ADIRONDACK HEALTH

TITLE:	Reporting of Serious Adverse Events (SAEs) and Form 3500A	POLICY #: SOP-9
FOLDER NAME:	Institutional Review Board (IRB)	PAGE: 1 OF: 2
PREPARED BY:	Patricia Druzba, Ph.D. Chair, Institutional Review Board (IRB)	
EFFECTIVE DATE: 12/8/14	REVIEWED/REVISED: 2/16	
APPROVED BY: Patricia Druzba, PhD (Chair, IRB) Patricia Druzba Ph.D. Chandler Ralph (President & CEO)		

For Drugs and Biologics:

For an SAE to be reportable to this IRB it must be Serious, Unexpected and Related to the product being studied. Sponsor requirements for reporting to them, may be different and those requirements must be followed. In the case of a double-blind study, the blind need not and generally should not be broken in order to file the report. In Section E of the report Form 3500A, add "Unknown-double-blind study". FDA Form 3500A must be used unless another form is supplied by the sponsor which contains the same information. In which case, the sponsor's form may be sent to the IRB. In either event, the form must be signed by the Principal Investigator (PI) and transmitted to the IRB within 5 working days after the PI becomes aware of the event.

The definition of a **Serious** Adverse Event is any adverse experience occurring at any dose that results in any one or more outcomes listed below:

Death
Life-threatening event
In-patient hospitalization
Prolongation of an existing hospitalization
Persistent or significant disability
Congenital anomaly or birth defect
Any significant medical event (generally requiring medical or surgical intervention to prevent one of the above-listed outcomes)

The definition of **Unexpected** is any adverse experience that by either specificity or severity is not consistent with data listed in the Investigator's Brochure (IB) or package insert. If there is no IB, compare the specificity and severity with the risk data available in the Protocol or in other information supplied by the sponsor.

Specificity: for example, the IB lists cerebral vascular accident but the event is categorized as cerebral thromboembolism, the event categorization is more specific and therefore would be considered Unexpected.

Severity: for example, the IB lists increased hepatic enzymes but the event is categorized as hepatic necrosis and it would therefore would be considered Unexpected due to increased severity.

The definition of **Related** is any adverse experience that has a reasonable possibility of having been caused by the drug. It does not mean that if the event happened in a more serious form, might have caused a listed outcome.

The sponsor is obligated to review the data in an SAE report and to forward that report to the FDA in a timely manner. These are known as IND Safety reports or CIOMS1 reports. Any increased toxicity or potentially increased risks to humans determined by animal studies usually will be reported by the sponsor and the Agency in a narrative form. IND or CIOMS forms from outside this institution need not be reported to this IRB unless they meet the criteria of serious and unexpected and related. Investigators may receive a number of those forms from the sponsor throughout the study which they should review, give evidence of review and keep in their files.

Follow-up with the subject must be done until the event abates or the subject returns to baseline values. Updated reports should be submitted to this IRB using the FDA 3500A form with only new information added in the appropriate section after identifiers in Section A of the form have been completed. It is entirely possible that the initial diagnosis of the event might change after the subject has further work-up or consults. In which case, simply draw our attention to the error by crossing out the old information with a single stroke, initialing and dating the error and adding the reason for the error. If the new information concludes that the event no longer meets the criteria for reporting to this IRB, send a final 3500A with the change and the reason for the change. The IRB will review the forms and determine if the ICD requires revision. The PI will be notified in writing about any revisions required by the IRB.

For Medical Devices Under Study

All of the above-reporting requirements and definitions apply. The report is made to the FDA on the same form, that is the FDA 3500A but are called Medical Device Reports. They will be reported to the sponsor per their reporting requirements and the sponsor is responsible for transmitting the report to the FDA.

REFERENCES:

CFR (Code of Federal Regulations): 21 CFR 312.32
NYCRR: N/A
HFAP: N/A

ATTACHMENT: FDA 3500A

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*

5. **Describe Event, Problem or Product Use Error**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
Name:
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
#1
#2

4. **Diagnosis or Reason for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. Common Device Name	2b. Procode

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Unique Identifier (UDI) #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Name:
Address:
City: State: ZIP:

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. ***If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:*** ☐

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

B. ...cribe Event or Problem *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

F. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*