**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 □ 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.

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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* | | | | |
|  | | | | |