Division of AIDS Safety Office
EXPEDITED ADVERSE EVENT (EAE) Form

Please type or print in English

To: DAIDS SAFETY OFFICE

Fax: 1-800-275-7619 (USA) or
+ 1-301-897-1710 (International)

Phone: 1-800-537-9979 (USA) or
+ 1-301-897-1709 (International)

Email: RCCSafetyOffice@Tech-Res.com

Sent by: _____

Phone: _____ **Fax:** _____

E-mail: _____

Date Sent: ☐☐☐☐☐☐☐☐ (D D/ M O N/ Y Y Y Y) **No. of Pages:** _____ (Including this cover sheet)

Patient/Volunteer ID Number: _____

REPORTER AND SITE INFORMATION

Site Name: _____ **Site Number:** _____

Site Awareness Date: ☐☐☐☐☐☐☐☐ (D D/ M O N/ Y Y Y Y)

Site Report Date: ☐☐☐☐☐☐☐☐ (D D/ M O N/ Y Y Y Y)

Reporter Same as Sender? YES ☐ **NO** ☐
If **YES**, do not repeat contact information provided above.

Reporter Name: _____

Phone: _____ **Fax:** _____

Email: _____

New Report: ☐ (Send all pages of the completed form.)

Follow-up Report: ☐ (If Follow-up Report, provide Date of Original Report.) **Date of Original Report:** ☐☐☐☐☐☐☐☐ (D D/ M O N/ Y Y Y Y)

Pages: ☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5** ☐ **6** ☐ **7** ☐ **ALL** (For Follow-up Reports, submit only updated pages. Check all that apply.)

SAFETY OFFICE USE ONLY

Received Date Stamp: _____

AE NUMBER: ☐☐☐☐☐☐☐☐ **PROTOCOL NUMBER(S):** _____

Report Received By: ☐ Fax ☐ E-mail ☐ Express Mail

Patient/Volunteer ID Number: _____ Site Report Date: ☐☐ ☐☐☐ ☐☐☐☐ D D / M O N / Y Y Y Y

Is this a Serious Adverse Event (SAE) as defined in ICH* E6 ? (* International Conference on Harmonisation) ☐ **YES** ☐ **NO**

- Results in death
- Is a congenital anomaly/birth defect
- Results in persistent or significant disability/incapacity
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization

1. PROTOCOL INFORMATION

Protocol Number: _____

Network Affiliation (check one): ☐ None

☐ AACTG ☐ AIEDRP ☐ CIPRA ☐ CPCRA

☐ ESPRIT ☐ HPTN ☐ HVTN ☐ IRP

☐ PACTG ☐ SMART ☐ Other Network, specify

_____

Protocol Number: _____ ☐ **N/A**

Network Affiliation (check one): ☐ None

☐ AACTG ☐ AIEDRP ☐ CIPRA ☐ CPCRA

☐ ESPRIT ☐ HPTN ☐ HVTN ☐ IRP

☐ PACTG ☐ SMART ☐ Other Network, specify

_____

Protocol Number: _____ ☐ **N/A**

Network Affiliation (check one): ☐ None

☐ AACTG ☐ AIEDRP ☐ CIPRA ☐ CPCRA

☐ ESPRIT ☐ HPTN ☐ HVTN ☐ IRP

☐ PACTG ☐ SMART ☐ Other Network, specify

_____

2. SUBJECT INFORMATION For each question below, please check the appropriate box.

Age: _____ ☐ Days* ☐ Months* ☐ Years

Sex at Birth: ☐ Male ☐ Female ☐ Unknown

Pregnant: ☐ Yes ☐ No ☐ Unknown

(If Yes) Duration _____ week(s)

Height * : _____ ☐ cm ☐ in

Weight: _____ ☐ kg ☐ lb

Race: ☐ Native American or Alaska Native ☐ Asian ☐ Black or African American

☐ Native Hawaiian or Other Pacific Islander ☐ Unknown ☐ White

☐ Other, specify _____

* Pediatric Studies Only

Patient/Volunteer ID Number: _____ Site Report Date: ☐☐ ☐☐☐ ☐☐☐☐ D D / M O N / Y Y Y Y

3. FOR ALL STUDY AGENTS For therapeutics administered on a cyclic schedule, also complete the Supplemental DAIDS EAE Report Form and check here ☐ if attached.

A	**Protocol Number**					
	Study Agent	**Agent 1**	**Agent 2**	**Agent 3**	**Agent 4**	**Agent 5**
B	**Generic/INN Name or the Study Agent Name/ Abbreviation as listed in the Protocol.** If Combination Agent, use Study Agent name/abbreviation or list individual components.					
C	**Dose**					
D	**Route**					

4. FOR STUDY AGENTS OTHER THAN VACCINES OR THERAPEUTIC VACCINES **N/A** ☐

* **C** – Continued Without Change; **O** – Course Completed or Subject Off Study Agent at AE Onset; **D** – Permanently Discontinued; **R** – Dose or Schedule Reduced; **T** – Temporarily Held; **U** – Unknown

	Study Agent	**Agent 1**	**Agent 2**	**Agent 3**	**Agent 4**	**Agent 5**
A	**Schedule of Administration**					
B	**Date of First Dose** (DD/MON/YYYY)					
C	**Date of Last Dose** (DD/MON/YYYY)					
D	**Action Taken with Study Agent ***					
E	**Date of Action Taken with Study Agent** (DD/MON/YYYY)					
F	**Distributed by DAIDS**	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
	If No, specify manufacturer. If unknown, specify distributor.					

Patient/Volunteer ID Number: _____ Site Report Date: | | | | | | | | | | | (D D / M O N / Y Y Y Y)

5. FOR VACCINES ONLY (INCLUDING THERAPEUTIC VACCINES) List all dates (DD/MON/YYYY) of vaccine administration.

N/A ☐

*** C** – Continued Without Change; **O** – Course Completed or Subject Off Study Agent at AE Onset; **D** – Permanently Discontinued; **R** – Dose or Schedule Reduced; **T** – Temporarily Held; **U** – Unknown

a. ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)	**c.** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)	**e.** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)
b. ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)	**d.** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)	**f.** ___ ___ / ___ ___ ___ / ___ ___ ___ ___ (D D M O N Y Y Y Y)

Action Taken with Study Agent * (enter code for the vaccine treatment regimen from codes listed above): _____

Patient/Volunteer ID Number: _____ Site Report Date: D D / M O N / Y Y Y Y

6. PRIMARY ADVERSE EVENT

PRIMARY AE List only one Primary AE.	Relationship to Study Agent(s) Listed in Section 3 *					Severity Grade of Primary AE	Onset Date (DD/MON/YYYY)	Status Code **	Status Date (DD/MON/YYYY)
	Agent 1	Agent 2	Agent 3	Agent 4	Agent 5				

*** Relationship Code**

1 – Definitely Related
2 – Probably Related
3 – Possibly Related
4 – Probably Not Related
5 – Not Related
6 – Pending (temporary assignment for death)

**** Status Code at Most Recent Observation**

1 – Recovered / Resolved
2 – Recovering / Resolving
3 – Not Recovered / Not Resolved
4 – Recovered / Resolved with Sequelae
5 – Death
6 – Unknown

7. OTHER CLINICALLY SIGNIFICANT EVENTS ASSOCIATED WITH PRIMARY AE

None ☐

Other Clinically Significant Events Associated with Primary AE	Severity Grade	Onset Date (DD/MON/YYYY)
1.		
2.		
3.		
4.		
5.		

Patient/Volunteer ID Number: _____ Site Report Date: D D / M O N / Y Y Y Y

8. RELEVANT LABORATORY TESTS

List normal or abnormal tests that help explain the Primary AE. List tests below **OR** attach copy of test results. **None** ☐

Test	Collection Date (DD/MON/YYYY)	Result	Units	Lab Normal Range	Lab Value Previous to this AE	Previous Lab Collection Date (DD/MON/YYYY)
1.						
2.						
3.						
4.						

9. RELEVANT DIAGNOSTIC TESTS (NON-LAB)

List tests below **OR** attach copy of test results. **None** ☐

Test	Test Date (DD/MON/YYYY)	Results/Comments
1.		
2.		
3.		
4.		

10. CONCOMITANT MEDICATIONS

List Concomitant Medications being taken at onset of primary AE **OR** attach copy of concomitant medication(s) list. **DO NOT** list medications used to treat the AE. **None** ☐

Concomitant Medication	Approximate Duration of Use
1.	
2.	
3.	
4.	
5.	
6.	
7.	

Patient/Volunteer ID Number: _____ Site Report Date: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y

11. NARRATIVE CASE SUMMARY Include clinical course, therapeutic measures, outcome, relevant past medical history, any other contributing factors, alternative etiologies, and other relevant information. Use additional page(s) as needed.

12. ADDITIONAL INFORMATION Check the box for each type of document attached. Check all that apply. **None** ☐

☐	Autopsy Report	☐	Diagnostic Imaging	☐	Progress Note(s)
☐	Pathology Report(s)	☐	Discharge Summary	☐	Laboratory Report(s)
☐	Other, specify _____			☐	Radiology Report(s)

CERTIFIER INFORMATION

I CERTIFY THAT THE DATA PROVIDED ON THIS FORM ARE ACCURATE AND COMPLETE.

Study Physician Signature: _____ Date: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y

Study Physician Name Printed: _____

Patient/Volunteer ID Number: _____

Site Report Date: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y

SUPPLEMENTAL DAIDS EXPEDITED ADVERSE EVENT (EAE) FORM

Use for therapeutic study agents administered on a cyclic schedule.

For multiple study agents on a cyclic schedule, use one page for each study agent.

Study Agent Name: _____

1. If event occurred during a dosing cycle: ☐ **N/A**	**2. If event did not occur during a dosing cycle:** ☐ **N/A**
a. Highest dose in this cycle:	a. Highest dose in previous cycle:
b. Dose at time of AE onset:	b. Last dose in previous cycle:
c. Date this cycle started: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y	c. Date previous cycle started: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y
d. Date previous cycle started: ☐☐☐☐☐☐☐☐ D D / M O N / Y Y Y Y	d. Number of previous cycles: ☐☐☐
e. Number of previous cycles: ☐☐☐	