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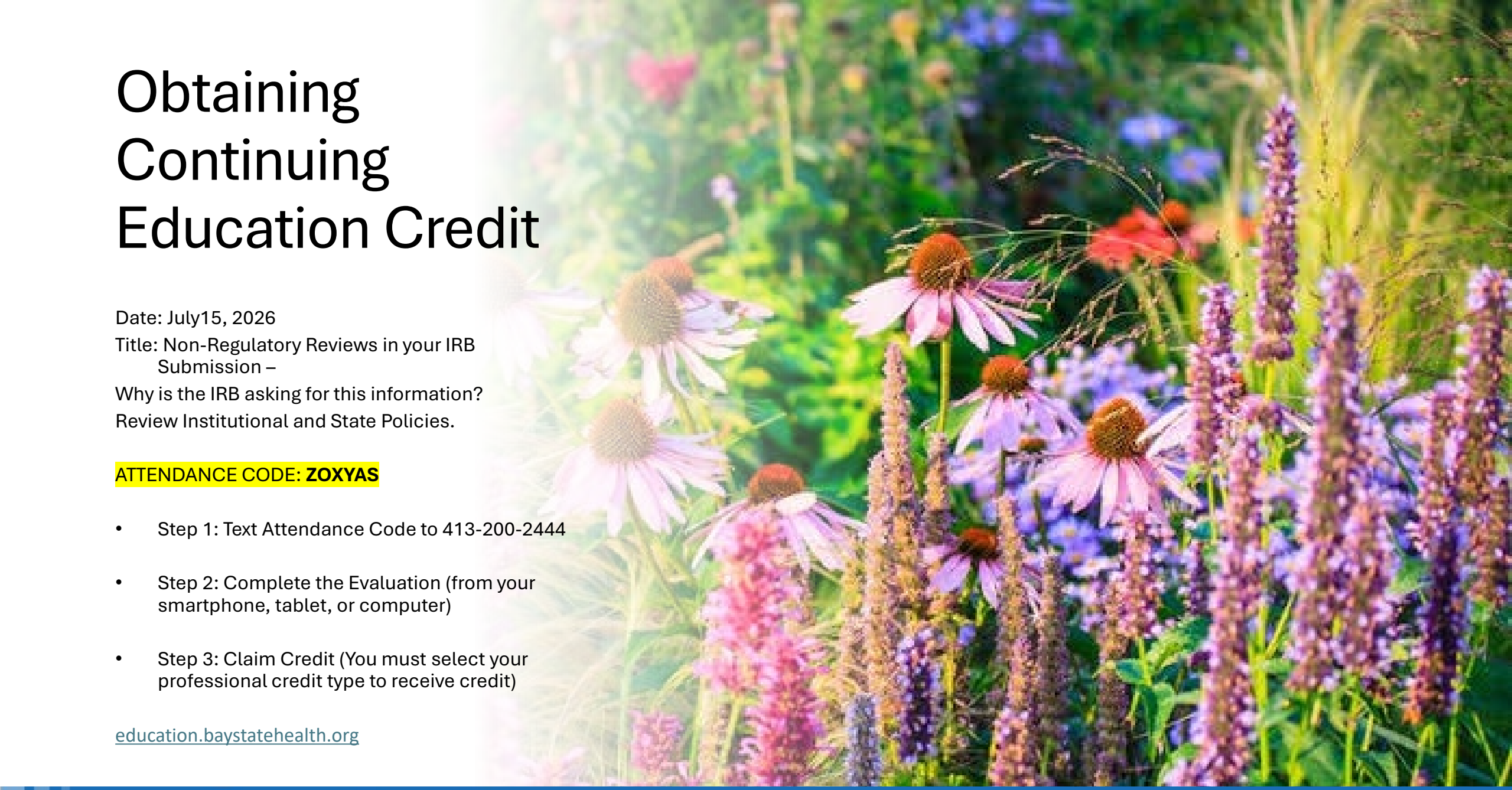

Date: July15, 2026

Title: Non-Regulatory Reviews in your IRB Submission –

Why is the IRB asking for this information?

Review Institutional and State Policies.

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NON-REGULATORY REVIEWS IN YOUR IRB SUBMISSION —WHY IS THE IRB ASKING FOR THIS INFORMATION? REVIEW INSTITUTIONAL AND STATE POLICIES

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Human Research Protection Program

Office of Research

Disclosures

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In accordance with institutional and accreditation requirements, the presenters have no relevant relationships to disclose. Nor do we have any conflicts of interest or relevant financial relationships with commercial entities.

Objectives

1

Explain Massachusetts Controlled Substance Registration (MCSR) registration requirements and apply rules to clinical research

2

Understand key federal and Massachusetts laws governing substance use confidentiality and practical implications for Massachusetts-based clinical researchers, including IRB review and consenting

3

Describe legal protections for genetic information in research and identify Massachusetts genetic privacy statutes

Massachusetts Controlled Substance Registration (MCSR)

What it is:

In Massachusetts **any drug** used as an intervention in a research study is considered a **controlled substance**. Each study drug is classified into Schedules I to VI or as an investigational new drug (IND) under an Investigational New Drug application. Massachusetts law, Title 105 CMR 700.009, requires that every principal investigator (PI) who is conducting research involving one of more drugs must be covered by a Massachusetts Controlled Substances Registration (MCSR) Research License.

Federal and State Regulations – Controlled Substances

Controlled substances are drugs regulated by federal and state law.

Federal Controlled Substances Act

is the statute establishing federal U.S. drug policy under which the manufacture, importation, possession, use, and distribution of certain substances is regulated.

Massachusetts General Laws Chapter 94C

categorizes drugs based on their potential for abuse, addiction, and accepted medical use.

State Controlled Substance Schedules

Class A

(Schedule I) Highest-risk narcotics and opioids (e.g., heroin, fentanyl).

Class B

(Schedule II) High-risk stimulants and depressants (e.g., cocaine, methamphetamine, oxycodone).

Class C

(Schedule III) Intermediate risk (e.g., benzodiazepines such as Valium, hydrocodone).

Class D

(Schedule IV) Includes marijuana and phenobarbital (marijuana, hashish, phenobarbital.

Class E

(Schedule V) Lower-risk prescription drugs with small amounts of opioids.

Schedule VI:

(Schedule VI) includes prescription drugs not listed in Classes A–E

Evolution



Beginning in 2018, this MA law requires that *each PI has to obtain their own individual MCSR License* ***if both of these conditions are met:***

- **the drug research involves an investigational new drug (IND)** *[no matter who holds the IND- whether the PI, another PI, the sponsor, or a pharmaceutical company],*
- **And**
- **the IND drug is stored at a site in MA*** [e.g. in the BMC Investigational Pharmacy Services/IPS, in Radiology, in the research office, or even at another institution]

**Note - If the IND drug is sent directly to participants and not stored in MA, the PI does not have to obtain an individual MCSR Research License.*

Official License vs. Renew License



The MCSR Researcher license is an annual license, and it must be renewed each year that the study drug is being dispensed to participants (unlike the clinical MCSR license which is a 3-year license).



For study drugs that meet the criteria for IND exemption, this MA law also allows institutions conducting drug research to fulfill this requirement by obtaining and annually renewing institution-wide "umbrella" MCSR research licenses. Therefore, PIs that only conduct research with study drugs under IND exemptions can be covered under the appropriate institutional umbrella license typically issued to the Department Chair.



The exception to the use of the "institutional/umbrella license" is that the PI of any study **using a Schedule I, II or III drug** will need to obtain an individual MCSR Research License, even if the use of the drug meets the criteria for IND exemption.

Institutional vs Investigator Responsibilities

Institutional Responsibility

- Institutions must oversee all registrations under their umbrella.
- Investigational pharmacy maintain policies for controlled substance handling, storage, disposal, and inspection.
- Provide training and report incidents promptly.

Investigator Responsibility

- Confirm whether the protocol uses scheduled substances and which staff need individual MCSR.
- Apply/renew via MA DPH eLicensing, keep records and reconcile inventory.
- Coordinate DEA and MCSR numbers on prescriptions/orders per state and federal rules.
- Document training, storage, and chain-of-custody procedures in SOPs.

What is Needed

If the PI needs to apply for a new, individual MCSR Research License for IND-related research, they will need to gather the following items to answer the questions and enter the information into the online application form:

- ❑ Massachusetts Board of Registration License Number
- ❑ DEA Federal Controlled Substance Registration Number (if possessed)
- ❑ Business Address (Under the applicable law and regulations, the address used for the MCSR license must be the PI's principal place of business or professional practice).
- ❑ Primary telephone number
- ❑ Primary email address
- ❑ Social Security number (Required by M.G.L. c. 30A, s. 13A)
- ❑ The names of all study IND/s being dispensed and the names and schedules for all non-IND drugs being dispensed in the PI's current research studies
- ❑ Application fee $150

Expectations After Receiving MCSR

Storage Requirements

Controlled substances must be:

- Stored in a securely locked cabinet or safe
- Access-limited to authorized personnel
- Separated appropriately by schedule

Schedule I and II substances often require:

- Higher security standards

Security is audited and taken seriously.

Recordkeeping Requirements

You must maintain:

- Inventory logs
- Usage logs
- Acquisition records
- Disposal documentation

Records must be:

- Accurate
- Up to date
- Available for inspection

Failure to maintain records can result in penalties and non-compliance with CO 13.350 and HRPP Policies Section 4.10

License Comparison

Feature	Researcher MCSR (Research)	Clinical MCSR (Practitioner)
Duration	**1 Year** (Annual Renewal)	**2 Years**
Renewal Trigger	Required every year drug is dispensed	Standard cycle
Who is included?	Individual PI & those identified as handling the study product	Individual Practitioner
Coverage	A separate registration is required at each location the registrant distributes or dispenses controlled substances or uses controlled substances in research.	A separate registration is required at each place of business or professional practice where the applicant distributes or dispenses controlled substances, or uses controlled substances in clinical care, teaching or chemical analysis.
Modifications	Must file an amendment if the authorized staff listed or location of product distribution or dispensing is changed.	Amendment filed if the location of business or practice is changed.

Final Takeaways

MCSR = Massachusetts state authorization

Required in addition to DEA registration

Mandatory for researchers handling controlled substances

Involves strict storage, recordkeeping, and compliance

Must be maintained and renewed annually

MSCR Case Study - Research License for an IND

A principal investigator (PI) is conducting a clinical trial that uses an IND. The medication will be utilized in both the Baystate Franklin surgical suite and the Baystate Medical Center surgical suites with additional self-administered doses shipped across state lines directly from the commercial pharmacy. The project is expected to last 5 years.

1. Can the PI rely solely on an institutional "umbrella" MCSR or must they obtain an individual license?
2. Are there storage considerations that need to be addressed with the license application?
3. Will the license need to be renewed?

1. Can the PI rely solely on an institutional "umbrella" MCSR or must they obtain an individual license?

   If the study has an IND, an individual license is necessary. Without an IND, an institutional license may suffice.

2. How many MCSR licenses will be required?

   The PI will need two MCSR licenses; one for BFMC and one for BMC. For the IND drug sent directly to participants and not stored in MA, the PI does not have to obtain an individual MCSR Research License.

3. Will the license need to be renewed?

   Each license will need to be renewed annually, so long as the drug maintains IND status and is stored on-site for the study.

Substance Use Records & Research



Substance Use Records & Research — 42 CFR Part 2

42 CFR Part 2 places strict limits on disclosure of patient-identifying Substance Use Disorders (SUD) treatment records. Part 2's protections can apply to programs and records used in research and may limit access and secondary uses.

Specific Research Requirements (§ 2.52):

- Recipients must be a HIPAA-covered entity or business associate, or subject to HHS regulations.
- Data must only be included in research reports in aggregate form.
- Researchers must adhere to strict security, storage, and destruction policies for patient-identifying information.
- Re-disclosure is prohibited, except back to the original source.
- The February 2024 final rule allows for a single, comprehensive consent for future research, aligning closely with HIPAA, but still requires the specific elements to protect sensitive SUD records.

What is a Substance Use Record?

Under Part 2 and M.G.L. c. 111B, it includes:

- Name or identifying details
- Clinical notes
- Toxicology reports
- Admission/discharge records
- Billing records if tied to SUD services

Even confirming someone is a patient is protected.

SUD Confidentiality — Impact on Clinical Research



Research using SUD treatment records or recruiting from Part 2 programs requires distinct patient consent with special language and data protection components.



Data sharing, audits, and law-enforcement access are restricted;

This approach ensures efforts for:

- ethical participant engagement
- Protect confidentiality
- Maintain treatment standards
- Preserve institutional credibility

SUD Informed Consent in Research Context

42 CFR Part 2 requires written, signed consent to disclose Substance Use Disorder (SUD) records for research, ensuring patient privacy. Key elements include identifying the patient and authorized recipients, specifying information to be disclosed, stating the research purpose, informing of the right to revoke consent, and including an expiration date.

- Must address Massachusetts patient rights
- Include disclosures about confidentiality limits
- Clearly distinguish research from treatment

Consenting

Requirements

A valid Part 2 consent must include:

- Patient name
- Specific name of program making disclosure
- Specific recipient(s)
- Description of information
- Purpose of disclosure
- Expiration date or event
- Patient signature and date

Exceptions

Disclosure without consent is allowed only in limited cases:

- Medical emergencies
- Court orders (strict process required)
- Child abuse reporting
- Crimes on program premises
- Audits and program evaluation

42 CFR Part 2 – Scientific Research with Consent Waiver

SUD data can be disclosed to researchers without consent for "scientific research" if certain conditions are met. If researchers are requesting linkages to data sets from data repositories: 42 CFR § 2.52(b)

1) the request must be approved by an IRB "to ensure that patient privacy is considered and the need for identifiable data is justified;"
2) no data can be disclosed to law enforcement; and
3) data linkages cannot be redisclosed, except as permitted by law. 42 CFR § 2.52(c)(1).

Finally, after the data is provided, the linked data must be deleted or destroyed and researchers who receive patient identifying information are prohibited from redisclosing the information to anyone except back to the program. 42 CFR § 2.52(c)(2)

Key Take Aways

SUD records are more protected than most medical records.

42 CFR Part 2 is the strictest governing rule.

105 CMR 164.083 & MGL c. 111E § 18 Massachusetts law reinforces federal protections.

Research use requires additional safeguards.

Always follow the most restrictive applicable rule.

Genetic Information Nondiscrimination Act —GINA



Definition of Genetic Information

Genetic information is the set of biological instructions, stored in DNA within every cell, that tells an organism how to grow, function, and develop. Often described as a blueprint, code, or instruction manual. It is passed down from parents to children.

In regulation, genetic information is often referenced in different ways:

Genetic tests of an individual	Genetic tests of family members	Family medical history	Participation in genetic research

Genetic Information Nondiscrimination Act (GINA) Overview

Federal and state protections make it unlawful for most employers and health insurers to discriminate based on genetic information. GINA applies to clinical research by influencing consent concerns, data handling and participant fears about discrimination.

- The Genetic Information Nondiscrimination Act of 2008 (GINA) is the federal law.
- MGL c. 175, §§ 114-161E is the Massachusetts law specifically prohibiting insurance discrimination based on genetic information.
- M.G.L. c. 111, § 70G is the Massachusetts law for disclosure of genetic information.

Why Genetic Privacy Matters



Massachusetts Genetic Privacy Law M.G.L. c.111 §70G

Employment Protection (Title II): Employers with 15 or more employees cannot use genetic information in hiring, firing, or promotion decisions. They are restricted from requesting, requiring, or purchasing genetic info.

Health Insurance Protection (Title I): Health insurers cannot use genetic information to determine eligibility, coverage, or premiums. It also prohibits insurers from requiring genetic testing.

Definition of Genetic Information: Includes family medical history (showing diseases in family members) and results of genetic tests.

Massachusetts Specifics: Massachusetts law reinforces these protections, prohibiting the requirement of genetic tests for life insurance policies, while also addressing referral to a genetic counselor.

Limitations: GINA does not cover life insurance, disability insurance, or long-term care insurance. It also does not cover routine tests like blood counts or cholesterol.

Research Applications: While GINA does not generally prohibit research, it protects research participants from having their genetic data used against them by employers or health insurers.

Why GINA Matters in Research

Research often collects:

DNA samples	Genomic sequencing data	Family history	Biobank specimens

GINA protects participants from discrimination based on participation or findings.

Confidentiality in Genetic Research

GINA includes confidentiality requirements:

- Genetic information must be treated as confidential medical information.
- Employers must store it separately from personnel files.
- Limited disclosure is permitted.

Research institutions typically use:

- IRB oversight
- Data encryption

De-identification

GINA & Informed Consent in Research

When collecting genetic data consent forms typically address:

- Risks of re-identification
- Limits of GINA protections
- Insurance limitations (life/disability not covered)
- Future data use
- Referral for genetic counseling

Participants should understand both protections and gaps.

Baystate utilizes a genetic rider with its consent documents to meet these state requirements.

Key Takeaways

- GINA prevents discrimination in employment and health insurance.
- Participation in genetic research is protected.
- Massachusetts law adds additional consent requirements.
- GINA does not cover life or disability insurance.
- Research consent must clearly explain both protections and limits.

Case Study - **Prenatal Genetic Testing and GINA Protections**

Patient Profile: 33-year-old female, 12 weeks gestation, enrolled in a prenatal research study.

Clinical Scenario:

During a research-integrated prenatal visit, the patient underwent Cystic Fibrosis (CF) carrier screening. Results identified her as a carrier of the delta F508 mutation. Subsequent testing of her partner revealed he carried a different CFTR mutation, giving the couple a 25% risk of having a child with CF. The couple is now considering amniocentesis for prenatal diagnosis but expresses concern regarding whether a positive diagnosis would be labeled a "pre-existing condition" for their child's future health insurance.

1. Who is responsible for the counseling referral?
2. Any consent form considerations?
3. Are there any protections for the family under GINA?

1. Who is responsible for the counseling referral?

The **lead researcher or the clinician** overseeing the prenatal care within the study is responsible for the referral. When a screening returns a high-risk result (like a 1 in 4 chance of a genetic disorder), the provider must ensure the patient has access to a certified genetic counselor to discuss diagnostic options (amniocentesis), Reproductive risks, and the implications of the Genetic Information Nondiscrimination Act (GINA).

2. Any consent form considerations?

Whether data can be shared depends on the **Informed Consent** and **HIPAA authorization** signed at enrollment:

- **Research Team:** Since the testing was part of the study protocol, the research team inherently has access to the data to fulfill study objectives.
- **Primary Care:** Information can only be shared with the patient's primary care physician if the patient has provided explicit written consent to do so.

3. Are there any protections for the family under GINA?

GINA protects individuals from discrimination by health insurers and employers based on genetic information.

Protected Data Includes:

- **Family History:** Carrier status of the parents or history of CF in the family.
- **Prenatal Results:** DNA results from the fetus obtained via amniocentesis or CVS.
- **Newborn Results:** Both biochemical screening (IRT levels) and definitive DNA testing for the infant after birth.

Key Limitation: While GINA prohibits using genetic information to determine eligibility or premiums, it **does not** govern "manifest disease." If the child is born and begins showing clinical symptoms of CF, the diagnosis transitions from "genetic information" to "manifest disease," at which point coverage for specific treatments is subject to the standard terms of the insurance provider (though the Affordable Care Act further protects against pre-existing condition exclusions).

Questions

When in doubt, reach out to the Human Research Protection Program (HRPP) team!

We're here to help.

Thank You!
Please register & provide a review of this presentation.
Your feedback is important.

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