

# The Texas Immunization Registry: Consent Overview

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## Background on Consent

Individuals are often given several consent forms to fill out at a provider's office or while at a healthcare facility. These consent forms vary in their meaning and usage. Some are used to determine the individual's preference for sharing their medical information with certain individuals or entities, others are used to obtain the individual's consent to receive treatment.

The Texas Immunization Registry (TIR), also known as ImmTrac2, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require individuals to sign types of consent to share their Protected Health Information (PHI).

## Purpose

This document will assist healthcare providers, clinical staff, and technical staff (such as electronic health records vendors) understand:

- The difference between registry consent and other types of consent,
- How consent to share information differs from registry consent,
- Responsibilities for reporting patient and immunization information based on federal guidelines and state laws,
- State laws pertaining to registry consent, and
- Frequently asked questions (FAQs) related to consent.

## Various Types of Consent

### Registry Consent

- The TIR has an official consent form for individuals to sign up (opt-in) to the registry and have their personal and immunization information stored in the registry.
- The TIR consent forms are required by state law and providers must abide by these laws.
- TIR consent can be captured electronically via tablet or a signature pad but no alterations to the TIR consent form can be made. More information on this can be found in the **Electronic or Digital Consent** section

### Consent to share

- Consent form used for granting or not granting permission for an individual's healthcare provider to share the individual's personal and medical information with medical staff within the healthcare facility or practice, family or friends, state agencies or programs (i.e., the state immunization registry), or similar entities.

### Consent for treatment

- Consent form to obtain an individual's consent to receive treatment or services.
- Often used to inform individuals of possible side-effects or concerns related to treatment or medication.

## Consent to Share vs Registry Consent

Regardless of whether individuals grant or do not grant their immunization data to be shared with the state registry, healthcare providers and entities must report the data to the TIR. This is in accordance with federal guidelines and Texas legislation.

The registry has mechanisms in place to ensure individuals who have not previously signed a registry consent form are not inadvertently added (i.e., including immunizations).

## State Laws and Federal Guidelines

### Texas Laws for Registry Consent

The Texas Administrative Code (TAC), Rule §100.4, requires individuals to give their written permission (via an official registry consent form or valid

electronic registry consent form) for their personal and immunization information to be stored in the registry. TIR is HIPAA compliant.

The registry's minor consent form covers an individual until they turn 18 years of age. At the age of 18, an individual must sign the registry's adult consent form to have their childhood immunizations retained in the registry for their lifetime. If the individual does not sign the registry's adult consent form prior to their 26<sup>th</sup> birthday, their records will be purged. The registry's adult consent form covers an adult for life for any provider.

Once a provider receives a signed registry consent from a patient, the provider must add the patient to the registry as a client (TIR has trainings available on how to perform this task). The signed registry consent form is retained by the provider and saved in the patient's medical record.

### **NOTES:**

- For organizations with full access to ImmTrac2, such as most clinical providers, it is the responsibility of the provider to store and retain all original signed registry consent forms. These forms should not be sent to the registry except at the registry's instruction.
- Organizations with limited access to ImmTrac2, such as most schools, should coordinate with their local or regional health department to determine the correct procedure for processing and storing signed registry consents.

## **Electronic or Digital Consent**

Digitized registry consent forms must contain all the same text and content as the most current official state registry consent forms and all of the same client information must be filled out to be valid. Alterations to the text and content are not allowed.

Digitized consent forms are subject to the same retention, production, and disposal requirements as written consents.

For the most recent versions of the official state registry consent forms, visit the Texas Department of State Health Services – Immunization Registry website at <https://www.dshs.texas.gov/immunize/immtrac/forms.shtm>. The registry consent forms are:

- Immunization Registry – Minor Consent Form is identified as C-7
- Immunization Registry – Adult Consent Form is identified as F11-13366

## Texas Laws for Reporting Data

Texas Administrative Code, Rule §100.6, mandates all healthcare providers and payors report all immunizations administered to any individual younger than 18 years of age to the TIR regardless of knowledge of consent into the registry.

## Federal Guidelines for Reporting Patient Data

The Centers for Medicare and Medicaid Services (CMS) recommends all healthcare providers and entities, especially those participating in Promoting Interoperability, to report all patient and immunization data to their state immunization registry regardless of an individual's consent to share preference.

## Frequently Asked Questions Related to Consent

### What is **NOT** covered by the registry consent form?

Registry consent does **NOT** allow providers to directly share an individual's demographic or immunization records with anyone other than the registry and does not cover the sharing of any other form of PHI.

### Do we need consent to share PHI from the patient before we can send records to the registry?

No. Providers are covered by HIPAA guidelines for reporting to Public Health Authorities and by the TAC to send all immunization records to the registry without needing any type of consent. The registry will accept or reject records based on the individual's registry consent status.

### What should we do if a patient chooses not to grant consent to share and/or registry consent? What should we do if a patient chooses not to grant consent for the registry and/or grant consent to share?

Continue to report all immunization records to the registry. Providers are required by state law to report ALL immunization records for minors and under guidance from CMS, providers should report all immunization data to the registry, regardless of age.

### Do we need to track our patients' registry consent status?

Providers must retain original copies of all signed registry consent forms they receive and be prepared to present them if requested. However, because registry consent may have been originally granted elsewhere, providers are **NOT** required to know the current registry consent status of their patients and should not keep logs of patients who refuse consent.

## **How does consent to share PHI differ from registry consent?**

Unlike registry consent, there is not a standardized consent to share PHI form. Instead, most consent to share PHI forms are unique to the organization that uses them. A typical consent to share PHI form that follows HIPAA guidelines grants provider permission to share an individual's PHI with others within certain constraints. There is a significant variation in what a specific provider's consent to share forms will cover. If you have any questions about the consents used by your organization, you should direct them to the appropriate individual within your organization.

## **Can a consent to share PHI form be used to add patients and/or their immunization records to the registry?**

No. Consent to share PHI does **NOT** cover affirming an individual with or storing their immunization records in the registry. Only the Texas Immunization Registry (ImmTrac2) Consent Forms, either "Minor Consent Form", C-7 or "Adult Consent Form" F11-13366, may be used to consent and affirm patients in the registry.

## **Can we add the registry consent language to our own consent forms?**

No. Only official TIR consent forms may be used to collect consent for TIR. Organizations may make electronic versions of the consent forms, but the form's language may not be altered in any other way. If using electronic consent, a process must be in place for ensuring that the most recent version of each form's language is used. Contact the Texas Immunization Registry for additional information or support.

## **How do providers add patients as registry clients?**

Providers can add patients as registry clients using the web-based ImmTrac2 application or via electronic data exchange. TIR offers training resources on both these methods. For more information contact us.

## **Registry Contact Information**

For more information and support contact the Texas Immunization Registry.

Email: [ImmTrac2@dshs.texas.gov](mailto:ImmTrac2@dshs.texas.gov)

Phone: 800-348-9158

Website: <https://www.dshs.texas.gov/immunize/immtrac/>