HuanYe Psychology Group Institutional Review Board (HYIRB)

Statutes

(Submitted to the Board of Directors of the HuanYe Psychology Group for review and approval on March 12, 2022, at the first meeting of the IRB (Institutional Review Board) of the Group, and implemented as of March 12, 2022.)

Chapter 1 General Provisions

Article 1 In order to promote the spirit of science, advocate a good academic atmosphere, strengthen academic ethics construction, and promote and ensure the healthy development of the group's academic activities, in accordance with the *HuanYe Psychological Group Charter*, the HuanYe Psychological Group Research Institutional Review Board (HYIRB) is established, and this charter is formulated.

Chapter 2: Organizational Structure

Article 2 The institutional review board is the advisory and deliberative body for decision-making on academic ethics, academic intellectual property rights, and other related matters within the group.

Article 3 The institutional review board shall carry out its work under the leadership of the group's board of directors and the party committee according to its own functions, report its annual work plan and work

summary to the group's board of directors and the party committee, and submit the filing materials for matters approved by its review.

Under the premise of implementing a dual leadership system of the board of directors and the party committee, the research institutional review board is led by the group

The Board of Directors has designated the Group's Scientific Research Management Center to handle administrative management on its behalf. Article 4 The institutional review board is composed of 7-9 members, including 1 chairman and 1 vice-chairman. The board must consider candidates who are familiar with scientific ethics. The candidates for committee members are selected by the Group's Scientific Research Management Center and recommended by the Chairman of the Board, with the number of candidates recommended by the Chairman not exceeding one-third of the total number of committee members. The chairman and vice-chairman of the committee are elected by all committee members.

Article 5 The Research Institutional Review Board adopts a term system, with each term lasting four years. Except for members recommended by the Chairman of the Board, members may be re-elected but not for more than two consecutive terms. In the event of a vacancy due to retirement or transfer of a member, the Board must fill the vacancy according to the method for selecting that member.

When there is a significant personnel change in the institutional review board, the board may be re-elected before the end of its term, subject to the approval of the group's board of directors.

Article 6 Members of the institutional review board shall meet the following conditions:

- (1) It has a good academic reputation and a rigorous academic atmosphere;
- (2) Adhere to principles and handle matters impartially;
- (3) Strong academic judgment;
- (4) Familiar with relevant rules and regulations;
- (5) Capable of fulfilling the duties of a committee member.

Chapter 3 Responsibilities

Article 7 The institutional review board shall conscientiously implement the national guidelines and policies related to academic ethics work, as well as the relevant regulations of the group, to provide public assurance that academic research and experimental protocols are ethical, thereby ensuring the safety, health, and rights of the subjects are protected.

Article 8 The main responsibilities of the institutional review board are:

- (1) Establish standards for academic ethics-related work within the group;
- (2) Establish rules and regulations for the management of academic ethics affairs within the group;

- (3) Discuss disputes and controversies related to scientific ethics, and provide suggestions for handling them;
- (4) Review and supervise the scientific ethical nature of academic research.

Article 9: Members of the institutional review board shall perform their duties in accordance with the charter, free from interference from any organization or individual. They shall properly exercise their academic authority, impartially and fairly express their academic review opinions, and strictly maintain confidentiality regarding matters discussed and decided upon at committee meetings.

Chapter 4: Authority and Basic Rules of Procedure

Article 10 The authority and basic rules of procedure of the institutional review board are as follows:

- (1)Researchers can be required to provide informed consent forms, or the informed consent procedure can be waived upon the researchers' request;

 (2)May request researchers to modify the plan;
- (3)Researchers may be required to suspend or terminate research activities;
- (4)The decision to approve, disapprove, or review after modification can be made for the research proposal;
- (5)The decision made by the institutional review board should be approved by two-thirds of the members of the institutional review board;

- (6)The review committee of the research ethics committee can make a decision to approve, disapprove, or make necessary modifications before re-reviewing;
- (7)The institutional review board conducts annual self-inspection and tracking inspection management, including reporting of major issues, for projects that have been reviewed and approved;
- (8)If the project application submitted by researchers is not approved by the institutional review board, the research work of the project shall not be carried out.

Chapter 5 Working principles

Article 11 Working Principles

- (1) Respect and safeguard the right of the subjects to independently decide whether to consent or not to consent to the trial, strictly fulfill the informed consent procedure, and shall not use deception, inducement, coercion, or other improper means to make the subjects agree to participate in the trial, allowing the subjects to withdraw from the trial at any stage;
- (2) Consideration of the safety, health, and rights of the subjects must take precedence over consideration of scientific and social interests, striving to maximize the benefits to the subjects and avoid harm as much as possible;
- (3) Respect and protect the privacy of the subjects, truthfully inform the

subjects of the storage and use of materials involving their privacy and confidentiality measures, and shall not disclose materials and information involving their privacy to unrelated third parties or the media;

(4) Special protection should be given to subjects who have lost or lack the ability to safeguard their own rights and interests (vulnerable groups), including children, pregnant women, mentally retarded individuals, mental patients, prisoners, and those with poor economic conditions and low educational levels.

Chapter 6: Review Procedure

Article 12: Research projects undergoing ethical review should submit the following materials to the institutional review board:

- (1) Ethical Review Application Form;
- (2) Informed consent form;
- (3) Research or related technology application schemes;
- (4) Other materials specified by the committee.

Article 13: Before applying for social science projects, project applicants should obtain written informed consent from the subjects voluntarily. If written informed consent cannot be obtained, oral informed consent should be obtained in advance, and supporting materials for obtaining oral informed consent should be submitted. For subjects who lack capacity and cannot make decisions on their own, written informed consent must be obtained from their guardians or agents.

Before applying for projects involving humans and human factors, such as human factors science projects, special medical use formula food projects, and pharmaceutical projects, project applicants must complete all materials used for recruiting subjects. After the project is approved, the materials used for recruiting subjects cannot be changed.

Before conducting animal experiments for special medical use formula food projects and pharmaceutical projects, the project applicant must complete all materials related to animal immunization and animal genetics (for pharmaceuticals, except for initial experiments, pharmacokinetic information must be clearly specified). After the project is approved, animal immunization and animal genetics materials cannot be altered; if there are new results in pharmacokinetic studies beyond the initial stage of drug experiments, they must be promptly submitted to the Group's Research Institutional Review Board.

Article 14: When obtaining informed consent from subjects, the applicant must provide them with complete and understandable necessary information. The informed consent form should be expressed in plain and easy-to-understand language (in ethnic minority areas, local language expression may be used), and sufficient time should be given for subjects to consider whether to consent to the trial.

Article 15: When the implementation procedures or conditions of the project change, informed consent from the subjects must be obtained again, and an ethical review application must be resubmitted to the

Institutional Review Board.

- **Article 16:** The Research Institutional Review Board conducts the following reviews for projects applying for ethical review:
- (1) whether the qualifications and experience of the researchers meet the trial requirements;
- (2) whether the research protocol complies with scientific and ethical principles;
- (3) whether the potential risks to subjects are appropriate compared to the expected benefits of the study;
- (4) during the process of obtaining informed consent, whether the relevant information provided to subjects (or their families, guardians, legal representatives) is complete and understandable, and whether the methods used to obtain informed consent are appropriate;
- (5) whether confidentiality measures have been taken for subjects' data;
- (6) whether the criteria for subject inclusion and exclusion are appropriate and fair;
- (7) whether subjects are clearly informed of their rights, including the right to withdraw at any time during the study without giving reasons and without discrimination;
- (8) whether subjects receive reasonable compensation for participating in the study, and if so, whether the treatment and compensation measures are appropriate;

- (9) whether there is a designated person among the researchers responsible for handling informed consent and subject safety issues;
- (10) Whether protective measures have been taken for the potential risks that the subjects may bear during the research;
- (11) Whether there is any conflict of interest between the researchers and the subjects.

Chapter 7 Specific Rules of Procedure

Article 17 The Research Institutional Review Board shall implement a regular meeting system, convening at least two plenary meetings of all committee members each year, primarily to discuss the policies and guidelines for academic ethics work within the group and to deliberate on major issues and activities. According to work needs, the chairperson may propose the convening of an extraordinary plenary meeting of all committee members.

Article 18 The meetings of the institutional review board shall be presided over by the chairman or a vice-chairman entrusted by the chairman. In principle, the plenary meeting of the committee shall be held only when at least two-thirds of the committee members are present. The committee shall make decisions based on the principle of democratic centralism and may adopt voting methods for decision-making. A resolution shall be passed only when at least two-thirds of the participants agree.

Article 19 The institutional review board meeting adopts a recusal system. When deliberating or evaluating matters related to the committee member himself or herself and his or her relatives, the committee member must voluntarily recuse himself or herself.

When the committee director recuses himself due to the provisions of this article, the deputy director of the committee shall exercise the committee's functions on his behalf

The full responsibilities of the director. When both the committee director and deputy director are required to withdraw due to the provisions of this article

At that time, a committee member shall be selected by the committee to exercise all the duties of the committee director on behalf of the committee.

Article 20: Based on the content of the agenda, the chairman of the committee may decide to invite relevant personnel to attend as non-voting delegates.

Article 21: If the relevant units and parties have objections to the deliberation results of the institutional review board, they must submit a request for reconsideration within one week; after obtaining the consent of not less than one-third of the committee members for the reconsideration request, the relevant matters shall be submitted to the group's academic committee for reconsideration. The conclusion made after reconsideration will not be further reconsidered.

Article 22: Archiving

- (1) The ethical review application form submitted by the applicant, as well as all application materials;
- (2) Notice of acceptance for review by the institutional review board, meeting schedule, attendance sheet for institutional review board meetings, voting form, meeting minutes, and approval document for review by the institutional review board;
- (3) Correspondence between members of the institutional review board and the applicant or relevant personnel regarding application, decision—making, and follow-up review issues. All written materials received during the follow-up review period. Notifications of study suspension or early termination. Final summary or report of the study;
- (4) Annual work summary of the institutional review board.

Chapter 8 Supplementary Provisions

Article 23: This charter shall be implemented after being submitted to the Board of Directors of HuanYe Psychological Group for review and approval by the full meeting of the Research Ethics Committee of HuanYe Psychological Group. Any amendments to this charter must go through the same procedure.

The implementation details, work standards, and rules and regulations regarding this charter, approved by the institutional review board, shall be implemented after deliberation by the full meeting of the institutional

review board. Any amendments to the aforementioned documents shall follow the same procedure.

Article 24 The interpretation of this charter shall be the responsibility of the Board of Directors of the Night Vision Psychological Group.

Article 25: These Articles of Association shall come into effect as of the date of promulgation.