

SUMMARY STATEMENT
(Privileged Communication)

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Application Number: 1 K01 HG008653-01

Principal Investigator

SABATELLO, MAYA PHD

Applicant Organization: NEW YORK STATE PSYCHIATRIC INSTITUTE

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

Meeting Date: 02/18/2015
Council: MAY 2015
Requested Start: 09/01/2015

RFA/PA: PA14-044
PCC: X5JM

Dual IC(s): MH

Project Title: Impact of Psychiatric Genetic Data on Civil Litigation and its Relationship with Stigma

SRG Action: Impact Score:

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

Human Subjects:

Animal Subjects:

Gender:

Minority:

Children:

Project
Year
1
2
3
4
5

Direct Costs
Requested

Estimated
Total Cost

TOTAL

Estimated Costs

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.

1K01HG008653-01 Sabatello, Maya

RESUME AND SUMMARY OF DISCUSSION: This is an application from an outstanding candidate with strong supportive letters of reference. The candidate is an experienced lawyer and disability rights advocate with a PhD in political science and post-doctoral experience in medical ethics. The purpose is to extend the candidate's training and expertise in advanced mixed methods research skills and the training plan includes formal training in research methods, genetics and clinical psychiatry. The research project is highly significant and innovative as it will focus on psychiatric genetic information in civil and criminal cases. The sponsors are outstanding and are directly relevant and involved with the candidate's research and training plan. Some of the reviewers questioned whether this candidate needs further training as she is already highly accomplished. However, the other reviewers believe this training plan will fill gaps in her education that are critical to her development as a researcher. The reviewers all agreed that the strengths outweigh any minor weaknesses in this application from a candidate who has a high likelihood to become an independent productive social science researcher in the area of ethical, legal and social implications of genetic discoveries and disclosure for individuals with disabilities.

DESCRIPTION (provided by applicant): Advances in psychiatric genetics are likely to offer major diagnostic and therapeutic benefits, but also legal and social-related risks, to individuals who were diagnosed with, or have a proclivity for, psychiatric disorders. In response, courts and policy-makers will have to ensure that psychiatric genetic data are used to promote, and not to obstruct, equality, justice, and social inclusion. However, few studies have queried how such data might impact judicial decision-making; none have explored this question in civil proceedings about parental rights, children's education, and responsibility for behavior in tort. This K01 proposes to study the impact of psychiatric genetic data on these 3 prominent areas of litigation and its relationship to stigma to better understand the implications of new discoveries in psychiatric genetics for law, society, and individual rights, and to inform policy-makers about this knowledge as they devise responses to these advances. The study's aims are: 1) To survey appellate court decisions in family law, education, and torts to determine the extent to which courts are considering psychiatric genetic data, and how they use such data in their decisions; 2) To investigate judicial views about the use of psychiatric genetic data and how such data may affect judges' and public perceptions of parental capacity, educational decisions, and civil responsibility for behavior in tort cases; and 3) To assess the association between psychiatric genetic data and stigma by studying if such data affect judges' and public perception of broader civil legal incapacity and treatment options, and the relationship to judicial bias against persons with psychiatric conditions. For Aim 1, I will use a mix of qualitative legal analysis and empirical methods. For Aim 2, I will use a vignette methodology, administered in 3 waves, with samples, respectively, of family court judges, parents, and state trial court judges and the jury-eligible general population. For Aim 3, I will use existing legal and sociological literature on psychiatric-related stigma to develop measures of explicit stigma, and a computer-based measure designed to detect implicit bias, administered as part of the vignettes, to assess the relationships among psychiatric genetic data, judicial decisions, and stigma. Findings will be published in peer-reviewed medical, psychological and policy journals. Complementing these studies will be an intensive training program comprised of didactic courses, tailored training, clinical exposure at the NY State Psychiatric Institute, and mentored experience. My primary mentor Dr. Appelbaum, co-mentors Drs. Link and Ottman, collaborator, Dr. Phelan, biostatistician, Dr. Goldsmith, and consultant, Dr. Parens will train and monitor my progress as I attain my training goals to: 1) develop the skills necessary for conducting empirical research; 2) learn about the clinical aspects of psychiatric disorders; and 3) build and expand national and international professional collaborations with scholars in psychiatry, genetics, social sciences, bioethics, and law. This training will culminate in R01 grant submission to further study the intended and unintended consequences of psychiatric genetic data on law, equality, and social inclusion.

PUBLIC HEALTH RELEVANCE: This Mentored Research Scientist Development Award (K01) will prepare the candidate to develop an independent mixed-methods research program to study the intended and unintended consequences of psychiatric genetic data for law, equality, and social inclusion. This study advances NHGRI research priorities relating to the ethical, legal, and social implications of genomic research. It will explore legal, regulatory and public policy issues by studying the effects of current and prospective use of psychiatric genetic data on civil judicial decision-making, and inform the development of new policies for the introduction of such data in non- medical settings (civil courts and schools). It also addresses broader societal issues by querying the implications of psychiatric genomic data for the conceptualization and understanding of mental disability, rights and treatment options for persons with, or proclivity for, psychiatric disorders, and concepts of free will, responsibility, and justice in the genomic era.

CRITIQUE 1:

Candidate: 1

Career Development Plan/Career Goals /Plan to Provide Mentoring: 1

Research Plan: 3

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1

Environment Commitment to the Candidate: 1

Overall Impact: This K01 application is from an exceedingly well qualified lawyer and political scientist who brings her considerable experience in disability rights and advocacy to develop advanced mixed-methods research skills and focus her efforts on genetics and psychiatry. She is working with an unparalleled group of mentors and consultants in the top rate NYS Psychiatric Institute and Columbia University. Her proposed research project is very thoroughly described, and is highly significant in that it offers to examine the largely unexplored area of civil litigation and the use of psychiatric genetic information. The only major reservation about the project is that "psychiatric genetic data" is not defined, but appears broad enough to encompass both molecular testing as well as family history and a more comprehensive account of how courts already deal with psychiatric diagnoses as well as with uncertain prognostic information would seem to be needed to ground the proposed study.

1. Candidate:

Strengths

- Dr. Sabatello is an experienced trial lawyer and disability rights advocate who secured her PhD in Political Science and post-doctoral experience in medical ethics;
- She has extremely strong letters of support and mentorship from an unparalleled group of mentors;
- She is extremely well qualified to undertake the proposed project and training.

Weaknesses

- None noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- The plan includes continued formal training in research methods, genetics and clinical psychiatry along with a mentored research project, all tightly drawn to further develop the applicant's mixed methods skills to be an independent researcher;

- The mentors are well chosen for their respective skills, and all are extremely supportive of the application and have committed to continued collaboration.

Weaknesses

- None noted

3. Research Plan:

Strengths

- The Aims of the study are all well chosen and important, and the results are highly likely to contribute significantly to knowledge and public policy discussion regarding the treatment of mental illness in civil litigation as genetic testing becomes more prevalent and pertinent;
- The focus on psychiatric genetic information in civil litigation arising in the 3 topic areas is innovative;
- The study methods are all appropriate and extremely well fleshed out in the application;
- Letters from each survey firm to be subcontracted are included.

Weaknesses

- The application fails to define "psychiatric genetic data" but implies that it includes results from "genetic tests", as well as family history or other markers or "psychiatric genetic evidence" (p.96), and the search for cases will include "gene!" or "family history" (p.100) – to this extent, it is unclear to what extent molecular testing will alter the courts' approaches to evidence of psychiatric illness, and a more full accounting of how courts already deal with diagnoses as well as with uncertain prognostic information would seem to be needed to ground the proposed study;
- Some analytic methods are inadequately described; for example, under C.1 Aim 1, it is unclear what the denominators would be for assessment of "comparative frequencies" of use of genetic data, and it is unclear that an analysis of how such data "are used in [judges' or jurors'] decisions" will be feasible, given that the analysis is drawn to appellate decisions in which jurists are often left guessing how decisions below by court and jury were reached.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Paul Appelbaum is Dr. Sabatello's primary mentor, and he is excellent, and the proposed work is a good extension of work he has done with others;
- The other mentors and consultants are all excellent, and each brings relevant expertise that will contribute to Dr. Sabatello's targeted development;
- All mentors and consultants have expressed extremely strong support for the applicant.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Columbia University and the New York Psychiatric Institute are fully supportive and provides an excellent environment for Dr. Sabatello's proposed activities;

- The Columbia CEER directed by Dr. Appelbaum provides an intellectual base for the applicant's collaborative activities.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- All protections are adequate.

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C1A - Children and Adults, Acceptable

- Plans for inclusion of women and minorities acceptable; oversampling of African Americans is planned for Wave 2 survey; children 18 and over may be included in on-line surveys if they otherwise meet entry criteria, which is completely acceptable.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Acceptable

Comments on Format (Required):

- Excellent overall approach to research ethics education, encompassing a full semester course, mentored oversight of research activities, and attendance at RCR and HSR workshops run by Columbia and NYSPI.

Comments on Subject Matter (Required):

- All relevant RCR and HSR topics to be comprehensively addressed.

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- Mentors Appelbaum, Ottman, and Link will all be directly involved.

Comments on Duration (Required):

- More than adequate, particularly in light of Dr. Sabatello's prior training and experience.

Comments on Frequency (Required):

- Excellent.

Budget and Period of Support:

Recommend as Requested

Additional Comments to Applicant:

- Excellent application and attention to detail.

CRITIQUE 2:

Candidate: 1

Career Development Plan/Career Goals /Plan to Provide Mentoring: 5

Research Plan: 5

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1

Environment Commitment to the Candidate: 1

Overall Impact: Professor Sabatellos is trained in law and holds a PhD in political science. She spent 2 years at Harvard Medical School as a fellow in medical ethics before moving to Columbia University in 2013 where she is a postdoctoral research fellow in the department of Psychiatry. Her aims are to survey appellate court decisions to determine the extent to which courts are considering psychiatric genetic data, and how they use such data in their decisions; to investigate judicial perspectives about the use of psychiatric genetic data and then to study the association between psychiatric genetic data and stigma by studying whether such data affect judges' and public perception of broader civil legal incapacity and treatment options, and the relationship to judicial bias against persons with psychiatric conditions. She is very well-trained and well-published.

1. Candidate:

Strengths

- She has excellent multidisciplinary training
- She has excellent writing skills, having already published a full-length manuscript

Weaknesses

- Not clear she needs a 5 year mentored training program.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- She seeks to become an R01 funded investigator
- She will pursue additional training in genetics and empirical (quantitative research)
- She has already provided mentorship to MA students.

Weaknesses

- She is too far advanced for a 5 year training program.

3. Research Plan:

Strengths

- Her research plan is to examine the use of genetics in both civil (family law [custody], education [use of genetic testing for special education]) and criminal cases. This is innovative
- She is trying to study the stigma related to mental health and mental health genetics which are important areas of study

Weaknesses

- The PI states interest in exploring genetic testing for special education, but there is no pediatric mentorship.
- I do fear that the opt-in YouGOV may not get a lot of educational and socioeconomic diversity in participants given the complexity of the topic being done on the internet without some education about the issues.
- The PI claims she needs time to learn how to write and present at medical conferences (career goal 4), but many of her outputs are at legal conferences and policy journals. Educating the legal profession about genetics and helping to devise policy is laudable, but not consistent with the training plan.
- The case studies presume an overly deterministic utility of genetic tests which makes the study limited to a genetic determinism bias—a problem already seen in legal use of genetic testing.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Very strong with broad range of knowledge
- Has excellent working relationship with many of the mentors

Weaknesses

- No one with pediatric expertise although one of her cases involves school setting.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Very strong

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Her participants are a non-vulnerable population and the risk is minimal.

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

- The judges will be representative of the legal system. Dr. Sabatello wants diverse public participation and is involving YouGov, which is a proprietary opt-in Internet organization that seeks to be representative of the US population.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

Comments on Format (Required):

- Format is both face-to-face and CITI. Will also attend Regulatory Knowledge and Ethics Workshops.

Comments on Subject Matter (Required):

- Includes all components of RCR training

Comments on Faculty Participation (Required; not applicable for mid- and senior-career awards):

- A course on Responsible Conduct of Research and Related Policy Issues (G4010). She plans to participate although she could be a leader or facilitator in this course given her experience and prior training

Comments on Duration (Required):

- Exceeds minimal requirements for training grant

Comments on Frequency (Required):

- She will do training throughout her training grant.

Resource Sharing Plans:

Acceptable

- Does plan to publish all of her findings. No discussion of resource sharing of raw data.

Budget and Period of Support:

Recommended budget modifications or possible overlap identified:

- 2-3 year training program at most.

CRITIQUE 3:

Candidate: 3

Career Development Plan/Career Goals /Plan to Provide Mentoring: 2

Research Plan: 3

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1

Environment Commitment to the Candidate: 1

Overall Impact: The candidate, Dr. Maya Sabatello, holds both a JD and PhD in Political Science and her goal is to transition a social science research career with a focus on the consequences of psychiatric genetic data for law and disability rights. The candidate has limited training in relevant skill sets, including research methods, study design, assessment, psychiatric genetics, and clinical psychiatry. However, she has developed some foundation in these areas during her current postdoctoral research fellowship in the Department of Psychiatry, Center of Excellence in ELSI Research (CEER) at Columbia University. As part of the K01 proposal, the candidate has outlined a training plan that covers those areas that represent gaps in her training and are critical to her advancement as a researcher. She has assembled an impressive mentoring team of seven experts who have well-defined roles in her training plan and have provided excellent letters of recommendation on her behalf. Her research plan is well-aligned with these training goals, especially her efforts to gain expertise in the development of assessments. Overall, she is an extremely strong candidate who has already demonstrated dedication and initiative in transitioning to a research career and, if funded, it is highly likely that she will emerge as a productive independent investigator.

1. Candidate:

Strengths

- The candidate, Maya Sabatello, holds both a JD and PhD in Political Science. Her primary research goal is to develop expertise in mixed methods approaches to the study of the consequences of psychiatric genetic data for law and disability rights.
- She has an impressive number of publications in law and human rights journals, with the majority of articles focused on disability law. This work is evidence of the depth of her current knowledge of this area and her potential productivity.
- Over the past several years, Dr. Sabatello has become increasingly motivated to design and conduct empirical research studies to investigate the ethical, legal, and social implications of genetic discoveries and disclosure for individuals with disabilities. This motivation is reflected in the work and training opportunities she has pursued. From 2011-2013, she was a Research Fellow in Medical Ethics at Harvard Medical School and since 2013, she has been a Postdoctoral Research Fellow in the Department of Psychiatry, Center of Excellence in ELSI Research (CEER) at Columbia University.
- Based on her letters of recommendation, Dr. Sabatello has already begun her transition from legal practice to social science researcher. She lists 7 faculty (1 primary mentor, 2 co-mentors, and 4 consultants) as members of her mentoring team. All have provided extremely strong letters of recommendation that emphasize Dr. Sabatello's initiative in creating learning opportunities that help to fill the gaps in training and background; her appreciation of interdisciplinary collaboration; and her capacity for innovative thinking. For example, the candidate audited a "Genetics in Epidemiology" course offered by proposed co-mentor, Dr. Ottman, and they met weekly to discuss research questions related to Dr. Ottman's ongoing research program. These meetings have resulted in a presentation at the 2014 American Epilepsy Society meeting and they are preparing a related manuscript for publication in a peer-reviewed journal.
- The letters of reference provided on the candidate's behalf are unequivocal in the expressed expectation that she will emerge as an independent investigator.

Weaknesses

- Beyond her recent experiences as a postdoctoral research fellow, Dr. Sabatello has almost no training as a researcher and acknowledges the need for intensive training in research methods, study design, assessment, psychiatric genetics, and clinical psychiatry

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:

Strengths

- Dr. Sabatello has identified five areas of training that are key to her career development: 1) research methods, 2) clinical psychiatry and psychiatric genetics, 3) grantsmanship, 4) publication in peer-reviewed medical journals, and 5) presentation at scientific meetings. Over the five-year period of the K01, she has proposed between 2-6 activities per training area, including formal academic courses at Columbia University, seminars, workshops, and attendance at five separate scientific conferences.
- She also plans to enroll in at least one course and participate in several workshops related to human subjects protection and the responsible conduct of research.
- Dr. Sabatello has proposed regular meetings with several members of her mentoring team, with frequencies ranging from weekly to monthly. Furthermore, the mentoring team will meet quarterly to monitor and evaluate the candidate's progress.

Weaknesses

- Dr. Sabatello plans to prepare 6 manuscripts for publication over the K award period so it would be useful to identify training opportunities in manuscript preparation specific to medical journals.

3. Research Plan:

Strengths

- Dr. Sabatello has proposed an ambitious research plan, with the overarching goal of examining responses to psychiatric genetic information with the legal system. This work will include a review of appellate court decisions in family law, education, and tort to determine the extent to which genetic information may have influenced these decisions. The research also includes a national survey of judges and members of the general public to examine their receptiveness to genetic data in the context of court cases. These surveys will use vignette methodology, with vignettes developed by Dr. Sabatello in collaboration with her mentors and focused on dispute of child custody, termination of parental rights, genetic testing in school settings, special education services, and psychiatric defense for civil tort liability, and comparative negligence.
- In addition to closed-ended responses to the vignettes, participants will be asked to complete measures assessing their understanding of genetics and stigma, including the Implicit Association Test (IAT) specific to bias regarding psychiatric disorders. The inclusion of these measures is consistent with her training goals in assessment methods.
- Participant recruitment and survey administration, including administration of the IAT, will be facilitated by three separate research firms and implementation will be web-based. Engagement with these firms is particularly important given the large scale of the proposed research (with recruitment goals of close to 1000 participants).

Weaknesses

- The research plan does not mention any theoretical framework that guides the proposed work and the focus on variables such as stigma and bias.
- There is limited discussion of how the data collected might inform an independent research program. If the aims are reached, what would be the next step?

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- The candidate has formed a mentoring team to include 1 primary mentor, 2 co-mentors, and 4 consultants. All have leadership positions within their institution related to the wide but

interrelated range of topics that Dr. Sabatello's research interest encompass, including psychiatry, ethics, social inequalities, stigma/bias, genetics, and epidemiology. The team members have strong track records in terms of mentoring trainees and/or teaching, and the majority maintain robust research programs.

- The letter of recommendation from Dr. Sabatello's primary mentor, Dr. Appelbaum, provides additional information regarding her training and career development plan, the nature and extent of her supervision and mentoring, and a plan for her transition to independent research status.

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- The training and research environments (Columbia University and New York Psychiatric Institute) are outstanding.
- The application includes a letter from the leadership of her institution and that fully supports her application and states that at least 90% of her time will be dedicated to the research activities described in the proposal and that she will not have any teaching assignments or administrative responsibilities for the duration of the award

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- The plan for human subjects protection is adequate.

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

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

- The justification for inclusion and exclusion of participants is adequate.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWER'S 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.

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.