

## Annex 11A: Adverse Event Following Immunization – Investigation Form

<b>AEFI Investigation</b>	
<p>An adverse event following immunization (AEFIs) is a medical incident that takes place after an immunization, causes concern and is believed to be caused by the immunization. Programmes providing immunization services should include a system for AEFI detection and reporting, investigation and management, data analysis, corrective action, relevant communication and evaluation of the system. The ultimate goal of an investigation is to determine whether the vaccine or immunization process is responsible for the reported event (s) or to find another cause and correct it if possible, and reassure the public.</p> <p><b>Further resources:</b></p> <p>Global Manual on Surveillance of Adverse Events Following Immunization” <a href="http://www.who.int/vaccine_safety/publications/Global_Manual_revised_12102015.pdf?ua=1">http://www.who.int/vaccine_safety/publications/Global_Manual_revised_12102015.pdf?ua=1</a></p>	
<b>1.</b>	<p><b>Be prepared (Steps to take before an event occurs)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Read the resource documents on reporting, management and investigation of AEFIs.</li> <li><input type="checkbox"/> Develop standards: case definitions for reportable AEFIs, use of reporting forms and investigation procedures.</li> <li><input type="checkbox"/> Designate and train staff to conduct an AEFI investigation using the investigation form.</li> <li><input type="checkbox"/> Train staff on how to collect specimens.</li> <li><input type="checkbox"/> Establish procedure, criteria and designated person for notifying WHO and UNICEF (if UN- supplied vaccine) or other relevant party depending on procurement mechanism</li> <li><input type="checkbox"/> Establish a National Technical Advisory Committee with representation from major medical Organisations</li> <li><input type="checkbox"/> Identify a spokesperson for public communications.</li> </ul>
<b>2.</b>	<p><b>Receiving a report</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Ensure immediate reporting of most serious events and rapid attention to reports received</li> <li><input type="checkbox"/> Verify the information in the report and classify and assess the AEFI using established case definitions. Decide whether it needs further investigating.</li> <li><input type="checkbox"/> If investigation is warranted, travel to the location of the AEFI, or delegate responsibility to another trained person</li> </ul>

<p><b>3.</b></p>	<p><b>Investigate and collect data</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Ask about the patient</li> <li><input type="checkbox"/> Ask about the vaccine and other drugs potentially received</li> <li><input type="checkbox"/> Ask about other vaccinees</li> <li><input type="checkbox"/> Ask about immunization services</li> <li><input type="checkbox"/> Observe the service in action</li> <li><input type="checkbox"/> Ask about cases in unvaccinated persons</li> <li><input type="checkbox"/> Establish a more specific case definition if needed</li> <li><input type="checkbox"/> Formulate a hypothesis as to what caused the AEFI</li> </ul>
<p><b>4.</b></p>	<p><b>Collect specimens if appropriate:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> from the patient</li> <li><input type="checkbox"/> the vaccine (and diluent if applicable)</li> <li><input type="checkbox"/> the syringes and needles</li> </ul>
	<p><b>Dispatch specimens</b> to appropriate testing facility (laboratory, regulatory authority, etc.)</p>
<p><b>5.</b></p>	<p><b>Analyse the data</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Review epidemiological, clinical, and laboratory findings</li> <li><input type="checkbox"/> Summarize and report findings</li> </ul>
<p><b>6.</b></p>	<p><b>Take action</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Communicate with health staff</li> <li><input type="checkbox"/> Communicate findings and action to the parents and public</li> <li><input type="checkbox"/> Correct problem (based on the cause) by improving training, supervision, and/or distribution of vaccines/injection equipment</li> <li><input type="checkbox"/> Replace vaccines if indicated</li> </ul>