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

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| 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** |
|  |  |  | □ Male □ Female |  kg |
| Describe Event, Problem: |
| **B.** OZONE TREATMENT |
| Dose or Amount\* | Frequency | Route | O3 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 or μgN/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 □ Died |
| **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 □ NoIf ozone was interrupted, stopped or dose reduced:Was ozone reintroduced(or dose increased)? □ Yes □ NoIf 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.

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| --- |
| Please provide relevant abnormal laboratory data below |
| Test | Date | Value | Units | Normal ranges |
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| **Remarks** *(Please provide a brief narrative description of the SAE, attaching extra pages e.g. Hospital discharge summary if necessary).* |
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| **Physitian signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ / /** |
| *(confirming that the above data are accurate and complete) Date: Day Month Year* |
|  |