Specific Aims:

In the US, there has been a polarized debate about whether life, long-term care, and disability insurers, referred to as 'supplemental' insurers, should be able to use an applicant's genetic information when setting rates or accepting policies. This debate usually references highly predictive and serious genetic diseases, such as Huntington's Disease or Lynch Syndrome. In reality, most variants have a wide range of predictive values, from unknown to low to high. There has been little debate about how predictive a variant must be for supplemental insurers to use—or to be legally allowed to use—the information. Additionally, for some highly predictive variants, medical interventions may be available to minimize one's indicated risk, and the law does not currently shed light on how insurers should consider this information. State unfair trade practice laws generally require insurers to have actuarial justification for using any risk factor in underwriting. Under these actuarial laws, to deny an application or charge an increased premium, insurers must show that a relevant risk factor is statistically associated with increased insurer cost. However, in the US, there has been little research regarding the application of these standards to genetic and genomic data. Internationally, several countries, such as the UK and Australia, have had actuarial policies for supplemental insurers specific to genetic testing since the early 2000s. Thus, most of the academic and policy discussions in this area have occurred abroad.

Although the Genetic Information Nondiscrimination Act (GINA) protects against genetic discrimination in employment and health insurance, individuals may fail to undertake medically recommended clinical genetic testing, or participate in genomic research, due to fears of discrimination in supplemental insurance. Policy responses tend to focus on whether supplemental insurers *should* be able to use genetic information, but do not explore the broader criteria that inform *when* and *how* such information can legally be used. Once studied, these criteria can inform a more nuanced policy discussion of the 'should'. This project has two primary goals: 1) to systematically examine the legal and policy landscape of supplemental insurer use of genetic information in the US and internationally, with particular focus on requirements of actuarial justification; and 2) to use these requirements to offer a variety of policy options for US state and federal governments that seek to address genetic discrimination in supplemental insurance. To meet these goals, I propose three specific aims.

Aim 1 – Analyze how international approaches to actuarial justification, supplemental insurance, and genetic information may be applicable to the US. Using methods and analysis techniques acquired during the mentored-phase, I will choose four countries that have robust policies regarding actuarial justification and insurer use of genetic information and conduct case studies of these examples. Focus on actuarial standards in the international privatized supplemental insurance sector ensures a more direct comparison with the US, despite differences across health insurance sectors. I will explore why specific policy options were chosen, whether these policies address issues related to predictive value or preventive measures, how effective the policies have been, and what lessons were learned. Case study analysis will combine both policy analysis and targeted interviews with key stakeholders such as academic/policy experts, government officials, advocacy group representatives, and insurance representatives.

Aim 2 – Interrogate how existing US state laws that require actuarial justification in supplemental insurance would apply to use of genetic information. Using multiple methods, I will explore how current state law may apply to genetic information. I will conduct a survey of US state insurance commissioners to examine how they are interpreting and enforcing actuarial and unfair trade practice laws (Aim 2a). I will combine this with legal analysis of statutes, regulations, and applicable case law to evaluate whether state law has been applied to the context of genetic information and how the laws may be interpreted and enforced in this area (Aim 2b). Survey responses will inform the legal analysis of how existing legislation may be enforced or interpreted.

Aim 3 – Provide policy analysis and recommendations for legislative and regulatory options to address concerns about the use of genetic information in supplemental insurance. I will undertake policy analysis of options available to US governments to address societal and individual concerns about supplemental insurer use of genetic information (Aim 3a). Additional policy analysis will explore legal and policy options for the threshold evidence levels needed to meet actuarial standards (Aim 3b). These options will incorporate feedback from policy experts. I will disseminate recommendations through policy briefs and manuscripts.

Aims 1 and 2a (**K99 phase)** will be completed in concert with training in qualitative and quantitative methods. For the **R00 phase**, my goal is to secure a tenured law position that involves teaching an experiential course and researching ELSI topics. Under this model, students will assist in the research goals of Aims 2b and 3.

By combining policy analysis and case studies from the international setting with detailed legal and survey analysis from the US, this project will produce a robust study of potential policy options for legislators.

Research Strategy

Significance

Imagine an individual who is known to have a genetic variant that was reported in a genome-wide association study (GWAS) to be weakly correlated with an increased risk of coronary artery disease, a leading cause of death worldwide. Should life, long-term care, or disability insurance companies be able to use this information in underwriting decisions, even if the genetic variant only explains about 1-2% of variation in risk? What if the variant explains 10% of risk? Or 80%? What if it explains 80% of risk, but there are measures that an individual can take to eliminate or mitigate this risk?

There has been a long-standing debate in the US regarding whether life, long-term care, or disability insurers, should be able to use genetic information in underwriting (Caulfield 2013, Joly 2013, Klitzman 2014, Ostrer 1993, Rothstein 1997). I refer to these insurers as supplemental insurers, in that they are purchased in addition to health insurance. I do not refer to health policies, such as a Medicare supplemental policy, that an individual acquires in addition to his or her existing health insurance. The supplemental insurer debates have often remained entrenched in discussion about whether or not insurers *should* be able to use genetic information (Mittra 2007). There has been little research and policy discussion of, if supplemental insurers have access to genetic information, *when* and *how* they should be able to use it in underwriting. This research project examines how law and policy address, or should address, the threshold of statistical significance between genetic information and increased risk necessary for insurers to charge higher premium rates or deny a policy.

In 2008, in response to the public's concerns of genetic discrimination, Congress passed the Genetic Information Nondiscrimination Act (GINA). GINA prevents employers and health insurers from using genetic information to discriminate, but does not regulate how supplemental insurers use genetic information (McGuire 2009). These insurers were not included in GINA due to political compromise and recognition that the economic models and social goals of supplemental insurance raise different policy considerations than health insurance (Hudson 2008). However, in the years since GINA's passage, individuals remain fearful of genetic discrimination in supplemental insurance (Allain 2012, Laedtke 2012, Parkman 2014). This fear may lead individuals not to undergo recommended clinical genetic testing or to decline participation in genomic research (Barlow-Stewart 2009, Feldman 2012, Joly 2010, Klitzman 2010, Peshkin 2013), potentially leading to detrimental health effects for those who do not undertake clinically beneficial testing (Otlowski 2012). Failure to undergo predictive testing for a medically actionable condition due to fear of discriminatory consequences could thwart an individual from preventing or mitigating disease.

Since federal law does not address supplemental insurer use of genetic information, any US-based policy in this area currently comes from state law. Several states address insurer use of genetic information (NCSL 2008). Three states are commonly cited as banning supplemental insurer use of genetic information (Peikoff 2014); in fact, these states do not completely prohibit insurer use, but rather, they prohibit use of family members' genetic information (O.R.S 2001, V.S.A. 1997) or have actuarial requirements for the use (Cal-GINA 2011, Chabner 2000). Requiring actuarial justification for use of genetic information in underwriting decisions, such as premium increases or denials, is a common legislative strategy. These laws generally require that insurers demonstrate statistical correlation between a risk and an increased likelihood of cost to the insurer (ASOP 2005, Jha 2012, Landes 2014). The interpretation, enforcement, and implementation of these actuarial laws, however, have not been fully analyzed. It is therefore surprisingly unclear how existing state laws have been or will be applied in the context of the predictive value and preventive measures of genetic variants.

Recent technological advances have drastically lowered the cost of sequencing, making genomic analysis potentially affordable for insurers. This information may be beneficial to insurers since underwriting involves categorizing applicants into risk classifications and genetic information can provide insight into future risk (Van Hoyweghen 2007). However, the use of genetic information also raises social concerns beyond the business considerations of insurers (Dubois 2011, Liukko 2010, Morris 2010, Moultrie 1997, Van Hoyweghen 2005, Van Hoyweghen 2012). For example, some, including myself, have argued or suggested that in order to fully address individual fears of genetic discrimination, supplemental insurers should be restricted from using genetic information (Ashcroft 2007, Gruber 2014, Klitzman 2014, Prince 2013, Wolf 2007). Others have argued that this would bankrupt the insurance system because it will skew risk classification and lead to adverse selection (Baker 2002, Dodge 2007, Green 2015, Joly 2010, Radetzki 2003, Rothstein 2004); yet there is little

empirical evidence of any effects of adverse selection following policy changes (Daykin 2003) and actuarial modeling has indicated low impacts on premiums (Macdonald 2011; 2010; 2003, Viswanathan 2007). The competing economic concerns of insurers and the privacy and justice concerns of individuals create polarizing interests and lead to an entrenched debate over insurers' use of genetic information (Joly 2010).

This proposed project is significant because it will provide policy-makers with in-depth analysis of policy and regulatory options and recommendations for how life, long-term care, and disability insurers use genetic information. The NHGRI has specifically identified use of genetic information by these supplemental insurance companies, determination of actuarial risk, and the impact of state laws as priorities for ELSI legal, regulatory, and public policy research (NHGRI 2014). Genomic technologies will not rise to their full clinical potential if fear of discrimination or misunderstanding of existing legal protections prevents individuals from undertaking genomic testing or participating in research. This project highlights lessons from international contexts; analyzes existing state legislation; and provides policy recommendations for future legislatures. Existing state laws offer an opportunity to suggest policy changes through a variety of mechanisms, from enforcement strategies to regulatory changes to new legislation. Providing meaningful and feasible policy options and a better understanding of how insurers can legally use genetic information can make several contributions: assuage fears of genetic discrimination, increase participation in genomic testing and research, and potentially prevent significant barriers in access to supplemental insurance. In turn, increased insurance coverage and utilization of genomic technologies can lead to greater economic stability and improved health for individuals.

Innovation

This proposal is original in its approach to the question of whether supplemental insurers should be able to use genetic information. By beginning the inquiry with how insurers can fairly or legally use such information, rather than if they should use it at all, this project can provide new insight to an entrenched US debate. Focusing on how international actuarial standards have been applied to genetic and genomic risk information allows this project to draw lessons from countries with distinct socio-historical contexts. Additionally, the proposed research project is innovative in the way that it combines legal and policy analysis with social science empirical analysis in a law school setting. Use of an experiential course model increases the amount of research that can be undertaken with the same amount of funding because students will provide research assistance as part of their experiential learning. Through this novel approach, I can simultaneously increase my chances of securing a position as an independent researcher, increase the impact of the project given the increased research that can be completed, and establish a mechanism to train future ELSI legal scholars. The proposal is also novel in its recognition of the importance of mentorship in the R00 phase and the inclusion of a specific professional development component on mentorship within the training plan.

Approach

Aim 1: Analyze how international approaches to actuarial justification, supplemental insurance, and genetic information may be applicable to the US.

Aim 1 Rationale: Several countries have long established policies that impose actuarial justification standards or regulate supplemental insurers in the context of genetic information. Because these countries often have universal health care systems that limit concerns of discrimination and access in the health care setting, policy discussions regarding concerns about genetic discrimination have focused on the supplemental insurances that are often privatized (Anderlik 2001, Knoppers 2004b). Compared to the US, these countries are generally more advanced in policy implementation in the context of supplemental insurance (Van Hoyweghen 2007).

There are three primary avenues that countries have used to address supplemental insurer use of genetic information (Knoppers 2004a, Lemmens 2003), although within these broad strategies there are a variety of types of policies (Joly 2010, Lemke 2013, Otlowski 2012, Quinn 2014, Varga 2012). First, insurers in some countries have voluntarily agreed to a moratorium on the use of genetic information for applications below a certain monetary value and to a requirement of actuarial justification for those above that value (Huijgen 2012, Soini 2012). For example, since 2001, supplemental insurers in the United Kingdom have had a voluntary moratorium, which was just recently extended to 2019 (HMG 2011, Thomas 2012). Second, some countries have passed legislation at the federal level requiring actuarial justification in this area (Soini 2012, Van Hoyweghen 2012). Utilizing this strategy, Australia has legislation that requires certain supplemental insurers to have actuarial justification for using genetic information (ALRC 2003, Keogh 2013, Taylor 2004). Third,

some countries have informal guidelines from a government advisory or regulatory body (Knoppers 2004a, Lemmens 2004). In these countries the guidance may not be legally binding on the insurers.

Exploration of the effectiveness of these approaches in the international context can provide lessons for policy implementation in the US. Although US states do have actuarial laws, there has not been robust policy discussion regarding how these laws may be enforced. As such, examining the international context first, where there have been debates, can inform the nuanced legal analysis of Aim 2. Although the health insurance systems across international contexts vary, the privatized supplemental insurance context provides a more directly comparable perspective to the US (Rothstein & Joly 2009). Specific focus on the standards of actuarial justification and the threshold levels of evidence needed to use genetic information in supplemental insurance underwriting also allows for an opportunity to gather lessons from international countries that have already been grappling with these nuances for many years, but without insurmountable concerns of applicability from differing socio-historical contexts. Through qualitative case studies of international experiences, Aim 1 will provide valuable information for the US-based policy analysis of Aims 2 and 3 of this project. Case study methods offer not only in-depth analysis of the individual cases but also analytic strategies for systematically comparing patterns observed across cases (Ragin 1999, Ragin 2014, Stake 2013, Yin 2003).

Aim 1 Methods: Aim 1 will utilize a qualitative, comparative case study analysis to explore how actuarial justification laws and policies in four countries have been applied to the use of genetic information in underwriting. Data sources include semi-structured interviews with stakeholders and analysis of policy documents, such as government reports or legislation, legislative history, internal government or insurance communications, legal case documents, and academic critiques or manuscripts regarding the policies. Each case study will utilize these multiple sources of data to allow for triangulation (Stake 2013, Yin 2003).

Initially I plan to conduct a pilot case study in Canada in order to test my interview protocol, determine the most efficient and effective ways to recruit stakeholders and collect data, and to confirm the feasibility of my case study methods. Canada is a fitting pilot study due to the proximity to the US, the robust discussions regarding actuarial justification policies that have occurred in the country to date (Joly 2006, Joly 2014, Lemmens 2010, Pullman 2010), and the support of a key stakeholder to assist with the identification and recruitment of other stakeholders (See Joly Support Letter). Canada has published guidance on use of genetic information in life insurance (Knoppers 2004b) and the legislature is currently considering a bill to ban insurer use of genetic information (Rennie 2013). Additionally, at the beginning of the project, I will undertake a screening process to select the remaining three purposively sampled cases (Yin 2003). These countries will be chosen to include representation of the three primary policy tactics (moratorium, legislation, or guidelines) utilized around the world. Cases will be selected that have had at least one policy mechanism in place for five years or more, have stakeholders with English language skills, and have similarities to the US for comparison.

I will explore the following research questions for each case study:

- Why was the particular policy option chosen in this country?
- How effective has the policy been, as judged by the stakeholders?
- How has the actuarial justification policy been applied to genetic information, specifically regarding the predictive value of genetic variants and the availability of preventive measures?
- Have there been any consequences, unexpected or expected, of the policy, and if so, what are they?
- From the stakeholders' perspectives, has the policy affected how often either individuals undertake genetic or genomic testing or apply for supplemental insurance?

Document Collection: Initially, I will collect policy documents and analysis available online through government websites and searches of academic databases such as LexisNexis, JSTOR, and PubMed. The CGS summer legal research assistant will assist with this task. However, since the availability of international documents may be limited in the US, I will also establish meetings with government and research librarians in the case study countries to gather additional relevant documents unavailable in the US. During each interview, I will also ask the respondents for suggestions of documents the respondent thinks might be informative to the study.

Interviews: Employing the skills I will acquire through focused trainings on qualitative interview design, I will create and conduct semi-structured interviews with key stakeholders (King 2010). For each case study I will interview at least 8 stakeholders representing policy experts, government officials, advocacy group members, and insurance representatives. To the extent possible in each country I will speak to at least two stakeholders

from each category. This targeted interviewing of a diverse group of stakeholders is important for minimizing single-source information bias, maximizing the range of perspectives, and collecting differential knowledge (Van de Ven 1999). These stakeholders will be identified through help from my international contacts (See De Paor, Joly, and Macdonald Letters), policy documents and research, and suggestions from individuals who have agreed to be interviewed. Although this approach has the potential to create a participant population skewed to one perspective, this will not be likely since the nature of policy discussions inevitably highlight diverse opinions. Therefore, already identified policy-makers and key stakeholders are likely to know, and will be asked to identify, individuals with a broad range of perspectives and opinions. They will be enrolled through a recruitment letter and follow-up phone call. I will pilot test my data collection protocol and semi-structured interview guide in Canada, and then conduct the three additional case studies. Interviews will be conducted in person to ensure convenience for the participants, quality of the interview, minimization of technological complications, and ease of document collection pre and post-interview (See Foreign Justification).

Data Analysis: I will undertake content analysis of the interview transcripts utilizing software, such as ATLAS.ti, that aids in this kind of analysis. I will be trained in content analysis through classes at the Odum Institute, AALS Qualitative Workshop, and ResearchTalk. I will also pursue my analysis by comparing the content of the policy documents collected with the themes extracted from the interviews.

Aim 1 Expected and Alternative Outcomes: For each country studied I will develop a written overview that includes: 1) a descriptive summary of the policy method(s) implemented and the context in which it was implemented, 2) a description of how actuarial justification standards have been applied to genetic information, 3) an overview of how effective the policy has been according to documents and interview respondents, and 4) an assessment of the benefits and challenges of each policy. After individual case analysis, I will perform a cross-case analysis, examining whether the application of actuarial justification standards differs across policy options. To disseminate these research findings I will publish at least one manuscript summarizing the case study research findings. Additionally, I will present my findings at national conferences such as the American Society for Bioethics and Humanities (ASBH) and the Law and Society Association (LSA).

International policy analysis and recruitment for interviews can be challenging; however, I believe that I will be able to recruit adequate numbers of interview participants. There is robust scholarship regarding actuarial justification policies and genetic information in the international setting, making it likely that I can find willing and interested participants to discuss the implications of these policies. Additionally, through my previous work and through support of my advisory committee members, Drs. De Paor and Macdonald, I have connections to the European genetics communities, and through my collaborator Dr. Joly, the Canadian community (See Support Letters). Thus, I will be able to reach out to a variety of contacts for suggestions of key stakeholders.

By undertaking a pilot feasibility case study and by waiting to choose the remaining three case study countries until the project is underway, I can foresee and avoid problems related to recruitment of stakeholders or conducting the case studies. If I am unable to gather sufficient research participant interest in a country, I will choose a different option for the case study. Additionally, if the Canadian pilot study highlights problems with the initial case study design I can rework the protocol with support from mentors for the remaining cases.

Aim 2 – Interrogate how existing US state laws that require actuarial justification in supplemental insurance would apply to use of genetic information

Aim 2 Rationale: Under state unfair trade practice laws, life insurers in all fifty states are required to have actuarial justification to use a risk factor in underwriting (Holmes 1996, McEwen 1993, UTPA 2004). Some states have expanded these rules to disability and long-term care insurers (Avraham 2014). In addition, eight states explicitly require actuarial justification for the use of genetic information in underwriting (NCSL 2008). These laws aim to restrict supplemental insurers from basing underwriting decisions on genetic information that is unrelated to risk. However, the genetic-specific actuarial justification laws likely do not provide any additional protections for individuals beyond the broader unfair trade practice laws (Rothstein 2007).

These state laws, both the genetic-specific and general unfair trade practice laws, have not been fully explored and further research is needed to understand how these rules will be applied in the context of genetic variants. Given the range of predictive value of genetic variants, it is uncertain how many will be sufficiently correlated to risk to meet actuarial standards (Evans 2001, Janssens 2006, Macdonald 2002) and how the preventive measures available to mitigate risk will and should fit into the legal actuarial standards (Keogh 2013). Although

insight into these questions will come from the international data obtained in Aim 1, it is also important to understand how the US state laws are being applied, and most significantly, could be applied, in this context.

Insurance companies, including life, long-term care, and disability insurers, are regulated through state insurance commissioners and in every state the insurance commissioner has the power to enforce state insurance laws and promulgate regulation (Randall 2008). The commissioner offices also provide services to consumers of these insurances through information and complaint systems (NAIC 2011). Through their work with both insurers and consumers, the insurance commissioners are an essential source of information for how actuarial justification laws are being used. Through surveys of state insurance commissioners, and legal analysis of state law, regulation, and court cases, Aim 2 will provide an opportunity to better understand how actuarial justification and unfair trade practice laws are currently being enforced and implemented in the US.

Aim 2 Methods: Aim 2 will employ multiple methods to analyze US actuarial justification laws and will involve two sub-aims: Aim 2a will survey state insurance commissioners to determine how they are enforcing and interpreting actuarial justification laws; based on survey results, Aim 2b will undertake a legal analysis of current state actuarial justification and unfair trade practice laws. There are already a handful of cursory state law reviews that will inform the survey (CLRC 2012, CRG 2014, NCSL 2008). I am proposing to undertake the in-depth legal analysis after the surveys in order to conduct a more nuanced and detailed legal analysis.

Survey: For Aim 2a, I will develop and implement a survey of state insurance commissioners about actuarial and unfair trade practice laws and how the commissioners interpret and enforce these laws. The survey will focus on genetic information, the low predictive value of most variants, and the preventive measures available for some genetic variants. Surveys and interviews of insurance commissioners have been used in prior studies to understand how health and life insurers could use genetic information, including a case study analysis completed by my co-mentor Prof. Hall (Hall 2000a, Hall 2000b, Hall 2000c, McEwen 1992). Aim 2a survey questions will be developed in concert with feedback from mentors and based on survey methodology trainings undertaken through the Odum Institute. In addition to questions on how current state laws are interpreted and enforced, the survey will include questions that draw upon policy themes discovered during Aim 1. It will include both closed and open-ended questions surrounding these themes. The surveys will be sent to all state commissioners and follow-up letters and phone calls will be made to reach state offices that have not responded. In a prior study surveying state commissioners, this method was found to lead to a remarkably high response rate (82.4%) (McEwen 1992). The CGS legal research assistant will assist with survey analysis and follow-up on any laws cited by the commissioners. To disseminate the survey results, I will publish findings in peer-reviewed journals, and use the information about enforcement and interpretation to assist with the legal analysis of Aim 2b. Additionally, I will present my work at national conferences such as ASBH and LSA.

Legal Analysis: For Aim 2b, I will conduct a fifty state review of laws, regulations, and court case decisions (case law) relating to actuarial justification, both genetic-specific and broader unfair trade practice laws. I will specifically explore whether and how actuarial standards are defined and whether genetic-specific actuarial justification laws provide, or potentially provide, protections beyond those the state unfair trade practice laws. If the plain text of the statute or regulation is unclear, I will employ statutory interpretation methodology I learned when I took the “Lawmaking and Statutory Interpretation Seminar” taught by Congresswoman Eleanor Holmes-Norton. This state review will provide a comprehensive guide to which state laws apply to which supplemental insurers. Several organizations have completed state guides regarding state laws covering genetic information in supplemental insurance (CLRC 2012, CRG 2014, NCSL 2008) and other sources have information on state unfair trade practice laws (Avraham 2014, Holmes 1996); however no study has combined information about how all these laws may work in practice, with specific focus on whether and how actuarial standards are defined. These previous guides will form my starting data points, so my initial data collection will involve updating available cites, rather than a new search. In addition to this background analysis of state laws and regulations, Aim 2b will use legal analysis to examine applicable case law to evaluate whether state law has been used in the context of genetic information and how the laws may be interpreted and enforced in this area. Both the state statutes and the case law will be compiled through searches of WestlawNext, a legal database.

The specific questions of inquiry in the case law analysis will include:

- Is there any case law explicitly addressing genetic information and actuarial justification or unfair trade practice laws?

- Does past case law define or discuss actuarial standards or address what level of statistical correlation is necessary for insurers to use risk factor information in underwriting?
- How might precedential case law regarding medical information or disability be applied in the context of genetic information?
- Is there any case law that discusses how supplemental insurers should take into account mitigating risk factors, such as available preventive measures?

Aim 2 Expected and Alternative Outcomes: Aim 2a will culminate in at least one published manuscript summarizing the state insurance commissioner survey design, methodology, and results. To disseminate the information from Aim 2b I will complete a published law review article describing the findings of the statute, regulation, and case law analysis. I am expecting to find that the genetic-specific actuarial justification laws do not provide any additional legal protections beyond state unfair trade practice laws. Additionally, I am expecting that few cases will explicitly address genetic information in this arena. However, because the genetic-specific and unfair trade practice laws are likely similar, case law regarding how unfair trade practice laws have applied to other medical information provides important legal precedent for how future courts will apply these laws to the context of genetic information.

Analysis of statutes in fifty states can be time consuming to complete and, depending upon the volume of applicable or precedential case law, the case analysis can also be time consuming. However, these tasks of Aim 2b will be completed during the R00 phase of the project. During this phase, my goal is to have students assist with the data collection and analysis as part of their experiential class. This model will allow for sufficient research support to complete the full fifty state analysis. If, however, I am unable to secure this teaching opportunity and/or do not have sufficient research support to analyze the case law and statutes from all states, I plan to limit the number of states that I examine to a representative sample.

Aim 3 - Provide policy analysis and recommendations for legislative and regulatory options to address concerns about the use of genetic information in supplemental insurance.

Aim 3 Rationale: Since the passage of GINA, there has been discussion of whether the federal government should pass additional legislation that expands protection against genetic discrimination in supplemental insurances. There are strong competing interests on both sides of this debate: Individuals fear the misuse of their genetic information and supplemental insurers fear the economic consequences and adverse selection in their businesses (Daykin 2003, Haidle 2014, Macdonald 2002, Rothstein & Joly 2009). These competing views create difficult policy decisions for state and federal legislators. However, international and US state experiences to date can provide valuable insight into the feasibility, implications, and benefits of various policy options. Aim 3 of this project will synthesize information and data collected through Aims 1 and 2 to create policy analyses and reports of various options, including the moratorium, legislative, and guideline options from the international context. Aims 1 and 2 will help to better understand the varying interpretations of the levels of evidence needed to meet actuarial justification and unfair trade practice laws. From there, Aim 3 can provide policy guidance to state insurance commissioners, state legislators, individuals, insurance companies, and advocates about enforcement, interpretations, and legal uses of genetic information in underwriting.

Aim 3 Methods: Using policy analysis skills I developed during my graduate training in my Masters of Public Policy, Aim 3 will include two levels of policy analysis and inquiry. First, Aim 3a will be a policy analysis of the legislative options available at the federal and state level to address supplemental insurer use of genetic information, ranging from status quo to a complete ban on use, and other options in between. The analysis will include an assessment of the potential limitations, benefits, and feasibility of various policy options.

The policy analysis will explore the following questions:

- Do current state policies effectively address supplemental insurer use of genetic information?
- Is additional, or different, enforcement of current state laws needed to afford effective protection?
- Would any of the policy mechanisms implemented in the international context be options for US federal or state governments?
- What are the limitations, benefits, and feasibility of various policy options?

Second, Aim 3b will assess how both international case studies and the states define evidence thresholds for the necessary level of statistical correlation to use genetic information in underwriting. I will conduct policy

analysis of these varying interpretations and actuarial definitions to assess the implications of various evidence thresholds. If there have not been clear evidence thresholds or if the thresholds are consistent, I will assess the implications of what the threshold could or should be. This will provide policy makers, insurance companies, insurance commissioners, and individuals undergoing genetic testing guidance on when and how genetic information can and should legally be used for underwriting. In order to receive feedback and suggestions on various policy options, I will vet options with US policy experts, such as Dr. Koontz, my advisory committee member, to discuss issues of actuarial justification, genetic information, and supplemental insurance.

As with Aim 2b, the research of Aim 3 will be completed within the R00 portion of the grant; therefore my goal is to complete this research within the context of the experiential class at a law school. The assistance of students in the legal and policy analysis creates the ability to increase the output of policy analysis to potential state-specific white papers or other in-depth policy analysis given findings from the previous Aim(s).

Aim 3 Expected and Alternative Outcomes: Aim 3 will culminate in a series of policy briefs, or white papers, that legislators at the federal and state levels can utilize. These briefs will be disseminated to the state insurance commissioners who participated in Aim 2 in order to have maximum impact. Discussions and feedback from policy experts will also be incorporated into the policy reports as well as compiled into a manuscript summarizing the key recommendations of the group. I will write at least one law review or peer-reviewed journal article summarizing the policy findings of the project in order to disseminate the information to a wider audience. I will also attend conferences, such as ASBH and LSA, to present my work.

Although Aim 3 will draw largely on the information gathered during Aims 1 and 2, the research and analysis of Aim 3 is not dependent upon a certain outcome in the previous aims. Even in the unlikely event that there is little information gathered on the interpretation of actuarial and unfair trade practice laws, this absence of guidance still provides a critical opportunity to explore possible options for the future.

Since the policy analysis of Aim 3 will occur in Years 4 and 5, it is possible that new state or federal legislation may be passed before the final years of the grant. I will track any changes in policy throughout the grant period. If changes occur, the skills gained during the K99 training will allow me to alter the policy analysis as needed. For example, if federal legislation addressing supplemental insurer use of genetic information is passed during the grant, I can conduct a case study of the new legislation to assess enforcement options, issues that can be addressed by ensuing regulation, and the potential effectiveness of the law.

Through detailed policy and case study analysis from the international setting and robust legal and survey analysis from the US, my proposed K99/R00 will recommend potential policy options for supplemental insurer use of genetic information, thus supporting and informing an important NHGRI ELSI research priority.

R00 Independent Phase Research	Year 3											
Aim 2b: Legal Analysis of State Statutes and Cases	S	O	N	D	J	F	M	A	M	J	J	A
Collect Statutes/Regulations through WestLaw												
Statute and Regulation Analysis												
Collect Case Law through Westlaw												
Case Law Comparison and Analysis												
Cross Comparison of Case Law/Statutes/Survey Results												
Dissemination at Conferences												
	Year 4											
Aim 2b: Legal Analysis of State Statutes and Cases	S	O	N	D	J	F	M	A	M	J	J	A
Preparation of Law Review												
Aim 3a and 3b: Policy Options	S	O	N	D	J	F	M	A	M	J	J	A
Identification of Policy Options from Aims 1 and 2												
Policy Analysis 3a												
Identification of Actuarial Standards from Aims 1 and 2												
Policy Analysis 3b												
Dissemination at Conferences												
	Year 5											
Aim 3b: Actuarial Justification Standards Policy Options	S	O	N	D	J	F	M	A	M	J	J	A
Preparation of Policy Brief(s)												
Preparation of Manuscript												
Dissemination at Conferences												
Grant Applications for Continued Independent Research												