenic

sterilization dataset to individual-level census microdata in order to statistically compare risk of sterilization across demographic groups, and by conducting qualitative analysis to better understand familial resistance to sterilization, patient refusals, the fraught process of consent, as well as individual experiences of institutionalization and sterilization.

CRITIQUE 1:

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 1
Environment: 1

Overall Impact: I am very enthusiastic about this proposal which takes advantage of the PI's discovery of microfilm reels containing documents related to sterilization in nine California hospitals, and subsequent creation of a large data set from information in these documents, to explore patterns of eugenic sterilization. The highly-innovative approach combines historical and epidemiologic methods and quantitative and qualitative analysis. It has the potential to ask questions about sterilization practice that could not be answered in the absence of such a large data set as well as interdisciplinary collaboration. My only (minor) reservation is that factors that made California a hotbed of sterilization may limit the ability to generalize, a possibility not acknowledged in the proposal. However, the opportunity to make use of this treasure-trove of data would be exciting even if California's sterilization practices were idiosyncratic in some respects.

1. Significance:

Strengths

- Concerns about eugenics continue to pervade discussions of genetics research and its applications; witness the current debates about the use of CRPR/Cas9 method for targeted gene editing. The practice that most often serves to exemplify past eugenics is the compulsory sterilization of institutionalized patients. But as the PI notes, "few empirical historical analyses of this practice are available." The few exceptions, such as Joanna Schoen's *Choice and Coercion* (2005) which was based on records of the North Carolina Eugenics Board, demonstrate that use of primary source material may generate truly surprising findings; e.g. that it is not always easy to distinguish victims from agents. The proposed project would use more sophisticated techniques of data analysis than the few other empirically-oriented studies and involve collaboration between a historian and epidemiologists. It thus has the potential to result in finer-grained analyses of sterilization practices than currently exist. To the extent that commentators continue to draw lessons for contemporary policy and practice in genetics from the history of eugenic sterilization, it is important to have as accurate and nuanced account of that history as possible.

Weaknesses

- The fact that a third of all known eugenic sterilizations in the U.S. occurred in California indicates that the state was atypical, raising issues of generalizability of findings from this case. Thus Alex Wellerstein has argued that institutional factors played a crucially important role in the California sterilization program. He notes that nearly 70% of sterilizations occurred in only three hospitals; also that the state's hospital system was highly decentralized, allowing superintendents unusual discretionary authority. Although his "States of Eugenics" is listed in the references, his arguments, which point to ways in which generalizations from the California case may be limited, are not taken into account.

2. Investigator(s):

Strengths

- The PI Alexandra Stern ▮▮▮▮▮▮▮▮▮▮▮▮▮▮) is extremely well-suited to this project. She is a well-respected historian of medicine who has published extensively on the history of eugenics, including a book. *Eugenic Nation*, that centers on California. Her most recent book, *Telling Genes*, is a history of genetic counseling that also analyzes the profession's complex relationship to eugenic ideas and practices. This project is a natural extension of her earlier research.

- There are two collaborators, both at the University of Michigan School of Public Health: Siobán Harlow, a reproductive epidemiologist, and Sharon Kardia, a genomic epidemiologist with an interest in translational medicine ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮ They will provide highly relevant complementary scientific expertise.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The application uses a novel methodology for analyzing the practice of eugenical sterilization. (Although the methodology itself is not new, its application to this field of research is novel). No other study of sterilization has involved such sophisticated quantitative analysis of data sets, or involved an interdisciplinary collaboration, which in this case allows historical to be combined with epidemiologic analysis.

Weaknesses

- None noted.

4. Approach:

Strengths

- The overall strategy, methodology, and analysis is well-reasoned and appropriate to the project's specific aims, which are to 1) conduct a quantitative analysis of a data set that includes information on 15,000 individuals recommended for eugenic sterilization between 1921 and 1952 in order to identify patterns related to over 200 demographic and other variables, 2) link the data set to census records of 100,000+ residents of institutions where sterilizations were performed in order to estimate population-based sterilization rates and test hypotheses about demographic and other factors associated with the risk of sterilization, 3) conduct qualitative analysis of the sterilization records and other materials in the microfilm reels and, 4) develop a companion digital archive.

- An acknowledged problem with their data set is that it only includes information on those who were sterilized, yet in order to test hypotheses about bias, they will need comparable information on institutionalized individuals who were not sterilized. That problem will be addressed through the creation of a companion data set using individual-level data from the 1920, '30, and '40 censuses and tract-level data from the 1950 census to produce a population profile of each institution to be used as a control.

Weaknesses

- None noted.

5. Environment:

Strengths

- The University of Michigan provides ample physical and other resources for this project and rich opportunities for collaboration with colleagues in diverse disciplines.

Weaknesses

- None noted.

Protections for Human Subjects:

- This project involves 15,000 historical patient records (from 1921 to 1952); there is no direct involvement of human subjects.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

  Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children and not IRB Exemption #4.

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically
- These historical records are as they are; the PI has no control over their distribution.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested.

Additional Comments to Applicant (Optional):

- Information on the institution were provided by several pages of boilerplate on the quality of the clinical care in the UM health system which has no relevance to the aims of this application, and indeed, some facts would seem irrelevant to any application; e.g. that the health system is located on 128 acres or that the medical school began with five faculty members. Lack of editing

increases the burden on reviewers to comb through searching for the details that are germane to the aims of the proposal.

CRITIQUE 2:

Significance: 2
Investigator(s): 2
Innovation: 2
Approach: 3
Environment: 2

Overall Impact: This application proposes to "conduct quantitative and qualitative analysis of 15,000 eugenic sterilization recommendations processed by the state of California from 1921 to 1952." The project is likely to yield a deeper understanding of the factors that are correlated with recommendations to sterilize an institutionalized person, with consent to sterilization, and sterilization without consent. The research team has relevant expertise in history and data analysis. While today's policies are very different from those of the 1920's-1950's, limiting the generalizability of the analyzed data to today's setting, the project nevertheless has the potential to have a high impact insofar as it draws attention to risks factors for unethical behavior that may cut across eras.

1. Significance:

Strengths

- The project is likely to yield a deeper understanding of the factors that are correlated with recommendations to sterilize an institutionalized person, with consent to sterilization, and sterilization without consent. These factors are expected to reveal a stronger association of sterilization with individuals who reveal a greater number of vulnerabilities (e.g., intellectual but also social stigma and minority status).
- Remembering and understanding the dynamics of abusive social and public health policies is important in an age that presents unprecedented opportunities to discriminate using genetic, health, and behavioral information.

Weaknesses

- Today's policies are so different from those of the period being studied, that the ability to extract important lessons for today might be a bit limited. On the other hand, the proposal cites some very recent examples of sterilization programs that are controversial.

2. Investigator(s):

Strengths

- The primary investigator has extensive knowledge of the general subject area with an appropriate publication track record. She is collaborating with two other faculty members with relevant experience analyzing large datasets.

Weaknesses

- None noted.

3. Innovation:

Strengths

- Few historical studies of eugenics and sterilizations involve empirical study of a large dataset. None have looked at the proposed dataset, which is the largest I am aware of, or explored the relationship between a very large set of variables.
- The interdisciplinary collaboration between history and epidemiology is novel.

Weaknesses

- None noted.

4. Approach:

Strengths

- The investigators have developed a large, HIPAA compliant database with 15,000 cases and over 200 variables per case. This is impressive and should enable some very interesting analyses.
- The idea of supplementing the current data with micro-data from the US Census reports makes sense.
- I appreciate the fact that they will not only analyze quantitative relationships, but will code narrative records and present qualitative data to remind readers of the personal nature of sterilization and the vulnerability of the institutionalized persons affected by sterilization policies.

Weaknesses

- The proposal is short on details on their qualitative research approach. I'm not sure what they mean by "using data captured via REDCap." I am familiar with RedCap as a survey tool, not a qualitative coding tool such as NVivo.

5. Environment:

Strengths

- The environment is strong and the researchers will have access to the resources they need to execute this project.

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children and not IRB Exemption #4.

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested.

CRITIQUE 3:

Significance: 2
Investigator(s): 3
Innovation: 2
Approach: 3
Environment: 3

Overall Impact: Considerable enthusiasm for this proposal that would, in addition to more conventional qualitative methods, apply rigorous quantitative methods to a unique dataset reflecting the eugenic sterilization practices of California institutions during the first half of the 20[h] century. The innovative combination of qualitative and quantitative methods is a significant strength. The experienced, multi-disciplinary team are well-positioned to complete this project, which is also a major strength. The most significant weakness noted was the very cursory description of the qualitative methods proposed for this element of the project. This could be attributed to the length limitation of the proposal, but is still an important element of a proposal for funding of qualitative research. The importance of this weakness is mitigated, however, by the manifest expertise of the principal investigator. The potential overall impact of this project is high, and is likely to have an important effect on scholarship looking at American eugenic sterilization practices.

1. Significance:

Strengths

- Although other scholarship on eugenic practices in the US is available, the proposed project would advance this field in significant and important ways. For example, it would provide quantitative analyses of eugenic practices that is unprecedented. It would also provide qualitative insights that are both unique and more rigorously analyzed than much of the existing anecdotal and qualitative scholarship on this topic.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- The PI has demonstrated expertise in historical scholarship related to medicine and health, and has published numerous articles on the topic eugenics. She has assembled a strong team of experts representing other key disciplines important for the successful completion of this proposal, including epidemiology and genetics.

Weaknesses

- None noted.

3. Innovation:

Strengths

- While the linking of census data with a second data source is not new, the proposed approach is innovative in a number of ways. First, the linking of census data with historical medical record data is an innovative way to answer historical hypotheses. Such a rigorous approach is not necessarily the normal in historical scholarship. Second, the investigators are proposing to utilize individual-level census data. This approach is not the norm for contemporary research because individual-level census data is only available 72 years after the decennial census. The investigators have adopted an innovative approach that takes advantage of this fact. Third, the dataset, generated in the preliminary stages of this project, is a powerful and unique resource.

Weaknesses

- None noted.

4. Approach:

Strengths

- The combination of qualitative and quantitative methods is a major strength, and will help maximize the research utility of this unique research database.

- The use of historical census data to provide information about controls is an effective way to answer important research questions about the demographic patterns of eugenic sterilization and uncover the role of biases in these practices.

Weaknesses

- While we can infer that the principal investigator is knowledgeable and experienced with the qualitative analysis of historical documents, she could have strengthened this application by describing in greater detail the qualitative methods she intends to use.

- I would assume that the use of historical census data raises a number of challenges. For example, the investigators must use data from the 1950 census that is significantly different from the 1920, 1930, and 1940 census. They are also proposing to compare decennial census data that gives an every-ten-years snapshot with sterilization recommendations that were generated in a continuous fashion. This proposal could be strengthened by noting these challenges and providing a brief discussion for how they will be addressed.

5. Environment:

Strengths

- The research environment is appropriate and seems to provide all of the resources the investigators require to successfully complete this project.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

       Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children and not IRB Exemption #4.

- Sex/Gender: Distribution justified scientifically

- Race/Ethnicity: Distribution justified scientifically

- Inclusion/Exclusion of Children under 21: Including ages < 21 justified scientifically

- Inclusion of records from children is central to one of the most important aims of this study. The investigators state that "The data collected in this study is not of a sensitive nature." I disagree with that assessment, but believe the overall program of human subjects protections, including efforts to minimize the extent to which personally-identifiable information will be utilized, is appropriate.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested.

Recommended budget modifications or possible overlap identified:

- The budget seems appropriate for the proposed work.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.