**Key Expert Stakeholder perceptions of the law of genomics:**

**Identified problems & potential solutions**

# **Supplemental information**

## *LawSeq Qualtrics™ Survey Instrument*

This is the form used with the most people. It was customized slightly for administration to different groups.

**LawSeq: Building a Sound Legal Foundation for Translating Genomics into Clinical Application**

You are invited to be in a research study to provide investigators with information to analyze current U.S. federal and state law, regulation, and guidance on translational genomics, and to generate consensus recommendations on what the law should be, to optimize successful translation of genomics into clinical use. The study will involve gathering information from various stakeholders to obtain their views to help inform the consensus process. You were selected as a possible participant because you have experience which may help inform how genomics information should be used. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: (information removed for peer review)

**Background Information**:

The purpose of this study is to provide information about what people involved in the legal and clinical use of genomics information think to inform recommendations about best practices.

**Procedures**:

If you agree to be in this study, we would ask you to do the following things: You are asked to provide your answers to the following questions about how genomics information should be used in research and clinics with patients to help inform a normative process combined with the perceptual information into recommendations for best practices. Your submission of these responses constitutes your agreement for the project to use your responses. All information will be aggregated and no information will be ascribed to individuals. Any identifying information will be removed from the data upon putting the information into the data base.

**Risks and Benefits of being in the Study:**

This study has several risks: First, thinking about how genomic information may be used may be unsettling. You might feel anxious about stating your opinions to others even though it is confidential. Actually committing to an opinion might be anxiety producing. If you feel anxious at any time the survey can be discontinued.

There are no benefits to you individually but the recommendations developed might be an advantage for society.

**Compensation:**

You will receive no compensation for participating in the survey.

**Confidentiality:**

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality.

**Voluntary Nature of the Study:**

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota or Vanderbilt. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

**Contacts and Questions:**

The researchers conducting this study are: (names removed for peer review). You may ask any questions you have now. If you have questions later, **you are encouraged** to contact them at (email and phone removed for peer review).

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Research Subjects’ Advocate Line, D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455; (612) 625-1650.

You may request a copy of this information to keep for your records.

**Statement of Consent:**

I have read the above information. I have asked questions and have received answers. I consent to participate in the study. Proceeding to the survey by clicking the button below implies your consent to participate. Your submission of these results constitutes your agreement for use of them.

Thank you for participating in this survey. The purpose of this survey is to learn what you think about the legal issues potentially posed by genomics in research and clinical care and to elicit your view of possible solutions. As someone with expertise and relevant perspectives on these issues, we greatly value your thoughts and opinions. Responding should take approximately 20 minutes.

This survey has six parts: (1) general questions about you and your work, (2) questions about liability in genomics, (3) questions about the law surrounding the quality of genomic analysis and interpretation, (4) questions about the law surrounding privacy and access, (5) questions about the framework question of when research vs. clinical rules apply, and (6) concluding questions. Part 6 will ask you to provide optional contact information; this identifying information will be kept separate from your responses to parts 1 – 5 of the survey.

The survey responses will be aggregated and no information will be linked to individuals. The data will be stored securely without identifiers.

Thank you in advance for contributing to this study!

1. **General Questions**

What is your age?

What is your gender?

* Male (1)
* Female (2)
* Other (3)
* Prefer not to answer (4)

What is your current occupational role?

How many years of experience do you have in your current role? What degree(s) do you hold? Please check all that apply.

* M.D. (1)
* Ph.D (2)
* J.D. (3)
* R.N. (4)
* M.A. or M.S. (5)
* B.A. or B.S. (6)
* Other (please list) (7)
* None of the above (8)

At what type of institution do you work? Please check all that apply:

* University (1)
* Health care institution (2)
* Pharmaceutical company (3)
* Other private company (4)
* Law firm (5)
* Federal government (6)
* State government (7)
* Other (please describe) (8)

Approximately what percentage of your work involves genetics or genomics?

* 100% (1)
* 75% (2)
* 50% (3)
* 25% (4)
* 0% (5)
* I don't know (6)
1. **Liability**

We are interested in knowing how you think about the potential liability of clinicians, researchers, and their institutions in clinical care and research involving genomics. One example of a potential liability issue in clinical care might be the failure of a physician to order genomic testing when indicated to determine drug choice or dose. Please note that in research, we are defining “liability” to include researchers’ susceptibility not only to lawsuits by research participants, but also to penalties imposed by funders or government agencies.

How important do you think it is to clarify and improve the law surrounding liability issues in genomics research and clinical care?

* Not at all important (1)
* Slightly important (2)
* Moderately important (3)
* Very important (4)
* Extremely important (5)

How important do you think it is to address the following issues?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all important (1) | Slightly important (2) | Moderately important (3) | Very important (4) | Extremely important (5) |
| Failure to create appropriate informed consent procedures and documents (1) |  |  |  |  |  |
| Negligent performance of genomic analysis (2) |  |  |  |  |  |
| Negligent interpretation of results (3) |  |  |  |  |  |
| Failure to inform research participants or patients about primary, secondary, or incidental findings (4) |  |  |  |  |  |
| Establishing the standard of care for clinical use of genomics in assessing risk, in diagnosing, and guiding prescribing and other treatment (5) |  |  |  |  |  |
| Defining the duty to re- interpret data due to changes in genomic knowledge (6) |  |  |  |  |  |
| Hospital or other organizational failure to adopt procedures, acquire equipment, or hire personnel for genomic analysis and integration into clinical care (7) |  |  |  |  |  |
| Health insurer/payer failure to pay for genomic testing (8) |  |  |  |  |  |

What other issues involving liability in genomics clinical care and research do you find most important to address?

What solutions would you suggest to help resolve these liability issues? (changes in the law, etc.)

1. **Quality**

We would next like to know what you think about legal issues involved in determining the quality of genomic analysis and interpretation in clinical care and research. Issues may include reconciling different standards and analytic platforms as well as ensuring validity of results and determining appropriate oversight.

How important do you think it is to clarify and improve the law surrounding quality issues?

* Not at all important (1)
* Slightly important (2)
* Moderately important (3)
* Very important (4)
* Extremely important (5)

How important do you think it is to address the following issues?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all important (1) | Slightly important (2) | Moderately important (3) | Very important (4) | Extremely important (5) |
| Ensuring adequate validity and reliability of results (1) |  |  |  |  |  |
| Ensuring consistency of interpretation and results across laboratories (2) |  |  |  |  |  |
| Determining when use of a CLIA-certified laboratory is needed (3) |  |  |  |  |  |
| Ensuring adequate quality in biospecimen repositories (4) |  |  |  |  |  |
| Ensuring adequate quality in data archives (5) |  |  |  |  |  |
| Determining the appropriate role of regulatory agencies such as the FDA, CDC,CMS, and NIST (6) |  |  |  |  |  |
| Determining the appropriate role of and standards from professional societies such as CAP, AMP, ACMG, ASHG, and NSGC (7)Harmonizing international standards (8) |  |  |  |  |  |

What other issues involving quality in genomics analysis and interpretation do you find most important to address?

What solutions would you suggest to help resolve these quality issues? (changes in standards, etc.)

1. **Privacy and Access**

We would also appreciate your perspective on legal issues involving privacy and access in genomics in clinical care and research. These include who should have access to data and interpreted results.

How important do you think it is to clarify and improve the law surrounding privacy and access issues?

* Not at all important (1)
* Slightly important (2)
* Moderately important (3)
* Very important (4)
* Extremely important (5)

How important do you think it is to address the following issues?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all important (1) | Slightly important (2) | Moderately important (3) | Very important (4) | Extremely important (5) |
| Determining who should have access to raw genomic data (e.g., patient or research participant, family, clinicians, others) (1) |  |  |  |  |  |
| Determining who should have access to interpreted genomic data (2) |  |  |  |  |  |
| Defining how much control individuals should have over how data about them is used-in research, quality control, or public health (3) |  |  |  |  |  |
| Determining how to handle access to genomic data and results after the patient's death (4) |  |  |  |  |  |
| Determining data sharing rules and practices (5) |  |  |  |  |  |
| Clarifying the law related to using de-identified data and biospecimens in research (6) |  |  |  |  |  |
| Determining how to prevent and penalize re- identification (7) |  |  |  |  |  |
| Addressing employer access to genomic results (8) |  |  |  |  |  |
| Addressing insurer access to genomic results (9) |  |  |  |  |  |
| Controlling potential use of genomic results in other contexts (e.g., to determine parentage, in forensic contexts, in adoption) (10) |  |  |  |  |  |

What other issues involving privacy and access in genomics do you find most important to address?

What solutions would you suggest to help resolve these privacy and access issues?

1. **Research vs. Clinical Framework**

Finally, we would like to know how you think about the framework question of when clinical rules vs. research rules apply in genomics. For example, when researchers investigate how best to integrate genomics into the care of cancer patients, should the researchers be required to use CLIA-certified laboratory, should they be required to seek an investigational device exemption (IDE) from the FDA, and should genomic results be placed in the medical record or research records (or both)? These are among the questions that may arise when genomic research and clinical care are intertwined.

How important do you think it is to clarify and improve the law surrounding the framework question of when clinical rules vs. research rules apply?

* Not at all important (1)
* Slightly important (2)
* Moderately important (3)
* Very important (4)
* Extremely important (5)

How important do you think it is to address the following issues?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Not at all important (1) | Slightly important (2) | Moderately important (3) | Very important (4) | Extremely important (5) |
| Determining when the laws and norms governing human subjects research should apply in genomics (1) |  |  |  |  |  |
| Determining when laws and norms governing clinical care should apply in genomics (e.g., malpractice liability, robust duty of clinical care) (2) |  |  |  |  |  |
| Determining when genomics researchers have duties to offer return of primary, secondary, or incidental findings (3) |  |  |  |  |  |
| Determining what laws and norms should apply to research with de-identified data or specimens that were not collected for the research (4) |  |  |  |  |  |
| Developing appropriate approaches for translational genomics that combine research and clinical care (5) |  |  |  |  |  |
| Determining when genomics researchers need to seek an investigational device exemption from the FDA (6) |  |  |  |  |  |
| Clarifying the law governing genomic research by private companies (7) |  |  |  |  |  |
| Determining what laws and norms should apply to companies offering direct-to- consumer (DTC) genomic testing services and research (8) |  |  |  |  |  |
| Determining what law applies when research crosses states or countries (9) |  |  |  |  |  |

What other issues involving research and clinical frameworks in genomics are most important to address?

What solutions would you suggest to help resolve these framework issues?

**Other**

What other issues and sub-issues do you believe are important to be considered in addition to those listed above (in the sections on liability, quality, privacy and access, and frameworks)?

**Conclusion and Final Optional Questions**

Thank you for your time spent taking this survey. We appreciate your contribution to this effort to improve the law of genomics.

Your responses will remain anonymous. Please click here to complete the remainder of the survey.

If you would be willing to potentially be interviewed about these topics, please provide your contact information here. (This information will not be connected to your previous responses.)

If you would be willing to potentially review a draft report from this project, please provide your contact information here. (This information will not be connected to your previous responses.)