Overview

The National Human Genome Research Institute (NHGRI) Ethical, Legal and Social Implications (ELSI) Research Program frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let excerpts of their ELSI grant applications be posted online.

Acknowledgement

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. We do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., budgets, biographical sketches, letters of recommendation or letters of support). NIH grant formats or rules may have changed since these applications were prepared; therefore, applicants should always follow the application format instructions included in the funding announcement.

PI: **Sabatello, Maya**	Title: Impact of Psychiatric Genetic Data on Civil Litigation and its Relationship with Stigma	
Received: 10/14/2014	FOA: PA14-044	Council: 05/2015
Competition ID: FORMS-C	FOA Title: MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (PARENT K01)	
1 K01 HG008653-01	Dual: MH	Accession Number: 3748664
IPF: 1590919	Organization: NEW YORK STATE PSYCHIATRIC INSTITUTE dba RESEARCH FOUNDATION FOR MENTAL HYGIENE, INC	
Former Number:	Department: 110 NYPI Psychiatric Education	
IRG/SRG: SEIR	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: [redacted] Year 2: Year 3: Year 4: Year 5:	Animals: N Humans: Y Clinical Trial: N Current HS Code: Evaluative Info HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Maya Sabatello	Research Foundation for Mental Hygiene, Inc.	PD/PI
Paul Appelbaum	Research Foundation for Mental Hygiene, Inc.	Other (Specify)-Primary Mentor
David Goldstein	Columbia University	Consultant
Bruce Link	Research Foundation for Mental Hygiene, Inc.	Other (Specify)-Co-Mentor
Ruth Ottman	Research Foundation for Mental Hygiene, Inc.	Other (Specify)-Co-Mentor
Jo Phelan Dr.	Mailman School of Public Health	Other (Specify)-Consultant

Appendices

appendix_for_

Reference Letters

[redacted]

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ❍ Application ● Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

c. Previous Grants.gov Tracking Number
GRANT11757209

2. DATE SUBMITTED
1900-01-01

Application Identifier
PD/2014/01130

5. APPLICANT INFORMATION

Organizational DUNS*: 1672049940000

Legal Name*: Research Foundation for Mental Hygiene, Inc.
Department: New York Psychiatric Institute
Division:
Street1*: NYPI
Street2: 1051 Riverside Dr
City*: New York
County: New York
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 10032

Person to be contacted on matters involving this application
Prefix: Ms. First Name*: Janelle Middle Name: Rene Last Name*: Greenhill Suffix: MPH
Position/Title: Director of Administration
Street1*: NYPI
Street2: 1051 Riverside Dr
City*: New York
County: New York
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 10032
Phone Number*: 646-774-6500 Fax Number: 646-774-6540 Email: nga@rf.cpmc.columbia.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1141410842A2

7. TYPE OF APPLICANT*
M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*
● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Impact of Psychiatric Genetic Data on Civil Litigation and its Relationship with Stigma

12. PROPOSED PROJECT
Start Date* 09/01/2015
Ending Date* 08/31/2020

13. CONGRESSIONAL DISTRICTS OF APPLICANT
NY-013

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Maya Middle Name: Last Name*: Sabatello Suffix:

Position/Title: Postdoctoral Research Fellow
Organization Name*: Research Foundation for Mental Hygiene, Inc.
Department: 110 NYPI Psychiatric Education
Division:
Street1*: NYPI
Street2: 1051 Riverside Dr
City*: New York
County: New York
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 10032
Phone Number*: 212-854-4933 Fax Number: Email*: ms4075@columbia.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$928,370.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$928,370.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: Ms. First Name*: Janelle Middle Name: Rene Last Name*: Greenhill Suffix: MPH

Position/Title*: Director of Administration
Organization Name*: Research Foundation for Mental Hygiene, Inc.
Department: 110 NYPI Facilities and Admini
Division:
Street1*: NYPI
Street2: 1051 Riverside Dr
City*: New York
County: New York
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 10032
Phone Number*: 646-774-6500 Fax Number: 646-774-6540 Email*: nga@rf.cpmc.columbia.edu

Signature of Authorized Representative*
Ms. Janelle Rene Greenhill MPH

Date Signed*
10/14/2014

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:Cover_Letter_Attachment.pdf

424 R&R and PHS-398 Specific Table Of Contents

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Research Foundation for Mental Hygiene, Inc.
Duns Number:	1672049940000
Street1*:	NYPI
Street2:	1051 Riverside Dr
City*:	New York
County:	New York
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	10032
Project/Performance Site Congressional District*:	NY-013

File Name

Additional Location(s)

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00006105

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	abstract.pdf
8. Project Narrative*	projplan.pdf
9. Bibliography & References Cited	ref.pdf
10.Facilities & Other Resources	Facilities_Upload.pdf
11.Equipment	
12. Other Attachments	OtherAttachments.pdf

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

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.

Project Narrative

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.

References

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245. Project Implicit. Privacy. https://implicit.harvard.edu/implicit/privacy.html

Facilities and Other Resources

Laboratory: The primary research setting is located at the New York State Psychiatric Institute (NYSPI). NYSPI was founded in 1895, as one of the first institutions in the US to integrate teaching, research, and therapeutic approaches to the care of patients with psychiatric disorders. The NYSPI, together with the Department of Psychiatry at Columbia University Medical Center which it houses, offer an extensive range of resources, including educational facilities, libraries, a computer center, grand rounds, departmental and divisional seminars, presentations, symposia, and access to a uniquely qualified and multidisciplinary group of faculty and research scientists who are available for further development of all aspects of the proposed research. Ample other resources (e.g., seminars, presentations, didactic courses, excellent faculty) are further available at Columbia University College of Physicians and Surgeons, New York Presbyterian Hospital, and the Mailman School of Public Health, all of which are located in proximity to one another within Columbia University Medical Center (CUMC). NYSPI consists of two buildings in CUMC, the Herbert Pardes Building and the high-rise Lawrence G. Kolb Research Laboratory ("Kolb Annex"). These 2 buildings are physically connected with a walkway bridge, as are the NYSPI and the Medical Center, including the Mailman School of Public Health and the Medical Center's Hammer Health Sciences Library. The location of Dr. Sabatello's office (see below) will allow for convenient access to the various resources available in these institutions and for the frequent collaborations and mentoring activities outlined in her proposal. In addition, Columbia University's Morningside Heights campus, site for training in the behavioral and social sciences and in the humanities, including Columbia Law School and its library, is a 15-minute ride away on Columbia's intercampus shuttle.

The Law, Ethics, and Psychiatry Division at NYSPI/Columbia Psychiatry, which will serve as Dr. Sabatello's primary research site, is located on the 6th floor of NYSPI's Pardes Building. It provides high-speed network access in its office spaces and is part of the high-speed campus Ethernet and wireless networks. The NYSPI has a wide area network of over 1,300 computers connected to a network backbone. Each machine has full access to the Internet, including E-Mail, Calendar, Outlook, and World Wide Web Services. All facilities within the NYSPI are connected via a fiber optics backbone, utilizing OC3 ATM protocol and 100 megabits per second (mbs) Fast Ethernet protocol to the desktop. The NYSPI's Office of Technology and Information Systems has established a Computer Training Center (CTC), a small drop-in center and group training facility composed of 12 networked PCs. The CTC is located at the NYSPI Kolb Annex, and classes are given in many types of statistical and application software throughout the year. In addition, NYSPI and Columbia University have purchased a number of licenses for software programs that faculty and trainees can access at a discounted rate or use free. These include SAS, SPSS, and NVivo, a software package that assists in analyzing unstructured data, which Dr. Sabatello will use in her research. 2-day NVivo workshops and individual consultations are available at no cost at the Columbia libraries. Dr. Sabatello will also have access to all the scholarly resources available at NYSPI/Columbia's libraries, including their on-line databases such as Medline, PsycINFO, PubMed, as well as the legal databases Westlaw Next and Lexis-Nexis Advance. A copy center at NYSPI is available for photocopying of documents.

Animals: N/A

Computer: Dr. Sabatello's computer (iMac desktop 21.5-inch; Mac OS X 10.9 Mavericks) and printer are more than sufficient to perform the qualitative and quantitative data analyses and the preparation of manuscripts required for the proposed research. Dr. Sabatello will have full access to the information and technology systems described above. In addition, Columbia University Information Technology Service Center serves as a walk-in support center to provide information and assistance on a broad range of topics relating to computing services, including software distribution, connectivity and other issues.

Office: Dr. Sabatello's office, including the computer, a printer, supplies, and technical capabilities required to carry out her proposed research will be located on the 6th floor of NYSPI's Pardes Building. The office of Dr. Appelbaum (primary mentor) is located on the same floor, and the offices of Drs. Link and Ottman (co-mentors), as well as consultants Drs. Jo Phelan and Jeff Goldsmith are all located in nearby buildings at CUMC, along with Dr. Goldstein's office (consultant). The proximity of the offices of Dr. Sabatello and her mentoring team will allow easy and frequent access to meetings and further development of the various aspects of the proposed study.

Clinical: The NYSPI provides exemplary care in the many inpatient and outpatient programs offered in its facilities, further augmented by other clinical services offered at New York-Presbyterian at CUMC and faculty

Budget Justification

The budget requested is for 5 years, Sept. 1, 2015-Aug. 31, 2020.

The Research Foundation for Mental Hygiene/New York State Psychiatric Institute (RFMH/NYSPI) implemented a new policy governing the proposing of effort for those investigators who possess an appointment at the RFMH/NYSPI and an academic appointment at Columbia University. Investigators at RFMH/NYSPI previously proposed their effort based on a percentage of their total professional effort ("TPE") across RFMH/NYSPI and Columbia University on an integrated basis. Now, modeled after the method utilized by those with joint Veterans Affairs/academic appointments,* all investigators at RFMH/NYSPI propose their effort based on a percentage of their RFMH/NYSPI effort.

* As described in the NIH Guide for Grants and Contracts, vol. 18, no. 27, August 11, 1989.

Personnel expenses

Primary Investigator

Maya Sabatello, LLB, PhD - Principal Investigator EFFORT Effort, EFFORT Effort in years 1-5, EFFORT salary support). Dr. Sabatello is a Postdoctoral Research Fellow at Columbia's CEER, the Center for Research on Ethical, Legal, and Social Implications of Psychiatric, Neurologic, and Behavioral Genetics. Her scholarship focuses on the intersection of law, medicine, disability, and society, and on the judicial responses to dilemmas arising from genetic technologies. Previously, Dr. Sabatello explored the impacts of genetic data on individual rights using qualitative legal analysis in a multidisciplinary framework. This K01 award will provide her the training, resources, and protected time to pursue her long-term goal of conducting mixed-methods research to study the intended and unintended consequences of psychiatric genetic data on law, equality, and social inclusion. Dr. Sabatello will lead this research effort. Working closely with a multidisciplinary team of experts, she will be responsible for survey design, data collection, qualitative and quantitative data analyses, and preparation of manuscripts about the use of psychiatric genetic data in civil litigation and its relationship with stigma. Dr. Sabatello will meet regularly with her primary mentor, Dr. Appelbaum, her co-mentors, Drs. Link and Ottman, and her consultant, Dr. Phelan to receive individualized training about all aspects of her proposed study (see *Sect. 4, Table 2*). She will meet with Dr. Goldstein, as needed, to consult on clinical and molecular genetic issues related to her research and training goals. She will perform biostatistics and categorical data analysis under the guidance of Dr. Goldsmith, her consultant, using, as needed, emails and in-person meetings, and will consult with Dr. Parens about the normative aspects of her findings through 3 annual in-person meetings, email and phone calls. Dr. Appelbaum will supervise each of the training goals and all aspects of the study. He and the co-mentors will meet quarterly to monitor Dr. Sabatello's progress, to ensure she has the support needed to achieve her training and career goals, and to facilitate her transition to an independent mixed-methods researcher investigating the relationships of psychiatric genetic data, law, disability, and society. Dr. Sabatello's base salary is Institutional Base Salary

Fringe for Primary Investigator: Salary fringe is calculated at 36% for all 5 years of the K01 Award period.

Other Professional

Paul Appelbaum, MD – Primary Mentor EFFORT requested; Years 1-5). Dr. Appelbaum is Dollard Professor of Psychiatry, Medicine and Law, and the Director of the Division of Law, Ethics, and Psychiatry at NYSPI/ Columbia Psychiatry. He is also the director of Columbia's CEER, the Center for Research on Ethical, Legal and Social Implications of Psychiatric, Neurologic and Behavioral Genetics, and has worked with Drs. Ottman, Phelan, and Parens to develop this program. Dr. Appelbaum is internationally recognized for his groundbreaking research and scholarship on the impact of legal and ethical rules on medical practice and research, as well as on the ethical and legal implications of neurologic and psychiatric genetic data. A recipient of multiple awards for his leadership in work on forensic psychiatry and the psychiatric aspects of jurisprudence, his NHGRI-funded ELSI studies include the exploration of approaches to informed consent for return of incidental findings in genomic research, the consequences of returning such data, and the use of behavioral genetic information in criminal and disciplinary settings, using methodological approaches that Dr. Sabatello will implement in this proposal. Additionally, Dr. Appelbaum has extensive experience in mentoring

trainees, a (non-degree) legal background, and he has worked closely with Dr. Sabatello in the development of this proposal. He is thus in an excellent position to mentor Dr. Sabatello throughout the K01 award period. He will be responsible for overseeing Dr. Sabatello's execution and timely implementation of the proposed study, supervising her preparation of manuscripts, and facilitating her professional transition and career development.

Bruce Link, PhD – Co-mentor (EFFORT requested; Years 1-5). Dr. Link is a professor of Epidemiology and Sociomedical Sciences at Columbia's Mailman School of Public Health, a research scientist at New York State Psychiatric Institute, and a director of, among others, the Psychiatric Epidemiology Training Program and the Private Source and Society Scholars Program at Columbia. Dr. Link is a world expert in the study of psychiatric and social epidemiology, especially the consequences of social stigma for persons with mental illness. His pioneering work (with Dr. Phelan), *Conceptualizing Stigma*, published in the 2001 Annual Review of Sociology is one of the most influential theoretical statements on stigma in the social sciences since Goffman's groundbreaking statement. His empirical work, which often uses a vignette methodology, established the negative effects of labeling on the quality of life and self-esteem of persons with such disorders, and his 2004 review of measurement of stigma as well as development of the "modified labeling theory" have laid the foundation for much of the research in this field. Dr. Link has received multiple awards for his distinguished scholarly contributions and his excellence in teaching, mentoring and training. He has worked extensively with Dr. Phelan on public attitudes toward psychiatric disorders and the geneticization of such disorders. Dr. Link will provide bimonthly, hourly meetings to guide vignette composition and development of quantitative measures of stigma among judges and public respondents that Dr. Sabatello will implement in Years 2-5. He will also provide invaluable guidance in writing manuscripts for medical journals and grantsmanship, journal placement advice, and participation in relevant professional meetings.

Ruth Ottman, PhD – Co-mentor (Private Source requested; Years 1-5). Dr. Ottman is the Deputy Director of Columbia's CEER, the Center for Research on Ethical, Legal and Social Implications of Psychiatric, Neurologic and Behavioral Genetics, and the Deputy Director for Research at Columbia's G. H. Sergievsky Center. She is a Professor of Epidemiology in Neurology and the G. H. Sergievsky Center, Mailman School of Public Heath, and also a research scientist in the Epidemiology of Brain Disorders Research Department, New York State Psychiatric Institute. An international expert in genetic epidemiology, her decades-long research addresses the role of inherited factors in susceptibility to complex neurological disorders, primarily focusing on seizure disorders, and on related methodologic issues. As a CEER Fellow, Dr. Sabatello met with Dr. Ottman weekly, and was introduced to clinical research methodology by studying the impact of genetic attribution on felt stigma in families with multiple members with epilepsy. Dr. Ottman has worked with Drs. Appelbaum, Phelan, and Goldsmith. Dr. Ottman will provide weekly, hourly meetings throughout the study to train Dr. Sabatello in quantitative data collection and analysis, to provide critical review of draft manuscripts, to instruct about responsible conduct of research, and to oversee Dr. Sabatello's professional development.

Jo Phelan, PhD – Consultant (Private Source requested; Years 1-5). Dr. Phelan is a Professor of Sociomedical Sciences and Co-Director of the Center for the Study of Social Inequalities and Health at Columbia's Mailman School of Public Health. She is internationally recognized for her research on social stigma, conceptions of mental illness, and inequalities in mental health. Dr. Phelan is also one of the few scholars to explore the sociological implications of the "genetics revolution" for mental illness, including genetic essentialism and stigma of mental illness, effect on orientation to treatment, perception of dangerousness and persistence of such illness, and (with Dr. Link) geneticization, race, and mental illness, and the impact of media coverage of genetics on public understanding and response to such information. A recipient of several NHGRI grants, she combines qualitative and quantitative methods, and she created a test to measure implicit attitudes towards mental illness that Dr. Sabatello will adjust to civil litigation contexts and implement in this proposal. In addition to working extensively with Dr. Link, Dr. Phelan has also worked with Drs. Appelbaum and Ottman on genetics-related ELSI projects. Dr. Phelan will provide monthly, hourly meetings to train and supervise Dr. Sabatello's empirical analysis of court cases (Aim 1) and modification of the implicit association test to measure implicit bias in judicial settings (Aim 3).

David Goldstein, PhD – Consultant (Private Source requested; Years 1-5). As of January 2015, Dr. Goldstein will be Professor of Genetics and Development, and the Director of the Institute for Genomic Medicine at Columbia.

He is an expert in molecular and population genetics, who is internationally known for this work on human genetic diversity, the genetics of disease, and pharmacogenetics. In particular, his research has focused on identifying the relationship between human genetic variations and diseases such as epilepsy and schizophrenia, as well as the response of these diseases to pharmacologic treatments, advancing the goal of personalized medicine. Dr. Goldstein received multiple awards in recognition of his work, including being a recipient of one of the first seven nationally awarded Royal Society/Wolfson research merit awards in the UK for his work in human population genetics and receiving a Honorary Professor appointment at the Institute of Neurology, University College, London. Dr. Goldstein is currently also serving on the Advisory Council at the National Institute of Neurological Disorders and Stroke at NIH. Dr. Goldstein will provide consultation, as needed, to train and develop Dr. Sabatello's understanding of clinical and psychiatric genetics and to advise her on clinical and molecular genetic issues related to her research and training goals (Aims 2-3).

Jeff Goldsmith, PhD – Consultant (salary requested; Years 1-5). Dr. Goldsmith is an Assistant Professor of Biostatistics at Columbia's Mailman School of Public Health. He holds a PhD in Biostatistics from Johns Hopkins, where his dissertation focused on statistical methods for high-dimensional structured data. Dr. Goldsmith's research focuses on developing general, principled methods for the analysis of challenging data sets arising from current scientific questions. His statistical methods examine relationships between complex data structures and patient-level information such as using MRI scans to predict patient function and examining effects of aging on daily activity patterns. Dr. Goldsmith is also the co-founder of Columbia's Functional Data Analysis Working Group, which focuses on statistical methods for and applications of functional data analysis, and an expert in categorical data analysis. He has previously worked with Dr. Ottman, and he will meet with Dr. Sabatello in-person and communicate via email, as needed, to provide statistical and categorical data analysis consultation throughout her study. Dr. Goldsmith will be compensated as a consultant EFFORT hrs each year (yrs 1-5), overall [redacted] per yr.

Erik Parens, PhD – Consultant (salary requested; Years 1-5). Dr. Parens is a Senior Research Scholar at The Hastings Center, a nonpartisan research institution dedicated to bioethics and the public interest, and a co-investigator with Dr. Appelbaum at Columbia's CEER, the Center for Research on Ethical, Legal and Social Implications of Psychiatric, Neurologic and Behavioral Genetics. An investigator on many ELSI projects, he uses interdisciplinary theories and qualitative methods to explore how we use new technologies to shape our selves and how emerging science shapes our self-understanding. His work on the disability community critique of prenatal testing has shaped the scholarly work in this area, and has greatly influenced Dr. Sabatello's own research since her PhD studies. Dr. Parens has also been a leading scholar studying the implications of behavioral genetics research on fundamental human values like equality, which Dr. Sabatello will explore with regard to psychiatric genetic data, and he wrote extensively on ethical and policy questions arising from the diagnosis and treatment of children with psychiatric conditions, which are integral to Dr. Sabatello's proposed study. As part of the study's policy-translation goal, Dr. Parens will serve as a consultant and provide insights (via 3 annual in-person meetings, phone calls and emails) about the normative aspects of the research findings. His consultancy will increase over the K01 period. In addition to his invaluable expertise, he will provide references to relevant literature about psychiatric genetics and genetic data more broadly, and will consult Dr. Sabatello about genetic-related normative research throughout the career development program. In years 3-4 he will also critically review the normative analyses in her manuscripts as Dr. Sabatello considers the policy implications of her findings. This consultancy will further increase in year 5 as Dr. Sabatello develops ethical and legal guidelines in light of her findings across contexts. Dr. Parens will be compensated as a consultant EFFORT EFFORT for yrs 1-2, EFFORT for yrs 3-4, and EFFORT for yr 5 (i.e., respectively, [redacted]

Research Assistant (yr 1; TBH). Hiring a research assistant as a second reader of court cases collected in Aim 1 to ensure independent and objective review of cases and identify coding of genetic-related themes [redacted]. Total cost requested is [redacted]

Training Budget, Yrs 1-5

A. Tuition/ Fees at Columbia University

- Coursework. Covers the cost of coursework at Columbia University, Department of Psychiatry, Mailman School of Public Health, Department of Psychology, and Bioethics Program as described in the training plan. Courses at Columbia University cost [redacted] per credit.
  - 3 didactic courses, 9 credits [redacted]
  - Auditing 3 didactic courses, 1 yr 1; 2 yr 2 (no charge)
  - 1 didactic course, 4 credits [redacted]
  - NVivo 2-day workshop, yr 1 (no charge)
  - Reach for the 1st R01, yr 4 (no charge)
- Human protection courses
  - Online course, yrs 1 & 5 (no charge)
  - 1 didactic courses, 1 credits [redacted]
- Experiential training, 3-mos rotation at NYSPI, yr 2 (no charge)

B. Other Direct Costs

Travel

- Travel for professional scientific and legal meetings for presentation of research findings and for national and international peer consultation and collaboration. Costs will include airfare, hotel, and conference registration fees. Conference travel costs are projected at a 3% inflationary increase in continuing years.
  - Yr 1 (overall: [redacted]
    - International Society of Psychiatric Genetics (international, 4-day), [redacted]
    - American Academy of Psychiatry and the Law (domestic, 4-day), [redacted]
  - Yr 2 (overall: [redacted]
    - American Society for Human Genetics (domestic, 4-day), [redacted]
  - Yr 3 (overall: [redacted]
    - International Society of Psychiatric Genetics (international, 4-day), [redacted]
    - American Psychiatric Association (domestic, 4-day), [redacted]
    - American Academy of Psychiatry and the Law (domestic, 4-day), [redacted]
  - Yr 4 (overall: [redacted]
    - American Society for Human Genetics (domestic, 4-day), [redacted]
  - Yr 5 (overall: [redacted]
    - International Society of Psychiatric Genetics (international, 4-day), [redacted]
    - American Psychiatric Association (domestic, 4-day), [redacted]
    - American Academy of Psychiatry and the Law (domestic, 4-day), [redacted]
- Travel for CEER networking meeting (yrs 1-5, 3-day). As per NOT-HG-14-018, funding is requested for Dr. Sabatello's participation at the CEER networking meeting. Costs include ground transportation, hotel, and per diem [redacted]
- Travel to meet consultant, Dr. Parens. To minimize costs associated with Dr. Parens' consultation services, most of the communication will be via conference calls and email. However, for particularly long consultations, Dr. Sabatello will travel to meet Dr. Parens in-person (3 times per year, yr 1-5). Costs will include ground transportation. [redacted]
- Translational meetings (yr 5). As part of the translational goal of the proposed study, I will offer to present my findings in conferences and educational forums for family and trial court judges to present my findings. In particular, I plan to attend 2 conferences organized by the American Bar Association (one for specialized judges, one for state trial court judges) and will engage in training initiatives of the National Council of Juvenile and Family Court Judges, web- or seminar series course of the National Judicial College (Nevada). Costs will include airfare, hotel, conference registration, and other costs related to the preparation of the material. [redacted]

Supplies

- Computer service costs
  - PsyIT. Funds are requested to cover the annual IT computing costs at NYSPI. Costs are increased 4% each year to adjust for inflation.

- Software costs
  - *Library access & online databases* (yrs 1-5)(no charge)
  - *SAS*. Support totaling [redacted] per year is requested for license fees for SAS quantitative data management and analysis software program. The costs include license fees (yrs 1-5 at [redacted] per yr), and installation fee (yr 1, [redacted].
  - License for *access to education data software* (yr 1). To conduct Aim 1, I will need to access "Special Ed Connection" software, which provides the most comprehensive source of cases in special education. This software is available on only 2 campuses – American University, Washington College of Law, and Southwestern Law School in Los Angeles –and using it would require travel for sufficient period of time to ensure that all material is collected. Purchasing a license for a year will thus be the most cost-effective option [redacted]
  - *NVivo software program* for the storage, organization, and retrieval of qualitative data (Aim 1) will be provided free by Columbia University (no charge).
- Consumables (yrs 1-5)
  - *Office & computer supplies*. Limited general office supplies are provided by the Department of Psychiatry. Support totaling [redacted] in yr 5 is requested for toner cartridges, other computer supplies, and photocopy charges. These supplies will be kept separate from routine supplies and will only be used for this project.
  - *Printer*. To purchase a printer for my office the requested sum is [redacted]

Research costs

- Amazon Mechanical Turk (MTurk) (yrs 3, 5). MTurk is a low-cost online service that allows for population sampling to pilot-test 2 waves of study (Aims 2-3). 25 participants x 2 waves x [redacted]
- Recruiting services.
  - *Abt SRBI*. To recruit a representative, national sample of 300 family court judges (wave 1, yr 2) and 400 trial court judges (wave 3, yr 4) to complete a 18-20 minute online survey, I will contract with Abt SRBI, the nation's largest survey and research organization. Abt was chosen given its unique expertise in surveying judges, its capacity to administer the survey, including the implicit association test (Aim 3), and its reasonable cost compared with other companies.
    - Wave 1, 300 family court judges (yr 2) = [redacted]
    - Wave 3, 400 trial court judges (yr 4) = [redacted]
  - YouGov. To recruit public participants (400 adult parents, wave 2, yr 3; 400 jury-eligible participants from the general public, wave 3, yr 5) to complete up to 30 minute online survey, I will contract YouGov, an international company that pioneered online market research and that operates an online panel of nearly 2 million respondents in over 11 countries, including 1.2 million US residents. YouGov was chosen given its ability to recruit nationally representative online samples and its high-quality and cost-effective recruitment services compared to other companies that provide such services.
    - Wave 2, 400 adult parents (yr 3) = [redacted]
    - Wave 3, 400 jury-eligible (yr 5) = [redacted]
- Implementing survey with Implicit Association Test (IAT)
  - *Project Implicit*. Project Implicit will host the 2 waves of public respondents (Yrs 3, 5), provide consulting services to build and customize the IAT (Aim 3, yrs 2-5), and provide processed data. The services of Project Implicit are essential for the proposed research because the IAT requires special technology that measures the speed of participants' responses. Project Implicit was founded as a multi-university research collaboration in 1998 and was incorporated as a non-profit in 2001 to foster dissemination and application of implicit social cognition. It was chosen because it possesses particular substantive and technical expertise in the design and delivery of research with survey and implicit measures. [redacted]

C. Indirect Costs

- Facilities & administrative 8%

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OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix: Dr.
First Name*: Maya
Middle Name:
Last Name*: Sabatello
Suffix:

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ● No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

○ Yes ● No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

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5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ● No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001

Introduction (if applicable)	
1. Introduction to Application (for RESUBMISSION applications only)	
Candidate Information	
2. Candidate's Background	rplan_cb.pdf
3. Career Goals and Objectives	rplan_cg.pdf
4. Career Development/Training Activities During Award Period	rplan_cd.pdf
5. Training in the Responsible Conduct of Research	rplan_tr.pdf
6.Candidate's Plan to Provide Mentoring (as applicable)	
Statements of Support	
7. Plans and Statements of Mentor and Co-Mentor(s)	rplan_con.pdf
8. Letters of Support from Collaborators, Contributors, and Consultants	rplan_los.pdf
Environment and Institutional Commitment to Candidate	
9. Description of Institutional Environment	rplan_env.pdf
10. Institutional Commitment to Candidate's Research Career Development	rplan_com.pdf
Research Plan	
11. Specific Aims	rplan_nar.pdf
12. Research Strategy*	rplan_rs.pdf
13. Progress Report Publication List (for RENEWAL applications only)	
Human Subject Sections	
14. Protection of Human Subjects	rplan_hs.pdf
15. Inclusion of Women and Minorities	Inclusion_Women_Upload.pdf
16. Inclusion of Children	Inclusion_Children_Upload.pdf
Other Research Plan Sections	
17. Vertebrate Animals	
18. Select Agent Research	
19. Consortium/Contractual Arrangements	
20. Resource Sharing Plan(s)	
Appendix (if applicable)	
21. Appendix	

Citizenship*:

- U.S. Citizen or noncitizen national
- Non-U.S. Citizen with temporary U.S. visa
- ● Permanent Resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award)
- Permanent Resident of U.S. Pending

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

2. Candidate's Background

I have a long-standing commitment to the study of law, medicine, disability and society, and judicial responses to dilemmas arising from biomedical technologies. While working primarily in the legal field – as a litigator, an instructor, and a disability and human rights consultant – my research has been transdisciplinary, including cross-cultural views. I used qualitative analysis and a mix of feminist, political and social theories, along with the perspective of medical ethics, to analyze court cases and legal policies. But conducting empirical studies is a notable shift in my career path. Although I became interested in disability and medicine early on, as a teenager volunteering with children with disabilities, personal encounters with the healthcare system mobilized me to choose Law School, to which I added Gender Studies (graduating in 1998 with distinction), with the goal of influencing relevant policies. My main research tool was narrative analysis of court cases to investigate why and how decisions are made.[1] Drawn to family matters and medical technologies, in several articles I revealed how judicial decisions in cases of genetic testing to establish paternity,[2] transgender individuals' quest for family rights,[3] and access to assisted reproduction[4] and posthumous conception[5] reflected biased views of gender and disability–and I offered novel legal approaches to undercut such biases. After passing the bar exams, I joined a law firm and specialized in medical malpractice, torts and civil rights. Being exposed to "wrongful life" cases (studied in two co-authored papers[6, 7]) and international views thereof, I became curious about how political institutions impact biomedical policies and decided to expand my disciplinary horizon.

I thus pursued a PhD in Political Science at the University of Southern California (graduating in 2006 with distinction) to study the impacts of genetic data on social structures and individual rights. My mentor, Dr. Alison D. Renteln, introduced me to political and philosophical theories about the "politics of recognition," group rights, and multiculturalism,[8-12] as well as work on social constructs of disability.[13-16] These theories resonated with my own experiences and they have had a tremendous influence on my work. In ensuing publications I explored their interaction with legal rules, innovatively and critically analyzing their application to *children* as subjects of the law. In my PhD thesis, *Children's Bioethics* (published in 2009 as a book)[17] I analyzed the interface between disability, society, and identity to probe whether the rise of genetic knowledge prompts a child's "right to a sound mind and body" and proposed a new normative framework that calls for a contextual-relational approach to uphold children's rights. Building on this work and staying focused on biomedical technologies, I later explored the Deaf Community's opposition to cochlear implants in light of its quest to be recognized as a linguistic/ethnic minority under international law[18]; the ELSI of genetic selection (for deafness, against disability, for a given sex, and in "savior sibling" scenarios),[19-21] and disability and enhancement in sports.[22, 23] I was honored to receive multiple pre-dissertation and scholarly awards for my work, and I presented my narrative analyses at various national and international forums and in expert opinions submitted in court proceedings. My interdisciplinary approach is also reflected in courses that I developed and taught as an adjunct faculty member at Columbia, NYU, and Barnard College, and as a mentor for students' MA theses.

However, after my participation in the drafting of the UN's Convention on the Rights of Persons with Disabilities (CRPD), which I discussed in several articles[23-31] and a co-edited book[32], I reached a turning point. Although I supported the social and barrier-based model of disability promoted in the CRPD (as opposed to a medical, deficit-based model), I was troubled by efforts to alienate the medical, especially psychiatric, profession, and the lack of empirical data to validate positions advocated for during the negotiations. The gaps between the disability rights and psychiatric communities broadened after the CRPD came into effect in 2008. Debates about the concepts of "legal capacity" versus "mental capacity" surfaced. Lobbying by some advocacy groups led UN officials to state that involuntary psychiatric interventions in healthcare facilities may constitute torture, a position that was rejected by the American and World Psychiatric Associations.[33-36] Concurrently, my case study on persons with traumatic brain injury in the workforce illustrated lingering gaps between disability theory and practice.[37] It became impossible to ignore that a reevaluation of approaches is needed and that it would require research and engagement beyond advocates' views. I thus pursued a Research Fellowship in Medical Ethics at Harvard Medical School (2011-13) that combined theoretical, research, and clinical ethics experience. I was very fortunate to work with Dr. Mildred Solomon (now President of The Hastings Center), and under her mentorship I explored the ELSI of the emerging "child's right to know her genetic origin"[38, 39] and of research with human subjects with cognitive impairments.[40] I continued this engagement as an awardee of the AAAS's Program for Excellence in Science (2012), where I co-lead a study on scientists' responsibilities. I was recently also nominated to co-chair the AAAS's Ethics and Human Rights working group. These

encounters reinforced my commitment to study the confluence of mental disability, medicine, and society, and my interest in conducting empirical studies to inform law and policies on the sensitive questions that arise.

One outcome of the CRPD process was that, due to concerns about stigma and medicalization, references to genetic research were excluded from this law. I began to question whether the views that influenced the negotiations were widely held by relevant stakeholders, what the legal and social implications of new genetic discoveries would be for persons with disabilities, and whether opposition to the use of genomic data serves the needs of those involved. Psychiatric genetics especially captivated me because of the distinct biases that persons with mental disabilities face in law and society. I realized that answering these questions requires empirical research, yet I lacked many of the skills necessary to conduct such research. Hence, I applied for my position as a Postdoctoral Research Fellow at Columbia's CEER, where I obtained excellent foundations in statistics, research design, quantitative data analysis, and psychiatric and genetic epidemiology. I also realize that this is only a first step. I need more training in research methods, stigma measures, psychiatric genetics and clinical psychiatry, and experience designing and conducting a study to achieve my long-term goal of becoming an independent mixed-methods researcher who studies the intended and unintended consequences of psychiatric genetic data on law, equality, and social inclusion. This K01 will enable me to attain this goal.

Although my legal-analytic skills and theoretical background about social structures and exclusion were useful in securing disability rights, the uses of psychiatric genetic data will present new opportunities, and challenges, for persons with such conditions. Regulating such uses will require consideration of stakeholders' views *and* evidence-based research to respond to concerns about representation, stigma, medicalization, and need, as arose during the CRPD negotiations. Yet few disability advocates have empirical skills, and the politicization of mental conditions as social constructs often hinders partnership with the psychiatric profession. This K01 will give me the additional training, resources, and protected time to transition on my professional journey and to achieve my long-term goal by studying, first, the impact of psychiatric genetic data on civil litigation, bridging it with a disability rights perspective, and informing ethical and legal policies.

3. Career Goals and Objectives

My short-term career goals are to: 1) develop the skills necessary for conducting quantitative research and apply this knowledge to study the ELSI of psychiatric genetic data in civil courts; 2) better understand clinical psychiatry and psychiatric genetics; 3) improve my grantsmanship skills in preparation for R01 submission; 4) publish my findings in peer-reviewed medical journals; and 5) build and expand national and international professional collaborations with scholars in psychiatry, genetics, social sciences, bioethics, and law.

My long-term career goals are to: 1) develop an independently funded, high quality, mixed-methods research program, to study the intended and unintended consequences of psychiatric genetic data on law, equality, and social inclusion; 2) inform ethical guidelines and legal policies about the uses of genetic data in non-medical settings; and 3) fill a gap in empirical work on the ELSI of the geneticization of psychiatric disorders from a disability rights perspective.

My professional career evolved over time and I developed as a litigator, an instructor, and a disability scholar. Yet my commitment to study the impacts of genetic data on disability rights and to produce actionable research propels me to transition from qualitative to mixed-methods research. The proposed study will address emerging dilemmas in psychiatric genetic data and will effectively inform policies on the use of such data in civil litigation in the US and other technologically advanced societies. The plan for additional training, mentorship and research proposed under this K01 is tailored to equip me with the methodological, genetic and psychiatric knowledge that I lack, and to successfully redirect the next phase of my career.

4. Candidate's Plan for Career Development/ Training Activities

This K01 award represents a shift in my approach to research, an effort to incorporate psychiatric views, and an opportunity to address questions at the forefront of genetic research, law, and social policy: the impact of psychiatric genetic data on civil litigation and its relationship with stigma (see *Sect. 11-12*). To attain these career goals, I will undergo an intensive structured program that includes coursework, individualized training with experts, clinical exposure at the New York State Psychiatric Institute (NYSPI), seminars, and conferences. The proposed training and research plan build on my research and work experiences, while enabling me to acquire new research methods and move the field of law, disability, genetics, and society in new directions:

1) Methodological skills. During my legal and PhD studies, I used qualitative analysis and had only limited exposure to quantitative methods. As a CEER Fellow for the past year, I obtained a strong foundation in research design and statistical analysis. Yet to actualize this new way of thinking, I need more time and mentoring to learn how to design surveys, collect data, and conduct quantitative data analysis. Also, although my work exposed me to the stigma surrounding disability, I need to develop social epidemiological skills to measure and test how such stigma impacts legal and social outcomes (Aim 3). For this training, I will: a) attend courses, seminars and workshops (*Table 1*); b) gain practical experience through direct instruction from a dedicated team of experts (see mentorship role and training area in *Table 2*); c) utilize design, statistical, and analytical support services provided by Columbia's Irving Institute for Clinical and Translational Research; and d) collaborate with Dr. Appelbaum on his study on the impact of behavioral genetic evidence in criminal and other disciplinary contexts. Dr. Appelbaum's proposed mentorship is vital for my professional transition as his expertise in psychiatry and law, methodological approaches, and leadership in ELSI research on genomic data will provide me the highest level of support in each of the training goals.

2) Clinical psychiatry and psychiatric genetics. Although I worked with persons with psychiatric disabilities for a long time and, as a CEER Fellow, acquired knowledge of genetic and psychiatric epidemiology, I never took courses in the phenomenology and treatment of mental disorders. Reading relevant literature critically and better understanding syndromes and therapeutic options arising in my study (and beyond) will be invaluable to my professional development. To achieve this training, I will: a) attend courses and seminars on the genetics, neurobiology, and treatment of psychiatric disorders (*Table 1*); b) rotate for 6 months (part-time) through NYSPI's inpatient units, outpatient clinics and the day treatment program for children, observing the treatment offered to patients and attending group meetings, staff reports, ethics consultations, and other training services offered by Columbia Psychiatry. I will thus be exposed to a range of psychiatric disorders, among diverse age groups, and in various settings that will maximize my understanding of the effects of psychiatric disorders in the contexts proposed in my study. Dr. David Lowenthal, NYSPI's Clinical Director and a faculty member at Columbia's College of Physicians and Surgeons and NY Presbyterian Hospital, will facilitate this training (see *letter of support*); and c) consult with Dr. Goldstein on psychiatric and molecular genetics (*Table 2*).

3) Grantsmanship. Having a legal background, I am a novice in writing NIH grant proposals. To develop the necessary writing skills, I will: a) attend workshops and seminars at Columbia, including *Reach for the First R01* offered by Columbia's Irving Institute (see *letter of support*); and b) collaborate with mentors on other grant proposals. This training will culminate in the submission of a R01 grant in year 4 of my K01 award to study the intended and unintended consequences of psychiatric genetic data for law, equality and social inclusion.

4) Publish in peer-reviewed medical journals. Although I published peer-reviewed books and articles in leading law and human rights journals and have served as a reviewer of manuscripts for such publications, the requirements for medical journals in genetics, psychiatry, and bioethics/ normative ethics are very different. During the K award period, I will prepare 6 manuscripts (see *Sec.12*). Mentored guidance by experts will train me in disseminating my findings across disciplines with the rigor required for high-impact medical publications.

5) Present my work and network at conferences on psychiatry, genetics, law, and bioethics that reflect my transition in research methods and substantive focus to psychiatry (see proposed list in *Table 1*).

Multidisciplinary mentoring. In addition to Dr. Appelbaum's primary mentorship, I will have exceptional support from a team of other accomplished experts who will train me during the K award (*Table 2*). Dr. Link is known for his work in social and psychiatric epidemiology, including developing tools to measure stigma, for which he received multiple prestigious awards. Dr. Ottman is an expert in genetic epidemiology, focusing on genetic susceptibility to neurologic disorders and related methodologic issues. As a CEER Fellow, I have worked with

Dr. Ottman to study the impact of genetic attribution on felt stigma in families with multiple members with epilepsy, work we will present at the American Epilepsy Society 2014 and publish as an article. Dr. Goldstein is an expert in molecular and population genetics, whose work focuses on human genetic diversity, the genetics of disease, and pharmacogenetics. Dr. Phelan is a leading researcher on the sociological implications of the genetic revolution. She uses mixed-methods analyses and has developed measures for *implicit* bias to study inequalities arising from mental illness. Dr. Parens is a bioethicist known for his cutting-edge explorations of disability, genetics, and new technologies. Dr. Goldsmith is an expert in biostatistics. I will have defined training tasks with each expert, which will also facilitate my learning to work with multidisciplinary teams. The mentors have received NIH funding to study the ELSI of genetic data and have vast experience in successfully mentoring K-awardees. They will convene quarterly to monitor my progress, to assure that I have the support to achieve my training and career goals, and to facilitate my transition to independence. They will communicate to me any concern and take remedial steps, if needed, to ensure the aptness of my work.

Table 1. Training Activities During 5-year Award		**Yr 1**	**Yr 2**	**Yr 3**	**Yr 4**	**Yr 5**
Goal 1: Methodological skills	P8777: Survey Research Methods; P8210: Analysis of Categorical Data					
	NVivo (2-day workshop) (see Sect. 12.C.1)					
	P8417: Selected Problems in Measurement					
	Seminar of Psychiatric Epidemiology Training Program (weekly)					
	Impact of behavioral genetic evidence/ Dr. Appelbaum; See also Table 2 & research timeline (*Sect. 12.C*)					
Goal 2: Clinical psychiatry and psychiatric genetics	P8419: Neurobiology and Genetics of Psychiatric Disorders (audit)					
	G4499: Behavioral Psychopharmacology (audit)					
	G4495: Ethics, Genetics, and the Brain					
	Rotation in NYSPI's psychiatric units & day program (6-mos.)					
	Seminar on Legal and Ethical Issues in Psychiatry and Medicine (monthly mtg)					
	Seminar on ELSI of Genetics (monthly mtg)					
	See Table 2 & research timeline (*Sect. 12.C*)					
Goal 3: Grantsmanship	Reach for the First R01 Workshop					
	Seminars and workshops related to grantsmanship					
Goal 4: Publish	See Table 2 & research timeline (*Sect. 12.C*)					
Goal 5: Scientific Conferences (encompassing all goals)	International Society of Psychiatric Genetics					
	American Society for Human Genetics					
	American Psychiatric Association					
	American Academy of Psychiatry and the Law					
	CEER networking meeting					
Training in responsible conduct of research	TC0087: Human Subjects Protection					
	G4010: Responsible Conduct of Research & Related Policy Issues					
	Seminars & workshops related to training in RCR					

Courses, workshops | Seminars | Research & hands-on experience | Conferences | Clinical

Table 2. Mentorship	**Mentorship Role, Frequency of Meetings**	**Training Goal**
Dr. Paul Appelbaum: Director, Columbia's NHGRI-funded CEER; Chair of APA's DSM Steering Committee; former President of the American Psychiatric Association and of the American Academy of Psychiatry and the Law.	Primary Mentor. Weekly hourly meetings to develop new skills in survey design, data collection, and all other aspects of study, writing for medical journals, grantsmanship, and career development.	1-5 (Aims 1-3)
Dr. Bruce Link: Director, Psychiatric Epidemiology Training Program. Most cited article about stigma.	Co-Mentor. Biweekly hourly meetings to develop new skills in composing vignettes, developing quantitative measures of stigma, and writing.	1-5 (Aims 2-3)
Dr. Ruth Ottman: Genetic epidemiologist and Deputy Director, Columbia's CEER.	Co-Mentor. Weekly hourly meetings to develop new skills in quantitative data analysis, writing, and career development.	1, 3-5 (Aims 1-3)
Dr. David Goldstein: human geneticist; entering Director, Columbia's Institute for Genomic Medicine	Consultant. Meetings as needed to develop new skills in psychiatric & molecular genetics.	2 (Aims 1-3)
Dr. Jo Phelan: Sociologist. R01 grants to study social impact of the genetic revolution on stigma, mental illness, and racism, and public understandings of 'genetic risk.'	Consultant. Monthly hourly meetings to develop new skills in empirical analysis of qualitative data and measures of implicit bias.	1, 4 (Aims 1 & 3)
Dr. Jeff Goldsmith. Assistant Professor in Biostatistics.	Consultant. Meetings as needed to develop new skills in statistics and categorical data analysis.	1, 4 (Aims 1-3)
Dr. Erik Parens. Bioethicist and Senior Research Scholar, The Hastings Center; Co-investigator, Columbia's CEER.	Consultant. 3 annual meetings, phone calls, and emails to develop new skills in bioethics/ normative research.	4 (Aims 2-3)

5. Training in the Responsible Conduct of Research

During my postdoctoral fellowship, I successfully completed Columbia's HIPAA, Security Essentials and Financial Conflict of Interest certifications. The content of these trainings included: 1) health information privacy and communication; 2) confidentiality, integrity, and availability of protected health information in electronic form; 3) data and safety monitoring; and 4) disclosure and monitoring of financial conflict of interest. Previously, I successfully completed NYU's University Committee on Activities Involving Human Subjects certification whilst mentoring students for their MA theses in human rights (2008); and completed the Harvard Bioethics Course (2010), an intensive 3-day program of lectures and seminars to train health professionals, members of ethics committees, and other legal and managerial professionals in ethical aspects of clinical practice. In 2010-2011, I attended monthly meetings of the Medical Ethics Committee at Columbia University Medical Center, which centered on ethical and policy aspects arising in medical practice. In addition, my research fellowship in Medical Ethics at Harvard Medical School (2011-2013) included training in ethics consultation, research with human subjects, and societal impact of scientific research, and in 2012, I successfully completed Harvard's Medical Ethics Consortium certification, which further increased my understanding of the challenges addressed by medical ethics committees.

To further enhance my knowledge about responsible conduct of research, I will combine didactic coursework, seminars and workshops, hands-on experience, and individual mentorship. In the fall of Year 1 of my K01 Award, I will complete NYSPI's Collaborative IRB Training Initiative (CITI) Human Subjects Protection Training (TC0087), which per the Research Foundation for Mental Hygiene/ NYSPI policy I will update in Year 4. In the spring of Year 1, I will attend a course on *Responsible Conduct of Research and Related Policy Issues* (G4010). The course includes lectures, class discussion, panel presentations, and case studies, and explores a variety of ethical and policy issues that arise during the conduct of basic, translational, epidemiological, and clinical biomedical research. Topics include: research misconduct, mentoring, research involving human research participants, data management and sharing, collaborative research and partnerships with industry, and stem cell research and other issues in modern genetics.

In addition, I will obtain practical experience throughout the K01 period by attending relevant workshops, seminars, and consultation services offered by the NYSPI IRB and at Columbia University Medical Center. These include: 1) *Regulatory Knowledge and Ethics Workshops*, offered bimonthly at Columbia's Irving Institute for Clinical and Translational Research on topics ranging from ethical and regulatory issues surrounding the informed consent process and conflict of interest to more narrowly-focused areas such as the regulatory issues for clinical trials with drugs and devices. I will further use, as needed, the Irving Institute's research ethics consultation services to discuss processes or procedures regarding ethical issues that arise in the conduct of my research, such as IRB submissions and procedures for protection of subjects; 2) *Precision IRB*, monthly research ethics workshops offered by the NY State Psychiatric Institute IRB. The workshops cover a range of topics relating to research with human subjects, as well as presentation of original research on research ethics issue; 3) *IRB 101* which is a quarterly informational session sponsored by the CUMC IRB, and includes protection of human subjects in research, federal regulations, considerations for vulnerable populations, and IRB review criteria and process; and 4) *Institutional Review Board Education Conference*, an annual conference sponsored by the CUMC IRB that provides advanced educational training on the challenges faced by IRBs and investigators. The exact topics vary and depend on current and emerging challenges.

My primary mentor, Dr. Appelbaum, and co-mentors, Drs. Link and Ottman, will further provide first-hand guidance about protection of human subjects, privacy and confidentiality, and data management, sharing, and safety monitoring, as I fulfill all requirements necessary for IRB approval of my proposed study (Year 1), develop the project, and implement it.

9. Description of Institutional Environment

This description of the institutional environment is for the New York State Psychiatric Institute (NYSPI), on whose behalf the Research Foundation for Mental Hygiene (RFMH) will sponsor the Award. The RFMH is a not-for-profit membership corporation organized in 1952 to assist and enhance the research and training objectives of the NY State Department of Mental Hygiene. It is responsible for administering and directing the conduct of all sponsored research programs performed by scientists at the Department's institutes or facilities. NYSPI is a State-supported research institution, standing at the forefront of psychiatry since its inception in 1895. Working closely with the Department of Psychiatry at Columbia University Medical Center (CUMC), it fulfills a tripartite mission of world-class psychiatric research, exemplary training programs, and the highest level of clinical care. NYSPI received a rare perfect score in its most recent hospital accreditation, and in 2013, the NIH ranked NYSPI and Columbia Psychiatry together #1 of all psychiatry departments in grants awarded.

NYSPI and Columbia Psychiatry provide a superb environment for excellence in academic research and training. Columbia Psychiatry has a large and remarkably diverse faculty comprising over 400 psychiatrists, psychologists, social workers, nurses, and neuro-behavioral scientists. NYSPI/Columbia Psychiatry run 23 research divisions and 19 centers (8 NIH-funded), reflecting their breadth of expertise. The many inpatient and outpatient programs (operated also through New York Presbyterian Hospital and faculty practice programs) serve as teaching sites for medical students, residents, and other trainees such as Dr. Sabatello (see Facilities and Other Resources). Likewise, scholarly resources available to faculty, staff, and trainees facilitate research. NYSPI's and CUMC's libraries are among the largest scientific and psychiatric libraries in the US. The CUMC's Hammer Health Sciences Library holds over 500,000 volumes, 4,400 subscriptions, and extensive holdings of media, electronic resources, rare books and archival materials. NYSPI's Library houses a unique, multidisciplinary collection specializing in the literature of psychiatry and mental health, with 35,000 volumes and over 450 subscriptions to journals. NYSPI/Columbia Psychiatry also host many ground rounds, seminars, and symposia that provide experiential training and a forum for networking with nationally and internationally renowned researchers.

NYSPI and Columbia Psychiatry view fostering young investigators' professional development as key to their mission. They oversee 35 training programs, including 1 policy- and 11 research-training programs, which capitalize on other resources at CUMC, such as the Irving Institute for Clinical and Translational Research, that Dr. Sabatello will utilize during her Award period. The distinguished faculty and research scientists, who include Dr. Bruce Link (co-mentor), further provide dedicated mentorship and multidisciplinary leadership across the breadth of modern psychiatry. NYSPI and Columbia Psychiatry currently support more than 40 Career Development ("K") Awardees. Both the facilities and infrastructure thus exist to successfully implement Dr. Sabatello's K01 Award.

The Law, Ethics, and Psychiatry Division at NYSPI/Columbia Psychiatry will be Dr. Sabatello's principal research site during her K01 Award. Led by Dr. Paul Appelbaum (primary mentor), this Division undertakes training and research on the impact of law and ethics on psychiatry and medicine more broadly, and on the role of psychiatry in the legal and correctional systems. It also holds monthly seminars on related issues, and faculty members consult to the NYS Office of Mental Health on issues related to law and psychiatry. Notably, the Division is home for Columbia's CEER, the Center for Research on ELSI of Psychiatric, Neurologic, and Behavioral (PNB) Genetics. Dr. Appelbaum is the Center's Director and Dr. Ruth Ottman (co-mentor) is its Deputy Director. The Center's aims are: 1) Research to explore the impact of psychiatric, neurologic and behavioral genetic information at the individual, familial, and societal levels, including its effect on stigma and self-image, attributions of responsibility, and responses to ambiguity, along with systematic consideration of the broader normative and translational implications; 2) Translating the empirical and normative output of the research into recommendations for policy and practice; 3) Developing a multidisciplinary post-doctoral training program focused on nurturing future leaders in ethical, legal, and social research and creating an environment that facilitates cross-disciplinary learning and research, drawing on outstanding mentors and monthly seminars; and 4) Creating a structure that enhances transdisciplinary collaboration, facilitates the conduct of innovative research, and fosters intellectual growth among faculty and trainees. Dr. Sabatello's research interests fit very well with NYSPI's and Columbia Psychiatry's missions. Their breadth of expertise, novel research, collegiality, and other resources will offer her access to excellent guidance and numerous educational, research, and collaborative opportunities.

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

11. Specific Aims

Psychiatric genetic data, including behavioral genetic findings are becoming more prevalent in judicial settings. While interest in the use of such data in courtrooms has to date focused on criminal responsibility, sentencing, and prediction of dangerousness,[41-49] genetic tests to determine health status are slowly entering civil cases. So far, such data have been used to rebut causation of injury[50-55] and to mitigate the amount of damages awarded.[56] However, it is likely only a matter of time before psychiatric genetic data are introduced in civil cases to support other claims, including those related to allocating responsibility for behavior due to the presence of, or proclivity for, psychiatric disorders. The use of such data may advance–or obstruct–justice.

The availability of these genetic data is likely to create new challenges for the courts. When and for what purposes should such data be admitted (e.g., child custody disputes)? Should submission of genetic data ever be required (e.g., special education placements)? How will–and should–psychiatric genetic data impact judicial perceptions of civil responsibility (e.g., for torts)? Will judicial decisions to assign parental or civil responsibility distinguish between genetic data introduced to support diagnostic conclusions of, or proclivity for, psychiatric disorders? Further, because genetic data suggest the *physical* nature of mental disorders, they are likely to be used to challenge longstanding body-mind dualism that has permeated the legal tort system. But what role should genetic knowledge have in adjusting these legal doctrines, and will courts be up to this task?

In addition, because psychiatric genetic data include both individual and communal (family, group) facets, questions arise as to how courts should respond when conflict of interests between the two emerge (e.g., introducing such data may promote individual justice and informed educational placement but also violate privacy of family members or negatively influence attitudes towards persons with similar mental conditions). My legal analysis of court cases involving family rights and scientific technologies,[3, 57] including genetic testing to establish paternity,[2] and emerging quantitative studies in other contexts,[58-61] suggest that litigants' gender, race, economic, and other social characteristics may impact judicial decisions. Relatedly, a central concern of disability rights advocates is that the geneticization of mental disorders may reinstate the primacy of medical and therapeutic (rather than social) constructs of disability,[62] and that creating legal exceptions to responsibility on the basis of mental disability may undermine efforts to reduce stigma and increase social inclusion and perceptions of capacity.[63] What impact will psychiatric genetic data have in this regard? And will such data equally affect judges and the public? As the introduction of psychiatric genetic evidence in judicial settings gains traction, it is imperative to understand whether, and how, this enhanced knowledge about the genetic and neurobiological bases of human behavior will affect notions of justice, equality, stigma, and treatment options of those involved. This study will be the first to explore these questions in civil proceedings about parental rights, children's education, and responsibility for behavior in tort.

My long-term goal is to study the intended and unintended consequences of psychiatric genetic data for law, equality, and social inclusion. I will draw on my experience as a former litigator and disability advocate, and on relevant empirical and qualitative work on the legal and social effects of the geneticization of mental disorders, including stigma and perceptions of treatment.[64-75] My goals for this research are:

Aim 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.

Aim 2: To investigate judicial perspectives 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, using a vignette methodology with samples, respectively, of family court judges, parents, and state trial court judges and the jury-eligible general population.

Aim 3: To assess, in connection with Aim 2, 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.

The proposed study has significant implications for 1) understanding and predicting how psychiatric genetic data will influence judicial decisions in tort, family law, and education cases; 2) developing legal policies for the use of such data in civil courtrooms in the US and other technologically advanced societies; and 3) enhancing social science research about stigma and judicial biases relating to psychiatric disorders and genetic data.

12. Research Strategy

A. Significance

A.1. The Rise of Psychiatric Genetic Data. It is well established that psychiatric disorders run in families. Numerous family, twin and adoption studies have demonstrated high heritability for such conditions, with genetic factors accounting for 40-70% of the variance.[76] Thus, significant efforts have aimed, with some level of success, at identifying genetic markers associated with a propensity to psychiatric disorders such as depression, schizophrenia, bipolar disorder, ADHD, and impulsive behavior.[76-79] However, difficulties in replicating such findings have led researchers to focus on gene-environment interaction (GxE). In 2002, Caspi et al. published results, demonstrating an interaction between child maltreatment, antisocial behavior, and low monoamine oxidase-A (MAOA), a mitochondrial enzyme that degrades neurotransmitters.[80] With some exceptions,[81-85] these findings have been largely replicated,[86, 87] and confirmed in meta-analyses.[88-90] Similarly, Caspi et al.'s (2003) findings of interaction between stressful life events, depression, and the short allele of the serotonin transporter (5-HTT) gene were mostly, but not always,[91-93] replicated in other studies.[94-101] In addition, studies on family relations have largely[102] found, and confirmed in a meta-analysis,[83, 103] that dopamine-receptor DRD4 7-repeat allele is associated with children's externalizing behavior such as ADHD, impulsivity, and sensation seeking.[104-108] Thus, despite concerns over publication bias and risk of false positive results,[109, 110] the impact of environmental stressors on genetic vulnerability to psychiatric disorders is generally well supported. Equally important are the emerging data in support of Boyce et al[111-113] and Belsky's[114-117] thesis that genetic vulnerability, or plasticity, is for better *and* for worse. That is, individuals with genetic sensitivity to the environment are also likely to benefit disproportionately from supportive environments. This differential-susceptibility thesis has now mostly (but not always[108]) been confirmed[98, 105] by correlational studies,[118] a few randomized trials,[118] and a meta-analysis.[118] As studies to identify other genetic links to psychiatric disorders and their interaction with genetic and environmental factors are underway (e.g., DRD2, COMT),[103, 108, 113, 119, 120] and neuroimaging techniques to explore the associations between genetic mutations and brain function are developing,[76, 121, 122] it seems likely that psychiatric genetic data will continue to emerge. Such data are also likely to enter civil courts and implicate concepts of equality and justice.

A.2. The Genetic Revolution in the Courts. Genetic data are today integral to legal proceedings. Along with the use of DNA sequences for identification purposes in criminal proceedings and family law,[123] genetic testing to confirm or predict certain health conditions is making its way to court. Indeed, genetic data, and brain neuroimaging data,[124, 125] have already been considered in medical malpractice cases,[51] toxic tort/product liability litigation,[50, 52, 53, 55, 126] and negligence cases.[56] Studies also suggest that judges, as the gatekeepers for scientific evidence,[127] are receptive to genetic information. In 2007, Hoffman and Rothenberg published the first empirical study on judicial responses to genetic testing to confirm or predict certain health conditions. They found that a large majority of state circuit judges and federal district court judges in Maryland would admit, and also compel, a genetic test to prove or refute a plaintiff's claim in medical malpractice and toxic tort/product liability cases.[128] A similar judicial receptiveness to the admission of behavioral genetic data in support of defense arguments was found in criminal cases.[41, 45, 46, 48, 128-130] It is thus reasonable to expect that civil courts will be amenable to the consideration of psychiatric genetic data. Yet the availability of such data in the civil justice system is likely to create new challenges for the courts. Unlike previous tort cases where genetic testing was introduced to prove or refute causation, exposure to toxic materials, and damages, psychiatric genetic data aim to explain behavior and to excuse or assign responsibility on the grounds of individuals' mental health. And while surveys of legal cases[41, 45, 130] and experimental studies to date[42-44] show that behavioral genetic data have limited impact on judicial decisions on criminal responsibility and sentencing, the civil system is philosophically and legally different. The civil system does not have the goal of moral condemnation or punishment as does the criminal justice system, and key concepts for civil verdicts (e.g., reasonableness, child's best interests) are inherently vague. Community sentiments[131] and attitudes towards genetic attribution of psychiatric disorders (see A.3) will thus likely have greater effect in civil trials. However, no study to date has examined judicial responses to psychiatric genetic data in civil proceedings–i.e., cases involving child custody, special education, and civil responsibility for torts–as proposed in this study, and how such data influence decisions. These civil adjudicatory contexts are illustrative of these new challenges, as well as of the need for these issues to be address in a meaningful way.

A.2.1. Child Custody. Evidence of psychiatric history plays a critical yet often unnoticed role in custody disputes. Although comprehensive data are unavailable, assertions of parental psychiatric disorders (truthful or

not) are common,[132] and at least one study of family court judges suggested that parental mental health is an issue in 50% of custody cases.[133] Further, because the child's best interests and psychological adjustment are paramount in judicial determinations of custody, parents' mental health and their comparative "emotional fitness" are commonly evaluated.[134-136] Although psychiatric diagnosis *per se* is insufficient to establish parental unfitness, the prospects for parents with such disorders winning custody are grim. Studies found that family judges are more likely (compared to psychologists) to use a *history* of psychiatric hospitalization as a criterion to endorse one parent over the other,[137] and that parents with mental disabilities are more likely to lose custody of their children (overall custody loss rates of 70-80%).[136, 138, 139] How *genetic data* about a parent's propensity for psychiatric disorders will impact custody decisions is unknown. Recent judicial decisions in parental disputes allowing, and ordering, disclosure of otherwise confidential mental health records despite a parent's objection raise further concerns.[140] Will these decisions be extended to include predictive psychiatric genetic data? And will parental gender impact the decision? Most studies available examined the impact of psychiatric disorders on mothering, though such conditions are also likely to impact fathering.[132] Comparing the effect of gender on judicial decisions on child custody will explore judicial biases about parenthood and attend to the empirical gap about fathers with mental disorders. Questions about the *child's* mental health are also likely to arise. How will the child's genetic proclivity for psychiatric conditions impact the decision as to whether a parent is a fit caretaker? This may be critical when Child Protective Services are involved, and given the overrepresentation of certain groups (e.g., African-Americans) in the foster care system it should be a cause for concern.[141] Clear guidelines are needed for family judges regarding the use of psychiatric genetic evidence.

A.2.2. Education. Education for children with psychiatric disorders is a major societal interest. Besides the impact of such disorders on personal development, data show that children with emotional disturbances are more likely to drop out of school,[142] to be unemployed as adults,[143] and to enter the criminal justice system.[144-147] Insofar as psychiatric genetic data can inform efforts to overcome educational barriers for children with such disorders, they will serve important goals. Specifically, hope has been expressed that such data will promote early identification of children at risk of developing psychiatric conditions, advance new preventive educational and developmental tools, and enable more effective individualized interventions to help children in school settings.[148-155] Arguably, personalized education also promotes an informed genomic concept of equality as it tailors interventions to individual's genetic differences.[156] Conversely, the use of genetic data in schools raises concerns that they will serve as tools of social control, lead to greater use of psychopharmacologic agents, promote organizational interests in classroom order rather than education, and repeat recent and past experiences of racist, classist and disability-based segregation.[157-160] Access of educators/other administrative personnel to students' genetic data further raises privacy concerns.[157, 158, 161] As the introduction of genomics in education is slowly but steadily progressing,[151] disputes over parental consent or refusal for psychiatric genetic testing, the impact of the results on decisions about educational placement or eligibility for special education services, the role of educational teams in these decisions,[149] and the effect of race and class are likely to reach the courts. As parents are the primary advocates for their children's education, attention to their perspectives about the uses of genetic data in schools is urgently needed, as are guidelines for minimizing possible misuse.

A.2.3. Civil Responsibility for Torts. Should persons with psychiatric disorders be held civilly responsible for behavior that caused physical or property harm to another person? Should they be required to provide compensation for the harm, in full or in part? Unlike other civil contexts (e.g., contract law) and criminal law, the long-standing common-law rule for torts is that a person's psychiatric disorder is *irrelevant* for determining liability.[162] An enduring legal debate continues on this rule, given emerging scientific knowledge about mental disorders.[163-173] In particular, psychiatric genetic data may support claims for defense from liability or for reduced liability by demonstrating a proclivity for a mental disorder or verifying a diagnosis that influenced individuals' behavior beyond their control. Further, because psychiatric genetic data and neuroimages may establish the *physical* nature of mental disorders,[170, 171, 174] they may challenge existing legal doctrine that holds persons with *physical* disabilities liable by a standard of "reasonable person with *the same disability*," but judges persons with *mental* disorders by a standard of "reasonable person of a *sound mind*."[162] Will judges approve such claims when presented with psychiatric genetic data? Will judicial decisions to assign liability distinguish between psychiatric genetic data introduced to support diagnostic conclusions of, or proclivity for, psychiatric disorder? Public views are also important: most tort cases are jury-trials,[175-179] jurors represent the public, and their beliefs affect policies and institutions.[180] Research about public attitudes shows that attributing mental disorders to genetics and neurological factors is associated with a greater likelihood of leniency toward persons who, because of their disorders, behaved violently.[65, 181] Yet, it is unknown how these views will

translate in civil courts, how the severity of conduct (intentional or negligent tort) will impact these views, and how other factors (e.g., the foreseeability of the psychiatric disorder) may affect judicial decisions. Moreover, although judges instruct jurors what legal rules ought to be followed when deciding a tort case, research suggests that jurors exposed to inadmissible evidence or impermissible comments by lawyers or witnesses during trial will be influenced by it.[182] Surveying judges' and the jury-eligible general public will predict how psychiatric genetic data will influence decisions regarding civil tort verdicts, and provide insight about how justice is conceptualized in the genomic era.

A.3. Psychiatric Genetics and Stigma. Stigma is a major obstacle to social inclusion, equality, and treatment of persons with psychiatric disorders.[183-185] Reducing this obstacle is thus a primary goal of public health policymakers, and the growing knowledge of psychiatric genetics has served a key role in this effort.[66] Hope has been expressed that attributing psychiatric disorders to genetics or brain disease will reduce stigma by diminishing perceived responsibility for the disorder and conveying the message that such disorder is "a disease like any other" that can be treated, controlled and cured.[66, 70, 186] In reality, this strategy has largely failed. While research has found greater public endorsement of such biogenetic explanations, stigma, including associative stigma,[65, 67, 68, 71] desire for social distance, and perception of dangerousness grew or remained constant.[66, 69, 187-192] Such biases may influence jurors' decisions,[193-196] but no empirical study to date has explored this question. Further, it is unknown if judges share these public views. Indeed, studies in *other contexts* found that biases exist.[2, 3, 57-59] Such stigma may pose significant legal, social, and treatment-related challenges to litigants in the civil cases examined in this study, especially when psychiatric genetic data are introduced. Because genetics is often understood in an essentialist manner (i.e., indicating the presence of conditions that are persistent, serious[65], and dangerous[66, 69, 72]), the mere introduction of psychiatric genetic propensity data may impact the decision. A deterministic view of genetics as fixed and of resulting behaviors as unmodifiable[65, 67] may expand judicial perceptions of civil legal incapacity beyond the dispute at stake. Also, because biogenetic explanations of psychiatric disorders are associated with increased recommendations for medication and psychiatric hospitalization,[64, 66, 186, 192] judges presented with psychiatric genetic propensity data may be inclined to recommend, or if legally possible impose, treatment. A study comparing the responses of judges, parents, and prospective jurors to psychiatric genetic evidence will inform understanding of the distinctive attitudes and possible biases of these groups and of mechanisms to improve decision making.

As psychiatric genetic data and judicial receptiveness to genetic evidence increase, it is likely only a matter of time before such data are introduced in civil cases proposed in this study–child custody, special education, and civil responsibility for torts. Consideration of how such data will impact judicial decisions in these areas and their relationship with stigma is urgently needed, as are clear guidelines to attend to the ensuing dilemmas.

B. Innovation

This proposed research explores issues at the forefront of genetic research, law, and social policy. The specific fields of inquiry–family law, special education, and civil responsibility for tort–are prominent areas for the introduction of genetic data, yet none has previously been explored in a systematic, empirical study. In addition, this proposal is interdisciplinary in design and purpose; it combines the latest research in genetics, legal scholarship, disability studies, and social science to spur collaboration among these disciplines in the study of intended and unintended implications of the use of psychiatric genetic data in civil courts. Finally, this proposal is both forward-looking and a new beginning. The systematic analysis of existing court cases (Aim 1), the prospective study of judicial responses to the use of psychiatric genetic data in determining parental capacity, eligibility for special education services, and civil responsibility for torts (Aim 2), and the impacts of genetic stigma in judicial decision-making (Aim 3) will provide solid grounding for developing informed legal rules and policies for the use of such data in civil courtrooms. As new psychiatric genetic data are emerging, this study will lay the foundation for future research in other civil adjudicatory contexts, and on the relationship among legal and social views of equality and justice in the genomic era.

C. Approach

C.1. Aim 1: To survey appellate court decisions in family law, education, and tort to determine the extent to which courts are considering psychiatric genetic data, and how they use such data in their decisions.

For this Aim, I will conduct a review of family law, education, and tort appellate cases to determine whether psychiatric genetic data, in the form of family histories or genetic tests, have been used to explain or predict

behavior. The inclusion criteria for family law cases will be when a parent or child's psychiatric disorder was considered with regard to parental capacity, custody, or visitation rights. For education, it will be cases where the child's behavioral or psychiatric disorder is raised for purposes of educational placement, provision of services, and challenges to disciplinary measures. For torts, it will include cases in which defendants or plaintiffs raise their psychiatric disorder to, respectively, absolve or reduce civil responsibility for torts or to dispute contributory or comparative negligence. In the latter cases the judge or jury in effect determines plaintiffs' full or partial responsibility for the conduct that caused the claimed damage.

To identify these cases I will search the computerized legal databases Westlaw Next and Lexis-Nexis Advance, and the most comprehensive database for special education cases, Special Ed Connect. The initial search strategy will seek general disorder-related key terms AND specific terms as relevant for each category, AND genetic-related terms within the resulting group. Disorder-related terms will include words for psychiatric disorders as evolved over time (e.g., insane, mental illness/incapacity, incompetent); and specific disorders (e.g., bipolar, Alzheimer, psychosis, emotional disturbance, retardation, and ADHD). Specific key terms will include: 1) for family law cases: child custody, unfitness, medical records; 2) for education: placement, special education, school/medical records, and relevant laws; 3) for torts: intentional, negligent and specific torts (e.g., battery, wrongful death). Genetic-related key terms will include: gene![197], family history, sibling, neuroimaging. Search strategy will be adjusted if other important key terms are identified in the initial search.

The timeframe covers cases decided within the past 5 years. This timeframe captures 1) the present-day use of genetic evidence in civil courts; 2) the courts' increased receptiveness to genetic and scientific data,[128] including to behavioral genetic evidence in *criminal* proceedings;[41, 45] and 3) the strengthened commitment of the Federal government to address disability-related stigma, discrimination and treatment.[66, 182, 198, 199] I will set the sample size at the most recent 50 cases retrieved for each category (overall 150). This sample will provide a sufficient basis to analyze trends relating to psychiatric genetic data in civil courts, and it will be amplified if relevant jury verdicts and settlements are retrieved as well. If this approach yields < 50 cases for any category, I will extend the timeframe for that category to 10 years. Two independent reviewers (myself and a Research Assistant who I will train) will systematically review each opinion. We will extract the case's category and subcategories (e.g., family law/custody, education/services, tort/negligence), relevant facts, procedural history, genetic evidence, the motion's initiator (e.g., Child Protective Services), and outcome. Litigants and judges' demographics, when available, type of court (e.g., family, federal), and geographic location will be recorded.

Data analysis. The appellate court decisions will serve as the unit of analysis. In appellate decisions delivered by 3 or more judges, unanimous and majority opinions will be regarded as the primary units for analysis; dissenting opinions will be analyzed separately as they can illuminate judicial disagreements that would otherwise be difficult to identify. The reviewers will sample 15 cases from each category to identify and code genetic-related themes and judicial rationales with regard to the genetic evidence. I will use mixed methods of analysis: 1) Qualitative analysis using well-established legal research methods, assisted by computerized methods (e.g., NVivo, a software package that assists in analyzing unstructured data[200]), to organize the data, identify trends and differences in the judicial responses to psychiatric genetic data in the three contexts, and asses the strength and consistency of rationales that appellate judges provide for the uses of psychiatric genetic data. 2) Quantitative analysis for ordinal data in SAS, with appropriate statistical tests, to assess: a) the comparative frequencies with which psychiatric genetic data are used in family, education, and tort cases using a chi-square test; b) how judges and juries in tort cases use such data in their decisions, and whether correlations exist between these uses and judicial outcome (defined as a holding in favor of the party requesting the use of genetic data) using logistic regression; c) the effect of litigants' and judges' demographic characteristics on judicial receptiveness to psychiatric genetic data, using multiple regression analysis. I will conduct this analysis under the guidance of my consultants, Dr. Jo Phelan, a sociologist who has worked extensively on the social consequences of the genetics revolution for the stigma of psychiatric disorders and is experienced in quantitative analysis of qualitative data, and Dr. Jeff Goldsmith, who is an expert in biostatistics and categorical data analysis. I will present my analyses in narrative and quantitative formats for publication in peer-reviewed policy and psychological journals, and provide my initial assessment of the extent to which the identified genetic-related themes correspond to national and international standards relating to disability rights and ethical guidelines on disclosure of genetic data in non-medical settings.

C.2. Aim 2: To investigate judicial perspectives 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.

To achieve this Aim, I will use a vignette methodology with different samples recruited for practical (time, costs) and training (participants, sample sizes) rationales in 3 waves of data collection. Wave 1 will examine the use of psychiatric genetic data in child custody cases, recruiting 300 state family judges. Wave 2 will examine the use of psychiatric genetic data in educational cases, recruiting 370 adult respondents who have children ages 0-21. How parents view the use of psychiatric genetic data in schools is important, as under the Individuals with Disabilities Education Act parents are full and equal participants in the educational decision-making process (i.e., in evaluation of their children's needs and development of an individualized education program), and their consent for their children's placement is required.[201] Wave 3 will focus on the use of psychiatric genetic data in tort cases, recruiting 400 state trial court judges (most tort cases are heard in state courts[177]) and 400 jury-eligible respondents from the general population (i.e., US citizens, over 18, non-felons, with spoken and reading proficiency in English, and who are registered to vote or hold driving licenses).[196] To provide the highest level of protection, all respondents will be asked to answer an anonymous survey online.

C.2.a. Recruitment. To recruit nationwide, random, representative samples of judges, I will contract with Abt SRBI, a professional survey firm. Abt will be responsible for data collection, including administering the survey and collecting demographic characteristics. The judges' samples will include judges sitting on state family/dependency courts (Wave 1) or trial courts of general jurisdiction (Wave 3), and reflect geographical location (Northeast, South, Midwest, and West, as determined by the US Census Bureau regions) and gender of the entire judicial population. To uphold confidentiality, Abt will not provide any information that could render judges identifiable. Following the standard protocol,[202] Abt will send judges a preliminary letter to introduce the study, followed by an emailed invitation with a link to the survey, and up to 3 reminder emails and a phone call to encourage participation among judges who do not respond. While recruiting judges is not easy (previous academic nationwide surveys of judges that targeted specific judicial populations (N>300) had 36-71% response rates, depending on the survey's length and complexity),[203-210] Abt has extensive experience in such surveys (see *letter of support*), and has achieved response rates of over 60%.[211]

To recruit samples of parents and jury-eligible adults (Waves 2 & 3), I will contract with YouGov, a professional research firm that operates an Internet-based panel of the general public that can be sampled to be representative of the US population (see *letter of support*).[212] The parents' sample will be adjusted to oversample African Americans (30%) to increase the power to detect differences among groups (see C.2.b). YouGov will collect demographic characteristics and will be responsible for participant payment. To administer these surveys and to collect data, I will contract with Project Implicit (see *letter of support*). Project Implicit is a non-profit collaborative network of researchers investigating implicit social cognition.[213] It was chosen due to its expertise in and computerized capacity to administer the Implicit Association Test (Aim 3).

For both judges and public participants, only those who choose to participate in the study by "clicking" their consent on a webpage will have access to the survey.

C.2.b. Design. The survey (of 18-22 minutes) will include: 1) information about the study and consent form; 2) presentation of two cases for each wave (overall 6 cases) that will be randomly assigned, following a fully crossed, between-subjects factorial design: each case will present a story, and variables that may affect judicial decisions will occur in every possible combination to study their effects (overall, 12, 18, or 24 options); 3) reaction questions to the case (on a 5-point Likert scale), varying by wave and respondents, including the primary dependent variables and the factors that influenced respondents' decision; 4) stigma measures and Implicit Association Test to measure bias regarding psychiatric disorders (Aim 3); and 5) measures to study respondents' understanding of genetics. Draft vignettes are included in *Appendix A*, though the final versions will be decided in consultation with Dr. Appelbaum, who has conducted similar vignette surveys addressing behavioral genetics data in criminal cases,[43, 44] and who will mentor me throughout this study; with Dr. Link, my co-mentor, who has extensive experience in vignette methodology; and with Dr. Goldstein (consultant) who will advise on clinical and molecular genetics as related to the study's design. While vignettes naturally present simplified stories, all surveys will first be reviewed for their accurate reflection of the legal issues at stake by 5 local judges who are known to the researchers, and revised accordingly. I will pilot test the public and parental

surveys before administering them to ensure the clarity of questions and assess the time required, recruiting 50 respondents through Amazon Mechanical Turk, a low-cost online service that allows population sampling.[214]

Wave 1 – Child Custody Adjudication Contexts

Case	Independent Variables	Outcome
1 – Parental Dispute about Child Custody	Evidence of Predisposition to Mental Disorder (genetic, family history, both, none) x Parent's Current Psychiatric Symptoms (none, moderate) x Gender (mother, father)	Aim 2: Custody (yes/ no)
2 – Terminating Parental Rights	Evidence of Predisposition to Mental Disorder (genetic, family history, both, none) x Child's Current Psychiatric Symptoms (none, moderate) x Race (Black, White)	Aim 2: Termination (yes/ no)

Case 1: *Dispute about Child Custody*. This case will examine the effect of evidence about a *parent's* predisposition to psychiatric disorder (genetic, family history, or both), with or without current symptoms, on judicial decisions about parental fitness—and whether the impact of such evidence depends on the parent's gender. The psychiatric condition will be bipolar disorder because this is the main condition that arises in custody disputes.[133] The study's design will be 4 (family history, genetic predisposition, both, none) x 2 (no, moderate disorder) x 2 (mother, father). Participants will thus be randomly assigned to 1 of 18 conditions. The primary outcome for Aim 2 is award of custody (binary yes/no).

Case 2: *Termination of Parental Rights*. This case will examine the effect of evidence about a *child's* predisposition to psychiatric disorder (genetic, family history, or both), with or without current symptoms, on judicial decisions to terminate parental rights. To focus on psychiatric genetic evidence, the case will present a mother struggling to raise her child who temporarily surrenders her girl to Child Protective Services (rather than a case involving overt neglect or abuse). Child Protective Services subsequently requests to terminate her parental rights. The mother's race will vary (Black, White). These characteristics were chosen as single-parent households are predominantly mother-led and as the disparity in the percentage of children in foster care relative to their percentage in the total population is starkest for black and white children.[141, 215] The condition will be generalized anxiety disorder as its diagnosis and treatment require attentive parenting. The child's sex will be female as girls are twice as likely to have this condition than boys.[216] The study's design will be 4 (family history, genetic predisposition, both, none) x 2 (no, moderate disorder) x 2 (Black, White). Participants will be randomly assigned to 1 of 18 conditions. The primary outcome for Aim 2 is award of custody (binary yes/ no).

Wave 2 – Educational Adjudication Contexts

Case	Independent Variables	Outcome
3 – Genetic Testing in School Settings	Evidence (genetic, none) x Family History (yes, no) x Evaluator (pediatrician, teacher) x Race (Black, White)	Aim 2: Compel treatment & genetic testing (Likert scale)
4 – Special Education Services	Evidence (genetic, family history, none) x Psychiatric Symptoms (consistent, inconsistent) x Education Impact (none, drop of grade) x Race (Black, White)	Aim 2: Special education Services (Likert scale)

Case 3: *Genetic Testing in School Settings*. This case will examine the comparative effect of evidence about a child's predisposition to psychiatric disorder (genetic, family history), given his behavioral difficulties, on parents' views about options for early intervention. The 2004 Individuals with Disabilities Education Act (IDEA) establishes "child-find" mandates that require states to actively seek out and find all children eligible for special education services.[217] Although parents' consent for their child's medical evaluation is needed, if they refuse such evaluation, the school may pursue its mandate with appropriate due process protections.[218] Parents' decisions may vary based on the source of the recommendation (pediatrician, teacher). The racial groups were chosen because black children 6-21 years old are twice as likely as white children to be served in special education programs.[143, 219] The psychiatric condition will be ADHD, which has the highest prevalence among white and black, non-Hispanic children.[220] The design of the study will be 2 (genetic, no evidence) x 2 (family history, no family history) x 2 (Black, White) x 2 (pediatrician, teacher). Participants will thus be randomly assigned to 1 of 16 conditions. The primary outcome for Aim 2 is compelled treatment; a secondary outcome is genetic testing over parental objection (4-point Likert scale).

Case 4: *Special Education Services*. This case will examine whether evidence about a child's predisposition to psychiatric disorder (genetic, family history), given his behavioral difficulties, interacts with race in decisions about eligibility for special education services. In line with the IDEA and judicial decisions,[221, 222] the case will also consider the impact of the child's disorder on his educational performance (none, drop of grade) and the consistency of his behavioral problems on such eligibility decisions. For reasons explained in case 3, the race will be black or white. The case will describe a dispute about the provision of special education services in a

mainstream school setting, where the parents introduce psychiatric genetic data about their child who exhibits behavioral problems. The disorder will be autism because despite increased awareness of this condition, studies show that diagnosis of high-functioning children with autism is often delayed,[223] and that parental dissatisfaction with the quantity of services their child receives and with the common provision of such services in separate educational settings, is higher compared to parents of children with other disabilities.[224] The study's design will be 3 (genetic, family history, no evidence) x 2 (Black, White) x 2 (none, drop of grade) x 2 (consistent, inconsistent symptoms). Participants will thus be randomly assigned to 1 of 24 conditions. The primary outcome for Aim 2 is eligibility for special education services (4-point Likert scale).

Wave 3 – Civil Responsibility for Behavior in Torts

Case	Independent Variables	Outcome
5 – Psychiatric Defense for Civil Tort Liability	Evidence of Mental Disorder (none, genetic, neuroimaging, both) x Tort (intentional, negligent) x Psychiatric Condition (no previous episode, previous episode with OR without treatment)	Aim 2: Liability (yes/ no)
6 – Plaintiff's Comparative Negligence	Evidence of Mental Disorder (none, genetic, neuroimaging, both) x Psychiatric Condition (no previous episode, previous episode with OR without treatment)	Aim 2: Liability (yes/ no)

Case 5: *Psychiatric Defense for Civil Tort Liability*. This case will examine whether the introduction of psychiatric genetic data may interact with the intentionality of the conduct (intentional or negligent) and with *defendants'* prior knowledge of their condition in impacting decisions about civil responsibility for behavior in tort. The case will describe a defendant with schizophrenia who raises his mental disorder as an excuse for his behavior and presents scientific evidence (genetic testing, neuroimaging, or both) to support his diagnosis. As the knowledge about relationships between brain activity and human behavior has entered legal practice, brain images have been used increasingly in criminal cases to support arguments for mitigation of defendants' sentences,[225] and in civil cases to determine, e.g., physical damage in torts, employment disability, and legal capacity to marry.[124] The use of genetics and/or brain scans in defense of a tort claim may further support an argument that scientific evidence establishes mental disorders as *physical* disabilities (see A.2.3). The variables of whether the defendant had prior episodes of the disorder and compliance with treatment at the time of the event correspond to legal doctrines governing liability of persons with physical disabilities.[226-228] The study's design will be 4 (no evidence, genetic, neuroimaging, both) x 2 (intentional, negligent) x 2 (no prior episode, prior episode with treatment, prior episode without treatment). Participants will be randomly assigned to 1 of 24 conditions. The primary outcome for Aim 2 is the decision about civil liability (binary yes/no).

Case 6: *Plaintiff's Comparative Negligence*. This case will explore whether the introduction of psychiatric evidence regarding a *plaintiff* in a negligence suit (genetic, neuroimaging, both), with and without prior psychiatric condition and treatment, impacts judges' and prospective jurors' decisions regarding comparative negligence. Comparative negligence allows allocations of liability and damage awards based on the relative degree of negligence of plaintiffs and defendants.[229] The scientific evidence and the examination of its interaction with plaintiff's prior knowledge of his psychiatric disorder and compliance with treatment at the time of the event were chosen for reasons explained in case 5 and to reflect legal doctrine.[230-232] The study's design will be 4 (no evidence, genetic, neuroimaging, both) x 3 (no prior episode, prior episode with treatment, prior episode without treatment). Participants will thus be randomly assigned to 1 of 12 conditions. The primary outcome for Aim 2 is judicial decisions regarding comparative civil liability (binary yes/no).

Sample Size. To calculate sample sizes required for the study, I performed power analyses based on the primary predictor (psychiatric genetic data) and the primary outcomes of interest (binary or Likert scale). To detect a difference of at least 0.18-0.20 effect size between the two closest groups (in the absence of prior data about likely effect sizes, this represents a plausible effect size), the minimum number of respondents needed to achieve at least 80% power at a 5% significance level (Type I error rate) is: 279 family court judges for cases 1-2; 351 and 279 parents respondents, respectively, for cases 3 and 4; and 372 state trial judges and 372 public participants for cases 5-6. To provide a buffer in case of lower-than-expected effect sizes, I will recruit: 300 judges (Wave 1), 370 parents (Wave 2), and 400 judges and 400 public participants (Wave 3).

Data Analysis. I will use SAS to perform logistic regression for binary outcomes (e.g., child custody). To control for confounding among the independent variables and demographic characteristics, I will use multiple logistic regression. Outcomes measured on a Likert-scale (e.g., case 4, special education services and reaction questions) will be treated as continuous dependent variables and analyzed using linear regression or analysis of variance (ANOVA). For internal reliability I will use Cronbach's alpha. I will conduct the data analysis under

the guidance of Dr. Ottman, my co-mentor, who is an expert in genetic epidemiology and related methodologic issues. I will consult with Dr. Goldsmith on statistics, and with Dr. Parens about the normative aspects of my findings. I will publish 3 case-based analyses and a paper comparing the findings across contexts in peer-reviewed medical, psychological and policy journals, and provide recommendations for introducing psychiatric genetic data in non-medical civil litigation. As part of the translational goal of this study, I will offer to present my findings at conferences and educational forums for family and trial court judges (e.g., national conferences for judges organized by the American Bar Association, training initiatives of the National Council of Juvenile and Family Court Judges, and web- or seminar series course of the National Judicial College).

C.3. Aim 3: To assess, in connection with Aim 2, the association between psychiatric genetic data and stigma by studying whether such data affect judges' and public perceptions of broader civil legal incapacity and treatment options, and the relationship to judicial bias against persons with psychiatric conditions.

After answering reaction questions for Aim 2, participants will be queried about stigma-specific measures that respond to the primary dependent variables for Aim 3 (perception of legal incapacity, treatment options). The list of questions will be developed with my co-mentor, Dr. Link, who has extensively studied the effects of social stigma for persons with psychiatric disorders and is an expert in stigma measurements. The list will be based on the 1996 and 2006 General Social Survey,[65, 66] asking about beliefs relating to the persistence, seriousness, and perceptions of dangerousness associated with mental disorders, including parental fitness. I will also solicit respondents' views about treatment options (recommended, imposed),[64] and about litigants' competency to engage in a range of societal activities with or without treatment (e.g., entering into a contract, working).[233] In keeping with studies about associative stigma of family members of persons with psychiatric disorders,[65, 67, 71] and the stigma-reducing effect of contact with such disorders,[69, 234, 235] I will ask respondents' about the competency of siblings and children of litigants with psychiatric disorders, as well as *other* persons with such conditions, to engage in such activities, and query respondents' contact with persons with mental disorders (self, family members, friends). The primary dependent variables for these questions about legal competency and treatment options will be evaluated on a 7-point Likert scale.

Implicit Association Test (IAT). To study how bias against persons with psychiatric disorders (and those with a proclivity for such conditions) may impact judicial decisions I will develop an IAT, a computer-based measure designed to detect unconscious bias by measuring the speed of a person's automatic association between a categorical status (e.g., black/white) and a given description (e.g., good/bad).[236] This method has been widely used in social science research to assess people's biases towards stigmatized groups, especially race[59] and gender.[237] Legal scholars have also used it increasingly to analyze court cases concerning race[59] and non-discrimination laws.[236] While studies have begun to explore implicit stigma toward persons with psychiatric disorders,[73-75, 238, 239] no study to date has examined its application in civil adjudicatory contexts as proposed in this study. With Dr. Phelan's guidance and Project's Implicit's consultation, I will adapt existing IATs to the civil justice arena and choose focal categories related to psychiatric disorders (e.g., mother with bipolar disorder) and attribute categories relevant to the study's contexts (e.g., fit/unfit parent).

Data Analysis. Stigma measures (7-point Likert scale) will be treated as continuous dependent variables and analyzed (with SAS) using regression analysis or analysis of variance (ANOVA). I will control for demographic characteristics using multiple regression analysis. Chi-square will be reported. Following Rusch et al.,[73] I will calculate IAT scores using a scoring algorithm, resulting in a D-measure (i.e., more positive values represent stronger associations between the focal and the attribute groups). I will present the analyses in the papers described in Aim 2, including the comparative paper, and will discuss the implications of psychiatric genetic data for the legal, social, and treatment interests of persons with psychiatric disorders.

C.4. Implications. As more widespread use of psychiatric genetic data in civil adjudication contexts is a matter of time, judges and juries are soon likely to grapple with questions considered in this study. The public will be equally invested in understanding such data and its relationship with equality and justice. The proposed study thus has significant implications for 1) understanding and predicting how psychiatric genetic data will influence judicial decisions in family law, tort, and education contexts; 2) developing legal policies for the use of such data in civil courtrooms in the US and other technologically advanced societies; and 3) enhancing social science research about stigma and judicial biases relating to psychiatric disorders and genetic data.

Research Timeline	Year 1 (2015-16)				Year 2 (2016-2017)				Year 3 (2017-2018)				Year 4 (2018-2019)				Year 5 (2019-2020)			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
IRB Submission																				
Aim 1: Survey Appellate Court Decisions in Family Law, Education & Torts																				
Data collection																				
Coding																				
Data Analysis																				
Quant. Paper																				
Qual. Paper																				
Aim 2: Investigate Judicial Perspectives About the Use of Psychiatric Genetic Data (Wave 3 survey design & paper - for both Public & Judges)																				
Design Survey																				
Recruitment																				
Conduct Survey																				
Data Analysis																				
Papers																				
Aim 3: Psychiatric Genetic Data & Stigma (data collection in Waves 1-3. Papers in Yr 3 – Q1, Yr 4 – Q1, Yr 5 – Q2 are part of papers in Aim 2)																				
Stigma Papers																				
	Wave 1			**Wave 2**			**Wave 3 – Public & Judges**						**Comparative Paper Waves 2 & 3**							

14. Protection of Human Subjects from Research Risks

A.1. Human Subjects Involvement, Characteristics, and Design

The involvement of human subjects is required to accomplish Aims 2-3 of the proposed study: investigating perspectives of judges, parents and members of the jury-eligible public about psychiatric genetic data in civil adjudicatory contexts and the relationship of such data with stigma.

Judges will be recruited by Abt SRBI, a professional survey firm. Parents and jury-eligible respondents will be recruited by YouGov, a professional market research firm that operates an Internet-based panel of the general public. The judges' surveys will be administered by Abt, and the surveys for public participants will be hosted by Project Implicit, a non-profit collaborative network of researchers investigating implicit social cognition. All participants will be invited to answer an 18-22-minute online, anonymous survey. These participants were chosen because of their status as decision makers in the civil adjudicatory contexts proposed in this study – child custody, special education, and civil responsibility for torts. The surveys will be administered in 3 waves. A group of local judges will review all surveys (Waves 1-3; hereinafter: "judge-reviewers"), and the parental and public surveys (Waves 2 and 3) will be pilot tested before their administration to the participants.

Only respondents who indicate their consent to participate in the study will have access to the survey.

A.1.a. Judges

300 state court judges sitting on the bench of a family/dependency court will be recruited for the survey on child custody cases (Wave 1), and 400 trial court judges sitting on the bench of state courts of general jurisdiction will be recruited for the survey on civil responsibility for torts (Wave 3). The judges will be identified using lists and contact information that are publicly available. Only active judges will be included. Recruitment will reflect the geographical location (Northeast, South, Midwest, and West, as determined by the US Census Bureau regions) and gender of the entire judicial population.

A.1.b. Parents and Jury-eligible Participants

370 parents who have children ages 0-21 will be recruited for the survey on special education cases (Wave 2), and 400 jury-eligible respondents from the general population will be recruited for the survey on civil responsibility for torts (Wave 3). Parents will be limited to those over 18 years of age. Jury-eligible respondents will satisfy the legal criteria for prospective jurors: US citizens, over 18, non-felons, with spoken and reading proficiency in English, and who are registered to vote or hold driver licenses. Parents and jury-eligible participants will be identified using a proprietary opt-in Internet-based panel of the general public that has been assembled by YouGov to be representative of the US population. Participants will be screened to ensure that they satisfy the inclusion criteria for the survey. YouGov will offer public participants "PollingPoints" for their time (YouGov offers between 500 and 5,000 points to complete a survey). The accumulated points are redeemable for small gifts (ranging from YouGov Tote Bag and YouGov T-shirt to 2 movie tickets to iPod Shuffle or $100).

A.1.c. Participants in Pilot-testing

Before the surveys are administered, 5 judge-reviewers will review them and provide substantive comments. Also, 25 public participants will be recruited to pilot test the parental and public surveys (overall n=50) using Amazon Mechanical Turk. We will offer public participants in the pilot-testing $10 for their time.

A.1.d. All Participants

I will fulfill all requirements necessary for IRB approval of my proposed research during the first year of the K01 Award. Also, Abt and YouGov will seek approval by, respectively, Abt's IRB and the Western IRB, and will collaborate, as necessary, with the IRB at the NY State Psychiatric Institute/Columbia University Medical Center. YouGov has filed an approved Federalwide Assurance (FWA) with the Department of Health and Human Services (FWA00010960, http://ohrp.cit.nih.gov/search.aspx).

A.2 Sources of Materials

The data will be obtained specifically for the purposes of the proposed research. For all participants, the surveys will be anonymous and administered on-line. The first page of the invitation to participate in the judges' survey will include contact information of the project managers at Abt in case participants have questions.

Survey invitations for parents and jury-eligible participants will include email address for YouGov staff in case participants have comments or concerns. For both judges and public participants, once participants submit the completed survey, their access code will be inactivated to prevent duplicate responses.

The surveys for all participants will comprise an information page about the study and general instructions, including a consent disclosure; 2 vignettes reflecting the civil adjudicatory context being examined in that wave; and rating tasks (reaction questions to the vignettes, a list of stigma measures, Implicit Association Test, and a measure of respondents' understanding of genetics). Judges will be asked a few additional legally- and jury-related questions, as well as their geographic area, type of court, and judicial experience.

A.2.a. Participants in Pilot Testing

Because pilot testing aims to ensure the clarity of questions and assess the time required for completion of the survey, the terminology, number of reaction questions and other rating tasks in the pilot testing may naturally be somewhat different than the final surveys. However, in general, the surveys for pilot-testing participants will have the same structure and components as the surveys for parents and public participants, and they will be as close as possible to the final versions. Also, as for other participants, the surveys for public pilot-testing participants will be anonymous and administered online. Amazon Mechanical Turk will create a system to collect necessary information from pilot-testing participants who wish to receive payment for their participation. Amazon Mechanical Turk will follow the amazon.com confidentiality policy, and no identifying information about pilot-testing public participants will be reported back to the researchers.

The judge-reviewers will be identifiable to researchers. However, they will not be requested to complete the surveys or provide their own responses to the vignettes and questions but only to provide substantive comments about the legal aspects of the cases (e.g., whether they accurately reflect the legal issues typically at stake in such litigation).

A.2.b. Judges, Parents and Jury-eligible Participants

Abt will administer the judges' surveys and collect demographic characteristics for judges using a unique Abt ID that each participant will be assigned. These unique Abt IDs will be confidential and no identifying information will be provided to the researchers.

YouGov will collect demographic characteristics for adult parents and jury-eligible participants using information that participants chose to provide when they registered for the panel. Participants' identifying information (e.g., name) that YouGov collects from panel registrants will be confidential and will not be provided to the researchers. Project Implicit will host these respective surveys and collect the data, however, it will not collect any identifying information about the participants.

A.3. Potential Risks

The risks for all participants are minimal. The data collected from judges, parents, jury-eligible respondents and participants in the pilot testing consist of their views about the use and relevance of psychiatric genetic data in the civil adjudicatory contexts under the study (child custody, special education, civil responsibility for torts), and of their perceptions, in light of genetic data, about civil incapacity and treatment options. There is a minimal risk that participants answering the stigma measures and the Implicit Association Test (Aim 3) will be sensitive to disclosing biased opinions, and that participants asked about their contact with psychiatric disorders (see *12.C.3*) will feel some discomfort disclosing such information. However, researchers will assure all participants that there are no correct answers to the questions asked, and that the researchers will have no access to their identities. For additional information, they will be referred to the appropriate Abt, YouGov, Project Implicit, or Amazon Mechanical Turk confidentiality policy.[242-245]

As explained above, the judge-reviewers will not be asked to complete the surveys at all, and thus, no sensitive information about them will be obtained. In any case, to minimize potential risk, all participants will be informed that they can refuse to answer any question and discontinue their participation at any time.

B. Adequacy of Protection Against Risks

B.1. Recruitment and Informed Consent

Judge participants will be identified and contacted by Abt using lists and contact information that are publicly available (e.g., State Judicial Web sites, *The American Bench*[240]). Parents and jury-eligible participants will be

identified by YouGov using personally identifying information (e.g., email address) that participants chose to provide when they registered for the YouGov panel. YouGov's recruiting methods include Web advertising campaigns, permission-based email campaigns, telephone-to-Web recruitment and voter registration-based sampling, and a double opt-in procedure is followed where respondents confirm their consent. Public participants will be screened to ensure that they satisfy the inclusion criteria for the survey. African American parent-participants in Wave 2 (special education contexts) will be oversampled (30% of the sample) to increase the power to detect differences among Black/White racial groups. The reasons for this are described in detail in *12.A.2.2.* and *12.C.2.b*

Judges will be initially contacted by letter, which will introduce the study and provide a link to the online survey, followed by an emailed invitation with a link to the survey. The letter will contain the participants' unique Abt ID that must be used to access the survey and that enables Abt to track respondents. In keeping with Abt's usual protocol for surveys with judges, as well as standard survey techniques,[202] up to 3 weekly follow-up email reminders with a link to the survey will be sent to participants who did not respond to the initial invitation. Abt will also call judges' administrative assistants for an additional reminder.

Public participants who are registered with YouGov's panel initially will be contacted by email, which will introduce the study and provide a link to the online survey hosted by Project Implicit's website; they will receive up to 3 weekly reminder emails.

The researchers will recruit public participants in pilot testing through Amazon Mechanical Turk, an online service that matches people interested in performing small tasks with persons (including researchers) in need of their assistance. Once they have indicated an interest, potential participants will be sent an email, which will introduce the study and provide a link to the online survey. Similar to other participants, up to 3 weekly reminder emails will be sent.

The researchers will recruit judge-reviewers who are personally known to them and will provide them with copies of the surveys.

All participants will undergo an IRB-approved consent process. This process will precede administration of the survey, and participants will have to "click" their consent on a specific button before being transferred to the survey. The informed consent disclosure will include information about the purpose of the study, i.e., soliciting their views about psychiatric genetic data in civil adjudicatory contexts, a description of the tasks involved, potential risks, incentives, and participants right to decline to participate or to stop at any time—along with any other information required by the IRB.

B.2. Protections Against Risks

As noted above, the risks for all participants, including public participants in the pilot testing and judge-reviewers, are minimal. Nonetheless, to further minimize any potential risks, the following steps will be taken: 1) no identifying information will be collected in the surveys; 2) all data collected will be kept confidential to the maximum extent possible. Abt's administration of the online surveys will use a unique Abt ID number, YouGov will store all identifying information in YouGov databases and will use firewalls to protect such information, and Amazon Mechanical Turk will use secured software that encrypts inputted information. Project Implicit will not collect any identifying information about participants; 3) To further minimize the likelihood of identification of judge respondents, Abt will collect demographic information that includes only broad geographic region (state level); 4) all data received from Abt, YouGov, Project Implicit, and AMT will be securely stored in an encrypted computer at the NY State Psychiatric Institute, where only the Principal Investigator and other authorized researchers will be able to access them. Abt, YouGov, and Project Implicit will store the collected data as a separate file on their databases and only link it through an ID number that is assigned to the survey. All these firms will destroy all data collected after the results from the surveys are accepted for publication; 5) all participants will be assured that there are no correct answers to the questions asked, minimizing the possibility of experiencing anxiety in response to the questions; and 6) participants will be informed that they can refuse to answer any question and discontinue their participation at any time. Since this is minimal risk research and does not involve a clinical trial, there is no plan for data and safety monitoring of the research subjects. However, the PI will monitor any adverse effects reported, and will adjust subsequent waves of the study accordingly.

C. Potential Benefits of the Proposed Research to the Subjects and Others

Participants will not receive any personal benefit from the proposed study. However, findings from the study are likely to yield societal benefit in the future by: 1) creating a foundation for the development of informed policies about the use and misuse of psychiatric genetic data in civil litigation; and 2) raising awareness of the increasing knowledge about psychiatric genetics and of biases that may influence its use.

D. Importance of the Knowledge to be Gained

Increasing knowledge about psychiatric genetics is likely to cause major changes in law and society in the next few decades. The broad-scale introduction of psychiatric genetic data in civil courtrooms is probably only a matter of time, and it will create new challenges for judicial decision-making. However, how judges and the public will respond to such genetic data in civil litigation is unknown, as is the extent to which their biases about genetics and psychiatric disorders will impact their decisions. Given the potential impact of psychiatric genetic data on litigants' interests–which may extend beyond specific legal proceedings to include their broader social, medical, and legal standing–there is urgency for consideration of these issues in a meaningful way. This study proposes to begin that process by studying 3 prominent areas in which the introduction of psychiatric genetic data is likely to occur–family law, special education, and civil responsibility for tort–and the relationship with stigma. As the potential risks to participants are minimal, the benefits to be gained far exceed the risks.

15. Inclusion of Women and Minorities

Inclusion of Women

All 3 waves of the proposed study will include both women and men participants, and no participant will be excluded on the basis of sex.

Judge participants (N=300 for Wave 1, N=400 for Wave 3) will be recruited using lists and contact information that are publicly available, and the samples will reflect the geographical location (Northeast, South, Midwest, and West as determined by the US Census Bureau regions) and gender of the entire judicial population. As of 2013, women judges comprised 29% of judges in US state courts,[240] and this is therefore the anticipated percentage of women judge participants.

With regard to parents and jury-eligible participants (N=370 for Wave 2, N=400 for Wave 3), as well as public participants in the pilot testing (N=25), it is expected that the proportion of women and men will reflect the gender ratio in the US population, i.e., approximately 50% of public participants will be women.

Inclusion of Minorities

No minority group will be excluded from the study. Nationally, the percentage of minority judges in state courts ranges from 0-56%, with African Americans comprising the majority (53.55%), followed by Hispanic Americans (28.41%).[241] It is thus expected that judge participants will reflect this diversity.

For parents and jury-eligible participants (Waves 2 and 3), as well as public participants in the pilot testing, it is expected that the use of probability-based random samples from an Internet-based panel of the general public will yield minority compositions that reflect the US population. In addition, in Wave 2 (special education contexts), adult African American parents will be oversampled (30% of the sample) because the vignettes in this wave include the independent variable of race (Black, White) and oversampling will increase the power to detect differences among groups. The reasons for this are described in detail in *12.A.2.2.* and *12.C.2.b*.

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Impact of Psychiatric Genetic Data in Civil Litigation and Its Relationship with Stigma - Wave 1: Family Court Judges

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	1	3	6	**10**
Asian	1	3	0	0	**4**
Native Hawaiian or Other Pacific Islander	1	1	0	0	**2**
Black or African American	8	11	0	0	**19**
White	77	184	1	1	**263**
More than One Race	1	1	0	0	**2**
Total	**88**	**201**	**4**	**7**	**300**

Study 1 of 3

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Impact of Psychiatric Genetic Data on Civil Litigation and Its Relationship with Stigma - Wave 2: Adult Parents

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	2	1	20	20	**43**
Asian	7	6	1	1	**15**
Native Hawaiian or Other Pacific Islander	10	10	1	1	**22**
Black or African American	60	60	1	1	**122**
White	92	99	1	1	**193**
More than One Race	2	1	1	1	**5**
Total	**173**	**177**	**25**	**25**	**400**

Study 2 of 3

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Impact of Psychiatric Genetic Data on Civil Litigation and Its Relationship with Stigma - Wave 3: Trial Court Judges & the Jury-eligible General Population

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	2	2	30	34	**68**
Asian	9	9	0	0	**18**
Native Hawaiian or Other Pacific Islander	11	12	0	0	**23**
Black or African American	32	36	1	1	**70**
White	234	381	1	1	**617**
More than One Race	1	1	1	1	**4**
Total	**289**	**441**	**33**	**37**	**800**

Study 3 of 3

Funding Opportunity Number: PA-14-044. Received Date: 2014-10-14T16:36:52.000-04:00

16. Inclusion of Children

Children under age 18 will be excluded from this study, for practical and methodologic reasons.

For Wave 2, which considers the perspectives of public participants who have children ages 0-21, informed consent from guardians of parents who are themselves younger than 18 will be difficult to obtain–and impossible to confirm–given that it will be an anonymous online survey. Although in some jurisdictions minor parents will be legally emancipated and hence able to provide consent, ascertaining this status would again raise difficult logistical issues. However, children ages 18-21 who have children and can provide their voluntary consent will be included.

Public participants for Wave 3 and its pilot-testing, which considers civil responsibility for torts, will have to be jury-eligible, i.e., US citizens, over 18, non-felons, with spoken and reading proficiency in English, and who are registered to vote or hold driver licenses. Accordingly, children ages 18-21 will be included, and younger children will be excluded.