Consortium on Law and Values in Health, Environment & the Life Sciences

2015-16 Student Proposal Cover Page

Applicant Information			
Applicant name:	Luke Haqq	Email:	haqq0004@umn.edu
Project title:	Genomic Healthcare and Incidental Findings of Reproductive Significance: Neonatal Litigation as Source of Liability		
Department:	Law School	College:	Law School
Degree program:	J.D.	Faculty advisor name & email:	☒ NA
Dept. Head:		Dept. Head's email:	
Dean:	Allan Erbsen	Dean's email:	aerbsen@umn.edu

How did you hear about this funding opportunity?
☐ Consortium e-mail ☐ The Brief ☒ Advisor ☐ Dept. email/newsletter ☐ Consortium website ☐ Other

Funding

Total amount of funding requested: **$ 7,000**

Executive summary (maximum 200 words)

As healthcare turns to genomics, clinicians will increasingly be faced with incidental findings germane to patients' reproductive decisionmaking. However, there is disagreement in relevant literatures and in courts regarding the scope of a clinical standard of care to notify patients when testing reveals information of reproductive significance, like carrier status and birth defect risks. A concern is that many of these results will be revealed whether or not they were why sequencing was sought, with the clinician's duty remaining unclear. The largest source of clinical liability for failing to return results of reproductive significance will be neonatal torts, those in which plaintiffs assert they would have avoided conception or aborted if it had not been for a clinician's failure to return such results. This project will produce two articles after sifting through ~15,000 cases to catalogue and code all neonatal litigation imputable to medical malpractice. It will substantially advance medical, legal, and philosophical literatures on reproductive ethics by its timely relevance, exhaustiveness, and interdisciplinary nature. It is timely because the Supreme Court is revisiting abortion jurisprudence this year, it will be the most exhaustive account of neonatal litigation, and it will bridge three disciplines with a focus on reproductive justice.

Approvals

Check all appropriate approvals required for your proposal. Approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

IRB ☐ Yes ☐ No ☒ NA ☐ Application pending

Other ☐ Yes ☐ No ☒ NA ☐ Application pending Specify:

Checklist—for reviewer use

- ☐ The proposal is 1000 words or less excluding budget, biographies, references and citations.
- ☐ The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.
- ☐ The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.
- ☐ The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.
- ☐ The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check NA.
- ☐ All necessary approvals are pending or received.

Title

Genomic Healthcare and Incidental Findings of Reproductive Significance: Neonatal Litigation as a Source of Liability

Nature and Importance

As genomic sequencing is being "rapidly introduced"[1] into clinical practice, hopes turn to precision medicine that can offer individualized healthcare and lower healthcare costs. This project explores two issues that it will be essential to resolve before adopting a regime of personalized medicine, namely, the impact of genomics on clinical neonatal liability and its impact on the abortion right.

Whether as a primary indication or incidental finding, sequencing often reveals information of reproductive significance, such as carrier status and birth defect risks. For half a century, neonatal torts have enabled many patients to seek compensation for a clinician's negligent failure to return information of reproductive significance, for example, by misreading an ultrasound[2] or not disclosing the results of a prenatal test revealing a fetal abnormality,[3] with the plaintiffs asserting they never would have conceived or would have opted to abort were it not for the clinician's malpractice. No cases have yet been brought for a failure to return *genomic* results of reproductive significance, but it is important to have the clinical standards of care clearly articulated before such litigation arises. However, there is ample disagreement in the literature and in courts regarding the scope of the clinical duty to return incidental findings of such information.

This project's methodology involves coding all wrongful birth and wrongful conception cases, and infant wrongful death cases imputable to a failure to return results of reproductive significance. The goal of the project will be to create two articles. The first will describe the coded cases chronologically, analyzing them alongside historical developments in federal reproductive rights jurisprudence, with the purpose of foreshadowing the key issues that will face a personalized medicine regime after the Supreme Court revisits abortion for the first time since 2007 in *Whole Women's Health v. Cole* (2016).[4] The second will use the judicial precedent to extrapolate clinical guidelines for mitigating the risk of neonatal liability in a genomic age.

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[1] Laurence B. McCullough et al., Clinical Sequencing Exploratory Res. Consortium Pediatrics Working Group, *Professionally Responsible Disclosure of Genomic Sequencing Results in Pediatric Practice*, 136 PEDIATRICS e974, e974 (2015).

[2] *E.g.*, Branca v. Miro, No. 0735/01, 2004 NY Jury Verdicts Review LEXIS 823 (N.Y. Sup. Ct. 2004).

[3] Confidential (S99-07-16), 1998 Jury Verdicts LEXIS 72413 (Ca. Super. Ct. 1998) (the prenatal testing revealing Down syndrome, and discovery revealing the doctor did not return the results because of his "firm policy against abortion").

[4] Whole Women's Health v. Cole, 2016 U.S. LEXIS 4427.

Innovative Contribution

The datasets generated will substantially advance medical, legal, and philosophical discussions of congenital harms by providing the most systematic, comprehensive history and analysis of neonatal litigation. This comprehensive account will advance these literatures by showing the nuanced way courts have attempted to strike a balance between the interests of patients, doctors, women, parents, and public interests.

There is disagreement within the medical literature regarding the scope of clinical duties to return incidental findings discovered from sequencing.[5] There is a substantial legal literature on neonatal torts,[6] but I have not found any systematically exhaustive articles nor any that critically analyze their importance to genomic healthcare. The philosophical literature on congenital harms is also robust, but discussions have primarily focused on parental rather than clinical liability.[7] This project will be an innovative contribution to all of these literatures because of its exhaustiveness, timely relevance, and its interdisciplinary nature.

Work Plan

Westlaw, LexisNexis, and HeinOnline searches have suggested I will need to sift through between 10,000 and 20,000 wrongful birth, wrongful conception, and infant wrongful death cases. I have already coded all wrongful *life* cases available on those databases. Cases will be coded for several variables including the underlying congenital condition, plaintiff and defendant characteristics, jurisdiction, and jury verdict or settlement figures. I may also develop statistical analyses showing any relevant associations between the coded variables. When seeking faculty comments, I will submit papers to Susanna Blumenthal, Susan Wolf, Brian Bix, and Antony Duff, as well as other relevant individuals.

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[5] E.g., Robert Green et al., Am Coll. Med Genetics & Genomics, ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing, 15 GENETICS MED. 565 (2013); Wylie Burke et al., Recommendations for Returning Genomic Incidental Findings? We Need to Talk!, 15 GENETIC MED. 854 (2013); Am. Coll. Med. Genetics & Genomics, ACMG Updates Recommendation on "Opt Out" on Genomic Sequencing Return of Results, ACMG NEWS (Apr. 1, 2014), https://www.acmg.net/docs/Release_ACMGUpdatesRecommendations_final.pdf.

[6] E.g., Rosamund Scott, Reconsidering "Wrongful Life" in England after Thirty Years: Legislative Mistakes and Unjustifiable Anomalies, 72 CAMBR. L.J 115 (2013); Seana Shiffrin, Wrongful Life, Procreative Responsibility, and the Significance of Harm, 5 LEG. THEORY 117 (1999); James Bopp et al., The "Rights" and "Wrongs" of Wrongful Birth and Wrongful Life: A Jurisprudential Analysis of Birth Related Torts, 27 DUQ. L. REV. 461 (1988).

[7] The inception of this field of philosophical inquiry only began after *Roe v. Wade*. *See*, e.g., Rahul Kumar, *Who Can Be Wronged?*, 31 PHIL. PUB. AFF. 99 (2003); R.M. Adams, *Existence, Self- Interest, and the Problem of Evil*, 13 NOÛS 53 (1977); Gregory Kavka, *The Futurity Problem*, *in* OBLIGATIONS TO FUTURE GENERATIONS 213 (Richard Sikora & Brian Barry eds., 1977); Derek Parfit, *On Doing the Best for Our Children*, *in* ETHICS & POPULATION, 100 (Michael Bayles ed. 1976); Derek Parfit, *Rights, Interests, & Possible People*, *in* MORAL PROBLEMS IN MEDICINE, 369 (Samuel Gorovitz ed., 1976).

Timeline

March – April, 2016: *total 15 hours*
- Draft outline of peer-reviewed article (on clinical guidelines)

March – December, 2016: *total 200 hours*
- Code cases
- Draft peer-reviewed article

April – May, 2016: *total 15 hours*
- Genetic counselor shadowing

June – August, 2016: *total 15 hours*
- Submit peer-reviewed article for faculty comments
- Prepare article for publication submission

October – December, 2016: *total 25 hours*
- Draft outline of law journal article (on genomics and the abortion right)

January – May, 2017: *total 20 hours*
- Draft law journal article
- Submit article for faculty comments

June 2017 onwards: *total 10 hours*
- Since most law journals do not accept submissions from law students, I would seek publication for the law journal article in first submission cycle following my graduation from law school
- Present at the 2017 annual conference of the American Society for Bioethics and Humanities, the Law and Society Association, or other appropriate conference

Biography

Luke Haqq, M.Sc., M.A., is a J.D. student at the University of Minnesota Law School. He is Senior Articles Editor for the *Minnesota Law Review* and is a legal project assistant for Professor Susan Wolf and the Consortium for Law and Values in Health, Environment, and the Life Sciences. Last summer, he worked at the Public Health Law Center. Prior to law school, he advanced to candidacy for his Ph.D. at UC-Berkeley, a degree for which he is currently pursuing dissertation research. At Berkeley, he taught sections in the legal studies department on reproductive justice, criminal law, and legal theory. Before his doctoral work, he spent time in the UK, first as a visiting student at Oxford University, then to pursue a master's degree in philosophy at the University of Edinburgh. He completed his undergrad at Northwestern College in Minnesota.

Budget

	Item	Description	Justification	Requested Funding
1	Stipend	Research (at $20/hr.) • Coding (200 hrs.) • Clinical–genetic counselor shadowing (15 hrs.) Writing (35 hrs.)	I believe shadowing a genetic counselor will be integral to understanding issues in genomic return of results. To this end, I have made arrangements with Bonnie LeRoy and Mary Ahrens in the U's genetic counseling program and have completed necessary HIPAA privacy training.	$4,000 $300 $700
2	Research supplies	• Clinical sequencing • Direct-to-consumer sequencing • Conference travel and lodging • STATA/IC	I similarly believe first-hand understanding of return of results, as both a clinical and DTC option, would be a huge benefit to the project. I would submit the resultant projects to present at the 2017 annual conference of the American Society for Bioethics and Humanities, the Law and Society Association, or other appropriate conference. STATA would enable statistical analysis. I have already received training on STATA.	$1,000 $200 $600 $200
	TOTAL			$7,000