



## General Comments

The Taiwan Addendum to the Evaluation Instrument for Accreditation is intended for use by organizations in Taiwan seeking accreditation, by site visitors evaluating organizations in Taiwan, and by accredited organizations in the US that conduct or oversee research in Taiwan. This Addendum includes Standards and Elements where Taiwan laws, regulations, and guidelines require significant additional protections beyond those defined in the Evaluation Instrument, and is intended to be used in conjunction with the Evaluation Instrument.

The Addendum is based on a review of the following laws, policies, and guidance:

- Human Subjects Research Act (Ministry of Health & Welfare, 2019)
- Medical Care Act (Ministry of Health & Welfare, 2020)
- Pharmaceutical Affairs Act (Ministry of Health & Welfare, 2018)
- Pharmaceutical Affairs Act Enforcement Rules (Ministry of Health & Welfare, 2020)
- Regulations for Good Clinical Practice (Ministry of Health & Welfare, 2014)
- Regulations on Human Trials (Ministry of Health & Welfare, 2016)
- Regulations for Organization and Operation of Human Research Ethics Review Board (Ministry of Health & Welfare, 2018)

This Addendum does not include additional requirements that may be required in any of the 22 sub-national divisions or administrative units.

This Addendum represents AAHRPP's current understanding of additional requirements covering organizations conducting or reviewing research in Taiwan. We appreciate questions, concerns, and suggestions to improve this document. Please email [accreditation@aahrpp.org](mailto:accreditation@aahrpp.org).

## Domain I: Organization

**Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.**

**Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.**

Written materials must define research involving human participants consistent with country law:

- Research, including a “human trial,” means experimental research of new medical technology, new medicament, new medical implement, or the bioavailability and bioequivalence of generic

drugs conducted by medical care institutions on humans based on medical theory. (Medical Care Act, Chapter I, Article 8)

- Clinical Trial: Any investigation in human participants intended to discover or verify the clinical. (Regulations on Good Clinical Practice, Article 3)
- Participant/trial participant: An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control. (Regulations on Good Clinical Practice, Article 3)
- Human participant research refers to research involving obtaining, investigating, analyzing, or using human specimens or an individual person's biological behavior, physiological, psychological, genetic, or medical information. (Human Research Act, Article 4)
- Human specimens refers to human (including a fetus and corpse) organs, tissues, cells, body fluids, or any derivative biomaterial arising from experimentation therewith. (Human Research Act, Article 4)

**Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate.**

Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. (Regulations on Good Clinical Practice, Article 4)

**Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.**

Written materials must describe the process for ensuring that researchers receive required education:

- Human trial related training of more than thirty hours within the past six years; being the trial conductor in human trials of somatic cells or gene therapy with additional five or more hours of relevant training.
- Medical ethics related courses for more than nine hours within the past six years.

(Regulations on Human Trials, Article 4)

**Element I.1.G. The Organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws.**

When research involves participants other than decisional adults, consent must be obtained from a surrogate, defined as follows:

- Where the research participant is a fetus, the consent shall be obtained from the mother.
- Where the participant has been judicially declared to be of limited legal capacity or under assistance, consent shall be obtained from both the individual and their legal representative or assistant.
- Where the person is incompetent or under guardianship, consent shall be obtained from their legal representative or guardian.

Consent shall be obtained in the following order of precedence from an appropriate relation:

1. A spouse
2. An adult child
3. Parents
4. Siblings
5. Grandparents

Where the consent is provided in writing by a surrogate meeting required criteria, such written consent may be sufficient where obtained from any such individual; where the express intent of such persons is not unanimous, the order of precedence above shall apply to determine the matter. In the preceding order of precedence, among the same order, closer relatives shall be accorded priority; where the relatives are of the same degree of closeness, cohabitation shall be accorded priority; and in case of non-cohabiting relatives, the elderly shall be accorded priority.

(Human Research Act, Chapter 2, Article 12; Regulations on Human Trials, Article 5)

**Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.**

**Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of noncompliance with Human Research Protection Program requirements. The Organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when noncompliance occurs. Such policies and procedures include reporting these actions, when appropriate.**

The IRB or EC shall, for every approved research protocol, throughout the conduct thereof, provide at least one annual audit.

Where the IRB or EC discovers any of the following conditions in the conduct of a research protocol, they shall order the research protocol into cessation for amelioration within a specified period of time, or to be terminated, and shall notify the research entity and the responsible ministry of central government:

- Where a required IRB or EC approval was not obtained, and amendments were undertaken in the research protocol without prior permission.
- Any matter materially affecting research participant rights or safety.
- Abnormal frequency of adverse events or irregular degrees of severity.
- Sufficient evidence evinces the research is not necessary.
- Any other matter arises affecting the research risks and benefits analysis.

After the research protocol is completed, should any of the following conditions arise, the IRB or EC shall undertake an investigation, and notify the research entity and central competent authority of relevant entities:

- Serious late onset adverse events.
- Any violation of law or act contrary to the research project's contents.
- Any serious adverse effect on human participant's rights.

(Human Research Act, Articles 16-17)

**Standard I-7: The organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.**

**Element I.7.A. When research involves investigational or unlicensed test articles, the organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.**

Prior to conducting a human trial involving drugs, devices (including *in vitro* diagnostic devices), or biological specimens, the organization must submit an application to the Taiwan Food and Drug Administration for review of the proposed clinical trial. After receiving appropriate approval and beginning clinical trials, the organization must submit reports as specified by the Taiwan Food and Drug Administration. (Pharmaceuticals Affairs Act, Chapter IV, Article 44)

**Element I.7.B. The Organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.**

The researcher may assign some or all duties for investigational articles accountability at the trial sites to an appropriate pharmacist or another appropriate individual who is under the supervision of the researcher.

The researcher, pharmacist, or other designated individual will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each participant, and then return to the sponsor or alternative disposition of unused products. These records will include dates, quantities, batch/serial numbers, expiration dates (if

applicable), and the unique code numbers assigned to the investigational products and trial participants.

Researchers should maintain records that document adequately that the participants are provided the doses specified by the protocol and reconcile all investigational products received from the sponsor.

(Regulations on Good Clinical Practice, Articles 92-93)

## Domain II: Institutional Review Board or Ethics Committee

**Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.**

**Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.**

The research institution may set up at least one IRB or EC, which may establish sub-groups for operational purposes. (Regulations for Organization and Operation of Human Research Ethics Review Board, Article 2)

- Where an entity does not have an established IRB or EC, the review may be conducted by an IRB or EC of another entity. (Human Research Act, Article 5)

According to IRB or EC rosters:

- Each IRB or EC has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization.
- People of either gender must constitute no less than one third of the IRB or EC.
- More than two-fifths shall not be affiliated with the research entity or have immediate family members who are affiliated with the organization.
- Each IRB or EC has at least one member whose primary concerns are in scientific areas.
- Each IRB or EC has at least one member whose primary concerns are in nonscientific areas, including legal specialists or other impartial members of the community.
- No IRB or EC may have members who represent a single profession.

- Each IRB or EC must have at least one member who represents the perspective of research participants. (Human Subjects Research Act, Article 7; Regulations on Good Clinical Practice, Chapter I, Article 3.5)

(A single member may represent more than one category.)

The name list of the joint IRB or EC members shall be disclosed to the public. (Regulations on Human Trials, Article 6)

**Element II.1.D. The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB or EC.**

IRB or EC members are considered to have a conflict of interest and must recuse themselves from review under the following circumstances:

- Serving as the trial conductor, assistant trial conductor, or entrustor of the human trial.
- Being, currently or in the past, the spouse, blood relative of four degrees or closer, or relative by marriage of three degrees or closer of the trial conductor.
- Being in an employment relationship with the entrustor of the human trial.
- Having an employment relationship with the commissioning enterprise of the research project under review.
- Being in other situations where the recusal of the IRB or EC member is deemed necessary by the IRB or EC.
- There are specific facts pointing to potential bias.

(Human Subjects Research Act, Chapter 2, Article 17; Regulations for Organization and Operation of Human Research Ethics Review Board, Article 8; Regulations on Human Trials, Article 8)

**Standard II-2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.**

**Element II.2.C. The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.**

A quorum must be present for research to be approved.

- For an IRB or EC or sub-IRB or sub-EC that consists of at least five but less than seven members, a meeting shall not be held unless it is attended by at least two-thirds of the members; for an IRB or EC or sub-IRB or sub-EC that consists of seven or more members, a meeting shall not be held unless it is attended by at least half of the members.
- A meeting shall not be held if all attending members are of the same gender.
- For research to be approved, it has to receive the approval of a majority of members present at the meeting.

- If quorum is lost during a meeting, the IRB or EC cannot take votes until the quorum is restored.

The following members must be present to conduct business:

- At least one scientist.
  - A licensed physician, if research involves an investigational article regulated by the TFDA or an international regulatory body such as the US FDA.
- At least one person without a biomedical science background outside the institution.
- At least one member who represents the general perspective of participants.

(Regulation for Organization and Operation of Human Research Ethics Review Board, Article 6; Human Subjects Research Act, Articles 6-7)

**Element II.2.F. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.**

Research may be reviewed using an expedited review procedure.

- Expedited review procedures apply where the scope of the research lies within approved expedited categories announced.
- Expedited review shall be conducted by at least one board member.
- The board member may exercise the approval granting power on behalf of the IRB or EC and the result shall be reported to the IRB or EC.
- If the project cannot be approved by the board member using the expedited procedure, it should undergo the standard review procedure. (Regulations for Organization and Operation of Human Research Ethics Review Board, Article 11; Human Subjects Research Act, Article 8)

**Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.**

The researcher shall immediately report any suspected unexpected serious adverse drug reactions to the IRB or EC. However, those serious adverse events (SAEs) that the protocol or other document identifies as not needing immediate reporting shall not apply. (Regulations on Good Clinical Practice, Article 106)

The medical care institution shall report to the Ministry of Health and Welfare, or other applicable agency, when the trial participant experiences any of the following occurrences during the human trial period, or anytime when any of the following occurrences are related to the human trial:

- Death.
- Life-threatening event.
- Permanent mental and physical disability.
- Where the fetus or newborn of the trial participant suffers congenital malformations.



- Complications requiring hospitalization or prolonged hospitalization.
- Other complications possibly causing permanent damages.

The medical care institution shall report within seven days after learning of the occurrence(s) and submit detailed investigation information to the central competent authority within fifteen days. (Regulations on Human Trials, Article 12)

**Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidances.**

**Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.**

The IRB or EC reviews advertising to ensure it does not:

- Include content involving efficacy related to sexual intercourse.
- Include the use of methods likely to encourage drug abuse, such as exchanges of drug containers for prizes or the provision of incentives.
- Include any representation that use of a drug will cure a particular disease or will improve a person's health or constitution in a particular area, or the creation of false or misleading scenarios as a means of publicizing the drug.

(Pharmaceutical Affairs Act Enforcement Rules, Article 47)

**Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately documents the consent process.**

Policies and procedures describe the requirements for consent. The following list represents the reconciled requirements of the Human Research Act and Regulations on Good Clinical Practice and AAHRPP. (Element II.3.F., Table II.3.F.1.)

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The trial treatment(s) and the probability for random assignment to each treatment.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed, including all invasive procedures.
- A description of the demands on participants or the participant's responsibilities.
- Identification of any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.

- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- A description of any benefits to the participant or to others, which may reasonably be expected from the research. When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- A disclosure of alternative procedures or courses of treatment, including any that might be advantageous to the participant.
- The compensation and/or treatment available to the participant in the event of trial-related injury.
- The anticipated prorated payment, if any, to the participant for participating in the trial.
- The anticipated expenses, if any, to the participant for participating in the trial.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- How privacy will be protected.
- That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential.
- How the research will be monitored.
- Provision of services to participants adversely affected by the research.
- Contact details of a person to receive complaints.
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participants' rights.
- An explanation of whom to contact in the event of a research-related injury to the participant.
- Contact details of the researchers for questions, concerns, or complaints.
- The participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data.
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
- A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.
- The approximate number of participants involved in the study.
- The amounts and sources of funding for the research.
- Financial or other relevant declarations of interests of researchers, sponsors, or institutions.

- Any additional costs to the participant that may result from participation in the research.
- The likelihood and form of dissemination of the research results, including publication.
- Any expected benefits to the wider community.
- A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.
- A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- A statement that the monitors, the auditors, the IRB or EC, and the regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorized representative is authorizing such access.
- That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
- The approximate number of participant involved in the trial.
- Subjects shall be informed of any commercial benefit possibly derived from human research; any necessary agreements shall be made in writing.

(Human Subjects Research Act, Article 14.9; Regulations on Good Clinical Practice, Art 22)

In addition, when research involves biological samples, the participant shall be informed of the preservation and reutilization of the participant's biological samples, personal data, or derivatives, including:

- The purposes and intended scope and duration of uses of tissue samples.
- Methods, types, volume of sample collection, and the part of the body where the sample will be taken from.
- Sample donors' rights and the responsibilities of sample processors and keepers.
- The identity of sample keepers and processors.
- Whether tissue samples will be provided for, rendered to, or authorized to be used by any other local or foreign parties.
- How remaining tissue samples will be handled.
- Sources of research funds and all agencies participating in this research.

- Other important issues in relation to sample collection, access to medical records, follow-up tests, or disease information, etc. as required by the protocol.

(Regulations on Human Trials, Article 8)

The participant's biological samples, personal data, or derivatives shall be destroyed immediately upon completion of the human trial. The reutilization of aforesaid material(s) as subject to the trial participant's consent shall be reviewed and approved by the Review Board. A new written consent shall be obtained from the trial participant with regard to any non-delinked material(s). (Regulations on Human Research, Article 14)

Where the research purpose involves indigenous people, there shall additionally be required consultations to obtain the consent of their indigenous group as specified by the Central Council of Indigenous Peoples; any publication of research results shall require the same consent. (Human Trial Regulations, Article 15)

Documentation of the consent process includes:

- Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the participant or by the participant's legally acceptable representative.
- Prior to a participant's participation in the trial, the written consent document should be signed and personally dated by the researcher and the person who conducted the informed consent discussion.
- If the participant or the participant's legally acceptable representative is unable to read, an impartial witness shall be present during the entire informed consent discussion. The participant or the participant's legally acceptable representative shall still sign and date the informed consent form. Finger print is an acceptable substitute for signature.
- The impartial witness should read the informed consent form and any other written information to be provided to participants and attests that the information was accurately explained by the investigator or designated person, and was fully understood by the participants or the participant's legally acceptable representative.
- The impartial witness attests that informed consent was freely given by the participants or the participant's legally acceptable representative by signing and dating the informed consent form.
- Trial staff shall not act as the impartial witness.

Prior to participation in the trial, the participant or the participant's legally acceptable representative should receive a copy of the signed and dated written consent document and any other written information provided to the participants. (Regulations on Good Clinical Practice, Articles 21 and 23)

**Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.**

**Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.**

Research involving children:

- Human research shall not be conducted on children, except when research is clearly beneficial to the participant's collective or individual interest, or when the participant's legal guardians or most appropriate relations have been notified, and their written consent obtained.
- Children are individuals under 20 years of age.
- The following can serve as a guardian for children:
  - A person appointed by a court to serve as the guardian.
  - Grandparents living in the same household with the child.
  - Elder brothers or sisters living in the same household with the child, provided they are not under 20 years of age.
  - Grandparents not living in the same household with the child.

(Human Subjects Research Act, Article 12)

Research involving adults who lack decision-making capacity:

- Human research shall not be conducted on adults without capacity to provide informed consent (adults with "limited disposing capacity"), except where apparently beneficial to the health of the specific population or patients with a special disease, in which case the EC must determine:
  - The objective of the trial cannot be met by conducting a trial in participants with the ability to give personal consent.
  - The foreseeable risks to the participants are low.
  - The negative impact on the participant's well-being is small.
  - The trial is not prohibited by law.
  - The trial has written approval from the EC.
  - The trials should be conducted in patients with a condition for which the investigational product(s) is intended to treat.
  - Trial participants are closely monitored and are withdrawn from a trial if they appear to be too uncomfortable.
  - Consent of the guardian is required when adults without capacity are to be enrolled in research. The following can serve as a guardian for adults who lack decision-making capacity:
    - A person appointed by a court to serve as the guardian.
    - Spouse.
    - Adult direct/blood relative.
    - Parents.
    - Siblings.
    - Grandparents.
    - Great-grandparents or collateral relatives by blood to the third degree. (Human Subjects Research Act, Article 12)

A non-therapeutic clinical trial (i.e., a trial in which there is no anticipated direct clinical benefit to the participant) cannot be

conducted in participants who personally give consent and who sign and date the written consent document, except where:

- The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
- The foreseeable risks to the participants are low.
- The negative impact on the participant's wellbeing is minimized and low.
- The clinical trial is not prohibited by law.
- The opinion of the IRB or EC is expressly sought on the inclusion of such participants, and the written opinion covers this aspect.
- Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

(Regulations for Good Clinical Practice, Article 24)

### **Standard II-5: The IRB or EC maintains documentation of its activities.**

**Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures..**

The IRB or EC meeting minutes and the list of ethics committee members must be published for disclosure to the public and maintained for public inspection. The published content shall at least include the date of the meeting, the name of the attending and absent board members, the name of the research project, a summary of the discussion, and the resolutions. (Regulations for Organization and Operation of Human Research Ethics Review Board, Article 12; Human Trials Regulations, Article 6)

Medical records for human trials should be retained indefinitely. (Medical Care Act, Chapter IV, Article 70)

## **Domain III: Researcher and Research Staff**

**Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Staff have the protection of the rights and welfare of research participants as a primary concern.**

**Element III.1.C. Researchers employ sound study design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants.**

During and following a participant's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the clinical trial. The investigator should be able to demonstrate a potential for recruiting the required number of suitable participants within the agreed recruitment period. (Regulations for Good Clinical Practice, Article 35)

The researcher follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the researcher promptly documents and explains to the Sponsor any premature unblinding. (Regulations for Good Clinical Practice, Article 6)

Researchers inform participants when medical care is needed for other illnesses of which the researchers become aware. (Regulations for Good Clinical Practice, Article 6)

**Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.**

The researcher informs the participant's primary physician about the participant's participation in the clinical trial if the participant has a primary physician and if the participant agrees to the primary physician being informed. (Regulations for Good Clinical Practice, Article 7)

Although a participant is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the researcher makes a reasonable effort to ascertain the reason, while fully respecting the participant's rights. (Regulations for Good Clinical Practice, Article 9)

**Standard III-2: Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.**

**Element III.2.A. Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.**

The investigator must meet all the qualifications and abilities specified by the Ministry of Health & Welfare and shall have experiences for the proper conduct of the trial. (Regulations for Good Clinical Practice, Article 30)

The investigator shall possess the following qualifications:

- Licensed as a physician, dentist, or traditional Chinese medicine physician with five or more years of experience in clinical treatment.
- Received human trial related training of more than thirty hours within the past six years.

- If the trial involves somatic cells or gene therapy, the investigator has received an additional five or more hours of relevant training.
- Completed medical ethics related courses for more than nine hours within the past six years.

Those who have been subject to physician disciplinary action or whose license has been suspended for more than one month or abolished due to any violation of laws and regulations related to human trials shall not serve as an investigator. (Regulations on Human Trials, Article 4)

Researchers should:

- Be familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator's brochure, in the product information, and in other information sources provided by the sponsor.
- Permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.

(Regulations on Good Clinical Practice, Chapter 4)

**Element III.2.B. Researchers maintain appropriate oversight of each research study, as well as Research Staff and trainees, and appropriately delegate research responsibilities and functions.**

The researcher shall have available an adequate number of qualified staff and adequate facilities to conduct the trial properly and safely.

The researcher must maintain a list of appropriately qualified persons to whom they have delegated significant clinical trial-related duties.

(Regulations on Good Clinical Practice, Article 34)

**Element III.2.D. Researchers and research staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the organizations policies and procedures; and the IRB's or EC's requirements.**

The investigator shall promptly provide written reports to the sponsor, the Ethics Committee and the Competent Authority on any situation significantly affecting the conduct of the trial and/or increasing the risk to participants.

The investigator shall immediately report any serious adverse events to the sponsor and shall provide detailed, written reports as soon as possible. The investigator shall immediately report any suspected unexpected serious adverse drug reactions to the Ethics Committee. However, those SAEs that the protocol or other document identifies as not needing immediate reporting shall not apply.

When adverse events or laboratory abnormalities are identified as critical to safety evaluations, the investigator should report to the sponsor within the time periods specified by the sponsor in the protocol.

For reported deaths, the researcher supplies the sponsor and the IRB or EC with any additional requested information (e.g., autopsy reports and terminal medical reports).



The researcher provides written reports to the sponsor, the IRB or EC, and, where applicable, the organization, on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.

If the trial is suspended or terminated, the investigator and the institution shall promptly inform the trial participants and should assure appropriate therapy and follow-up for the participants.

If the investigator suspended or terminated a trial without prior agreement of the sponsor, the investigator and the institution shall promptly inform the sponsor and the Ethics Committee, and provide detailed written reports.

If the Ethics Committee terminated or suspended a trial, the investigator and the institution shall promptly inform the sponsor, and provide the detailed written reports.

Upon completion of the clinical trial, the researcher informs the organization; the IRB or EC with a summary of the trial's outcome; and the regulatory authority with any reports required.

(Regulations on Good Clinical Practice, Chapters III and IV)