

**SUMMARY STATEMENT**  
( Privileged Communication )

*Release Date:* 07/10/2015

**PROGRAM CONTACT:**  
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*Application Number:* 1 K99 HG008819-01

**Principal Investigator**

**PRINCE, ANYA**

**Applicant Organization: UNIV OF NORTH CAROLINA CHAPEL HILL**

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

*Meeting Date:* 06/17/2015  
*Council:* OCT 2015  
*Requested Start:* 09/01/2015

*RFA/PA:* PA15-083  
*PCC:* X5JM

*Dual IC(s):* NR, AG

**Project Title:** Use of Genetic Information by Life, Long-term Care, and Disability Insurers:  
Exploring International Lessons, the Domestic Legal Landscape, and Options for  
U.S. Policy

**SRG Action:** Impact Score:

**Next Steps:** Visit [http://grants.nih.gov/grants/next\\_steps.htm](http://grants.nih.gov/grants/next_steps.htm)

**Human Subjects:** 30-Human subjects involved - Certified, no SRG concerns  
**Animal Subjects:** 10-No live vertebrate animals involved for competing appl.  
**Gender:** 1A-Both genders, scientifically acceptable  
**Minority:** 1A-Minorities and non-minorities, scientifically acceptable  
**Children:** 1A-Both Children and Adults, scientifically acceptable  
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	84,474	<input type="text" value="Estimated Costs"/>
2	86,710	
3	163,816	
4	163,816	
5	163,816	
<b>TOTAL</b>	<b>662,632</b>	

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

### **1K99HG008819-01 Prince, Anya**

**RESUME AND SUMMARY OF DISCUSSION:** This is a Pathway to Independence application from an outstanding candidate with outstanding supportive letters of reference. The candidate has training in bioethics, law and genetics and she has been productive and shown initiative in seeking out new opportunities. The purpose of the application is to extend the candidate's training and expertise in qualitative case study methods and quantitative survey methods which will augment her legal and policy training. The research project will evaluate the legal and policy issues related to how insurers will use genetic information. The research project is innovative and timely as it is important to see how genetic information is used and how the actuarial standards are applied. The project will also use foreign case studies to see how other countries handle genetic information. A minor concern is that the research project has not identified an in-country collaborator who could help with identifying possible informants. The sponsor is outstanding and the candidate has gathered a strong team of mentors. The reviewers all agreed that this is an exceptionally qualified candidate who has a high likelihood of becoming an independent productive researcher in the field of genetics and law.

**DESCRIPTION (provided by applicant):** This project employs multiple methods and a transdisciplinary approach to explore policy options for US federal and state governments seeking to address how life, long-term care, and disability insurers use genetic information. The analysis will focus on legal standards of actuarial justification, that is, the requirement that insurers must show a statistical correlation between a risk factor and increased cost in order to use that factor in an underwriting decision such as a policy denial or an increased premium. Policies in this area can significantly affect the health of individuals in two ways. First, barriers of access to life, long-term care, or disability insurance can threaten economic stability of individuals and families, leading to inability to pay for healthcare or other necessities. Second, fear of genetic discrimination may prevent individuals from undergoing predictive genetic testing, testing that could provide clinically relevant information to help prevent or mitigate future disease. This project has two primary goals: 1) to systematically examine the legal and policy landscape of life, long-term care, and disability insurer use of genetic information in the US and internationally; and 2) to offer a variety of policy options for US federal and state governments that seek to address genetic discrimination in this area. To meet these goals, I propose three specific aims. Aim 1 employs a case study methodology to explore the policy mechanisms that four countries outside the US have utilized to address insurer use of genetic information, with particular focus on how these policies use and define standards of actuarial justification. For each case study I will conduct a search and analysis of relevant policy documents as well as conduct and analyze targeted, in-depth interviews with key stakeholders such as academic/policy experts, government officials, advocacy group representatives, and insurance representatives. Aim 2 interrogates how existing US state actuarial justification laws have been interpreted and enforced in the context of genetic information through two sub-aims. Aim 2a utilizes survey methodology to empirically examine how US state insurance commissioners are interpreting and enforcing state actuarial laws. Aim 2b employs legal analysis of statutes, regulations, and applicable state law to evaluate how states have legally defined and deployed actuarial justification standards. The survey responses of Aim 2a will inform the legal analysis regarding how existing legislation may be enforced or interpreted. Aim 3 undertakes policy analysis of the legislative and regulatory options available to US governments at the state and federal level. Through policy analysis and critique, conclusions drawn from Aims 1 and 2, and feedback from a policy-experts, Aim 3 will provide policy options to address life, long-term care, and disability insurer use of genetic information and to address the threshold evidence levels needed to meet actuarial standards in this area. This project and the final policy recommendations directly support an identified ELSI research priority of the NHGRI regarding life, long-term care, and disability insurer use of genetic information.

**PUBLIC HEALTH RELEVANCE:** As clinicians and researchers explore how genomic sequencing can be utilized to prevent or mitigate genetic conditions and diseases, many individuals who are expected to benefit from these findings remain fearful of how insurers not currently included under federal genetic discrimination legislation can use their sequencing and test results, with potentially harmful outcomes. Through exploration of both the US and international context, this project seeks to better understand the ways that life, long-term care, and disability insurers can legally use genetic information, with particular focus on legal standards of actuarial justification. By providing policy recommendations to address possible discrimination, this project addresses an important NHGRI legal, regulatory, and public policy research priority to investigate the use of genetic information by life, disability, and long-term care insurance companies, determination of actuarial risk, and the impact of state laws.

## **CRITIQUE 1:**

Candidate: 1

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

Research Plan: 3

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2

Environment Commitment to the Candidate: 1

**Overall Impact:** This K99/R00 application is from a highly qualified candidate who holds law and MPP degrees from Georgetown, has worked in academic (e.g., NIH bioethics) and advocacy organizations, and is currently a post-doctoral fellow working in the UNC Center for Genomics and Policy; institutional support is excellent; her mentors are excellent; her advisors round out an extremely well-tuned group of experts to help guide Ms. Prince in her training development as well as her proposed research; the training plan is excellent, including the RCR components; the research is innovative and likely to be highly significant, and the methods are well described and well suited for the purposes of each Aim; the only concerns are: 1) except for 1 person, the advisors are at great distances from UNC, and the nature and frequency of interactions are left open ended; and 2) there is one minor concern regarding the Aim 1 methods, as the international case study and interview process would be greatly enhanced by having an in-country collaborator who could facilitate identification of possible informants, opening doors with local groups and officials, and assuring compliance with country IRB requirements.

### **1. Candidate:**

#### **Strengths**

- Ms. Prince is a lawyer with a Masters in Public Policy, and is a post-doctoral fellow in the UNC Center for Genomics and Society;
- Ms. Prince has worked on related genetics and policy issues for more than 5 years, and the proposed project is an excellent extension of her prior work.

#### **Weaknesses**

- None noted.

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

#### **Strengths**

- Ms. Prince's goal is to develop advanced skills in qualitative and quantitative research skills that will augment her legal and policy training, enabling her to become a skilled interdisciplinary scholar working on ELSI issues as a law professor

- Her mentors are highly skilled experts in the methods and subject matter in which Ms. Prince's training and project will be based, and will be excellent mentors to help her reach her goals.

#### **Weaknesses**

- None noted.

### **3. Research Plan:**

#### **Strengths**

- The proposed research involves mixed methods of 1) qualitative case studies, including stakeholder interviews, in countries that have implemented policies; 2) quantitative survey of US state insurance commissioners regarding the interpretation and enforcement of state laws; and 3) policy analysis in order to understand the ways in which the requirements for actuarial justification have been applied in the supplemental insurance markets and to develop policy options for addressing concerns about discrimination in those markets;
- The application draws upon Ms. Prince's excellent law and policy background, augmented by her proposed training;
- The topic is an important one, identified as high priority by the NHGRI, and the results may be quite useful to states and policy makers as they consider their options for assessing appropriate insurance practices as genetics becomes a larger part of medical care;
- Case study examination of foreign countries' policies and interpolation for development of domestic US policy options, and survey of US state insurance commissioners for understanding the current US posture, are both innovative;
- Empirical methods are appropriate for the planned studies and the proposed legal and policy analyses are thoroughly described and appropriate.

#### **Weaknesses**

- Selection of countries whose policies are to be examined are limited to English-speaking countries, which may limit the scope of the project;
- As with Canada and Yann Joly, it might be extremely helpful to identify an in-country collaborator/academic to provide on-the-ground assistance with the case study and interview processes; this would also overcome what appears to be a thin and unconvincing plan for identification of initial interview subjects in each target country; note too that if snowball sampling is to be done, it should be done before the actual interviews so that all interviews can be scheduled in the planned 2-week visit period; finally, it may be necessary to secure IRB approval in the target countries, which would make having a local collaborator critical;
- There are various mentions (e.g., p.94) of "policy experts" to be engaged for review of Aim 3 policy analyses, but who these experts are and precisely what role they are to play is not described.

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

#### **Strengths**

- Primary mentor Gail Henderson and secondary mentors Debra Skinner and Mark Hall are unparalleled in their abilities and backgrounds in social science methods and health law, and Ms. Prince has already established working relationships with each that prepares them well for this program;

- Recommendation letters are extremely strong, with no reservations, extolling Ms. Prince's skills and high motivation to pursue advanced training that will enable her to succeed as an ELSI researcher;
- Advisors for Ms. Prince are perhaps the best people working in the area of study, notably including Yann Joly at McGill, Mark Rothstein at Louisville, Aisling de Paor at Dublic City University, and Angus Macdonald from Heriot Watt University, with genetics expertise provided by James Evans at UNC; all are strongly supportive of the project and committed to helping Ms. Prince with her project.

#### **Weaknesses**

- Given that Ms. Prince's advisors are all (except for Dr. Evans) at some distance (3 of 6 are out of the US), it would be helpful to have some idea of the nature and frequency of the planned interactions, such as regularly scheduled Skype calls, which are left someone undefined in the application.

### **5. Environment and Institutional Commitment to the Candidate:**

#### **Strengths**

- Ms. Prince is a post-doctoral fellow at UNC, and the institution fully supports her application;
- Ms. Prince seeks a career as professor in a law school, for which she will be well qualified; notably, she will be well qualified and trained for faculty positions outside of law schools, as well.

#### **Weaknesses**

- None noted.

#### **Protections for Human Subjects:**

##### Acceptable Risks and Adequate Protections

- It may be necessary to secure in-country IRB approvals, depending on laws in the target countries.

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

Not Applicable (No Clinical Trials)

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

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 21: Excluding ages < 21 justified scientifically
- Inclusion plans are appropriate.

#### **Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

#### **Biohazards:**

Not Applicable (No Biohazards)

### **Training in the Responsible Conduct of Research:**

Acceptable

Comments on Format (Required):

- Ms. Prince's prior training has included short courses, seminars, and participation in regularly scheduled seminars focused on RCR topics, and she will continue with similar training (as well as project focused mentorship) during the first 2 years of the project.

Comments on Subject Matter (Required):

- All relevant RCR and human subjects topics are addressed.

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

- Numerous faculty from different schools and departments have been and will be involved in her RCR training; her mentors will provide direct training relevant to development of her research plan and RCR requirements.

Comments on Duration (Required):

- More than adequate hours of training have been and will be engaged in RCR training activities.

Comments on Frequency (Required):

- RCR training is a continuous activity that will be engaged throughout Ms. Prince's training program.

### **Resource Sharing Plans:**

Not Applicable (No Relevant Resources)

### **Budget and Period of Support:**

Recommend as Requested.

### **CRITIQUE 2:**

Candidate: 1

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

Research Plan: 2

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

Environment Commitment to the Candidate: 1

**Overall Impact:** This is an extremely strong proposal and an exceptionally qualified candidate. Ms. Price has strong and interdisciplinary training in law, research methodology and ethics. She also has unique real world experience in advocacy in her area of scholarship: legal protections against genetic discrimination. She has recently been a postdoctoral fellow at UNC, where she has gotten a breadth of training experiences in bioethics, genetics and new genomic technologies, and research methodology. She has an extremely productive publication record in high quality journals. She has demonstrated independence and initiative in her training and her scholarship. Her chosen area of focus is critical to ELSI and genetics and genomics translation, and is understudied in the field. It is notable that she has clearly sought out interdisciplinary training, collaboration and scholarship opportunities at every step of her training, and that this will serve her well as she works towards her goal of become an independent law professor who conducts empirical research. She has already made a strong contribution for someone at her training level to the field, and her proposed training plan will fill in gaps in case study

and survey methodology, which she has clear and innovative plans to apply to conduct research on actuarial approaches to genetics and genetic information. Of note is her creative plan to obtaining training in mentorship, and build an experiential class for law students to provide mentorship will obtain support for her research projects. This proposal is exceptional and has virtually no weaknesses. It seems highly likely that Ms. Price will be successful in obtaining the needed skills and training to obtain an independent position in the time of the K99, and become an incredibly strong independent researcher who is working on a critical area to the field.

## **1. Candidate:**

### **Strengths**

- An exceptionally qualified candidate, demonstrating initiative and excellence in prior training and research, including training in bioethics, law, experience in law and advocacy around genetics, and extremely productive pre-doctoral training in law, and postdoctoral training at UNC to date, with numerous publications in excellent journals in the area of focus and interest.
- The candidate's work and experience demonstrates tremendous originality and initiative, and also independence, seeking out new opportunities for training, research and experience. This is a tremendous strength, and suggests that she is very likely to become a successful independent investigator who will make critical and substantial contributions in the field. It is hard to imagine a candidate having a stronger record in this area.
- The candidate has a strong record of research productivity in the area of law, insurance and genetics. Including first authored publications in the last two years in the American Journal of Bioethics, the Journal of Genetic Counseling, Health Matrix and the Journal of Law, Medicine and Ethics. This demonstrates an excellent production and publication track record, and potential for future scholarship and publication, and is a highly significant strength of the application.
- The candidate is extremely likely to achieve independence, tenure track or equivalent faculty position within the time period of the K99.

### **Weaknesses**

- None noted.

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

### **Strengths**

- The candidate proposes to gain training in survey and case study methodology, which is very appropriate given her existing training, research plan and career goals. It fills in the only significant gap she has to accomplish her goals and complements her existing training.
- The content and duration of the components is excellent and a strength of the application. The candidate has clearly worked to identify training opportunities both in her institution and outside but pertinent to her field and ultimate career track (e.g. law school).
- The candidate's plan for mentorship training and integration of that training into a practical experience that will help facilitate her research is innovative and likely to significantly contribute to her goal of obtaining a faculty position, and likely to help her be a successful mentor in the future. All trainees should consider such mentorship directed and experiential training, and this component of the proposed training plan could be a model for others.
- The timeline for transition to independent is appropriate, given the candidate's strong training, experience, productivity, and mentors and mentorship committee and strong training environment.

### **Weaknesses**

- None noted.

### **3. Research Plan:**

#### **Strengths**

- Important, understudied area critical to the field, likely to make a significant contribution.
- Well thought through and justified approach, case study and surveys excellent approaches to answer these questions, has anticipated potential challenges and solutions.
- Excellent justification for selection of countries to study for Aim 1, will provide important information with an innovative conceptual model to addressing issues involved in actuarial justification and insurer use of information. Will build on experience and case study training in K99 portion.
- Strong use of survey methodology to characterize states' approach to how state insurance commissioners enforce and interpret actuarial and unfair trade practice laws in the context of genetic information. Builds on advocacy experience and survey methodology training in K99.
- Policy recommendations work in Specific Aim 3 is innovative and likely to contribute significantly to the field. Although it will draw on work in Aims 1 and 2, it does not depend on it, which increases the likelihood of success.
- Excellent and innovative proposed use of an experiential class at a law school to assist in completion of research work for Specific Aims 2b and 3.

#### **Weaknesses**

- None noted.

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

#### **Strengths**

- Extremely strong mentor, co-mentors and advisory group. Expertise across all the disciplines and areas needed for the candidate's training and research plan. Strongest possible letters of support and commitment to mentor and support. Significant strength of application.

#### **Weaknesses**

- None noted.

### **5. Environment and Institutional Commitment to the Candidate:**

#### **Strengths**

- Excellent environment, with many strong mentors, colleagues and resources available for the training and research that the investigator proposes. Major strength of application.

#### **Weaknesses**

- None noted.

### **Protections for Human Subjects:**

Acceptable Risks and Adequate Protections

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



Not Applicable (No Clinical Trials)

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

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

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Training in the Responsible Conduct of Research:**

Acceptable

**Resource Sharing Plans:**

Acceptable

**Budget and Period of Support:**

Recommend as Requested.

**CRITIQUE 3:**

Candidate: 2

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

Research Plan: 2

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2

Environment Commitment to the Candidate: 1

**Overall Impact:** This productive candidate has high potential impact as an independent researcher and legal and policy scholar. The proposed research is significant, the mentors and Advisory committee are excellent, and the career development, training and mentoring plans are excellent.

**1. Candidate:**

**Strengths**

- Anya Prince, JD has a background in political science, law and ELSI genomics.
- She has been involved in policy analysis and research on insurers and laws related to access to genetic testing, follow up and discrimination, both in the US and globally.
- This K99 application will formally support her research training and career development in this field.

- She is a superb candidate with great strength in her training and productivity.

**Weaknesses**

- None noted.

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

**Strengths**

- The proposed career development plan, goals and objectives are excellent and are detailed.
- The training plan and mentoring plans are also detailed and appropriate. Training is prosed in qualitative case study review and analysis, survey design and professional development and mentoring.
- Mentors are excellent.

**Weaknesses**

- None noted.

**3. Research Plan:**

**Strengths**

- The research plan examines laws protecting genetic rights for individuals and policies that provide access to genetic testing and follow up services.
- Fears related to genetic discrimination and what laws are designed to protect individuals from discrimination will also be examined.
- The plan aims and methods are sound.

**Weaknesses**

- The policy experts are a component of the implementation of Aim 3 but the names and expertise of the experts is not provided.

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

**Strengths**

- Mentors include:
- Dr. Gail Henderson who will serve as primary mentor in areas of qualitative and quantitative research. She is an expert is ELSI issues in genomic technologies. In addition, she is an expert in global health will provide insight and support for the research plan and training plan.
- Dr. Debra Skinner will serve as a mentor. She is an expert in research on how families of children with disabilities and adults understand and use genetic information.
- Mark Law, JD is an expert in insurance law, public policy and bioethics as well as insurers use of genetic information.
- An outstanding advisory committee has been assembled.

**Weaknesses**

- None noted.

**5. Environment and Institutional Commitment to the Candidate:**

**Strengths**

- Outstanding resources and institutional support are documented in this application

**Weaknesses**

- None noted.

**Protections for Human Subjects:**

Acceptable Risks and Adequate Protections

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

Not Applicable

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

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

**Vertebrate Animals:**

Not Applicable

**Training in the Responsible Conduct of Research:**

Comments on Format (Required):

- Acceptable

Comments on Subject Matter (Required):

- Content acceptable

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

- Adequate

Comments on Duration (Required):

- Throughout K99

Comments on Frequency (Required):

- Acceptable

**Budget and Period of Support:**

Recommend as Requested.

#### **CRITIQUE 4:**

Candidate: 2

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

Research Plan: 3

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

Environment Commitment to the Candidate: 1

**Overall Impact:** This is a timely proposed project that explores legal and policy issues relating to insurance discrimination by non-health insurers that are not covered by GINA. As more genetic testing is conducted, these types of insurance plans will come more into play in the relatively near future, and so the inquiry into these insurers' criteria, and particularly how they might use genetic info and the actuarial standards they would apply, is both innovative and timely. I have some concerns about the failure to address adequately the insurers' perspective and the pressures that may compel them to seek to use genetic info (elaborated below). The training and mentorship components of this proposal are outstanding, although again I have some concerns about the planning for the R phases (elaborated below).

#### **1. Candidate:**

##### **Strengths**

- Candidate is well trained and motivated to pursue academic career in this field.
- Excellent background and experience in working in the Center for Genomics in Society (CGS).
- Productive publication record in first year at CGS.

##### **Weaknesses**

- Gaps in training (recognized by candidate) that this project is intended to address.
- Some concerns about lack of balance to appreciate perspectives and concerns of insurance companies if their clients start using genetic info for insurance purchase decisions.

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

##### **Strengths**

- Logical and well-planned objective to publish legally relevant research and then leverage that work to pursue law professor position.

##### **Weaknesses**

- R00 phase not well thought out – full 100% funding for research/teaching experiential course for first 3 years on law school tenure track would likely be disadvantageous for candidate – law schools make tenure decisions very quickly usually after 3-4 years, and require some service teaching, committee work, etc. for successful tenure application, none of which would be possible with fully funded 100% time commitment grant position.

#### **3. Research Plan:**

##### **Strengths**

- General subject area of timely interest.
- Specific approach of investigating how genetic info may be used by supplemental insurers, such as inquiry into actuarial standards, is unique and would be important contribution to debate.

### **Weaknesses**

- Proposal does not seem to incorporate perspective/positions of supplemental insurers, who are quite satisfied if no one uses genetic data in underwriting, but are concerned about adverse selection. This fear quickly dismissed in research plan and not addressed again, but is a key issue.
- Proposed solutions all address only governmental solutions, and not for example, what insurance companies might do, again demonstrating preference/tilt for governments banning use of genetic info even if consumers start using genetics in insurance purchase decisions on a widespread basis.
- More clarification on how case studies of other countries would be useful for American policy, especially considering none of the jurisdictions have yet to face implications of widespread consumer access to genetic info.

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

#### **Strengths**

- Top level mentors.
- Multi-disciplinary set of mentors.

#### **Weaknesses**

- None noted.

### **5. Environment and Institutional Commitment to the Candidate:**

#### **Strengths**

- Strong institutional environment within CGR.
- Letters from mentors and advisors demonstrate strong interest and support for project.

#### **Weaknesses**

- None noted.

### **Protections for Human Subjects:**

#### Acceptable Risks and Adequate Protections

- Fine, well developed

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

Not Applicable

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

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

### **Vertebrate Animals:**

Not Applicable

**Biohazards:**

Not Applicable

**Training in the Responsible Conduct of Research:**

Comments on Format (Required):

- Excellent

Comments on Subject Matter (Required):

- Excellent

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

- Satisfactory

Comments on Duration (Required):

- Satisfactory

Comments on Frequency (Required):

- Excellent

**Budget and Period of Support:**

Recommended budget modifications or possible overlap identified:

- Full grant funding for 3 years of research period would actually be harmful for law school tenure case because it would preclude law school service teaching and committee work essential for tenure. Recommend 50% rather than 100% salary support.

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

**PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE**

**INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE**

**INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE**

**INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE**

**COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.**

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NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and

multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see [http://grants.nih.gov/grants/peer\\_review\\_process.htm#scoring](http://grants.nih.gov/grants/peer_review_process.htm#scoring).