Annexure 1

AEFI CASE REPORTING FORM (CRF)

AEFI reporting ID: IND (AEFI) /__ST_/DIS_/_YR _/_NUM_ (to be allotted by DIO)

Section A (To be submitted by MO within 24 hours of case notification to DIO)

State	**District**
Block/ward	**Village/urban area**

Name of reporting MO (person filling this form):	Today's date:
Posted at: Designation:	Time of preparing this form: a.m./p.m.
Contact phone number: email:	Date case visited and examined/interviewed: __ __/__ __/__ __ __ __
Notified by (name): Date notified to MO: __ __/__ __/__ __ __ __	Designation (please circle): health worker/government doctor/private practitioner/community/media/others (specify) _____ _____

Patient's name																				

Date of birth DD/MM/YYYY	**Age** (in months): _____ months	**Sex**	Male / Female

Mother's name																				
Father's name																				

Complete address of the case with landmarks *(street name, house number, village, block, tehsil, pin no., telephone no.)*

P	**i**	**n**	-							**P**	**h**	**o**	**n**	**e**	-												

Date of vaccination: __ __/__ __/__ __ __ __ Time of vaccination: __ __: __ __a.m./p.m.	Address of session site:
Session: Routine (including SIW)* **Campaign** (SIA)-IPPI/MR/JE/others (specify):_____ Other _____	**Place of vaccination:** govt health facility/outreach/private health facility/others ____

Names of vaccines received (write vaccine & diluent details in separate rows)	Dose no. (zero/first/second/etc. as applicable)	Name of manufacturer	Batch/lot No.	Expiry date	Date of opening of vial	Time of opening the vial (for reconstituted vaccine)	No. of OTHER beneficiaries who received vaccine from the SAME vial in this session

Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	a.m.	p.m.
Hospitalization: No/yes – (Date)	D	D	M	M	Y	Y	Y	Y	Time of hospitalization	H	H	M	M	a.m.	p.m.

Name and address of hospital (if hospitalized):

*Special immunization week

Current status (encircle)	Death/still hospitalized/recovered & discharged with sequelae/recovered completely and discharged/left against medical advice (LAMA)/not hospitalized																		
If died, date of death	D	D	M	M	Y	Y	Y	Y	Time of death	H	H	M	M	a.m.		p.m			
Post mortem done? Yes/no/unknown If yes, then write date post mortem done	D	D	M	M	Y	Y	Y	Y	If not done, but planned, write date planned	H	H	M	M	Y	Y	Y	Y		

Describe AEFI (signs and symptoms):

Suspected adverse event(s) (tick at least one):

☐ Severe local reaction
- ○ *>3 days*
- ○ *beyond nearest joint*

☐ Seizures
- ○ *febrile*
- ○ *afebrile*

☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Intussusception

☐ Fever≥39 °C (102 °F) ☐ Hypotonic hyporesponsive episode (HHE) ☐ Acute flaccid paralysis ☐ Sudden unexplained death syndrome

☐ Death due to any reason other than above – specify……

☐ Hospitalization due to any reason other than above – specify…… ☐ Disability

☐ Cluster – is this case part of a cluster? Yes/no/unknown

If Yes, no of other cases in the cluster _____ (use separate form for each case in a cluster)

Signature and name of reporting medical officer:

Section B: District immunization office to complete and forward to state and national level within 24 hours of receiving the above information

Date case reporting form received at the district: __ __/__ __/__ __ __ __

Proposed date of preliminary investigation: __ __/__ __/__ __ __ __

Remarks:

DIO/district nodal person *(officer forwarding this report)*

Name …… Date……Designation……Mobile No……

Landline (with STD code)…… Fax No. ……

email id…… Complete office address (with Pin code)……

……

……Signature/seal

To be sent to: State Immunization Officer & Deputy Commissioner (UIP),
Immunization Division of Govt of India, MoHFW,
Nirman Bhawan, New Delhi – 110108.
Fax: 011-23062728 **email**: aefiindia@gmail.com

Date report received at state level – __ __/__ __/__ __ __ __

Remarks:

Section C: National level to complete

Date report received at national level – __ __/__ __/__ __ __ __

Remarks:

Annexure 2

PRELIMINARY CASE INVESTIGATION FORM

AEFI reporting ID: IND (AEFI) /__ST_/DIS_/_YR _/_NUM_ (To be allotted by DIO)

Section A Basic details

State	**District**
Block/ward	**Village/urban area**

Place of vaccination: Govt health facility/outreach/private health facility/others (specify) ____

Session: Routine (including SIW) Campaign (SIA)-IPPI/MR/JE/others (specify):_____

Other _____

Name of investigator:	Date case visited and investigated: __ __/__ __/__ __ __ __
Posted at: Designation:	Date of preparing this form:__ __/__ __/__ __ __ __ Time of preparing this form: _____ a.m./p.m. This report is ☐ Preliminary ☐ Final
Contact phone number: email:	

Patient's name																		

Date of Birth DD/MM/YYYY Age (in months): _____ months | Sex | Male | Female |

Mother's name																		
Father's name																		

Complete address of the case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No.)*

P	i	n	-							P	h	o	n	e	-												

Date of vaccination: __ __/__ __/__ __ __ __ Time of vaccination: __ __: __ __ a.m./p.m.	Address of session site:
Date first notified to government health system: __ __/__ __/__ __ __ __	Notified by (please circle): Health worker/government doctor/private doctor/community/media/others (specify) _____

Name of vaccines received (write vaccine & diluent details in separate rows)	Dose no. (zero/ first/ second, etc.)	Name of manufacturer	Batch/lot No.	Expiry date	Date of opening of vial	Time of opening the vial (in case of reconstituted vaccines)	No. of OTHER beneficiaries who received vaccine from SAME vial in this session

Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	a.m.	p.m.	
Date of key symptom	D	D	M	M	Y	Y	Y	Y	Time of key symptom	H	H	M	M	a.m.	p.m.	
Hospitalization No/Yes – Date	D	D	M	M	Y	Y	Y	Y	Time of hospitalization	H	H	M	M	a.m.	p.m.	
Name and address of hospital (if hospitalized):																
Current status **(encircle)**	**Death/still hospitalized/recovered & discharged with sequelae/ recovered completely and discharged/left against medical advice (LAMA)/not hospitalized**															
If died, date of death	D	D	M	M	Y	Y	Y	Y	Time of death	H	H	M	M	a.m.	p.m.	
Post mortem done? Yes/no/unknown If yes, then write date post mortem done	D	D	M	M	Y	Y	Y	Y	If not done, but planned, write date planned	H	H	M	M	Y	Y	Y	Y

Section B Relevant patient information prior to immunization

Criteria	Finding	Remarks (If "Yes" provide details)
Past history of similar event	Yes/No/UK	
Adverse event after previous vaccination (s)	Yes/No/UK	
History of vaccine, drug or food allergy	Yes/No/UK	
Pre-existing illness (past 30 days)	Yes/No/UK	
Congenital disorder	Yes/No/UK	
History of hospitalization in past 30 days with reasons (in remarks column)	Yes/No/UK	
Was the patient on any concomitant medication at the time of AEFI? (If yes, name the drug, indication, doses & treatment dates – write in remarks column)	Yes/No/UK	
Family history of any disease (relevant to AEFI) or allergy	Yes/No/UK	

If patient is an adult woman

- Currently pregnant? Yes; Weeks _____/No/UK
- Currently breastfeeding? Yes/No

If patient is an infant, birth details	Any birth complication (specify)
1. Birth weight:	
2. Duration of pregnancy ☐ Full term ☐ Premature ☐ Postdated	
3. Place of birth ☐ Home delivery ☐ Institutional	
4. Delivery procedure ☐ Normal ☐ Caesarian ☐ Assisted	

Section C Details of first examination** of reported AEFI case

Source of information (✓ *all that* apply): ☐ Examination by the investigator ☐ Medical case records ☐ Verbal autopsy ☐ Other_____ If from verbal autopsy, please mention relationship with the deceased_____

In case of sudden unexplained death, please also fill SUD verbal autopsy form as per the guidelines)

Name of the person who first examined/treated the patient_____

Name of other persons from whom care was sought _____

Other sources who provided information (specify)_____

Signs and symptoms (in chronological order from the time of vaccination)

****Instructions** – Attach copies of ALL available documents (including case sheet, discharge summary, case notes, lab and autopsy reports) and then complete additional information NOT AVAILABLE in existing documents, i.e. • ***If patient has taken medical care*** – attach copies of all available documents (including case sheet, discharge summary, laboratory reports and post mortem reports, if available) and write only information unavailable in the attached documents below • ***If patient has not taken medical care*** – obtain history, examine the patient and write down your findings below (add additional sheets as required)

Name of person filling up clinical details given below:	Designation:	Date/time

Consciousness	Alert/Drowsy/Unconscious/Other (specify)_____ Describe:
Vitals	Pulse Temperature Respiratory rate BP Weight
Skin	Rash/Cyanosis/Petechiae/Pallor/Jaundice/Others (specify)_____ Describe:
Eyes	Vision: Normal/impaired Pupil: Normal/Constricted/Dilated/Reacting to light
Hearing, speech	Normal/Impaired: Describe Normal/Abnormal: Describe
Neck	Neck stiffness: Present/Absent
Chest	Auscultation Normal/Crepts/Rhonchi Heart sounds Normal/Murmur (describe)
Respiration	Normal/Cough/Shortness Of Breath/Others (specify)_____ Describe:
GI	Pain abdomen/Vomiting/Diarrhoea/Dysentery/Others (specify)_____ Describe:
Abdomen	Normal/distended/tender Liver: Not palpable/Palpable (If palpable specify size) Spleen: Not palpable/Palpable (If palpable specify size) Describe:
Limbs	Tone • Upper limbs: Normal/Increased /Decreased • Lower limbs: Normal/Increased /Decreased Reflexes

	• Biceps Normal/Increased /Decreased/Absent • Triceps Normal/Increased /Decreased/Absent • Supinator Normal/Increased /Decreased/Absent Plantar Extensor/Flexor

Any other abnormal signs

Treatment provided

Provisional diagnosis

Section D	**Details of vaccines provided on vaccination day at the site linked to AEFI**													
Number immunized for each vaccine at session site. Attach record if available.	Vaccine name													
	No of doses administered													

1. When was the patient immunized? (✓ the ☐ below and respond to ALL questions)

☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown

2. In case of multi-dose vials, was the vaccine given – ☐Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐Unknown

3. **Based on your investigation, is it possible that:** *(Please provide explanation for any "yes" answer in the remark column)*

A	There was an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes/No/Unable to assess	Remark
B	The vaccine (ingredients) administered could have been unsterile?	Yes/No/Unable to assess	Remark
C	The vaccine's physical condition (colour, turbidity, foreign substances) was abnormal at the time of administration?	Yes/No/Unable to assess	Remark
D	There was an error in vaccine reconstitution/preparation by the vaccinator (wrong product, wrong diluent, improper mixing, improper syringe filling)?	Yes/No/Unable to assess	Remark
E	There was an error in vaccine handling (break in cold chain during transport, storage and/or immunization session)?	Yes/No/Unable to assess	Remark
F	The vaccine was administered incorrectly (wrong dose, site or route of administration, wrong needle size, not following good injection practice)?	Yes/No/Unable to assess	Remark

4. Number immunized from the concerned vaccine vial/ampoule in this session	
5. Number immunized from the concerned vaccine vial/ampoule since vial was opened (in case of open vial policy)	
6. Number immunized with the concerned vaccine having the same batch number in other locations. Specify locations _____	
7. **Is this case a part of a cluster?**	Yes/No/UK
A If yes, how many other cases have been detected in the cluster?	
B Did all the cases in the cluster receive vaccine from the same vial?	Yes/No/UK
C If no, number of vials used in the cluster	

Section E Immunization practices at the place(s) where concerned vaccine was used

(fill up this section by asking and/or observing practice)

Syringes and needles used:

• Are AD syringes used for immunization?	Yes/No/UK
If "No", specify the type of syringes used: ☐Glass ☐Disposable ☐Recycled disposable ☐Other _____	
Specific key findings/additional observations and comments:	

Reconstitution: (complete only if applicable, ✓ NA if not applicable)

	Status		
• Reconstitution procedure (✓)			
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
Separate reconstitution syringe for each vaccination?	Yes	No	NA
• Are the vaccines and diluents used the same as recommended by the manufacturer?	Yes	No	NA
Specific key findings/additional observations and comments:			

Section F Cold chain and transport

(fill up this section by asking and/or observing practice)

Last vaccine storage point:	
• Is the temperature of the vaccine storage refrigerator monitored?	Yes/No
○ If, "Yes", has there been any deviation outside of 2–8 °C after the vaccine was placed inside?	Yes/No
○ If, "Yes", provide details of monitoring separately:	
• Is the correct procedure of storing vaccines, diluents and syringes being followed?	Yes/No/UK
• Any other item (other than EPI vaccines and diluents) in the refrigerator or freezer?	Yes/No/UK
• Are partially used reconstituted vaccines stored in the refrigerator?	Yes/No/UK
• Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) in the refrigerator?	Yes/No/UK
• Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes/No/UK
Specific key findings/additional observations and comments:	
Vaccine transportation:	

• Type of vaccine carrier used	
• Vaccine carrier sent to the site on the same day of vaccination?	Yes/No/UK
• Vaccination carrier returned from the site on the same day of vaccination?	Yes/No/UK
• Conditioned ice pack used?	Yes/No/UK
Specific key findings/additional observations and comments:	

Section G Community investigation (please visit locality and interview parents/others)

Any similar events reported recently in the locality? Yes/No/UK
If "Yes", describe:

If "Yes", how many events/episodes?

Of those affected, how many are
- Vaccinated:_____
- Not Vaccinated:_____
- Unknown:_____

Other comments:

Section H Other findings/observations/comments

Section I District AEFI committee review & investigation report

a. Was the case discussed by the district AEFI committee? *If "Yes", then date case discussed by district AEFI committee*	Yes D D M M Y Y Y Y	No
b. *What was the provisional diagnosis of the case concluded by the district AEFI committee?*		
c. Did the district AEFI committee recommend that samples be sent for testing?	Yes	No

Details of vaccine/diluent samples sent to CDL Kasauli

Vaccine/diluent name	Site of collection	Used vial/amp quantity	Batch no, lot no, date of expiry	Date sent	Unused vial/amp quantity	Batch no, lot no, date of expiry	Date sent

Details of syringe/needle samples sent to CDL Kolkata								
Type of syringes	Quantity	Site of collection	Batch no, lot no, date of expiry	Date sent	Type of needles	Quantity	Batch no, lot no, date of expiry	Date sent
a) Any biological product (CSF, blood, urine) sent for testing? *If "Yes", specify details of the lab; attach copy of report if available* *Note: for AEFI resulting within 28 days following JE vaccine, send sample of CSF, serum to nearest NIV lab in Pune or Gorakhpur*							Yes	No
b) Was the local drug inspector involved in collecting additional samples?							Yes	No
c) Specify any other relevant investigation done and attach reports.								

Attached copies of reports/documents with this case investigation report:			
Ser No.	**List of document copies received**	**Availability** *(encircle)*	**Remarks (if any)**
1.	Case reporting form (CRF)	Yes/No	
2.	Post mortem report *(in case of death)*	Yes/No	
3.	Verbal autopsy form (in case of sudden unexplained death)	Yes/No	
4.	**Any pathology/microbiology test report**		
4A	Blood test report	Yes/No	
4B	CSF report	Yes/No	
4C	Urine test report	Yes/No	
5.	Doctor's prescription/treatment record for AEFI	Yes/No	
6.	Doctor's prescription/treatment record for other illness	Yes/No	
7.	Laboratory result of vaccine (if sent for testing)	Yes/No	
8.	Laboratory result of syringes/other drugs (if sent for testing)	Yes/No	
9.	Any other document relevant to case	Yes/No	

District AEFI committee that conducted the investigation			
Name	**Designation**	**Phone #**	**Signature**
1.			
2.			
3.			
4.			

5.			
6.			
7.			

Section J **DIO/district nodal person** ***(Officer forwarding this report)***

Name …… Designation……..…Date of submission to state/national level……

Mobile No……..……. Landline (with STD code)……..…… Fax No. ……

email id……. Complete office address (with Pin code)……

……..…
……Signature and seal……. Date……

Please ensure that this preliminary investigation form reaches within 10 days of notification to:
1.State Immunization Officer
2. Deputy commissioner, Immunization Division of Govt. of India, MoHFW, Nirman Bhawan, New Delhi–110108.
(Fax: 011 23062728. email: **aefiindia@gmail.com**)

Annexure 3

FINAL CASE INVESTIGATION FORM

AEFI reporting ID: IND (AEFI) /__ST_/DIS_/_YR _/_NUM_ (To be allotted by DIO)

Section A

State	**District**
Block/ward	**Village/urban area**
Place of vaccination: Govt health facility/outreach/private health facility/other ____ **Session**: Routine (including SIW) Campaign (SIA)-IPPI/MR/JE/others (specify):_____ Other _____	
Name of investigator:	Date case visited and investigated: __ __/__ __/__ __ __ __
Posted at: Designation:	Date of preparing this form:__ __/__ __/__ __ __ __ Time of preparing this form: _____ a.m./p.m. This report is ☐ Preliminary ☐ Final
Contact phone number: email:	

Patient's name																		

Date of birth DD/MM/YYYY	Age (in months): _____ months	Sex	Male / Female

Mother's name																		
Father's name																		

Complete address of the case with landmarks *(street name, house number, village, block, tehsil, Pin no., telephone no.)*

P	**i**	**n**	-							**P**	**h**	**o**	**n**	**e**	-												

Attached copies of reports/documents with the final case investigation report:

Sl	List of document copies received	Availability *(encircle)*	Remarks (if any)
1	Case reporting form (CRF)	Yes/No	
2.	Preliminary case investigation form	Yes/No	
3	Any pathology/microbiology test report		
3a	Blood test report	Yes/No	
3b	CSF report	Yes/No	
3c	Urine test report	Yes/No	
4	Doctor's prescription/treatment record for AEFI	Yes/No	
5	Doctor's prescription/treatment record for other illness	Yes/No	
6	Laboratory result of vaccine (if sent for testing)	Yes/No	
7	Verbal autopsy form (in case of reported sudden unexplained death)	Yes/ No	
8	Post mortem report (based on guidelines for autopsy in case of reported unexplained death)	Yes/No	
9	Laboratory result of syringes/other drugs (if sent for testing)	Yes/No	
10	Any other document relevant to case	Yes/No	

Date of Vaccination: __ __/__ __/__ __ __ __ Time of Vaccination: __ __: __ __ a.m./p.m.	Address of session site:
Date first notified to government health system: __ __/__ __/__ __ __ __	Notified by (please circle): Health worker/government doctor/private doctor/community/media/others (specify) _____

Date of first symptom	D	D	M	M	Y	Y	Y	Y	Time of first symptom	H	H	M	M	a.m.	p.m.	
Date of key symptom	D	D	M	M	Y	Y	Y	Y	Time of key symptom	H	H	M	M	a.m.	p.m.	
Hospitalization No/Yes – Date	D	D	M	M	Y	Y	Y	Y	Time of hospitalization	H	H	M	M	a.m.	p.m.	

Name and address of hospital (if hospitalized):

Current status **(encircle)**	**Death/still hospitalized/recovered & discharged with sequelae / recovered completely and discharged/left against medical advice (LAMA)/not hospitalized**

If died, date of death	D	D	M	M	Y	Y	Y	Y	Time of death	H	H	M	M	a.m.		p.m.			
Postmortem done? YES/No/Unknown If yes, then give date postmortem done	D	D	M	M	Y	Y	Y	Y	If not done, but planned, give date planned	H	H	M	M	Y	Y	Y	Y		

SECTION B: Refer to CRF, PCIF and updated information available for writing the case summary. Remember to include the following points, add additional sheet as necessary

Relevant information prior to immunization:

Status of immunization on the day AEFI reported (completed doses before the event):

Vaccines administered on the day of the event:

Post immunization event:

Examination findings:
Laboratory findings:
Details of community investigation, if conducted:
Any other findings:
Treatment provided:
Post mortem report if available:
Provisional diagnosis:

Add additional pages if needed

SECTION C:

Report of vaccine/diluent samples sent to CDL Kasauli as per details mentioned below

Vaccine/diluent name	Used vial/amp quantity	Batch No, lot No, date of expiry	Date sent	Lab finding	Unused vial/amp quantity	Batch No, lot No, date of expiry	Date sent	Lab finding

Report of syringe/needle samples sent to CDL Kolkata as per details mentioned below

Type of Syringes	Quantity	Batch No, Lot No, date of expiry	Date Sent	Lab finding	Type of needles	Quantity	Batch No, Lot No, date of expiry	Date Sent	Lab finding

Any biological product (CSF, blood, urine) sent for testing? *If yes, specify details of the lab; attach copy of report if available* *Note: For AEFI resulting within 28 days following JE vaccine, send sample of CSF, serum to nearest NIV lab in Pune or Gorakhpur.*	Yes	No	**Lab finding**
Specify any other relevant investigations done and attach reports			

District AEFI committee meeting when case was discussed

Name	Designation	Phone #	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Section D **DIO/district nodal person** ***(Officer forwarding this report)***

Name …….. Designation……..…Date of submission to state/national level……

Mobile No…….…….. Landline (with STD code)…….…… Fax No. ……

email id…….. Complete office address (with Pin code)……

……

……Signature and seal……. Date……

Please ensure that this investigation form reaches within 70 days of notification to:

1.State Immunization Officer

2. Deputy commissioner, Immunization Division of Govt of India, MoHFW, Nirman Bhawan, New Delhi – 110108. (Fax: 011 23062728. email: aefiindia@gmail.com)