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PI: CLAYTON, ELLEN W	Title: Returning Research Results of Pediatric Genomic Research to Participants	
Received: 03/10/2011	FOA: HG11-004	Council: 10/2011
Competition ID: ADOBE-FORMS-B1	FOA Title: ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF RETURNING RESEARCH RESULTS TO GENOMIC RESEARCH PARTICIPANTS (R21)	
1 R21 HG006612-01	Dual: HD	Accession Number: 3378416
IPF: 8721001	Organization: VANDERBILT UNIVERSITY	
Former Number:	Department: Center for Biomedical Ethics a	
IRG/SRG: ZHG1 ELSI-P (O1)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 125,000 Year 2: 125,000	Animals: N Humans: N Clinical Trial: N Current HS Code: 10 HESC: N	New Investigator: N Early Stage Investigator: N
<i>Senior/Key Personnel:</i>		
	<i>Organization:</i>	<i>Role Category:</i>
Ellen Clayton	Vanderbilt University Medical Center	PD/PI
Bartha Knoppers	Vanderbilt University Medical Center	Other (Specify)-Co-Investigator
Amy McGuire	Baylor College of Medicine	Other (Specify)-Co-Investigator
Lainie Ross	University of Chicago	Other (Specify)-Consultant

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PROJECT SUMMARY: The specific aim of this project is to determine what criteria should govern return of individual results of pediatric genomic research, using analysis of US law and international guidelines regarding decision making for and by minors as the foundation. This issue, which has received remarkably little attention, must be resolved if this research, which is vital to understanding the contributions of genetic variation to the health of children, is to proceed. In order to develop these criteria, it will be necessary to draw upon a host of ethical, legal, and sociocultural factors, using standard legal analytic tools.

- There is a long tradition within genetics, embodied in policy statements, such as those by the American Society of Human Genetics, the American College of Medical Genetics, and the American Academy of Pediatrics, of performing genetic tests on minors only when the results would alter the minor's immediate medical care. These limits are justified in part by the claim that, in the absence of need for immediate intervention, the minor should be allowed to decide about genetic testing upon reaching adulthood.
- More generally, decisions regarding the health care of children are treated differently from those of adults because children, as a matter of law, typically cannot make their own health care decisions. Procedurally, ethical and legal decision making authority, instead, is allocated among: 1) Parents who have broad authority to make choices among available options that affect their children. The scope of parental permission for their children's care, however, is not as broad as their discretion with regard to their own health care; 2) Clinicians who have an independent obligation to the welfare of the minor, which is bounded by the standards of clinical practice as well as legal requirements; 3) Minors who many hold have an increasingly important ethical and legal voice as they mature; and 4) In cases of abuse, neglect, or need to protect public health, the state. Substantively, defining the minor's best interest is often contested. One issue that is particularly challenging is deciding what weight should be given to various potential benefits from returning results, ranging from immediate benefit to the minor's health or reproductive information for the minor's later use to benefits that redound primarily to the family unit as a whole or exclusively to the parents or even to other minors of the same age or with the same condition.
- Research involving minors is subject to more legal and ethical requirements and limitations than apply to adults.

This project brings together three internationally known lawyers, each of whom has written extensively about legal and policy issues in genomics research and in pediatrics, as well as an internationally known pediatrician-philosopher as a consultant, to define the applicable legal rules and to develop guidelines for returning results of genomic research involving minors.

NARRATIVE: Determining what criteria should govern the return of individual results of pediatric genomics research has to date received remarkably little attention. This issue must be resolved if this research, which is vital to understanding the contributions of genetic variation to the health of children, is to proceed. This project brings together three internationally known lawyers, each of whom has written extensively about legal and policy issues in genomics research and in pediatrics, as well as an internationally known pediatrician-philosopher as a consultant, to define the applicable legal rules and to develop guidelines for returning results of genomic research involving minors.

Facilities

Vanderbilt Laboratory

Due to the nature of the proposed research, wet/dry lab space will not be used. Interviews will be conducted in readily available behavioral laboratory space on VUMC's campus, as well as meeting rooms on campus and off. Telephone surveys will be conducted from private offices using computer assisted interviewing.

Clinical

N/A

Animal

No animal research will be conducted in this project.

Computer

Members of the Center all have computers as well as access to secure servers to back up their work

Office

All the members have offices in the respective departments as well as space for graduate students and research assistants. In addition, the Center has access to meeting rooms to facilitate collaboration

Other

Vanderbilt has venues to house conferences of all sizes, including the brand-new Student Life Center, with kitchen and auditorium space, state-of-the-art AV and computer equipment, and Special Events staff. VUMC also has cutting edge communications technology to facilitate collaborative work between institutions.

Equipment

Vanderbilt

Major Equipment

N/A

PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001

Budget Period: 1			
Start Date:	09/30/2011	End Date:	09/29/2012
A. Direct Costs			* Funds Requested (\$)
* Direct Cost less Consortium F&A			125,000.00
Consortium F&A			25,799.00
* Total Direct Costs			150,799.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC, Research On/ Off campus-Remote	5%	61,782.56
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Department of Health and Human Services, Robbin Powell 202-401-2808	
Indirect Cost Rate Agreement Date		06/04/2010	Total Indirect Costs
			61,782.56
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			212,581.56
Budget Period: 2			
Start Date:	09/30/2012	End Date:	09/29/2013
A. Direct Costs			* Funds Requested (\$)
* Direct Cost less Consortium F&A			125,000.00
Consortium F&A			14,190.00
* Total Direct Costs			139,190.00
B. Indirect Costs			
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)
1.	MTDC, Research On/ Off campus-Remote	5%	37,413.59
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)		Department of Health and Human Services, Robbin Powell 202-401-2808	
Indirect Cost Rate Agreement Date		06/04/2010	Total Indirect Costs
			37,413.59
C. Total Direct and Indirect Costs (A + B)			Funds Requested (\$)
			176,603.59

PHS 398 Modular Budget, Periods 3 and 4

Budget Period: 3	Start Date: <input style="width: 80%;" type="text"/>	End Date: <input style="width: 80%;" type="text"/>
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A. Direct Costs	* Direct Cost less Consortium F&A	* Funds Requested (\$)
	Consortium F&A	
	* Total Direct Costs	

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
2.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
3.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
4.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>

Cognizant Agency (Agency Name, POC Name and Phone Number)	<input style="width: 95%;" type="text"/>
Indirect Cost Rate Agreement Date <input style="width: 80%;" type="text"/>	Total Indirect Costs <input style="width: 50%;" type="text"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)
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Budget Period: 4	Start Date: <input style="width: 80%;" type="text"/>	End Date: <input style="width: 80%;" type="text"/>
-------------------------	--	--

A. Direct Costs	* Direct Cost less Consortium F&A	* Funds Requested (\$)
	Consortium F&A	
	* Total Direct Costs	

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
2.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
3.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>
4.	<input style="width: 95%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>	<input style="width: 50%;" type="text"/>

Cognizant Agency (Agency Name, POC Name and Phone Number)	<input style="width: 95%;" type="text"/>
Indirect Cost Rate Agreement Date <input style="width: 80%;" type="text"/>	Total Indirect Costs <input style="width: 50%;" type="text"/>

C. Total Direct and Indirect Costs (A + B)	Funds Requested (\$)
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PHS 398 Modular Budget, Periods 5 and Cumulative

Budget Period: 5	Start Date: <input style="width: 100%;" type="text"/>	End Date: <input style="width: 100%;" type="text"/>
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A. Direct Costs

* Direct Cost less Consortium F&A	* Funds Requested (\$)
Consortium F&A	
* Total Direct Costs	

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
2.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
3.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
4.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date Total Indirect Costs

C. Total Direct and Indirect Costs (A + B) Funds Requested (\$)

Cumulative Budget Information

1. Total Costs, Entire Project Period

*Section A, Total Direct Cost less Consortium F&A for Entire Project Period	\$	<input style="width: 100%;" type="text" value="250,000.00"/>
Section A, Total Consortium F&A for Entire Project Period	\$	<input style="width: 100%;" type="text" value="39,989.00"/>
*Section A, Total Direct Costs for Entire Project Period	\$	<input style="width: 100%;" type="text" value="289,989.00"/>
*Section B, Total Indirect Costs for Entire Project Period	\$	<input style="width: 100%;" type="text" value="99,196.15"/>
*Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period	\$	<input style="width: 100%;" type="text" value="389,185.15"/>

2. Budget Justifications

Personnel Justification	<input style="width: 100%;" type="text" value="M-15_PHS_ModBud_PersonJustific"/>	Delete Attachment	View Attachment
Consortium Justification	<input style="width: 100%;" type="text" value="M-16_PHS_ModBud_ConsortiumJust"/>	Delete Attachment	View Attachment
Additional Narrative Justification	<input style="width: 100%;" type="text"/>	Add Attachment	

MODULAR PERSONNEL JUSTIFICATION:

Ellen Wright Clayton (PD/PI) [EFFORT] months per year, [% Effort] will be in charge of the overall management of the project as well as directing the work at her center on the specific focus on legal issues related to making health care decisions that affect minors in the US.

Lainie Friedman Ross (Consultant) (\$7,500 each year) will advise the group on ethical issues in pediatrics and research involving minors.

CONSORTIUM JUSTIFICATION

Consortium with Baylor College of Medicine, Houston Texas
Calculations are based on a 56.5% F&S rate for Baylor

Amy McGuire, JD, PhD, (PD/PI) [EFFORT] months per year, [% Effort]) will be primarily responsible for the oversight and structure of the legal search and analysis of decision making authority regarding children in a research context within the United States. Dr. McGuire will be responsible for writing summary documents for presentation to the research team, as well writing papers for the dissemination of research findings. She will expend 1.2 calendar months in Years 1-2 of the project.

Research Assistant, TBN, (Y1 [EFFORT] months, [% Effort] ; Y2 [EFFORT] months, [% Effort] effort) will provide research assistance and administration of all project-related activities at Baylor College of Medicine. Specifically, the research assistant will assist with the legal search, analysis and will help prepare summary documents and papers for publication. H/she will expend [EFFORT] months in Year 1 and [EFFORT] months in Year 2 of the project.

Consortium with McGill University, Montreal QC, Canada
Calculations are based on a 8% F&A rate for McGill.

Prof. B M. Knoppers (PD/PI) [EFFORT] months per year, [% Effort]) to the conduct of this project at McGill University, including data collection and analysis. No salary support is requested as supported by institutional funds.

Academic associate (to be determined): skilled in law and policy research and previous experience in international policy research. This individual requires a level of autonomy sufficient to organize, carry out and interpret study findings. The associate will devote 6 months effort in year 1 and 3 months effort in year 2. Fringe benefits are calculated at 25%.

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

New Resubmission Renewal Continuation Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application (for RESUBMISSION or REVISION only)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2. Specific Aims	X-7_PHS_ResearchPlan_Specif	<input type="text"/>	Delete Attachment	View Attachment
3. *Research Strategy	X-19_PHS_ResearchPlan_Resea	<input type="text"/>	Delete Attachment	View Attachment
4. Inclusion Enrollment Report	<input type="text"/>	Add Attachment	<input type="text"/>	<input type="text"/>
5. Progress Report Publication List	<input type="text"/>	Add Attachment	<input type="text"/>	<input type="text"/>

Human Subjects Sections

6. Protection of Human Subjects	X-8_PHS_ResearchPlan_Protec	<input type="text"/>	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	X-9_PHS_ResearchPlan_Inclus	<input type="text"/>	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	X-10_PHS_ResearchPlan_Targe	<input type="text"/>	Delete Attachment	View Attachment
9. Inclusion of Children	X-11_PHS_ResearchPlan_Inclu	<input type="text"/>	Delete Attachment	View Attachment

Other Research Plan Sections

10. Vertebrate Animals	<input type="text"/>	Add Attachment	<input type="text"/>	<input type="text"/>
11. Select Agent Research	<input type="text"/>	Add Attachment	<input type="text"/>	<input type="text"/>
12. Multiple PD/PI Leadership Plan	<input type="text"/>	Add Attachment	<input type="text"/>	<input type="text"/>
13. Consortium/Contractual Arrangements	X-2_PHS_ResearchPlan_Consort	<input type="text"/>	Delete Attachment	View Attachment
14. Letters of Support	X-12_PHS_ResearchPlan_Letter	<input type="text"/>	Delete Attachment	View Attachment
15. Resource Sharing Plan(s)	M-13_PHS_ResearchPlan_Resou	<input type="text"/>	Delete Attachment	View Attachment

16. Appendix [Add Attachments](#)

Returning Research Results of Pediatric Genomic Research to Participants

A general consensus has emerged in recent years that returning at least some personal results of genomic research to individual research participants is permissible, and in some cases, ethically or legally required. A variety of ethical, legal, and sociohistorical factors, however, requires inquiry into whether the same criteria should apply to research results regarding minors.

- There is a longstanding tradition within genetics, embodied in policy statements of the American Society of Human Genetics, the American College of Medical Genetics, and the American Academy of Pediatrics, of performing genetic tests on minors only when the results would alter the minor's immediate medical care. These limits are justified in part by the claim that, in the absence of immediate benefit, the minor should be allowed to decide about genetic testing him- or herself upon reaching adulthood.
- More generally, decisions regarding the health care of minors are treated differently than those of adults because minors, as a matter of law, typically cannot make their own health care decisions. Ethical and legal decision making authority, instead, is allocated among
 - Parents who have broad authority to make choices among available options that affect their children. The scope of parental permission for their children's care, however, is not as broad as their discretion with regard to their own health care;
 - Clinicians who have an independent obligation to the welfare of the minor, which is bounded by the standards of clinical practice as well as legal requirements;
 - Minors themselves who many hold have an increasingly important ethical voice as they mature; and
 - In cases of abuse, neglect, or public health concerns, the state.
- The regulations for the Protection of Human Research Participants impose greater requirements and limitations on research involving children.

Substantively, defining the minor's best interest is often contested. One issue that is particularly challenging is deciding what weight should be given to various potential benefits from returning results, ranging from immediate benefit to the minor's health or reproductive information for the minor's later use to benefits that redound primarily to the family unit as a whole or exclusively to the parents or even to other minors of the same age or with the same condition.

The ethical and legal principles regarding the involvement of minors in each of these domains -- genetics, health care, and research – are contested, both in the United States and abroad. The need to address these debates about who decides what for minors regarding genetic testing is made all the more urgent by the widespread availability of DTC genetic testing to adults and children alike and the imminent deployment of whole exome and genome sequencing in the clinical setting as well as the need to provide the foundation for the issue of returning genomic research results. This project brings together three internationally known lawyers, each with expertise in the implications of pediatric genomics research as well as the return of research results to minors, as well as an internationally known pediatrician-philosopher as a consultant, to define guidelines for returning results of genomic research involving children.

Specific Aim:

To determine what criteria should govern return of individual results of pediatric genomic research, using analysis of US law and international guidelines regarding decision making for and by minors as the foundation.

Research Strategy

Significance

The issue of whether and, if so under what conditions, to return individual results of genomics research to research participants is one of the most contentious issues in research ethics today. Numerous guidelines have been published,[1-4] as have a host of normative analyses.[5-10] Other investigators have surveyed potential and actual research participants about what research results they want to receive.[11, 12] Currently espoused policy opinions represent a continuum, from a stance that returning at least some results is ethically permissible[1] and even legally required,[13] often citing the contributions of participants to the research enterprise, to a view that returning results is typically misguided, fosters therapeutic misconception, promotes increased health care costs with few corresponding benefits, and possibly violates the law.[14, 15]

The development of research techniques that assay the human genome comprehensively, using such approaches as “million-SNP” chips, whole exome and whole genome sequencing, makes the issue of return of results all the more pressing. All of these strategies can and do have the power to reveal genetic variants that contribute to a host of conditions beyond the focus of the particular research study. The only questions are whether to examine all the results and which, if any, to reveal and act upon. The findings of whole genome strategies vary in their predictive power and in their “actionability,” a concept whose scope is also strongly contested.[16] The inevitability of these revelations in whole genome approaches calls into question the utility of the concept of “incidental findings” proposed by Susan Wolf and her colleagues.[2] Nonetheless, a consensus of sorts has emerged that at least some individual research results may and even should be returned. The purpose of this set of FOAs is create a consortium to clarify what results should be returned and to develop and evaluate strategies for accomplishing this.

Despite all the debate to date, little attention has been paid to the dilemmas posed by returning genomic research results regarding children and adolescents.[17-21] In the United States, there are several published guidelines for the return of genetic research results.[1, 22-26] All of these call for the return of results in some circumstances, but none specifically address the unique issues related to returning results in research involving minors. The last decade’s international guidance regarding return of results reveals two trends: (i) there is little “pediatric-specific” guidance and (ii) the general guidance that is provided fails to provide a clear demarcation either between the clinical and research settings or on the nature of the results in question and to whom and where results (if any) should be communicated.[27] Only a few investigators have asked minors and their parents what results they want,[28-30] and the few studies of what researchers say and do regarding return of research results involving children reveal wide variation.[19, 31]

A host of ethical, legal, and sociohistorical factors requires inquiry into whether the criteria for return of research results to adults should be the same as those applied to research results regarding minors.

- There is a longstanding tradition within genetics, embodied in policy statements, such as those by the American Society of Human Genetics, the American College of Medical Genetics,[32] and the American Academy of Pediatrics,[33] of performing genetic tests on minors only when the results would alter the minor’s immediate medical care.[34, 35] These limits are justified in part by the claim that, in the absence of need for immediate intervention, the minor should be allowed to decide about genetic testing upon reaching adulthood.
- More generally, decisions regarding the health care of children are treated differently from those of adults because children, as a matter of law, typically cannot make their own health care decisions.[36] Procedurally, ethical and legal decision making authority, instead, is allocated among:
 1. Parents who have broad authority to make choices among available options that affect their children.[37] The scope of parental permission for their children’s care, however, is not as broad as their discretion with regard to their own health care:[38, 39]
 2. Clinicians who have an independent obligation to the welfare of the minor, which is bounded by the standards of clinical practice as well as legal requirements:[40]
 3. Minors who many hold have an increasingly important ethical and legal voice as they mature:[41, 42] and
 4. In cases of abuse, neglect, or need to protect public health, the state.[36]

Substantively, defining the minor's best interest is often contested. One issue that is particularly challenging is deciding what weight should be given to various potential benefits from returning results, ranging from immediate benefit to the minor's health or reproductive information for the minor's later use to benefits that redound primarily to the family unit as a whole or exclusively to the parents or even to other minors of the same age or with the same condition.

- Research involving children is subject to more legal and ethical requirements and limitations than apply to adults.[43-45]

The ethical and legal principles regarding the involvement of minors in each of these domains -- genetics, health care, and research – are contested, both in the United States and abroad. The need to address these debates about who decides what for minors regarding returning genetic results, bringing together legal and ethical analyses from national and international perspectives, is made all the more urgent by the widespread availability of direct to consumer (DTC) genetic testing to adults and children alike,[46-49] the imminent deployment of whole exome and whole genome sequencing in the clinical setting,[50, 51] as well as the need to provide the foundation for the issue of returning genomic research results regarding minors, which is the focus of this proposal. This project brings together three internationally known lawyers, each of whom has written extensively about legal and policy issues in genomics research and in pediatrics, as well as an internationally known pediatrician-philosopher as a consultant, to define the applicable legal rules and to develop guidelines for returning results of genomic research involving minors.

Preliminary data

In addition to the extensive legal and policy scholarship in genomics research and in pediatrics of all of the investigators and the consultant on this proposal, which is well documented in their biosketches, all of them have conducted relevant empirical research.

Evidence regarding investigators' views about returning research results to minors. Avard et al.[31] from Knoppers' team interviewed prominent pediatric pharmacogenomics researchers in Canada about ethical issues that arise in this type of research. The respondents identified an array of concerns, including return of results. While there seemed to be consensus in this qualitative study that some results ought to be returned, their views differed widely about which results should be disclosed, how, and to whom.

Evidence that parents of pediatric patients participating in genetic research make decisions according to what they believe is in their child's best long term interest. *The Ethics of Consent for the Public Release of Potentially Identifiable DNA Data* (NIH 1 R01 HG004333, PI: McGuire) researchers found that parents of pediatric patients were more concerned about protecting their child's privacy and were more likely to restrict access to their genomic data (unpublished data). Parents expressed discomfort with the future uncertainty associated with how genetic information might be used in ways to harm their child, opting to make more conservative decisions now in order to minimize the risks of future harm.

Evidence regarding views of IRBs and investigators. Amy McGuire and colleagues are currently studying genome-wide association study (GWAS) investigators' and IRB chairs' practices and perspectives with regard to the return of results to study participants. Many of the respondents have experience conducting and/or reviewing pediatric genetic research, so we have been able to probe in our qualitative interviews some of the unique challenges associated with returning results to this population.

Evidence that adults view disease susceptibility differently from pharmacogenomics. *Translating Pharmacogenomic Research to the Clinic: PREDICT Focus Groups* study (Brothers PI, Clayton Co-I) included 10 focus group sessions with adult patients on their preferences and understandings of the information that is generated incidental to non-research pharmacogenomic testing. Phase 1 of this study revealed that patients' preferences about the depth and formality of consent procedures depended on whether disease susceptibility information would be generated. If testing could be limited to pharmacogenomic results, informal verbal consent was acceptable. If patients would be given information about disease risk, they preferred a more formal consent process so they could assess whether they desired those results.

Evidence that patients expect to be informed of the non-pharmacogenomic implications of pharmacogenomic tests. Phase 2 of *Translating Pharmacogenomic Research to the Clinic: PREDICT Focus Groups* study

(Brothers PI, Clayton Co-I) discussed in more depth patients' expectations about receiving genetic information generated incidental to pharmacogenomic testing. While some patients would not want information about their genetic susceptibility to diseases, most were interested in learning about disease susceptibility information that is considered accurate, even if the risks are not modifiable.

Innovation

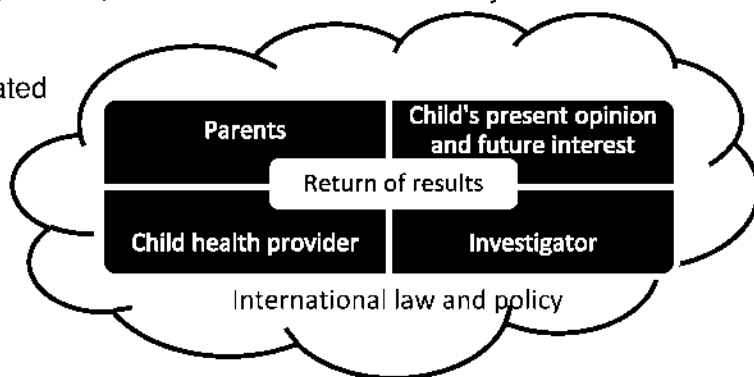
This proposal is innovative in three regards:

1. Most of the legal discussion about return of results to date has focused on the applicability of the Clinical Laboratory Improvement Amendments.[1, 52] As required by the FOA, we will assume that these requirements do apply to return of results in genomics research. We, by contrast, will focus our attention on case, statutory, and regulatory law and professional ethics guidance insofar as they contribute to the standard of care as they affect child research participants, their parents, their physicians, and investigators.
2. This analysis requires us to look beyond genomics research to examine parental decision making regarding their child's health care and research participation, the legal weight given to the child's choices and to the child's future interests, the independent obligations of child health care providers and investigators to the minor, as well as any role of the government. Our goal is not to develop a comprehensive analysis for all these issues but rather to define the legal environment or underpinnings for addressing returning genomic research results involving minors.
3. We plan also to examine international law in this area. Much genomics research today is conducted in multinational consortia. Different countries and cultures have different approaches to the allocation of authority regarding research participation involving minors, the examination of which may inform the strategies we adopt in the United States.

The relationships among these areas of inquiry are illustrated to the right.

Specific Aim:

To determine what criteria should govern return of individual results of pediatric genomic research, using analysis of US law and international guidelines regarding decision making for and by minors as the foundation.



Approach

We will proceed by defining the legal rules that govern the allocation of decision making authority regarding children in health care and research, as these provide the foundation for policy development. Each of us will use law students or lawyers for research assistance to aid our work. Although all of us will work together (details below) to develop comprehensive criteria, each of us will take primary responsibility for analyzing a particular question regarding the allocation of decision making authority regarding minors:

- Ellen Wright Clayton -- clinical context in the United States;
- Amy McGuire -- research context in the United States;
- Bartha Knoppers – international law and guidance regarding research.

Data Collection: Based on a preliminary review of the literature, we anticipate finding little law or policy that directly addresses the return of results in pediatric studies. Therefore, our search strategy will be broader and will be designed to capture law and policy related generally to U.S. laws and policies on pediatric decision making in the clinical context and U.S. and international laws and policies on pediatric participation and decision making in research. For U.S. law and policy, we will conduct searches in each of the following Westlaw databases: JLR (Journals and Law Reviews), ST-ALL (Statutes Annotated – All States), USCA (U.S. Statutes Annotated); LEGIS-ALL (Legislative Service – All States), and ALLCASES (All Federal and State Cases). We will also conduct a more comprehensive review and analysis of relevant sources of law, including: the HIPAA Privacy Rule, the Genetic Information Nondiscrimination Act, the Common Rule and the similar although not identical regulations of the U.S. Food and Drug Administration found at 21 C.F.R. Part 56 (rules for IRBs) and 21 C.F.R Part 59 (informed consent), and the Patient Self Determination Act of 1990. We will also include related interpretive guidance from the Office for Civil Rights, OHRP, and FDA.

Having taught Family Law and Bioethics and Law for more than a decade, Ellen Wright Clayton has in depth knowledge of the foundational principles in these areas of U.S. law. Amy McGuire has also taught medical jurisprudence and bioethics and has conducted a survey of state laws on pediatric consent and confidentiality.[53]

For international law, Bartha Maria Knoppers has taught comparative law courses (Family; Children; Medical) and has a research focus on international policymaking. Her Centre will review not only international guidance, but a typology of national approaches that reflect a range of positions (eg. Spain; France; UK; Netherlands and Canada). Under her direction, the Centre of Genomics and Policy has collated the most thorough collection of international materials related to genetics and genomics in clinical care and research in the world. A total of 4,230 international regional and country-specific laws and policies are coded and entered into the international database (www.humgen.org) (560 users; 3,294 hits a day). Its most recent (Jan. 2011) GenEdit addresses return of results issue for adults. The collection of international and Canadian materials will use the humgen database (and its PediaGen module), augmented for the four European countries by a legal-informant approach, which involves contact with specific persons with health law expertise from those countries. While there is no difficulty accessing the legislation, case law or literature of the countries under study, their interpretation in the specific context of WGS (usually by REB's) requires validation with such experts.

Recognizing that the applicable legal regimes, at best, define the outer limits of permissibility and often fail to provide comprehensive guidance for evolving issues, we will also need to collect and analyze existing scholarly literature and guidelines regarding the return of genomics research results regarding minors. We will begin this search with the excellent resources available at McGill University, www.humgen.org and www.PediaGen.org. We will supplement these resources with searches using PubMed, Ovid, and Scholar Google. We will also need to examine broader ethical and legal norms regarding the allocation of decision making authority among children, parents, child health care providers, and the state for guidance and to ensure consistency. It is in the domain of ethical analysis where Lainie Friedman Ross will provide particularly invaluable contributions.

Data Analysis: We will rely on standard tools of legal analysis, including balancing respect for precedent with the need for innovation in response to changed conditions or evidence of shifts in public values and standard canons of construction for statutory and administrative law.[54] In an area such as return of research results to minors where there is little existing law, reasoning by analogy from existing precedent – one of the central tools of legal analysis -- about the roles that parents, health care providers, and the government play in making decisions about how children are raised in general and what health care they receive in particular will be particularly important. Thus, each of the investigators will develop a paper in her area of primary responsibility with the following structure to enhance later comparison and synthesis: 1) summary of the law; 2) application of the law to a) potential issues presented by children and genetic testing/research; b) return of results specifically; and c) gaps in relevant law. These papers will be shared among the investigators, who will then collaboratively develop a synthesis of the relevance and guidance that these bodies of law shed on the issue of returning genomic research results to minors. Together they will also make recommendations where appropriate for legislative or regulatory action.

The consortium created as a result of these FOAs, which will include investigators who are returning research results through the R01 and U01 mechanisms, will be an enormous resource for our work. In addition, all three of us work with groups and researchers who are concerned with the issue of returning research results involving children. Ellen Wright Clayton was a member of the Institute of Medicine committee that comprehensively reviewed the National Children's Study, including its ethical issues.[55] She is also advisor on Kyle Brothers' grant application to study return of genetic test results related to risk of obesity to children and their parents. Amy McGuire has consulted with several pediatric oncologists at Baylor College of Medicine about the return of results in their genomic studies and has worked with Dr. Sharon Plon (pediatric geneticist) to develop a management plan for returning results to pediatric patients and their parents, both in circumstances when the patient is still alive and after he or she is dead. Dr. McGuire is also responsible, as Co-Investigator on The Human Microbiome in Pediatric Abdominal Pain and Intestinal Inflammation (NIH UH3DK083990, PI: James Versalovic, MD, PhD) for studying the ethics of sharing genomic and metagenomic results (from microbial DNA as well as human DNA) with parents of pediatric patients. Finally, Dr. McGuire is Co-Investigator on a U01 application in response to the complementary FOA for Clinical Sequencing Exploratory Studies that, if funded, will provide whole exome sequence results to parents of pediatric cancer

patients. In the event that both of these projects are funded, she will coordinate the work between the two studies so that they maximally inform each other. The Centre of Genomics and Policy (CGP) (Director: Knoppers) at McGill University has 10 pediatric research projects underway. The latest is a Canadian Paediatric Research Consortium (FORGE) on Rare Diseases. This project shares a return of results empirical project with the Canadian Pediatric Cancer Consortium. Moreover, together with the Ethics Office of the Canadian Institutes of Health Research, the CGP has developed the **Best Practices for Health Research Involving Children and Adolescents**, 189pp (June 2011). The CGP is preparing a special issue on the Return of Results for the American Journal of Law Medicine and Ethics (2011) including international positions and issues particular to pediatric research. All the investigators in this project will rely on these collaborative, empirical research projects and lived experiences to help inform our legal and ethical analysis and to identify gaps or uncertainty in the interpretation of law and policy that need to be addressed.

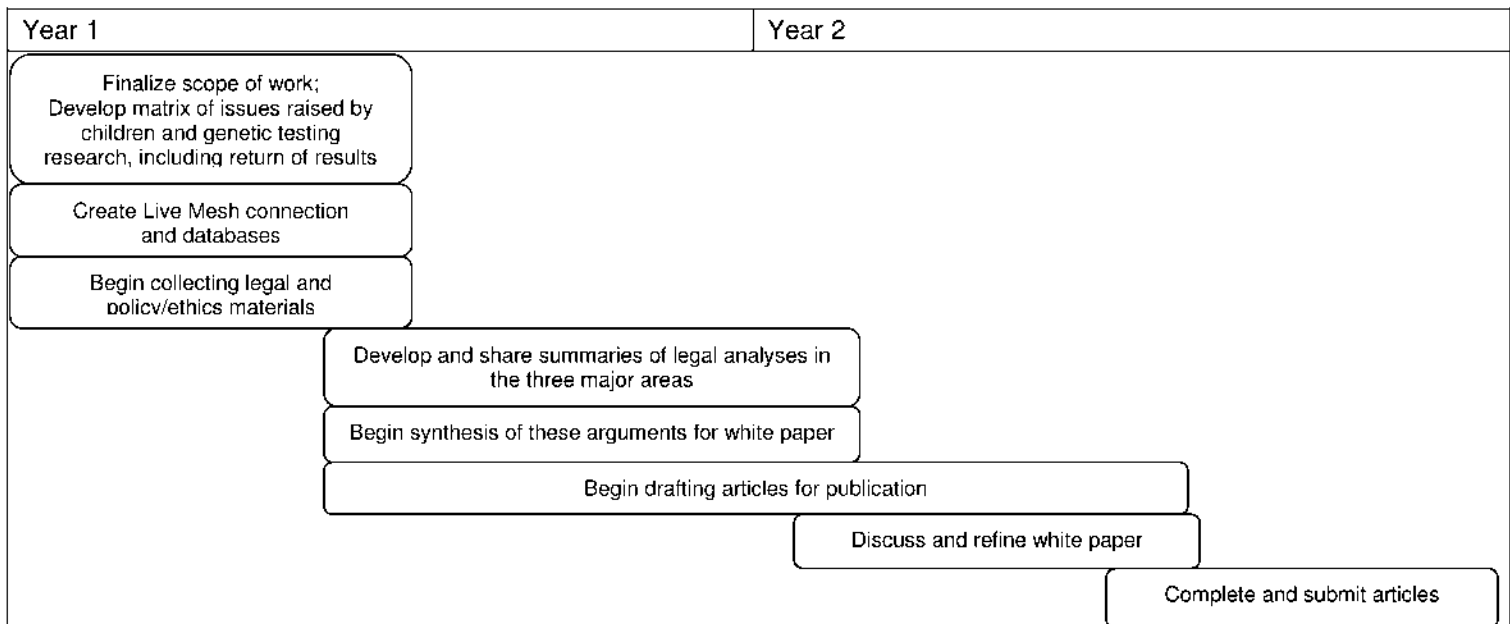
Mechanisms for collaboration

1. We will meet twice a year, each time overnight in Nashville, to plan and update our work.
2. We will also meet separately at the yearly consortium meetings.
3. We will talk at least monthly on the telephone.
4. We will create a shared file in the "cloud" using Microsoft SkyDrive and Live Mesh, which will permit us to share all our primary research as well as drafts of our analyses

Products

Each of the area papers will be published individually as well as distilled into a background white paper for presentation to the research team. The latter document will provide: (a) a summary of relevant laws and policies, (b) information about interpretation and implementation of these laws and policies, and (c) analysis of the implications for the return of genetic research results in pediatric studies, including areas of uncertainty, any areas of consensus, major gaps, plus major alternatives in areas where law or policy diverges significantly across jurisdictions or institutions, respectively. We will use this summary, informed by ethical and policy analysis, to recommend how investigators should address returning research results to minors, as well as legislative and regulatory change, if appropriate. We will disseminate the findings from our legal research and analysis through publications and presentations intended for a variety of audiences, including members of the scientific community, major pediatric societies, funders, and policy makers.

Timeline



PROTECTION OF HUMAN SUBJECTS: No human subjects will be involved in this project.

INCLUSION OF WOMEN AND CHILDREN: Although ethical and legal issues regarding returning genomics results in research involving minors are the focus of this grant, no human subjects, and hence no women or children will be involved.

TARGETED PLANNED ENROLLMENT: No human subjects will be involved in this project.

INCLUSION OF CHILDREN: No children will be involved in this project.

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CONSORTIUM/CONTRACTUAL AGREEMENTS: Ellen Wright Clayton at the Center for Biomedical Ethics and Society at Vanderbilt University (VU) in Nashville, TN, will have subcontracts with both: 1) Bartha Knoppers and her collaborators at the Centre for Genomics and Policy and McGill University (MU) in Montreal, CA, and 2) Amy McGuire and her collaborators at the Center for Medical Ethics and Health Policy at Baylor College of Medicine (BCM) in Houston, TX. Drs. Knoppers and McGuire will be responsible for paying for research results at their own Centers. Dr. Lainie Friedman Ross will receive direct payment for her consultation on the project. VU will be responsible for creating the research infrastructure, including the mechanisms for sharing documents, as well as paying for all travel by the investigators and the consultant.

The following letter of support was included as part of the original application and is provided with the permission of Dr. McGuire. An additional 2 letters were included in the original application but have been redacted to protect the privacy of individuals providing letters of support.

February 25, 2011

Ellen Wright Clayton, MD, JD
Professor and Director
Center for Biomedical Ethics and Society
Vanderbilt University
2525 West End Ave., Suite 400
Nashville, Tennessee 37203



Dear Dr. Clayton,

I am writing to express my enthusiastic support for and eagerness to participate as Co-PI in this proposal entitled "Returning Research Results of Pediatric Genomic Research to Participants." Whole genome and whole exome sequencing (WGS and WES) may soon be a routine part of patient care and is already part of many research protocols. Developing an ethically and legally justified strategy for what, how, and to whom to return the vast amount of data generated through WES and WGS, which will vary dramatically in its clinical implications and actionability, is a pressing issue, especially in pediatric populations. This project is an important opportunity to determine what criteria should govern return of individual results of pediatric genomic research. I am eager to contribute to the critical legal and ethical analysis and to developing the criteria for returning results. I will bring to bear my extensive experience studying this issue as co-investigator on two of the first individual WGS studies, PI of a funded study of GWAS investigators' and IRB chairs' practices and perspectives regarding return of genetic research results, co-author of the most recent NHLBI guidelines for return of genetic research results, member of the ELSI-Samples Committee for the 1000 Genomes Project, and member of the Consent and Community Consultation Working Group of the eMERGE Consortium. I look forward to working with you and Bartha Knoppers on this important and timely study.

Sincerely,

Amy McGuire, JD, PhD
Associate Professor of Medicine and Medical Ethics
Associate Director of Research
Center for Medical Ethics
Baylor College of Medicine

RESOURCE SHARING PLAN: As noted in our application, the Centre for Genomics and Policy at McGill University already has made publically available the most complete collection of materials related to ethical, legal, and social issues in genomics in the world, available at www.humgen.org and www.PediaGen.org. We will happily make available any additional resources we collect as part of this project as well as any of our work products on these or newly created websites.

PHS 398 Checklist

OMB Number: 0925-0001

1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

New Resubmission Renewal Continuation Revision

Federal Identifier:

2. 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:

3. 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

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)
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5. * Disclosure 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