

|  |   |                                |   |
|--|---|--------------------------------|---|
|  | <b>SERIOUS ADVERSE EVENT NOTIFICATION</b> | <b>STUDY ID:</b><br>iPROVE-EAL | <b>SPONSOR:</b><br>Department of Anesthesiology and<br>Critical Care. Hospital Clinic de<br>Barcelona |
|--|---|--------------------------------|---|

La notificación y definiciones de efectos adversos se ajusta a la legislación española (Real Decreto 1090/2015).

| <b>PATIENT INFORMATION</b> |               |               |               |
|----------------------------|---------------|---------------|---------------|
| <b>STUDY ID</b>            | <b>Gender</b> | <b>Weight</b> | <b>Height</b> |
|                            |               |               |               |

| <b>ADVERSE EVENT INFORMATION</b>  |                             |                                   |
|---|-----------------------------|-----------------------------------|
| <b>Event term</b> (grouping symptoms as a single disease)   | <b>Type of notification</b> | <b>Data and time of the event</b> |
|   |                             |                                   |
| <b>Event's description</b> (state before onset, course of AE indicating significant findings, laboratory data, measurements taken, etc.)  |                             |                                   |
|   |                             |                                   |
| <b>Seriousness</b>  |                             |                                   |
| <input type="checkbox"/> Death <input type="checkbox"/> Life in danger <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Hospitalization<br><input type="checkbox"/> Permanent / significant disability <input type="checkbox"/> Another major medical condition |                             |                                   |
| <b>Intensity:</b>   |                             |                                   |
| <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild   |                             |                                   |
| <b>Result:</b>  |                             |                                   |
| <input type="checkbox"/> Solved <input type="checkbox"/> Non Solved <input type="checkbox"/> Unknown <input type="checkbox"/> Solved with con sequels <input type="checkbox"/> Fatal    Data:   |                             |                                   |

| <b>INFORMATION METHODOLOGY IN RESEARCH</b> |   |
|--|---|
| <b>IMP</b>                                 | <b>Relationship to the adverse event</b>  |
|  | <input type="checkbox"/> True <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related<br><input type="checkbox"/> Unclassifiable <input type="checkbox"/> Not classified |
| <b>START DATE:</b>                         | <b>END DATE:</b>  |
|  |   |

|  |   |                         |  |
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| <b>RESEARCHER INFORMATION</b> |               |                                 |             |                  |
|-------------------------------|---------------|---------------------------------|-------------|------------------|
| <b>Principal investigator</b> | <b>Center</b> | <b>Reported by (researcher)</b> | <b>Data</b> | <b>Signature</b> |
|                               |               |                                 |             |                  |