

# INVESTIGATOR GUIDANCE: Additional ISO 14155 Obligations

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## 1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting a <Clinical Trial> subject to ISO 14155.

## 2. GUIDANCE

### 2.1. General

- 2.1.1. The role of the principal investigator is to implement and manage the day-to-day conduct of the clinical investigation as well as ensure data integrity and the rights, safety and well-being of the subjects involved in the clinical investigation.
- 2.1.2. If the sponsor contracts an institution to conduct the clinical investigation, the institution shall appoint an appropriately qualified person to be the principal investigator.

### 2.2. Qualification of the principal investigator: The principal investigator shall

- 2.2.1. Be qualified by education, training and experience to assume responsibility for the proper conduct of the clinical investigation in accordance with this International Standard; evidence of such qualifications of the principal investigator and key members of the investigation site team shall be provided to the sponsor through up-to-date CVs or other relevant documentation.
- 2.2.2. Be experienced in the field of application and trained in the use of the investigational device under consideration.
- 2.2.3. Disclose potential conflicts of interest, including financial, that interfere with the conduct of the clinical investigation or interpretation of results.
- 2.2.4. Be knowledgeable with the method of obtaining informed consent.

### 2.3. Qualification of investigation site: The principal investigator shall be able to demonstrate that the proposed investigation site

- 2.3.1. Has the required number of eligible subjects needed within the agreed recruitment period.
- 2.3.2. Has one or more qualified investigators, a qualified investigation site team and adequate facilities for the foreseen duration of the clinical investigation.

### 2.4. Communication with the IRB: The principal investigator shall

- 2.4.1. Provide the sponsor with copies of any clinical-investigation-related communications between the principal investigator and the IRB.
- 2.4.2. Comply with the requirements to communicate with the IRB.
- 2.4.3. Obtain the written and dated approval/favorable opinion of the IRB for the clinical investigation before recruiting subjects and implementing all subsequent amendments, if required.
- 2.4.4. Perform safety reporting as specified below.
- 2.4.5. Promptly report any deviations from the clinical investigational plan that affect the rights, safety or well-being of the subject or the scientific integrity of the clinical investigation, including those which occur under emergency circumstances, if required by the IRB, clinical investigational plan or national regulations.
- 2.4.6. In particular circumstances, the communication with the IRB can be performed by the sponsor, partly or in full, in which case the sponsor shall keep the principal investigator informed.

### 2.5. Informed consent process: The principal investigator shall

- 2.5.1. Comply with the requirements specified by the IRB to obtain informed consent.
- 2.5.2. Ensure compliance with the applicable regulatory requirements and ethical principles for the process of obtaining informed consent.

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- 2.5.3. Ensure and document appropriate training if an authorized designee is appointed to conduct the informed consent process.
- 2.6. Compliance with the clinical investigational plan: The principal investigator shall
  - 2.6.1. Indicate his/her acceptance of the clinical investigational plan in writing.
  - 2.6.2. Conduct the clinical investigation in compliance with the clinical investigational plan.
  - 2.6.3. Create and maintain source documents throughout the clinical investigation and make them available as requested during monitoring visits or audits.
  - 2.6.4. Ensure that the investigational device is used solely by authorized users as specified in 6.2, and in accordance with the clinical investigational plan and instructions for use.
  - 2.6.5. Propose to the sponsor any appropriate modification(s) of the clinical investigational plan or investigational device or of the use of the investigational device.
  - 2.6.6. Refrain from implementing any modifications to the clinical investigational plan without agreement from the sponsor, IRB and regulatory authorities, if required.
  - 2.6.7. Document and explain any deviation from the approved clinical investigational plan that occurred during the course of the clinical investigation.
  - 2.6.8. Ensure that an adequate investigation site team and facilities exist and are maintained and documented during the clinical investigation.
  - 2.6.9. Ensure that maintenance and calibration of the equipment relevant for the assessment of the clinical investigation is appropriately performed and documented, where applicable.
  - 2.6.10. Ensure the accuracy, completeness, legibility and timeliness of the data reported to the sponsor in the case report forms and in all required reports.
  - 2.6.11. Maintain the device accountability records.
  - 2.6.12. Allow and support the sponsor to perform monitoring and auditing activities.
  - 2.6.13. Be accessible to the monitor and respond to questions during monitoring visits.
  - 2.6.14. Allow and support regulatory authorities and the IRB when performing auditing activities.
  - 2.6.15. Ensure that all clinical-investigation-related records are retained as required.
  - 2.6.16.
  - 2.6.17. Sign the clinical investigation report.
- 2.7. Medical care of subjects: The principal investigator shall
  - 2.7.1. Provide adequate medical care to a subject during and after a subject's participation in a clinical investigation in the case of adverse events, as described in the informed consent.
  - 2.7.2. Inform the subject of the nature and possible cause of any adverse events experienced.
  - 2.7.3. Provide the subject with the necessary instructions on proper use, handling, storage and return of the investigational device, when it is used or operated by the subject.
  - 2.7.4. Inform the subject of any new significant findings occurring during the clinical investigation, including the need for additional medical care that may be required.
  - 2.7.5. Provide the subject with well-defined procedures for possible emergency situations related to the clinical investigation, and make the necessary arrangements for emergency treatment, including decoding procedures for blinded/masked clinical investigations, as needed.
  - 2.7.6. Ensure that clinical records are clearly marked to indicate that the subject is enrolled in a particular clinical investigation.
  - 2.7.7. If appropriate, subjects enrolled in the clinical investigation shall be provided with some means of showing their participation in the clinical investigation, together

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- with identification and compliance information for concomitant treatment measures (contact address and telephone numbers shall be provided).
- 2.7.8. Inform, with the subject's approval or when required by national regulations, the subject's personal physician about the subject's participation in the clinical investigation.
  - 2.7.9. Make all reasonable efforts to ascertain the reason(s) for a subject's premature withdrawal from the clinical investigation while fully respecting the subject's rights.
- 2.8. Safety reporting: The principal investigator shall
- 2.8.1. Record every adverse event and observed device deficiency, together with an assessment.
  - 2.8.2. Report to the sponsor, without unjustified delay, all serious adverse events and device deficiencies that could have led to a serious adverse device effect; this information shall be promptly followed by detailed
  - 2.8.3. Written reports, as specified in the clinical investigational plan.
  - 2.8.4. Report to the IRB serious adverse events and device deficiencies that could have led to a serious adverse device effect, if required by the national regulations or clinical investigational plan or by the IRB.
  - 2.8.5. Report to regulatory authorities serious adverse events and device deficiencies that could have led to a serious adverse device effect, as required by the national regulations.
  - 2.8.6. \supply the sponsor, upon sponsor's request, with any additional information related to the safety reporting of a particular event.

### 3. REFERENCES

- 3.1. ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice