**ICF Verification List**

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| **# Study, project or research product** | **Number of verified version** | **Date of verified version** |
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**1. Information concerning the informed consent procedure**

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| --- | --- | --- | --- | --- |
| **No** | Verified Items | Yes | **No** | **Comments** |
| 1.1 | Form confirming that the subject freely gave his consent. |  |  |  |
| 1.2 | Form confirming that the subject had ample time and opportunity to find out about the details of the study. |  |  |  |
| 1.3 | Form confirming that the subject will have ample time and opportunity to decide whether or not to participate |  |  |  |
| 1.4 | Form confirming that the subject’s participation is entirely voluntary. |  |  |  |
| 1.5 | Form confirming that the subject’s refusal to participate will not result in any penalty or loss of benefits. |  |  |  |
| 1.6 | Form confirming that the subject has the right to withdraw at any time without prejudice of suffering any consequences. |  |  |  |
| 1.7 | Form describing the foreseeable circumstances or reasons for terminating the subject’s participation in the study. |  |  |  |
| 1.8 | Form confirming that the subject will receive a written explanation and the signed and dated consent form for future reference. |  |  |  |

**2. Study information**

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| --- | --- | --- | --- | --- |
| **No** | Verified Items | **Yes** | **No** | Comments |
| 2.1 | Explanation that the study involves research. |  |  |  |
| 2.2 | Purpose of the study. |  |  |  |
| 2.3 | Experimental vs. standard treatments (medications or devices). |  |  |  |
| 2.4 | The study procedures description including all invasive procedures. |  |  |  |
| 2.5 | Description of the study’s experimental aspects. |  |  |  |

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| **No** | **Verified Items** | Yes | **No** | **\*NA** | **Comments** |
| 2.6 | Description of the comparative study treatment (active treatment vs. placebo-controlled). |  |  |  |  |
| 2.7 | Explanation on randomization procedure and the probability for assignment to different treatment. |  |  |  |  |

**\* Not applicable**

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| **No** | Verified Items | **Yes** | **No** | Comments |
| 2.8 | The expected duration of the subject’s participation in the study. |  |  |  |
| 2.9 | Description of consequences of the decision by the subject to withdraw from the study and the methods to end the subject’s participation. |  |  |  |
| 2.10 | The approximate number of subjects participating in the study, for the duration of the study as well as for the site. |  |  |  |
| 2.11 | Description of the subject’s responsibilities . |  |  |  |
| 2.12 | It is suggested to specify the approximate duration of each visit.  \* See Appendix 1, *Instructions Specific to the Site*. |  |  |  |

**3. Information concerning foreseeable risks and benefits**

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| --- | --- | --- | --- | --- |
| No | Verified Items | **Yes** | **No** | Comments |
| 3.1 | The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to the embryo, the fetus or the nursing infant. |  |  |  |
| 3.2 | Form confirming that procedure or treatment may involve potential risks to the subject or, when applicable, to the unborn child. |  |  |  |
| 3.3 | Description of the anticipated benefits; if no benefits are forthcoming, the subject should be informed. |  |  |  |
| 3.4 | Description of the alternative treatment that may be available to the subject and their potential risks and benefits. |  |  |  |
| 3.5 | Form confirming that subject or the subject’s legal representative will be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to participate in the study. |  |  |  |
| 3.6 | Explanation on the compensation or treatment that is available to the subject in the event of study-related loss or injury. |  |  |  |
| 3.7 | Explanation on the availability of alternative treatment in the event of study-related loss or injury, and if applicable, what is the course of treatment and when other information will become available. |  |  |  |
| 3.8 | The anticipated costs, if any, to the subject. |  |  |  |
| 3.9 | Description of the anticipated proportional payment, in this occurrence, made to the subject for participating in the study. |  |  |  |

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**4. Confidential data and new information**

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| --- | --- | --- | --- | --- |
| **No** | Verified Items | **Yes** | **No** | Comments |
| 4.1 | Form confirming that records identifying the subject will be kept confidential, to the extent permitted by the applicable laws and regulations. These records will not be made public. If the results of the study are published, the subject’s identity will remain confidential. |  |  |  |
| 4.2 | Explanation on the representatives of the sponsor/sponsor-investigator, the REB and the regulatory authorities will be granted access to the subject’s medical records for verification of the clinical procedures or clinical data, without violating the confidentiality of the subject, and that by signing the informed consent form, the subject or the subject’s legal representative is authorizing access. |  |  |  |
| 4.3 | Form confirming that if the subject or the subject’s legal representative has consented, the subject’s personal physician will be kept informed of the subject’s condition during the study. |  |  |  |
| 4.4 | The name, address and telephone number of the person to contact for further information or in the case of a study-related injury. |  |  |  |

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| **No** | Verified Items | **Yes** | **No** | **\*NA** | Comments |
| 4.5 | Identifying the study sponsor. |  |  |  |  |
| 4.6 | Purpose of the clinical study. |  |  |  |  |
| 4.7 | Description of the categories of individuals or research organizations under contract or regulatory authorities to whom will be granted access to study-related records. |  |  |  |  |
| 4.8 | Explanation on other individuals have access to personal records, appropriate measures will be taken to protect the confidentiality of said data. |  |  |  |  |
| 4.9 | Explanation on confidentiality requirements concerning the personnel directly or indirectly involved in data management permitting the identification of the subject. |  |  |  |  |

**\* Not applicable**

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| --- | --- | --- | --- | --- | --- |
| **No** | Verified Items | **Yes** | **No** | **\*NA** | Comments |

**\* Not applicable**

**5. Formal Aspects**

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| --- | --- | --- | --- | --- |
| No | Verified Items | **Yes** | **No** | Comments |
| 5.1 | Identification of the subject: i.e., the subject’s complete name and initials \* see Appendix 1. |  |  |  |
| 5.2 | A space for signatures of the subject or the subject’s legal representative, the person who led the discussion on the ICF and, when applicable, the investigator or a witness. Each person signing the ICF should also personally date it. |  |  |  |
| 5.3 | Site identification according to Appendix 1. |  |  |  |

**6. Vulnerable Subjects**

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| --- | --- | --- | --- | --- | --- |
| **No** | Verified Items | **Yes** | **No** | **\*NA** | Comments |
| 6.1 | Confirm that when minors (<18 years of age) are involved in a study, that their parents’ consent is required. |  |  |  |  |
| 6.2 | Confirm that when minors are involved in a study, that the ICF is written in terms understood by the subject. A space should be set aside for the subject’s signature. |  |  |  |  |

**\* Not applicable**

**7. Miscellaneous – to be added if applicable**

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| --- | --- | --- | --- | --- |
| No | Verified Items | **Yes** | **No** | Comments |
| 7.1 | The language used in this consent form should be non-technical and easily understood by the subject. |  |  |  |
| 7.2 | Ensure that the ICF provided to the subject or to the subject’s legal representative contains the information that the ICF was approved by the REB. |  |  |  |
| 7.3 | The ICF should contain the names and addresses of the people to contact for information concerning the subject’s participation in the study (ombudsman, subject’s representative). |  |  |  |

**CONFIRMATION OF THE ICF VERIFICATION LIST**

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| --- | --- |
| **STUDY NAME, PROJECT OR NUMBER OF THE DRUG:** | |
| **ICF VERSION:** | **DATE OF THE VERSION:**  **dd/ mmm /yyyy** |
| **AUTHOR OF THE ICF:** | |

**DATE OF THIS REVISION: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**dd/ mmm /yyyy**

**REVIEWED BY:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name in block letters Signature Title**

**ICF Verification list, attached ⬜ or comments:**

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ICF approved ⬜ Amendments required ⬜

**\* Please identify the attached comments by referring to the study number, the number and date of the ICF version**

**ICF for submission**

| **Date of the ICF version dd/mmm/yyyy** | **Version** | Signature of the investigator/qualified investigator or his delegate |
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**ICF approved versions**

| Date  dd/mmm/yyyy | Version | Pages | Signature of the investigator/qualified investigator or his delegate |
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