The ISCO3 Safety Information and Adverse Event Reporting Program Form

This document provides guidance and templates to get the records of adverse event during the practice of ozone therapy. The template to prepare the report (Annex II-IV) is useful to collect information related to the safety in the use of ozone therapy. A template with general instruction is available in Annex I.

Procedure: To use the template (Annex II-IV) users should copy / paste the template in a new document, and fill the blank.

Acronyms:
AE, Adverse Experiences
SAE, Serious Adverse Experiences

References:
1. Global Health Trials. gov USA (2015).
2. FDA (2015) Safety Information and Adverse Event Reporting Program.

Change History

SOP no.	Effective Date	Significant Changes	Previous SOP no.
ISCO3/REC/00/03	1/11/2015	First version approved by ISCO3 Board	First version

Document Records

	Name	Title	Signature	Date
Author	Gregorio Martínez-Sánchez	Elected president Ph.D.; Pharm. D.		10/10/2015
Co. Authors / Reviewer	Fadi Sabbah	Elected vice- president D.DS.		10/10/2015
	Adriana Schwartz	Elected secretary M.D.		1/11/2015
Authoriser / Approved	ISCO3 Board 2015-2020			

Annex I. Instructions for Reporting Adverse Experiences (AE) or Serious Adverse Experiences (SAE).

AE must be reported within 30 d and SAE's must be reported within 24 h

COMPLETE THE Annex II - IV

Please complete these pages as fully and accurately as possible in order to minimize the time you spend dealing with data queries.

If the SAE is still ongoing at the time of reporting, please leave 'Experience Course' blank and update it later.

SIGN AND DATE THE SAE PAGE

PLEASE ENSURE THAT ALL OF THE INFORMATION ON THE FOLLOWING Annex II-IV PAGES IS COMPLETE

Scan the AE/SAE pages
E-mail AE/SAE pages and all relevant data to: info@isco3.org

Annex II: The ISCO3 Safety Information and Adverse Event Reporting Program Form.

For VOLUNTARY reporting of adverse events to ozone therapy	**ISCO3 Report No.**	

A. PATIENT INFORMATION

Patient **Name / Surname** or identified number (if confidential)		**Date of Birth** (dd/mm/yyyy)	**Gender**	**Body weight**
		/ /20__	☐ Male ☐ Female	kg

Describe event, problem:

B. OZONE TREATMENT

Dose or Amount*	Frequency	Route	O_3 Generator brand	Device model

Diagnosis or Reason for Use (Indication)	Device Manufacturer Name, City and State
Type of Single-use material	Single-use material, Manufacturer Name, City and State

C. OTHER (CONCOMITANT) MEDICAL PRODUCTS

D. REPORTER

Name	Surname	Phone	E-mail
Address:			Health Professional □ Yes □ No
			Occupation:

E. OTHER RELEVANT HISTORY. Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.).

F. OTHER RELEVANT INFORMATION

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event. Note: * Please inform: Gas concentration in µg/mL and gas volume in mL.

Physician Signature _____ **Date:** _____ **Place:** _____

Annex III. Template to record ADVERSE EXPERIENCES (AE) or SERIOUS ADVERSE EXPERIENCES (SAE). Record any adverse experiences (AE) (using medical terminology) observed or elicited. Provide the diagnosis not symptoms where possible. One adverse experience per column.

☐ Adverse Experience ☐ Serious Adverse Experiences (SAE) (please print clearly)	AE + SAE	SAE
☐ Onset Date and Time	____/_____/_____ ____:_____ Day Month Year Hour : min	*Specify reason(s) for considering this a serious AE. Mark all that apply:* ☐ fatal ☐ life threatening ☐ disabling/incapacitating ☐ results in hospitalization (excluding elective surgery or routine clinical procedures) ☐ hospitalization prolonged ☐ congenital abnormality ☐ cancer ☐ overdose ☐ Investigator considers serious or a significant hazard, contra-indication, side effect or precaution.
☐ End Date and Time. *(If ongoing please leave blank)*	____/_____/_____ ____:_____ Day Month Year Hour : min	
Outcome	☐ Resolved ☐ Ongoing ☐ Dead	
Experience course.	☐ Intermittent ☐ No. of episodes ☐ Constant	
Intensity (maximum).	☐ Mild ☐ Moderate ☐ Severe	
Action Taken with Respect to Ozone treatment	☐ None ☐ Dose reduced ☐ Interrupted/restarted ☐ Stopped	Did the SAE abate? ☐ Yes ☐ No If ozone was interrupted, stopped or dose reduced: Was ozone reintroduced (or dose increased)? ☐ Yes ☐ No If yes, did SAE recur? ☐ Yes ☐ No
Relationship to Ozone treatment	☐ Not related ☐ Unlikely ☐ Suspected ☐ Probable	**Assessment** The SAE is probably associated with: ☐ Protocol design or procedures (but not ozone) *Please specify:* _____ ☐ Another condition (e.g. Condition under study, inter-current illness) *Please specify:* _____ ☐ Another drug *Please specify:* _____
Corrective Therapy If 'Yes' Record details in Concomitant Medication section	☐ Yes ☐ No	
Was the patient withdrawn due to this specific AE?	☐ Yes ☐ No	

Physician Signature: _____ **Date:** _____ **Place:** _____

Annex IV. Serious Adverse Experience (SAE). Relevant Laboratory Data.

Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal ranges

Remarks *(Please provide a brief narrative description of the SAE, attaching extra pages e.g. Hospital discharge summary if necessary).*

Phycician signature : _____ / /

(confirming that the above data are accurate and complete) *Date: Day Month Year*