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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 fact for Manual Affirmation



# Log in to ImmTrac2

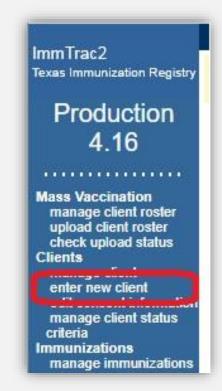
- Log in to ImmTrac2
- Use the right org code
  - This site will get credit





## **Enter New Client**

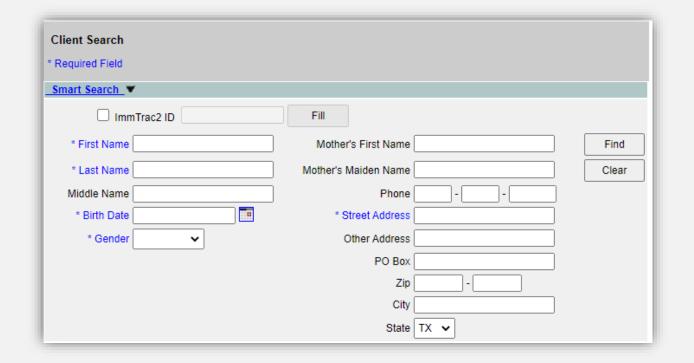
• Click enter new client





### **Smart Search**

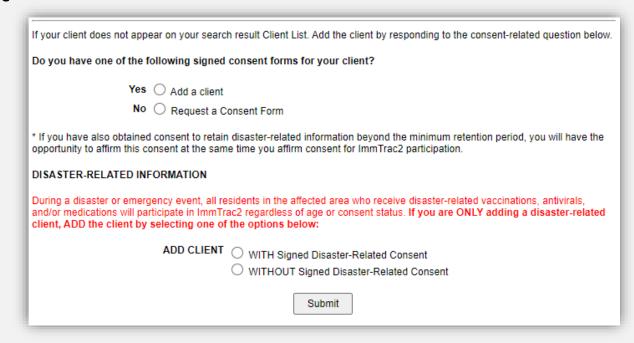
- Fill out patient information
- Click Find





### **Add A Client**

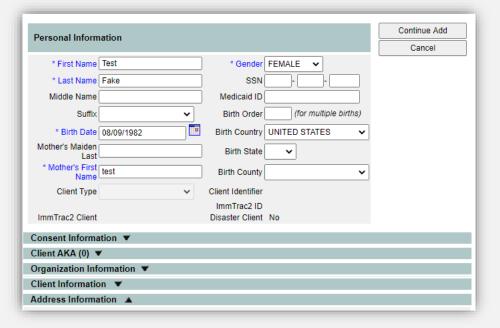
- If found, stop. The patient already has consent.
- If new, select Add a client
- Submit





## **Client Information**

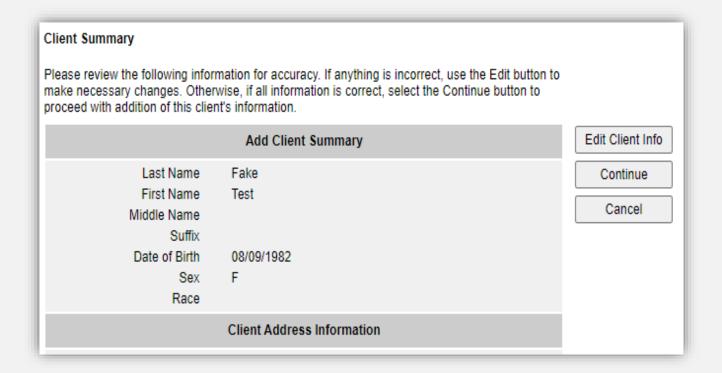
- Add additional information
- Click Continue Add





# **Client Summary**

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

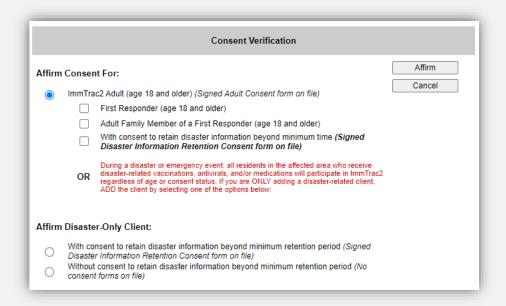




**Health Services** 

## **Affirm Consent**

- Select the type of consent
- Click Affirm





#### **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



#### **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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Data exchange and promoting interoperability