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Registry Consent and Electronic Affirmation

Texas Immunization Registry

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Introduction

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Overview

- Registry Consent and Affirmation
- Types of Consent
- Withdrawal of Consent
- Manual Affirmation
- Electronic Affirmation Methods
- Importance to Providers

Terminology

Terminology we will use in this presentation:

- BiDX = Bidirectional data exchange
- FTP = File Transfer Protocol
- Registry = Texas Immunization Registry
- Orgs = Providers, healthcare entities, organizations
- EHR = Electronic Health Records systems

Registry Consent



Registry Consent Overview

What is Registry Consent?

- Unique form of consent specific to the registry
- Registry consent required by the Texas Administrative Code
 - Once as a minor
 - Once more after turning 18
 - Covers all providers



Legislation

- Texas HB 2641 requires the use of data standards for systems implemented after Sept. 1, 2015
 - ImmTrac2 predates this, but use of Health Level 7 (HL7)
- Texas Administrative Code requires consent to be granted before the registry may store any records
 - §100.4 Consent for minors
 - §100.7 Consent for disasters
 - §100.8 for first responders and their family



Non-consented Patients

- Records for non-consented patients must be rejected by the registry
 - Disaster related Antiviral and Immunization Medications (AIMs) are an exception
 - Disaster related AIMs are kept for 5 years



Types of Registry Consent

- Minor Consent Form
 - Allows parents or legal guardians to give consent for a minor
- Adult Consent Form
 - Allows an adult to grant consent for themselves
- Disaster Consent Form
 - Allows disaster related AIMs to be stored indefinitely



Affirmation

What is Affirmation?

- Process of orgs notifying the registry of a patient's signed registry consent form
 - Online via ImmTrac2
 - Electronically via Electronic Health Records (EHR) system



Withdrawal of Consent

- Patients may withdraw their consent from the registry at any time
 - Request must be sent to the registry in writing
 - ALL record of that person is removed
 - Patients are asked to notify their providers
 - At their own discretion



Important Note

- Consent should only be affirmed once
 - Do NOT send consent with every immunization message
- Reaffirming without a new signed consent is a violation of Texas law



Manual Affirmation



What is Manual Affirmation?

What is Manual Affirmation?

- Adding patients using ImmTrac2
- Same method as prior to data exchange
- Most common method of affirmation for FTP
- Not an option for Bidirectional Data Exchange
 - Bidirectional is too fast for Manual Affirmation



Log in to ImmTrac2

- Log in to ImmTrac2
- Use the right org code
 - This site will get credit



The screenshot shows a login interface with a blue header containing the word "Production" and a dotted line separator. Below the header are three input fields: "Org Code:", "Username:", and "Password:". A "Login" button is positioned at the bottom right of the form.



Enter New Client

- Click *enter new client*



Smart Search

- Fill out patient information
- Click *Find*

Client Search

* Required Field

Smart Search ▾

ImmTrac2 ID

* First Name Mother's First Name

* Last Name Mother's Maiden Name

Middle Name Phone - -

* Birth Date * Street Address

* Gender Other Address

PO Box

Zip -

City

State TX ▾



Add A Client

- If found, stop. The patient already has consent.
- If new, select *Add a client*
- *Submit*

If your client does not appear on your search result Client List. Add the client by responding to the consent-related question below.

Do you have one of the following signed consent forms for your client?

Yes Add a client

No Request a Consent Form

* If you have also obtained consent to retain disaster-related information beyond the minimum retention period, you will have the opportunity to affirm this consent at the same time you affirm consent for ImmTrac2 participation.

DISASTER-RELATED INFORMATION

During a disaster or emergency event, all residents in the affected area who receive disaster-related vaccinations, antivirals, and/or medications will participate in ImmTrac2 regardless of age or consent status. If you are **ONLY** adding a disaster-related client, **ADD the client by selecting one of the options below:**

ADD CLIENT WITH Signed Disaster-Related Consent

WITHOUT Signed Disaster-Related Consent

Submit



Client Information

- Add additional information
- Click *Continue Add*

The screenshot shows a web form titled "Personal Information" with the following fields and values:

- * First Name: Test
- * Last Name: Fake
- Middle Name: (empty)
- Suffix: (empty)
- * Birth Date: 08/09/1982
- Mother's Maiden Last: (empty)
- * Mother's First Name: test
- Client Type: (empty)
- * Gender: FEMALE
- SSN: (empty)
- Medicaid ID: (empty)
- Birth Order: (empty) (for multiple births)
- Birth Country: UNITED STATES
- Birth State: (empty)
- Birth County: (empty)
- Client Identifier: (empty)
- ImmTrac2 ID: (empty)
- Disaster Client: No

At the bottom of the form, there are several expandable sections:

- Consent Information ▼
- Client AKA (0) ▼
- Organization Information ▼
- Client Information ▼
- Address Information ▲

Buttons for "Continue Add" and "Cancel" are located in the top right corner of the form.



Client Summary

- Review the summary
- Click *Continue* if everything is correct

Client Summary

Please review the following information for accuracy. If anything is incorrect, use the Edit button to make necessary changes. Otherwise, if all information is correct, select the Continue button to proceed with addition of this client's information.

Add Client Summary	
Last Name	Fake
First Name	Test
Middle Name	
Suffix	
Date of Birth	08/09/1982
Sex	F
Race	

Client Address Information

Edit Client Info

Continue

Cancel



Affirm Consent

- Select the type of consent
- Click *Affirm*

Consent Verification

Affirm Consent For:

ImmTrac2 Adult (age 18 and older) *(Signed Adult Consent form on file)*

First Responder (age 18 and older)

Adult Family Member of a First Responder (age 18 and older)

With consent to retain disaster information beyond minimum time ***(Signed Disaster Information Retention Consent form on file)***

OR During a disaster or emergency event, all residents in the affected area who receive disaster-related vaccinations, antivirals, and/or medications will participate in ImmTrac2 regardless of age or consent status. If you are ONLY adding a disaster-related client, ADD the client by selecting one of the options below.

Affirm Disaster-Only Client:

With consent to retain disaster information beyond minimum retention period *(Signed Disaster Information Retention Consent form on file)*

Without consent to retain disaster information beyond minimum retention period *(No consent forms on file)*



Manual Affirmation Overview

- Add soon after receiving consent (within 24 hours)
- More details in ImmTrac2 training video



Electronic Affirmation



What Is Electronic Affirmation?

What is Electronic Affirmation?

- Affirmation using a data exchange connection



Texas Department of State
Health Services

Methods of Electronic Affirmation

- Two methods to send affirmation of registry consent via data exchange:
 - Affirmation files
 - HL7 Affirmation
- Both use the current data exchange connection



Methods of Electronic Affirmation *(continued)*

- Electronic affirmation is important for BiDX
- Providers collect signed registry consent and document consent electronically
- Providers will retain the signed registry consent



Affirmation Files

- Simple text file that contains information needed to affirm a patient in the registry
- Uses precise spacing, not HL7
- Cannot be sent with Antiviral, Immunization, and other Medication (AIM) records
- Must be sent BEFORE AIM records



Affirmation File Specifications

- Specifications covered in *Electronic Standards for Affirmation of Registry Consent*
- Affirmation File consent types:
 - A – Adult consent
 - Y – Minor consent
 - D – Disaster consent



HL7 Affirmation

- HL7 Affirmation
 - Uses a unique set of codes developed for the Texas Immunization Registry
 - Sends affirmation with immunization messages
- One webservice connection for VXU, QBP, and affirmation messages
 - No timing problems
 - Requires special setup and upgrades for most EHRs



Changes for HL7 Affirmation

- Specifications covered in the *Affirmation of Registry Consent via Health Level Seven* Guide
- MSH-22: Affirming site's TX IIS ID number
 - Should be the same as RXA-11.4
- PD1-12: Unique code for registry consent type
 - 'Y' and 'N' are not used by the registry
- PD1-13: Date registry consent was signed



HL7 Consent Codes

- HL7 consent uses a unique set of codes
 - TXY – Minor Consent
 - TXA – Adult Consent
 - TXD – Disaster Consent



When to Transmit Records

	Registry Consent	No Registry Consent
Consent to Share	✓ Yes	✓ Yes
No Consent to Share	✓ Yes	✓ Yes

- ✓ **Records should always be transmitted to the registry!**
- Never withhold records due to consent
- Registry consent is reviewed by the registry



Improvements for Providers

- Electronic affirmation improves acceptance rates
- More complete and accurate records in the registry
- Improved workflows, less manual processing



Resources



Resource Guides

- *Electronic Data Exchange Resource Guide, #11-15231*
- *Informational Guide on Bidirectional Data Exchange, #11-15957*
- *Registry Consent Overview, #11-15702*
- *Electronic Standards for Affirmation of Registry Consent, #E11-13415*
- *Affirmation of Registry Consent via Health Level Seven, #11-15773*
- www.dshs.texas.gov/immunize/immtrac/forms.shtm

Email

- ImmTrac2@dshs.texas.gov

Access, site registrations or renewals, ImmTrac2 user changes, registry trainings or publications

- ImmTracMU@dshs.texas.gov

Data exchange questions, promoting interoperability, data quality reports

Thank you!

Registry Consent and Electronic Affirmation

Q & A

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Access, site registrations or renewals, etc.

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Data exchange and promoting interoperability