



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Texas Vaccines for Children and Adult Safety Net Program

New Enrollment Checklist



Texas Department of State Health Services

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TVFC

Vision and Mission

Vision: A Texas free of vaccine-preventable diseases.

Mission: To provide leadership to increase vaccine coverage levels and reduce the burden of vaccine-preventable diseases for all Texas infants, children, adolescents, and adults.

Supplies

Available from DSHS VOG staff:

- Landscape clipboard (to hold temperature recording form).
- Fine point pen (for documenting temperatures).
- Command strip to hold clipboard.
- Pen holder.
- Plug guards.
- Data logger(s), with certificate of calibration and docking station.
- Backup data logger.
- Room thermometer.
- Trays/bins for vaccine storage in refrigerator and freezer.
- Handle with Care, Save Vaccine, Save Money poster, stock no. 11-13794.
- Vaccine quarantine bags.
- Storage and Handling What You Need to Know DVD, stock no. DV0684-11.

Available from:

https://marcomcentral.app.pti.com/printmailpro/printmailproetail/login.aspx?uigroup_id=3500

- Recommendations for Storage and Handling poster, stock no. 6-26P.
- Recommended immunization schedules for children (stock nos. 6-105 & 6-105L [Laminated]) and adults (stock nos. 6-104 & 6-104L [Laminated]).
- Refrigerator warning signs for vaccine storage “Do not disconnect”, “Do not unplug” sign/stickers (refrigerator warning signs for vaccine storage), stock no. 6-180.
- Giving all the doses, stock no. 11-12155.
- Contraindications and Precautions poster, stock no. 6-61.

Available from

<https://www.dshs.texas.gov/immunize/tvfc/publications.aspx>:

- The most current TVFC/ASN Provider Manual.
- TVFC Patient Eligibility Screening Record, stock no. C-10.
- Monthly Vaccine Report-Form, stock no. C-33.
- Combined Tally and Physical Inventory, stock no. C-88.
- Vaccine Management Plan Templates, stock no. E11-14498.
- Best Practices Refrigerated Vaccines, stock no. E11-14481.
- Best Practices Frozen Vaccines, stock no. E11-14482.
- Vaccine Temperature Best Practices, Freezer, stock no. E11-14483.
- Vaccine Temperature Best Practices, Refrigerated, stock no. E11-14484.
- Vaccine Transfer Authorization Form, stock no. EC-67.
- Pediatric Biological Order Form, stock no. EC-68-1.
- Temperature Recording Forms for Refrigerator and Freezer in Fahrenheit or Celsius, stock nos. EC-105-FC, EC-105-FF, EC-105-RC, and EC-105-RF.
- Storage Calculation Tool and Instructions, stock nos. EF11-13613 and E11-13605.
- Vaccine Borrowing Form, stock no. EF11-14171.

Available from

<https://www.dshs.texas.gov/immunize/ASN/publications.aspx>:

- Adult Biological Order Form, stock no. EC-68-2.
- Adult Eligibility Screening Record, stock no. EF11-12842.

Available from

www.dshs.texas.gov/immunize/school/publications.aspx:

- Communicable Disease Chart, stock no. 6-30.

- Texas Minimum State Vaccine Requirements for Students Grades K - 12, stock no. 6-14.
- Texas Minimum State Vaccine Requirements for Child-Care and Pre-K Facilities, stock no. 6-15.
- FAQs about Vaccine Exemptions for Reasons Conscience, stock no. E11-13159.
- FAQs about Questions on Immunization Requirements for School Admittance, stock no. E11-13160.
- Request for Exemptions from Immunizations for Reasons of Conscience, stock no. EF11-13140.

Available from

[http://www.dshs.texas.gov/idcu/investigation/conditions/:](http://www.dshs.texas.gov/idcu/investigation/conditions/)

- Texas Notifiable Conditions List, stock no. E59-11364.

Available from

[https://www.dshs.texas.gov/idcu/investigation/forms.aspx:](https://www.dshs.texas.gov/idcu/investigation/forms.aspx)

- Varicella Reporting Form, stock no. F11-11046.

Available from [https://vaers.hhs.gov/:](https://vaers.hhs.gov/)

- Vaccine Adverse Event Reporting System (VAERS).

Available from [www.immunize.org:](http://www.immunize.org)

- Summary of Recommendations for Children & Teens, stock no. P2010
<http://www.immunize.org/catg.d/p2010.pdf>.
- Summary of Recommendations for Adults, stock no. P2011 <http://www.immunize.org/catg.d/p2011.pdf>.
- How to Administer IM/SC, stock no. P2020 & P2020a
<http://www.immunize.org/catg.d/p2020.pdf>.
- "It's Federal Law! You Must Give Your Patients Current VISs", stock no. P2027
<http://www.immunize.org/catg.d/p2027.pdf>.
- List of Current Vaccine Information Statements, stock no. P2029 <http://www.immunize.org/vis/>.
- Administering Vaccine, (Pedi), stock no. P3085
<http://www.immunize.org/catg.d/p3085.pdf>.

Supplies

- Administering Vaccine, (Adult), stock no. P3084
<http://www.immunize.org/catg.d/p3084.pdf>.
- Screening Checklists for Contraindications to Vaccines for Children and Teens, stock no. P4060
<http://www.immunize.org/catg.d/p4060.pdf>.
- Screening Checklists for Contraindications to Vaccines for Adults, stock no. P4065
<http://www.immunize.org/catg.d/p4065.pdf>.
- Screening Checklist for Contraindications to Inactivated Influenza Injectable Vaccination, stock no. P4066
<http://www.immunize.org/catg.d/p4066.pdf>.

Available from www.cdc.gov:

- Contraindications and Precautions, Table 4-1
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html#t-01>.
- Current immunization schedules
<https://www.cdc.gov/vaccines/schedules/index.html>.
- Vaccine labels
www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf.
- CDC Vaccine Storage & Handling Toolkit
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>.

Required trainings

Available from www.vaccineeducationonline.org:

- The most current TVFC/ASN Provider Policy Training.

Available from

www.cdc.gov/vaccines/ed/youcalltheshots.html:

- Module 10: Vaccine Storage and Handling.
- Module 16: Vaccines for Children Program.

Other

- Business card.

Supplies

- Sheet protectors (for Vaccine Management Plan, and the data logger certificates).
- Magnets (to assist in holding sheet protectors with documents inserted).
- Other incentives.

Supplies

TRAINING TYPE	NEW clinics to the TVFC/ASN Program	Currently enrolled clinics with NEW staff	All clinics at re-enrollment
TVFC/ASN Provider Policy Training www.vaccineeducationonline.org	REQUIRED	REQUIRED	REQUIRED
CDCs You Call the Shots: <u>Module 10: Vaccine Storage & Handling</u> and <u>Module 16: Vaccines for Children Program</u> www.cdc.gov/vaccines/ed/youcalltheshots.html	REQUIRED	REQUIRED	RECOMMENDED
Site visit training conducted by RE	REQUIRED	RECOMMENDED (if available)	RECOMMENDED (if available)
Group training conducted by RE	REQUIRED FOR SOME	REQUIRED FOR SOME	RECOMMENDED (if available)
Annual training conducted by RE	REQUIRED FOR SOME	REQUIRED FOR SOME	REQUIRED FOR SOME
EVI Training Webinar https://register.gotowebinar.com/recording/466799160867767297	RECOMMENDED	RECOMMENDED	RECOMMENDED

Initial Contact/Visit

The RE must provide education to the new or returning clinic staff about the TVFC/ASN Program using the most current DSHS TVFC/ASN Provider Manual. All new or returning clinics to the TVFC/ASN Program must receive an initial contact/visit prior to receiving vaccine that includes all the following elements.

Check each item as they are communicated to clinic staff.

- Assist in filling out the enrollment form for TVFC or ASN (if not already completed).
- Review each bullet on the enrollment form with the staff to facilitate understanding.
- Stress CHIP patients cannot be seen unless the clinic bills CHIP for the administration fee.
- Provide guidance for collecting information for the patient population section of the enrollment form.
- Describe TVFC/ASN record retention requirement (5 years).
- Educate staff on documentation requirements when accidental borrowing occurs.
- Inform staff about site reviews (by contractor and unannounced).
- Describe TVFC and ASN eligibility criteria.
- Stress the maximum to charge a non-Medicaid and non-CHIP client is \$14.85 per dose of TVFC vaccine, and \$25.00 per ASN dose of vaccine.
- Inform staff Medicaid or CHIP patients must not be charged any out-of-pocket expenses.
- Inform clinic staff that transferring vaccine from one clinic to another is not allowed.
- Describe fraud and abuse.
- Identify staff that will serve as a primary and back-up coordinator.

- Ensure both coordinators have taken the required trainings. Staff at newly enrolled sites must have their primary and back-up vaccine coordinators complete the most current TVFC/ASN Provider Policy Training available at www.vaccineeducationonline.org and CDC “You Call the Shots” training modules (module 10: Vaccine Storage & Handling and module 16: Vaccines for Children Program) available at www.cdc.gov/vaccines/ed/youcalltheshots.html. The same training requirements apply to existing clinics with new vaccine coordinators.
- Gather training certificates for the primary and back-up coordinators for the required trainings.
- Explain VAERS and how to report.
- Describe the importance of notifying the RE when the facility name, signing clinician, prescribing authorities or patient population has changed.
- Describe Standards for Pediatric Immunization Practices (article is listed under Helpful Resources) <https://www.dshs.texas.gov/immunize/schedule/>.
- Describe Standards for Adult Immunization Practice <https://journals.sagepub.com/doi/pdf/10.1177/003335491412900203>.
- Suggest staff bookmark www.immunizetexas.com on their computer for access to the most current TVFC/ASN Provider Manual, forms, and other information.
- Suggest staff bookmark www.cdc.gov on their computer for access to contraindications and precautions.
- Suggest staff bookmark www.immunize.org on their computer for access to immunization questions.
- Suggest staff bookmark www.dshs.texas.gov/immunize/immtrac/default.shtm to access ImmTrac2, Texas’ Immunization Registry.

- Assist staff with subscribing to the TVFC/ASN Provider Digest
<https://www.dshs.texas.gov/immunize/ImmunizationNews/The-TVFC/ASN-Digest/>
- Discuss the importance and benefits of ImmTrac2.
- Assist staff with registering their organization with ImmTrac2 (if necessary).
- Educate staff on reporting requirements to ImmTrac2 when vaccinating patients younger than 18 years of age. Research, if necessary, the site's ImmTrac2 org code and suggest they keep it nearby.
- Inspect the type of units in place (refrigerator and freezer)
 - If combo unit, strongly recommend a stand-alone freezer.
 - A dorm style unit that has a freezer behind a refrigerator door, is NOT allowed for storage of TVFC/ASN vaccine at any time.
- Discuss the requirement of water bottles in the fridge and freezer.
 - Mark as "do not drink".
 - Define "sufficient" (all empty space).
 - Caution about putting too many in the doors.
- Discuss that ice packs are not allowed in the refrigerator or freezer.
- Discuss that flat, hard-sided "water containers" are not allowed.
- Discuss the requirement that food or drinks are NOT allowed in units that contain TVFC/ASN vaccine at any time. Discuss the proper placement of vaccines in the units.
 - Not in the doors.
 - Not on the top shelf close to the unit ceiling and vents.
 - Not in the vegetable bins.

- Not on the floor of the unit.
 - Not against walls.
 - Not against back of unit.
 - In the middle of the unit.
 - 2"-3" between vaccines.
 - Kept in original boxes with lids closed until ready for administration, unless stored in an auto-dispensing unit that requires vaccines to be removed from original packaging.
 - Use baskets/bins.
 - Rotate stock to use shortest expiration first.
 - Label clearly for pedi/adol/adult and private/TVFC/ASN.
- Demonstrate how to properly locate bins to hold vaccines without crowding.
 - Demonstrate how to label each bin, with the pediatric vaccines separate from the adolescent and the adult (if applicable).
 - Verify that the serial numbers of the data logger(s) match the certificates of calibration, and that expiration dates are current.
 - Review all data logger(s) (including a back-up) that will be used for monitoring the storage of TVFC/ASN vaccine to ensure they are functional and meet compliance requirements.
 - Place data logger probe(s) in the unit(s) to begin taking the temperature or verify the probe is correctly placed.
 - Review the proper use of the data logger (if provided by responsible entity).
 - Setting appropriate ranges.
 - Checking and documenting min/max in the morning and resetting the min/max before leaving for the day, if the data logger requires this.
 - Acknowledging alarms.

- Running reports.
 - Recommend downloading weekly, preferably on Mondays.
- Educate staff on temperature ranges for refrigerator and freezer, clarifying Fahrenheit and Celsius.
- Explain the requirement of maintaining data logger certificates and having them readily available.
- Explain the requirement of a back-up data logger and when it should be used.
- Explain the requirement of why a primary and back-up data logger must not have the same expiration dates.
- Review proper documentation of recording temperatures to inform staff to not round the numbers up or down – record only the number to the left of the decimal point.
- Educate staff on how to read current, min and max temperatures from the data logger and demonstrate how to properly document the information on the EC-105.
- Educate staff on the requirement of submitting all EC-105s monthly to RE.
- Assist in filling out the vaccine management plan templates.
- Install plug guard or strongly encourage staff get it installed (this is a Texas requirement).
- Install “do not disconnect”, “do not unplug” signs at outlets, on refrigerator(s) & freezer(s) and on circuit breakers or strongly encourage staff to get them installed.
- Using the storage & handling poster, stock no. 6-26P, inform that:
 - Open or multi-dose vials of vaccine do not expire until the expiration date.
 - Some vaccines must be protected from light.
- Discuss the reasons why vaccines should be kept in their original boxes, with the lids closed.

- Discuss that there are some vaccines that require diluents and others that require mixing.
- Discuss the importance of reviewing vaccine choices carefully – single dose vials, multi-dose vials, pre-filled syringes, and preservative free.
- Review steps staff must take in the event of a temperature excursion either in the current temperature or the min/max (immediately contacting the RE, and vaccine manufacturers).
- Explain that the temperature of the room is required to be recorded on the temperature recording form, page 1 and 3, when a temperature excursion occurs.
- Explain that page 3 of the temperature recording form must be filled out completely and submitted following an excursion.
- Review steps necessary to transport vaccine in the event of an emergency (loss of electricity, unit failure, etc.) and discuss the importance of having packing supplies on-hand.
 - Hard-sided insulated or Styrofoam cooler(s).
 - Conditioned water bottles (enough for 2 layers).
 - Corrugated cardboard (enough for 2 layers).
 - Bubble wrap or other material (2") (enough for 2 layers).
 - Valid calibrated back-up data logger.
 - Ensure receiving facility agrees to receive vaccine in an emergency.
- Provide copies and review immunization schedules for children, adolescents, & adults (if applicable).
- Explain the federal law that requires all patients must receive a VIS prior to vaccine administration.
- Discuss maximum stock levels and how they are calculated.

- Assist with filling out the biological order form, EC-68-1, or EC-68-2 (if applicable) to set MSLs and select vaccine choice.
- Review and explain vaccine choice.
- Inform the clinic staff that vaccine choice is opened quarterly and is found on the "Welcome Tab" in EVI.
- Discuss the effects of splitting percentages for vaccine choice and how it may impact maximum stock levels.
- Ensure the staff are aware of how to contact you or others at your office.
- Request 7 operational days of temperature monitoring on EC-105(s).
- Explain that longer temperature monitoring may be required if stabilization is not achieved within the first 7 operational days of monitoring the storage unit(s).
- Discuss the requirements of notifying RE about vaccine expiring in the next 60-90 days.
- Inform staff to not refuse vaccine shipments.
- Discuss what staff are to do with vaccines that are:
 - Damaged (missing cap, broken vial)
 - Refused by patient.
 - Lost.
 - Given to ineligible clients.
- Discuss what staff are to do when package is:
 - Received without diluent.
 - Delivered to a different address.
 - Missing the packing slip.
- Inform staff to contact you immediately if a vaccine shipment was received warm or is suspected of being damaged or ruined. It is important to be able to provide the temperature of the received vaccine. See Chapter 3: Vaccine Management, III Vaccine Distribution., D. Vaccine Received Warm or Questionable for detailed information.

- Inform staff to place the back-up data logger probe in a shipment that was received warm or questionable, to gain the current temperature. Place the probe in the shipment, near the vaccine and put the lid back on it. Check it frequently to see when the temp stabilizes then proceed below.
- Inform staff to store questionable shipments appropriately, until official word is received from vaccine distributor or RE.
- Inform staff to check packing slip dates, and UPS/FEDEX tracking to assist with the timeframe of the vaccine cold-chain.
- Shipping/Return labels expire after 30 days. If UPS has not picked up package(s) within 30 days, another shipping label will need to be requested.
- Inform staff what procedures to take in the event of a storage unit failure.

All items with an asterisk (*) are required to be reviewed with staff and checked as completed.

*PEAR requirements. RE must certify all the following by checking each item as they are communicated to site staff.

- *There are key staff in place and they have adequate training protocols in place to maintain the requirements of the TVFC/ASN Program.
- *Staff understands the TVFC/ASN eligibility categories and billing practices.
- *Staff understands and has appropriate processes in place to maintain documentation consistent with program requirements (5 years) for all TVFC and ASN-related documents including: eligibility screening, dose documentation, borrowing, temperature recording forms, packing slips, and VAERS reporting.
- *A vaccine management plan and emergency plan that meet TVFC/ASN requirements are current and complete.

- *The vaccine storage equipment (storage units and data loggers) that are consistent with TVFC/ASN requirements including;
 - *Sufficient space.
 - *Proper placement.
 - *Current and valid certificate of calibration testing.
 - *Ability to maintain proper temperatures.
 - *Placement of “do not disconnect” and “do not unplug” labels on plugs and circuit breakers.
- *Staff have been educated on what to do in the event of a temperature excursion.
- *There are processes in place to:
 - *Maintain a separate TVFC and ASN inventory from private stock;
 - *Place vaccine orders monthly to maintain appropriate stock to serve population; and
 - *Offer all ACIP-recommended vaccines (unless a specialty provider).

Submit the following completed documents for a PIN assignment:

- Enrollment form (with changes documented, if any).
- All pages of this checklist with *.
- All pages of this checklist that contain the signatures of the site staff.
- All pages of this checklist that contains the RE signature.
- EC-68-1 and/or EC-68-2 biological order form.

NOTE: If a clinic is unable to meet all requirements, the site may be unable to join the TVFC/ASN Program.

Initial Contact/Visit

Has this clinic been enrolled in the TVFC/ASN Program before?

___ Yes ___ No If yes, what was their PIN? _____

Clinic Name:

Who was present at this initial visit/contact?

Please print.

Signing Clinician	Primary Coordinator*	Back-up Coordinator*
1.	2.	3.
Other staff trained	Other staff trained	Other staff trained
4.	5.	6.

*Required attendance

Clinic staff signatures – I certify all checked items have been reviewed/discussed with me/my staff.

1. _____

2.* _____

3.* _____

4. _____

5. _____

6. _____

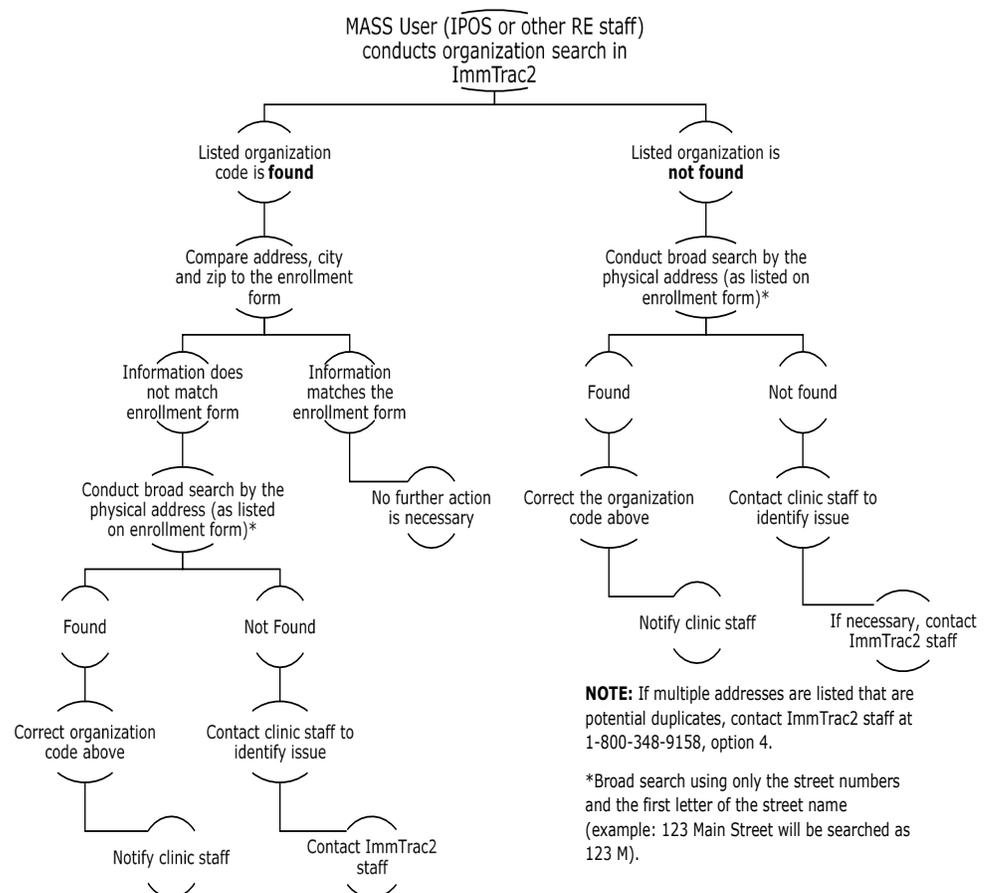
ImmTrac2 Organization Code Verification

_____ ImmTrac2 organization code (from enrollment form).

A Modified Access Sub-State (MASS) User must verify the ImmTrac2 organization code.

- Go to "manage access"
- Select "edit organization"
- Search by org code

Follow the flowchart below to identify the correct steps for verification.



Initial Contact/Visit

ImmTrac2 Organization Code Verifier Information

Verifier name:

Verifier signature:

Date of verification:

I certify that all the items checked above have been reviewed/discussed/provided to the staff of this clinic and they have the necessary processes, staff, and infrastructure in place to meet the TVFC/ASN requirements.

I certify that the primary and back-up coordinators have taken the 3 required trainings and have provided copies of certificates.

RE Information

Reviewer name:

Reviewer signature:

Date of initial contact/visit:

PIN Assignment

Via email, the clinic staff will receive a PIN and a password to EVI along with a link to EVI once all correct initial contact/visit documentation has been received.

Immunization Unit staff will also forward the PIN assignment to the responsible DSHS PHR. It is the regions responsibility to forward this information to the responsible LHD RE, if applicable.

Second Contact/Visit

After a PIN has been assigned, review the following with site staff.

- Demonstrate how to sign into EVI.
- Assist staff with changing their password.
- Explain the importance of verifying and correcting the site information and the information of primary and back-up coordinator in EVI on a monthly basis.
- Inform staff that the EVI Webinar Training link is located on the welcome page of EVI.
- Place first vaccine order in EVI using stock nos. EC-68-1 or EC-68-2
- Verify sufficient water bottles are present in the refrigerator and freezer and are labeled "do not drink".
- Verify the vaccine management plan has been filled out and is available for review.
- Verify plug guards have been installed.
- Verify circuit breaker and outlets are labeled "do not disconnect", "do not unplug".

Second Contact/Visit

Clinic PIN:

Clinic Name:

Who was present at this second visit/contact?

Please print

Signing Clinician	Primary Coordinator*	Back-up Coordinator*
1.	2.	3.
Other staff trained	Other staff trained	Other staff trained
4.	5.	6.

*Required attendance

Clinic staff signatures – I certify all checked items have been reviewed/discussed with me/my staff.

1. _____

2.* _____

3.* _____

4. _____

5. _____

6. _____

Second Contact/Visit

I certify that all the items checked above have been reviewed/discussed/provided to the staff of this clinic and they have the necessary processes, staff, and infrastructure in place to meet the TVFC/ASN requirements.

RE Information

Reviewer name:

Reviewer signature:

Date of initial contact/visit:

Third Contact/Visit

When vaccine arrives at the clinic site, RE staff assist by conducting the following:

- Discuss how to receive the vaccine in EVI.
- Discuss the importance of verifying the date vaccine was shipped, NDC, lot number, expiration dates, and quantities received to the packing slip.
- Provide education on how to print a tally and physical count sheet from EVI.
- Encourage staff to post the tally sheet from EVI in the area of the units that contain TVFC/ASN vaccine.
- Educate staff how to use the tally and physical count sheet form to document doses administered to patients by lot numbers.
- Inform staff to unpack the vaccine and store it immediately.

Third Contact/Visit

Clinic PIN:

Clinic Name:

Who was present at this third visit/contact?

Please print

Signing Clinician	Primary Coordinator*	Back-up Coordinator*
1.	2.	3.
Other staff trained	Other staff trained	Other staff trained
4.	5.	6.

*Required attendance

Clinic staff signatures – I certify all checked items have been reviewed/discussed with me/my staff.

1. _____

2.* _____

3.* _____

4. _____

5. _____

6. _____

Third Contact/Visit

I certify that all the items checked above have been reviewed/discussed/provided to the staff of this clinic and they have the necessary processes, staff, and infrastructure in place to meet the TVFC/ASN requirements.

RE Information

Reviewer name:

Reviewer signature:

Date of initial contact/visit:

Fourth Contact/Visit

At the beginning of the first month on the program, provide hands-on training to staff on the proper use of EVI, explaining each tab.

- Tab 1** Welcome.
- Tab 2** Site information.
- Tab 3** Receiving.
- Tab 4** Doses (doses administered reporting).
- Tab 5** Inventory (transfers, wasted, and expired [vaccine loss report], stock no. C-33).
- Tab 6** Place orders.
- Tab 7** Update choice (when open and available).
- Tab 8** Reports (monthly biological, tally and physical count, wasted and expired, doses about to expire, and stock no. C-33 history).
- Tab 9** Help.

Discuss the following items:

- Encourage staff to NOT adjust inventory but instead to contact RE when the doses in EVI do not equal the doses on hand.
- Explain vaccine choice (opened quarterly).
- Inform staff of the requirement to complete monthly reporting by the 5th of every month.
- Explain the automatic 3-day waiting period once a vaccine order has been approved.
- Explain the length of time it takes to receive a vaccine shipment once approved.
- Explain vaccine delays due to late monthly reporting, holidays, and inclement weather conditions.
- Inform staff that EVI reporting is required monthly even if vaccine is not ordered.

- Explain the importance of describing all circumstances when a vaccine loss report must be completed.
- Explain vaccine losses using the following information.
 - **Negligent losses**
 - Drew up dose and parent/patient refused;
 - Drew up wrong vaccine including:
 - Vaccine mixed with wrong diluent or
 - Only diluent was administered;
 - Dropped dose resulting in:
 - Damage to vial integrity or sterility or
 - Compromised vial;
 - Expired - did not notify RE 60-90 days before expiration;
 - Failure to store properly including:
 - Vaccines left out of storage or
 - Improper monitoring of temperatures in refrigerator or freezer;
 - Refrigerator temperature too cold;
 - Storage temperature too warm including:
 - Unit that was unplugged and a plug guard was not used,
 - Unit door was left open, or
 - Temperatures were not documented or were monitored improperly;
 - Vaccine spoiled in transit due to clinic staff error including:
 - Vaccine transfers,
 - Refused vaccine shipment, or
 - Vaccine delivered when clinic is closed, and the closure was not documented in EVI;

- Vaccine stored improperly including:
 - Vaccine left out of appropriate storage unit or
 - Not stored properly upon receipt.
- **Non-negligent losses**
 - Damaged needle or seal, particulate in the vial, discolored liquid, etc.
 - Expired flu, DT, pediatric PPSV23 and pediatric Td
 - Expired - notified RE 60-90 days before expiration and RE was unable to transfer
 - Mechanical failure of refrigerator or freezer
 - Natural disaster or power outage
 - Unable to transfer open multi-dose vial
 - Vaccine spoiled in shipment due to shipper error

Temperature excursions and vaccine loss

- Explain the steps to take when vaccine has been compromised.
- Explain to quarantine compromised vaccine so others won't inadvertently administer it.
- Store vaccine in vaccine quarantine bags within the unit.
- Contact the RE to report the issue.
- Contact the vaccine manufacturer(s) for viability reports.
- Submit manufacturer viability reports to RE, along with a copy of all 3 pages of the EC-105 temperature recording form or email a PDF copy of the data logger report.
 - Remove some or all vaccine from storage unit if, the manufacturer has deemed them non-viable to use.

- Generate a vaccine loss report VLR within 4 days of occurrence.

Expired vaccine

- Remove expired vaccine from the refrigerator or freezer at the close of the business day, or the day after expiration.
- Generate a VLR within 4 days of vaccine expiring.
 - Explain the process of how a return shipping label will be distributed to return ruined/expired vaccine to the distributor.
 - Explain that a VLR should be included with only the vaccine being returned to the manufacturer.
 - Inform that the label will expire in 30 days.
 - Explain the following should NOT be returned:
 - Diluents,
 - opened multi-dose vials,
 - syringes with needles attached,
 - broken vials, and
 - vaccine that has been drawn into a syringe.

Fourth Contact/Visit

Clinic PIN:

Clinic Name:

Who was present at this third visit/contact?

Please print

Signing Clinician	Primary Coordinator*	Back-up Coordinator*
1.	2.	3.
Other staff trained	Other staff trained	Other staff trained
4.	5.	6.

*Required attendance

Clinic staff signatures – I certify all checked items have been reviewed/discussed with me/my staff.

1. _____

2.* _____

3.* _____

4. _____

5. _____

6. _____

Fourth Contact/Visit

I certify that all the items checked above have been reviewed/discussed/provided to the staff of this clinic and they have the necessary processes, staff, and infrastructure in place to meet the TVFC/ASN requirements.

RE Information

Reviewer name:

Reviewer signature:

Date of fourth contact/visit:

