

BACKGROUND:

Over the past few decades, genetic testing has come to play a larger role in clinical care by providing opportunities to establish a diagnosis more readily, which has implications for both the patient and their family.¹ Currently, over 100,000 genetic tests exist in the US for genetic conditions; of these, more than 3000 tests have been newly introduced in 2023.² Despite the increasing medical importance of genetic tests, however, there are often issues obtaining insurance coverage. This is due to limited data and lack of professional guidelines for newly developed genetic tests to effectively inform coverage decisions on medical necessity.³ As a result, genetic testing is often considered “investigational” or “experimental” by insurance companies and may not be covered.⁴ Inadequate insurance coverage can therefore present access issues, since the cost for genetic tests can range up to several thousand dollars.^{4,5} The extent to which this amount is covered by insurance varies and depends on a patient’s insurer and specific policy; in some cases, genetic testing may not be covered at all by certain insurance policies.^{3,6}

Given this wide variability and uncertainty, insurance coverage and out-of-pocket costs are major factors which impact decisions regarding genetic testing for patients.⁷ Consequently, financial discussions have played an increasingly significant role in genetic counseling sessions.⁷ Billing options, types of insurance accepted, and laboratory-offered services like prior authorization assistance also greatly influence the genetic testing laboratories that genetic counselors choose to work with.⁸ At the same time, insurance coverage, cost, and institutional contract restrictions can hinder genetic counselors’ ability to order the ideal test for their patient.⁸ The influence of these financial factors on the type of genetic testing that can be offered to patients poses barriers to equitable access to care. For example, one study assessing patients who underwent germline testing for hereditary cancer conditions after being denied insurance coverage found that they had similar rates of carrying a pathogenic, likely pathogenic, or variant of uncertain significance result compared to patients who had their testing covered by insurance.⁹ In that respect, insurance policies may not meaningfully distinguish who can benefit from receiving genetic testing.⁹ These coverage disparities are especially prominent for individuals with government-sponsored insurance, like Medicaid, who are less likely to obtain coverage for a genetic test in the absence of separate billing policies created by the commercial laboratory to accommodate these plans.^{10,11}

One of the duties of genetic counselors is to seek out genetic testing options for patients, which includes vetting resources that are developed by labs in order to identify optimal tests at the lowest cost.⁵ One such resource that has become available over the past few years has been genetic testing offered through a sponsored program. In this case, biopharmaceutical companies initiate a partnership with commercial genetic testing laboratories to sponsor genetic testing programs at no cost for patients who meet pre-determined eligibility criteria based on their personal and family history. These tests are otherwise typically offered by the commercial laboratory through insurance or self-pay billing. In exchange for the no-cost testing, the third-party biopharmaceutical sponsor receives de-identified patient data from the commercial genetic testing laboratory which can be used for research and therapeutic development.¹² Furthermore, these companies obtain indirect access to a pool of participants for future clinical trials.¹² The data reported back to these companies can include information on patient symptoms, age of onset, family history, genetic results, and the contact information of the provider who ordered the test.¹² Shared information varies widely across the different sponsored programs and labs and no explicit guidance is provided on how a patient’s information will be shared or used.¹²

Website review by Ms. Ramesh of four major commercial laboratories demonstrate that over 40 sponsored programs are available that pertain to neurology, cardiology, urology, metabolic, immunology, ophthalmology, and skeletal conditions.^{13, 14, 15, 16} However, the eligibility criteria and duration in which these programs are available are subject to change at the behest of either the biopharma company or the commercial laboratory. For instance, the sponsored Detect program, previously offered through Invitae Genetics Laboratory, had launched in 2019 and provided patients with prostate or pancreatic cancer germline testing for hereditary cancer conditions¹⁷; in a phone conversation with Invitae Client Services (August 2023), they confirmed these programs were discontinued in early 2023 due to company restructuring.

Sponsored programs allow for genetic testing to be done in situations where it may otherwise not be accessible for patients, such as when insurance either denies or just partially covers the cost of testing, or when there is a limited ability to use patient-pay or financial assistance options. Removing the financial barrier for genetic testing services can therefore help facilitate access, and potentially make a genetic diagnosis possible for patients who otherwise cannot afford genetic testing. However, the fact that patients must consent to the testing lab's external sharing of their data with the biopharma company in order to have their testing covered places them in a potentially vulnerable position, especially when testing may be necessary to guide their health management. Patients, providers and institutions have concerns surrounding patient privacy and patient consent for data-sharing and data use, particularly since a non-clinical entity is involved.¹² In one recent study assessing public opinion in the UK on data sharing of clinical information, it was revealed that while there was general support for sharing data to academia, health charities, or government health services, there was strong opposition for sharing information to other companies.¹⁸ Furthermore, patients may be at risk of receiving inadequate consent by a provider if they are not fully informed of a laboratory's relationship with a biopharma company and the anticipated use of their data provided through these sponsored test programs.¹² Informed consent documents for these sponsored test programs vary from website review, with some labs not having a consent form specifically for testing through a sponsored program.^{13,14,15,16} The number of genes included or the testing methodology for these sponsored panels may also not be fully concordant with traditional clinical testing that would otherwise be offered.¹²

Taken together, it is currently unclear how genetic counselors initially learn about these programs and weigh these risk-benefit considerations on an individual and institutional level for clinical care. Research on sponsored genetic testing is currently limited, with recent publications on the subject primarily focusing on the yield of genetic diagnosis among participants in these programs.^{19, 20, 21} However, little data is available on the factors that contribute to the integration of these programs in clinical practice. For cases where it is being used, how this option is introduced to patients when discussing genetic testing has not yet been explored.

STATEMENT OF THE RESEARCH PROBLEM:

OBJECTIVE: To investigate genetic counselors' inclusion of sponsored programs as an option for patients considering clinical genetic testing

SPECIFIC AIMS:

1. To characterize genetic counselors' awareness and attitudes toward sponsored genetic testing
2. To identify the internal and external factors driving genetic counselors' decisions to offer sponsored genetic testing to patients.
3. To ascertain the information conveyed about sponsored genetic testing with patients as part of obtaining informed consent.

SIGNIFICANCE: Despite the growing number of biopharmaceutical-sponsored genetic tests available, how genetic counselors initially learn about these programs and how they are being introduced to patients when discussing options for genetic testing is not known. This study will be the first to capture genetic counselor utilization of sponsored genetic testing programs and the factors which influence its use. Understanding the current landscape regarding genetic counselor attitudes, use, and communication of these programs can inform best practices for its implementation in patient care. Because sponsored testing is also available for non-genetics providers to order, recognizing these perspectives from the genetics community can broaden education on such practices. Since there are currently no national guidelines or position statements regarding the use and communication about sponsored genetic testing programs in clinical care, study results can also guide the development of such policies.

RESEARCH DESIGN AND METHODS:

STUDY POPULATION: We plan to survey genetic counselors practicing across the U.S. who provide direct patient care. Broad recruitment of genetic counselors will be done by sending emails through both the National Society of Genetic Counselors (NSGC) and the American Board of Genetic Counselors (ABGC) mailing lists that will include a link to the study description, informed consent form, and survey itself if they elect to participate. As of March 2023 there are approximately 6,517 ABGC certified genetic counselors in the US, of which 4,700 are also members of NSGC.²²

STUDY DESIGN: Members of the research team include a genetic counseling graduate student, and certified genetic counselors through Michigan Medicine and Penn Medicine who have prior experience with survey design and discussing sponsored genetic testing practices with patients. Furthermore, one of the committee members (L. Hipp) has been involved in addressing institutional policy on the use of sponsored genetic testing. A national online anonymous survey, programmed in Qualtrics, will be accessible for participants to complete and will be comprised of multiple choice, Likert scale, and open response questions. For the purposes of this study, sponsored genetic testing has been defined as a "a program which is offered by a commercial laboratory, in partnership with a third-party company, to waive the cost of genetic testing for patients in exchange for the third-party company receiving de-identified patient data from the commercial laboratory." Questions for the survey are being developed by members of the research team and are adapted from the NSGC Professional Status Survey (PSS) pertaining to demographic information, as well as literature review of previous studies that have addressed decision-making with the introduction of new and emerging genetic tests, such as whole exome/whole genome sequencing, direct-to-consumer testing, expanded carrier screening, to focus on the research question.²²⁻²⁶

Major topics to be assessed include:

- Demographics, particularly participants' area of clinical genetic practice, work setting, and patient population
- Participant familiarity with sponsored genetic programs
- Experience ordering sponsored genetic testing for patients
- Circumstances in which sponsored genetic testing is or is not offered to patients
- General attitudes on sponsored programs as an option for clinical genetic testing
- Communication of sponsored testing information to patients

Depending on whether or not participants have current, prior, or no experiences ordering testing through a sponsored program with patients, survey logic will be used to direct participants to relevant questions for their experience. All participants will be asked questions about their familiarity, perspectives, and information important to communicate with patients on sponsored genetic testing regardless of personal experience ordering this testing.

DATA ANALYSIS: Statistical analysis will be completed using Statistical Package for the Social Sciences (SPSS) software and with support through statistical consultants at the University of Michigan Center for Statistical Consultation and Research (CSCAR). It is anticipated that descriptive statistics reporting percentage responses to questions will be used. Linear regression analysis will evaluate trends between work setting, specialty practice, and genetic counselor perceptions in relation to frequency of sponsored testing use. Qualitative analysis of open-ended responses will be double coded using Dedoose software to identify common themes.

LIMITATIONS:

This is a novel study so many questions will be developed by the research team and will not be from previously validated instruments. Therefore, a preliminary pilot test of the survey will be conducted to help ensure survey questions reflect its intended measures. Although all genetic counselors who are board-certified by ABGC and/or who are members of NSGC will be eligible to take the survey, the survey response could be low. To help increase the response rate, an incentive will be offered to participants. While this survey will assess general attitudes about sponsored genetic testing programs regardless of whether or not participants have personal experience with the test, genetic counselors who are more familiar with sponsored testing may be more likely to respond to the survey. This could potentially bias factors such as overall awareness of sponsored testing and frequency of its use. Additionally, as this study population will be limited to genetic counselors, the results may not be generalizable to other healthcare providers who order sponsored genetic testing. However, given the limited research on sponsored genetic testing practices overall, understanding first how these programs are perceived and used within the genetics community will allow for future studies on this topic among other healthcare groups.

TIMELINE:

April/May 2023

- Identified sponsored testing as broad area of interest in the context of access/utilization
- Identified and established research committee members

- Performed initial literature search and recognized need for further research on topic
- Conducted informant interviews with three genetic counselors and 1 non-genetics MD to learn about sponsored genetic testing for basic understanding of its use
- Developed research objective and specific aims
- Wrote first draft of research proposal

June/July 2023

- Continued literature review
- Continued to refine research proposal
- Finalized objective and specific aims
- Began developing survey instrument
- Applied for funding through NSGC Neurology Special Interest Group and Michigan Association of Genetic Counselor (MAGC) Student Award

August 2023

- Finalized research proposal
- Continued to develop survey instrument
- Began IRB application

September 2023

- Submit research proposal for Neel Fellowship
- Finalize survey instrument
- Pilot test survey
- Revise instrument based on pilot results

October 2023

- Submit IRB application
- Apply for remaining funding through Rackham Graduate Student Research Grant
- Present poster at Department of Human Genetics Retreat

November 2023

- Obtain IRB approval
- Begin recruitment of study participants

December 2023

- Complete recruitment and data collection
- Complete research progress report

January 2024

- Begin data analysis
- Begin research project report (introduction/methods)

February 2024

- Continue data analysis

March/April 2024

- Complete data analysis
- Continue literature search to determine any relevant publications since initial review
- Submit final research project report
- Present research at department seminar

May 2024

- Submit Abstract for NSGC Annual Conference

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APPENDIX: QUESTIONNAIRE DRAFT

BLOCK 1: Demographics

Q1. What is your age?

- ☐ 20-24
- ☐ 25-29
- ☐ 30-34
- ☐ 35-39
- ☐ 40-44
- ☐ 45-49
- ☐ 50-54
- ☐ 55-59
- ☐ 60-64
- ☐ 64-69
- ☐ 70+

Q2. In which NSGC region are you located?

- ☐ Region 1 (CT,MA,ME,NH,RI,VT,CN Maritime Provinces)
- ☐ Region 2 (DC,DE,MD,NJ,NY,PA,VA,WV, PR,VI,Quebec)
- ☐ Region 3 (AL,FL,GA,KY,LA,MS,NC,SC,TN)
- ☐ Region 4 (AR,IA,IL,IN,KS,MI,MN,MO,ND,NE,OH,OK,SD,WI,Ontario)
- ☐ Region 5 (AZ,CO,MT,NM,TX,UT,WY,Alberta, Manitoba, Sask)
- ☐ Region 6 (AK,CA,HI,ID,NV,OR,WA,British Columbia, Yukon)

Q3. How would you describe your geographic work environment?

- ☐ Urban
- ☐ Suburban
- ☐ Rural
- ☐ National

Q4. How many years have you been working in the field of genetic counseling?

- ☐ <1 year
- ☐ 1-4 years
- ☐ 5-9 years
- ☐ 10-14 years
- ☐ 15-19 years
- ☐ 20-24 years
- ☐ 25+ years

Q5. How many years have you been employed at your current practice?

- ☐ <1 year
- ☐ 1-4 years
- ☐ 5-9 years
- ☐ 10-14 years
- ☐ 15-19 years
- ☐ 20-24 years

- ☐ 25+ years

Q6. What are your current primary area(s) of practice? (Select all that apply)

- ☐ Prenatal
- ☐ Pediatrics
- ☐ Cancer
- ☐ General Adult
- ☐ Neurogenetics
- ☐ Cardiology
- ☐ Metabolic disease
- ☐ Ophthalmology
- ☐ Hematology
- ☐ Immunology
- ☐ Laboratory
- ☐ Other (please specify)

Q7. How many years have you been working in this/these area(s) of practice?

- ☐ <1 year
- ☐ 1-4 years
- ☐ 5-9 years
- ☐ 10-14 years
- ☐ 15-19 years
- ☐ 20-24 years
- ☐ 25+ years

Q8. Which of the following best describes your current employer work setting?

- ☐ Academic Hospital/Medical Facility
- ☐ Private Hospital/Medical Facility
- ☐ Public Hospital/Medical Facility
- ☐ Physicians Private Practice
- ☐ Private Company
- ☐ Commercial Laboratory
- ☐ Noncommercial Laboratory
- ☐ Other (please specify)

Q9. In a typical month, approximately how many patients do you see?

- ☐ 1-10
- ☐ 11-20
- ☐ 21-30
- ☐ 31-40
- ☐ 41-50
- ☐ 51-60
- ☐ 61-70
- ☐ 71-80
- ☐ 81-90
- ☐ 91-100

- 100+

Q10. Approximately what percentage of your patient population has Medicare insurance?
(Defined as federal health insurance for anyone age 65 and older, and some people under 65 with certain disabilities or conditions)

- Less than 10%
- 10-29%
- 30-49%
- 50-69%
- 70-100%
- I don't know

Q11. Approximately what percentage of your patient population has Medicaid insurance?
(Defined as federal and state program that gives health coverage to some people with limited income and resources)

- Less than 10%
- 10-29%
- 30-49%
- 50-69%
- 70-100%
- I don't know

Q12. Approximately what percentage of your patient population has no health insurance?

- Less than 10%
- 10-29%
- 30-49%
- 50-69%
- 70-100%
- I don't know

BLOCK 2: Sponsored Testing Knowledge

Sponsored Genetic Testing is defined as a program which is offered by a commercial laboratory, in partnership with a third-party company, to waive the cost of genetic testing for patients in exchange for the third-party company receiving de-identified data on the patient from the commercial laboratory

Q1. How have you learned about new sponsored genetic testing programs? (Select all that apply)

- Email sent by lab
- Lab Website
- Colleague (Genetics Provider)
- Colleague (Non-Genetics Provider)
- I have never previously heard of sponsored genetic programs

Q2. Please answer the following true/false statements regarding sponsored genetic testing programs

Q2.1. Sponsored programs are only available for patients who cannot afford the cost of genetic testing.

- ☐ True
- ☐ False
- ☐ I don't know

Q2.2. Sponsored programs may be used to identify potential participants for clinical trials.

- ☐ True
- ☐ False
- ☐ I don't know

Q2.3. The third-party company receives identifiable patient information from the commercial laboratory, such as name and date of birth

- ☐ True
- ☐ False
- ☐ I don't know

Q2.4. Labs may share the contact information of the ordering provider with the third-party sponsoring company

- ☐ True
- ☐ False
- ☐ I don't know

Q2.5. Sponsored programs can be discontinued at any time under the discretion of the commercial laboratory or the third-party company.

- ☐ True
- ☐ False
- ☐ I don't know

Q3. What resources or information, if any, have you accessed to learn more about the use of sponsored genetic testing?

- ☐ Training or seminar at an annual conference
- ☐ Discussion within special interest groups
- ☐ Written guidance provided by clinic/department/institution
- ☐ Webinars offered by commercial laboratory
- ☐ Other (please specify)

Q4. Please define your prior experience with sponsored genetic testing:

- ☐ I have and continue to order sponsored genetic testing for patients (*Direct to Block 3 if selected*)
- ☐ I have previously ordered sponsored genetic testing for patients, but not currently (*Direct to Block 4 if selected*)
- ☐ I have not ordered sponsored genetic testing personally for patients, but it is offered by others within my practice and/or my institution (*Direct to Block 5 if selected*)
- ☐ I have not ordered sponsored genetic testing personally for patients, and I am not aware that it has been ordered by others at my institution (*Direct to Block 5 if selected*)

BLOCK 3: Current Experiences Ordering Sponsored Testing

Q1. How long has your practice been offering sponsored genetic testing as an option to patients?

- Less than 6 months
- Less than 12 months but more than 6 months
- More than 12 months

Q2. Who decides whether to offer genetic testing through a sponsored program? (Select all that apply)

- Genetic counselors
- Geneticists
- Non-genetics provider (e.g. referring physician, nurse, physician assistant)
- Patient-initiated request

Q3. For which of the following areas have you ordered genetic testing through a sponsored program? (Select all that apply)

- Cardiology
- Neurology
- Metabolic
- Immunology
- Nephrology
- Ophthalmology
- Skeletal
- Hematology
- Cancer
- Dermatology
- Endocrinology
- Other (please specify)

Q4. Please describe your process for looking into sponsored genetic test options

- I actively seek out sponsored testing options for all of my patients
- I actively seek out options for sponsored testing on a patient by patient basis
- I do not actively seek out options for sponsored testing
- Other (please specify)

Q5. When sponsored genetic testing is available, at what point is it typically offered to patients in your practice?

- Genetic testing through a sponsored program is the first test offered to a patient or family when it is an option
- Genetic testing through a sponsored program is offered at the same time as other options for financial coverage (e.g. insurance, self-pay)
- Genetic testing through a sponsored program is offered to patients when testing cannot be covered by other financial means
- Other (please specify)

Q6. Over the past year, approximately what percentage of your patients have you offered testing through a sponsored program?

- Less than 10%
- 10-29%
- 30-49%

- ☐ 50-69%
- ☐ 70-100%
- ☐ I don't know

Q7. Over the past year, approximately what percentage of your patients have consented to sponsored genetic testing when it is offered?

- ☐ Less than 10%
- ☐ 10-29%
- ☐ 30-49%
- ☐ 50-69%
- ☐ 70-100%
- ☐ I don't know

Q8. What are reasons why sponsored genetic testing may not be offered to your patients? (Select all that apply)

- ☐ Clinic or institutional policies surrounding use of sponsored programs
- ☐ Lack of information on sponsored genetic testing programs that are currently available
- ☐ Lack of guidelines on appropriate use of sponsored genetic testing
- ☐ Other testing options are better/more comprehensive for patient indication
- ☐ Patient does not meet program's eligibility criteria
- ☐ Personal concerns over the ethics of sponsored genetic testing
- ☐ Other (please specify)

Q9. To your knowledge, do any others within your practice and/or institution order genetic testing through a sponsored program?

- ☐ Yes
- ☐ No

Q10. What level of discussions regarding the use of sponsored genetic testing have taken place? (Select all that apply)

- ☐ Individual, patient-focused discussions with ordering provider or another colleague
- ☐ General discussion across all genetic counselors at clinic
- ☐ General discussion with providers in other departments
- ☐ General discussions at an institutional level

Q11. Are you aware of any policies at your institution regarding the use of sponsored genetic testing?

- ☐ Yes, specific policies are in place to guide use of sponsored testing
- ☐ Policies are under discussion or are pending review/approval
- ☐ No policies are in place at this time
- ☐ I do not know

(If "Yes, specific policies are in place to guide use of sponsored testing is selected"):

Q11.1. Please provide a 1-2 sentence summary of the current policy at your institution

Q12. Please provide additional comments on your experiences and challenges with the introduction of sponsored genetic testing in your practice

BLOCK 4: Previous Experiences Ordering Sponsored Testing

Q1. When was the last time you offered sponsored genetic testing as an option to patients?

- ☐ Less than 6 months ago
- ☐ Less than 12 months but more than 6 months ago
- ☐ More than 12 months ago

Q2. What are the reasons why you are not currently ordering sponsored testing?

- ☐ Sponsored testing program was discontinued/is no longer offered
- ☐ I am no longer working in a position that orders sponsored testing for patients
- ☐ Clinic or institutional policies surrounding use of sponsored programs
- ☐ Other (please specify)

Q2.1 Please elaborate on your above response.

Q3. Who would decide whether to offer genetic testing through a sponsored program? (Select all that apply)

- ☐ Genetic counselors
- ☐ Geneticists
- ☐ Non-genetics provider (e.g. referring physician, nurse, physician assistant)
- ☐ Patient-initiated request

Q4. For which of the following areas have you ordered genetic testing through a sponsored program? (Select all that apply)

- ☐ Cardiology
- ☐ Neurology
- ☐ Metabolic
- ☐ Immunology
- ☐ Nephrology
- ☐ Ophthalmology
- ☐ Skeletal
- ☐ Hematology
- ☐ Cancer
- ☐ Dermatology
- ☐ Endocrinology
- ☐ Other (please specify)

Q5. Please describe your process for looking into sponsored genetic test options

- ☐ I actively sought out sponsored testing options for all of my patients
- ☐ I actively sought out options for sponsored testing on a patient by patient basis
- ☐ I do not actively seek out options for sponsored testing
- ☐ Other (please specify)

Q6. At what point was sponsored genetic testing typically offered to patients in your practice?

- Genetic testing through a sponsored program would be the first test offered to a patient or family when an option
- Genetic testing through a sponsored program would be offered at the same time as other options for financial coverage (e.g. insurance, self-pay)
- Genetic testing through a sponsored program would be offered to patients when testing cannot be covered by other financial means
- Other (please specify)

Q7. Approximately what percentage of your patients have you offered testing through a sponsored program?

- Less than 10%
- 10-29%
- 30-49%
- 50-69%
- 70-100%
- I don't know

Q8. Approximately what percentage of your patients have you consented to sponsored genetic testing when offered?

- Less than 10%
- 10-29%
- 30-49%
- 50-69%
- 70-100%
- I don't know

Q9. What are reasons why sponsored genetic testing may not have been offered to your patients? (Select all that apply)

- Clinic or institutional policies surrounding use of sponsored programs
- Lack of information on sponsored genetic testing programs that are currently available
- Lack of guidelines on appropriate use of sponsored genetic testing
- Other testing options are better/more comprehensive for patient indication
- Patient does not meet program's eligibility criteria
- Personal concerns over the ethics of sponsored genetic testing
- Other (please specify)

Q10. To your knowledge, have any others within your practice and/or institution ordered genetic testing through a sponsored program?

- Yes
- No

Q11. What level of discussions regarding the use of sponsored genetic testing had taken place at your previous experience? (Select all that apply)

- Individual, patient-focused discussions with ordering provider
- General discussion across all genetic counselors at clinic
- General discussion with providers in other departments
- General discussions at an institutional level

Q12. Are you aware of any policies at your institution regarding the use of sponsored genetic testing from your previous experience?

- ☐ Yes, specific policies had been in place to guide use of sponsored testing
- ☐ Policies were under discussion or were pending review/approval
- ☐ No policies were in place at that time
- ☐ I do not know

(If “Yes, , specific policies had been in place to guide use of sponsored testing is selected”):

Q12.1. Please provide a 1-2 sentence summary of the policy at your institution.

Q13. Please provide additional comments on your experiences and challenges with the introduction of sponsored genetic testing in your previous experience.

BLOCK 5: Sponsored Testing Not Ordered in Practice

Q1. What are the reasons you are not offering sponsored genetic testing? Please select all that apply.

- ☐ Sponsored genetic testing is not currently available in my specialty
- ☐ Clinic or institutional policies surrounding use of sponsored programs
- ☐ Lack of information on sponsored genetic testing programs that are currently available
- ☐ Lack of guidelines on appropriate use of sponsored genetic testing
- ☐ Other testing options are better/more comprehensive for patient indication
- ☐ Patient does not meet program’s eligibility criteria
- ☐ Personal concerns over the ethics of sponsored genetic testing
- ☐ Other (please specify)

Q1.2. Please elaborate on your response(s) to the question above.

BLOCK 6: Attitudes about Sponsored Genetic Testing

Q1. In general, how do you feel about sponsored genetic testing?

- ☐ Very Negative
- ☐ Negative
- ☐ Neutral
- ☐ Positive
- ☐ Very Positive

Q2. Has your opinion of sponsored testing changed over time?

- ☐ Yes
- ☐ No

Q2.1 *(If yes selected)* What factors prompted the change? (Select all that apply)

- ☐ Learning more about sponsored genetic testing
- ☐ Discussing sponsored genetic testing with patients
- ☐ Ordering sponsored genetic testing
- ☐ Discussing sponsored genetic testing with other providers

- Discussing sponsored genetic testing on a legal/administrative level
- Other (please specify)

Q3. What do you consider to be the benefits of offering genetic testing through a sponsored program to a patient?

Q4. What do you consider to be the risks of offering genetic testing through a sponsored program to a patient?

Q5. We are interested in how you feel about the following statements on sponsored genetic testing. Read each statement carefully. Indicate how strongly you agree or disagree with these statements.

Q5.1 Sponsored Genetic Testing in General

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Sponsored programs give patients better access to genetic testing.	☐	☐	☐	☐	☐
The potential risks of sponsored genetic testing are minimal for a patient.	☐	☐	☐	☐	☐
The benefits of sponsored genetic testing outweigh the potential risks.	☐	☐	☐	☐	☐
Sponsored genetic testing can be potentially coercive for patients who have no other means of getting genetic testing.	☐	☐	☐	☐	☐
Laboratory websites provide sufficient information about how a patient's genetic and personal information may be used through a sponsored program.	☐	☐	☐	☐	☐
Laboratory websites provide sufficient informed consent documentation for sponsored genetic programs.	☐	☐	☐	☐	☐
There should be departmental or institutional guidance or policies on when sponsored genetic testing can be offered.	☐	☐	☐	☐	☐

An official position statement on the use of sponsored genetic testing would help me feel better about when to offer it in practice.	☐	☐	☐	☐	☐

Q5.2 Discussing Sponsored Genetic Testing with Patients

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Sponsored genetic testing should be discussed as an option for patients whenever it is available.	☐	☐	☐	☐	☐
Patients should be made aware of all financial coverage options when discussing genetic testing.	☐	☐	☐	☐	☐
I would offer sponsored genetic testing as the primary option when patients express concerns about financial cost of testing upfront.	☐	☐	☐	☐	☐
I feel that my patients have the ability to make an informed, independent choice about the genetic testing option that is best for them.	☐	☐	☐	☐	☐
I am/would be comfortable personally counseling a patient about genetic testing through a sponsored program.	☐	☐	☐	☐	☐
I am/would be comfortable answering questions a patient has about genetic testing through a sponsored program.	☐	☐	☐	☐	☐
If I or a patient has questions about a particular sponsored program, I would be able to get a satisfactory answer from the laboratory.	☐	☐	☐	☐	☐
I think it is appropriate for a non-genetics provider working	☐	☐	☐	☐	☐

in a specialty (e.g. cardiology, neurology) to discuss sponsored genetic testing with a patient.					
I think it is appropriate for a primary care or general practice provider to discuss sponsored genetic testing with a patient.	☐	☐	☐	☐	☐

Q6. Please use this space to provide any additional comments or thoughts about sponsored genetic testing.

BLOCK 7: Communication of Sponsored Testing Information with Patients

Q1. What do you think is necessary for a patient to understand about genetic testing through a sponsored program?

Q2. When explaining sponsored genetic testing to a patient, how often do you discuss the following topics with patients?

	Never Discussed	Sometimes Discussed	Always Discussed
Sponsored genetic testing means this test will be completed at no financial cost.	☐	☐	☐
The sponsoring company will receive de-identified patient data from the ordering test lab.	☐	☐	☐
Patient data received by the lab can aid in research development and potential therapies.	☐	☐	☐
Patients may have the option of being contacted to learn about research opportunities or clinical trials.	☐	☐	☐
The same genetic test can also be completed through insurance or self-pay depending on your coverage.	☐	☐	☐

Q3. How would you rank the above statements on a scale of 1 (least important) to 5 (most important)?

Sponsored genetic testing means this test will be completed at no financial cost.	
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The sponsoring company will receive de-identified patient data from the ordering test lab.	
Patient data received by the lab can aid in research development and potential therapies.	
Patients may have the option of being contacted to learn about research opportunities or clinical trials.	
The same genetic test can also be completed through insurance or self-pay depending on your coverage.	

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Q4. Did you have to modify some of your counseling strategies since you started offering sponsored genetic testing?

- ☐ Yes
- ☐ No
- ☐ I have never offered sponsored genetic testing

Q5. *(If yes was answered to above)* Please elaborate on how your counseling strategies have changed to accommodate discussions on sponsored testing