温 州 肯 恩 大 学 文 件

温肯大发〔2021〕54 号

关于印发《温州肯恩大学伦理委员会章程（试行）》的通知

各学院、各部门:

《温州肯恩大学伦理委员会章程（试行）》已经2021年第七十九次校务会通过，现予以印发，请遵照执行。

特此通知。

附件：温州肯恩大学伦理委员会章程（试行）

温州肯恩大学

2021 年 10 月 21 日

附件：

温州肯恩大学伦理委员会章程（试行）

第一章 总则

第一条 为了规范学校开展涉及人体和动物的相关实验，尊重和保护人类受试者的合法权益，维护学校实验动物福利，规范伦理审查和从业人员的职业行为，根据《涉及人的生物医学研究伦理审查办法》、《涉及人的生物医学研究伦理审查规范》、《实验动物管理条例》等文件，参照国家有关法律、法规和国际惯例，结合我校实际，制订本章程。

第二条 温州肯恩大学伦理委员会（以下简称校伦理委员会）是统筹规范和指导协调学校伦理治理的议事机构。

第三条 本校各部门（学院）和个人从事涉及人的以及涉及实验动物的科研活动，均应事先申请伦理审查，经校伦理委员会的批准后方可进行，并接受校伦理委员会监督检查。

第四条 伦理审查应遵守国家法律、法规和本校相关规章制度以及公认的生命伦理原则，伦理审查过程应当独立、客观、公正和透明。

第二章 组织机构

第五条 校伦理委员会是学校伦理事项的最高议事机构，下设两个分委员会负责专项伦理审查和监管，分别为涉及人的伦理委员会（以下简称“涉人伦理委员会”）和实验动物伦

理委员会（以下简称“动物伦理委员会”）。校伦理委员会下设办公室，设在科研办，并有储存审查项目资料的档案设备。

第六条 校伦理委员会由生物医学、法学、伦理学、社会学等领域的专家及相关师生代表、社会人士组成。涉人伦理委员会由若干名委员组成，其中主任1名，副主任2名；动物伦理委员会由若干名委员组成，其中主任1名，副主任1名。主任、副主任由校伦理委员会委员协商推举产生，报校务会研究决定。

第七条 两个分委员会的委员每届任期5年，可以连选连任。委员因故需要调整时，调整人选由校伦理委员会各分委员会主任会议提出，报校务会研究决定。

第八条 学校在经费等方面支持和保障校伦理委员会的运作。

第三章 工作职责

第九条 校伦理委员会应当制定章程、审查程序、监督制度、专业培训计划等，定期开展国家政策、法规和伦理原则宣传。

第十条 各分委员会主任负责召集例会、组织项目伦理审查活动、签发或授权审查决议等。

第十一条 涉人伦理委员会负责对学校涉及人的研究项目进行伦理审查和监督。在医疗单位开展的任何类型的涉及人的医学研究项目由项目负责人向该医疗单位申请伦理审查。

第十二条 动物伦理委员会负责对学校开展的有关实验动物研究项目进行伦理审查和监督。

第十三条 制止违反人体或动物伦理原则的行为。对违反伦理原则的单位和个人，有权作出限期整改决定。对情节严重者提出处理意见，直至终止其实验。

第四章 涉及人的伦理审查程序

第十四条 涉及人的科技研究活动应当符合以下伦理原则:

（一）知情同意原则。尊重和保障受试者是否参加研究的自主决定权，严格履行知情同意程序，防止使用欺骗、利诱、胁迫等手段使受试者同意参加研究，允许受试者在任何阶段无条件退出研究。

（二）控制风险原则。首先将受试者人身安全、健康权益放在优先地位，其次才是科学和社会利益，研究风险与受益比例应当合理，力求使受试者尽可能避免伤害。

（三）免费和补偿原则。应当公平、合理地选择受试者，对受试者参加研究不得收取任何费用，对于受试者在受试过程中支出的合理费用还应当给予适当补偿。

（四）保护隐私原则。切实保护受试者的隐私，如实将受试者个人信息的储存、使用及保密措施情况告知受试者，未经授权不得将受试者个人信息向第三方透露。

（五）依法赔偿原则。受试者参加研究受到损害时，应当得到及时、免费治疗，并依据法律法规及双方约定得到赔偿。

（六）特殊保护原则。对儿童、孕妇、智力低下者、精神障碍患者 等特殊人群的受试者，应当予以特别保护。

第十五条 涉及人的科研项目负责人为伦理审查申请人，在申请伦理审查时应当向涉人伦理委员会提交下列材料:

（一）伦理审查申请表;

（二）研究项目方案，包括项目负责人信息、项目意义、必要性、文献综述、临床前研究和动物实验数据、实验方案、预期可能出现的对人、动物、自然、社会造成的伤害或意外情况及其处理预案等;

（三）受试者知情同意书;

（四）遵守生命伦理基本原则、接受校伦理委员会监督与检查的承诺书;

（五）需要提交的其他相关材料。

第十六条 涉人伦理委员会的审查程序

（一）项目负责人向校伦理委员会提交科研伦理审查的申请;

（二）校伦理委员会办公室对申请进行形式审查，移交涉人伦理委员会。涉人伦理委员会可根据具体情况采取会议评审或函审。必要时，可邀请申请者或其他合适的研究人员进行说明;

（三）原则上不涉及弱势群体的研究且研究风险不大于最小风险时，可以以函审方式进行快速审查。校伦理委员会办公室指定2名委员为项目评审的主审委员，主审委员对项目进行初审，提出初审意见。必要时，也可一次性聘用相关人员作为临时委员协助评审。当主审意见一致并为同意时，该申请将在审查例会上快速通过或由分委员会主任审核通过；当主审意见为作必要修正后同意时，申请人根据要求修正并再次交由主审委员审核，主审意见一致并为同意时，该申请将在审查例会上快速通过或由分委员会主任审核通过；主审委员意见不一致或出现不同意时，由分委员会主任召集进行会议审查。分委员会以投票表决的方式作出决定，最少到会委员人数应超过半数成员。如无法协商一致，应根据少数服从多数的原则做出审查决定；

（四）其他重大或对受试者风险较大的项目，须以会议形式进行评审，到会委员及决定方式同上；

（五）评审决议应由主任签发。对于否定性的决议，应有明确的解释；

（六）校伦理委员会办公室以书面方式向项目负责人传达伦理审查决议。

第十七条 评审主要内容

（一）研究方案和支持性文件，要特别注意签署知情同意书的过程、文件和方案的适当性和可行性；

（二）研究的科学设计与实施。研究设计的合适性、统计学合理性、应用最少研究对象获得可靠结论的可能性、权

衡研究对象和有关社区预期利益与预计风险的理由、应用对照组的理由、提前取消研究对象的标准、暂停或终止研究的标准等;

（三）招募研究对象。研究对象的人群特征、接触和招募研究对象的方式、向研究对象或其代表传达信息的方式、研究对象的入选标准、研究对象排除标准;

（四）研究对象的保护。研究人员的资历和经验、为研究对象提供的医疗保障及医疗监督和心理、社会支持、研究过程中研究对象自愿退出时将采取的措施、研究后项目参与者获得研究产品的计划、研究参与者的奖励和补偿、对研究参与者因参与研究而造成损害的治疗/补偿的规定、对保险和赔偿的安排;

（五）研究参与者隐私的保护。对有可能接触研究参与者个人资料人员的描述、保证研究参与者个人信息保密与安全的措施;

（六）签署知情同意书的程序。详细介绍获得知情同意书的程序，包括取得知情同意书的负责人，向研究参与者或其合法代表人提供书面或口头信息的充分性、完整性和可理解性，拟将不能签署知情同意 书者包括进来的理由，为研究参与者的参与而取得同意或授权的详细说明，保证研究参与者在研究过程中获得关于他们的权利、安全与福利的信息等;

（七）社区的考虑。从当地社区抽取研究参与者的影响、研究设计阶段向社区咨询的步骤、研究过程中提供的社区咨

询、研究对提高当地医疗保健和公共卫生需求的应对能力、研究后成功产品在有关社区的可获得性和可负担性的描述、研究参与者和有关社区获得研究结果的方式等。

第十八条 项目伦理审查通过后，有下列情况的，均需上报涉人伦理委员会:

（一）研究方案需要变更修改的;

（二）征求受试者的资料、可能的受试者的信息或知情同意书需要变更修改的;

（三）发生与研究相关的严重的和未预料的不良事件的;

（四）遇到无法预料的情况、研究工作中断的。

第十九条 对已批准实施的研究项目，涉人伦理委员会应当指定委员进行跟踪审查。在项目研究结束时，申请人应当向伦理委员会办公室提交总结等相关材料。

第二十条 有下列情况或事件需要对研究进行后续审查:

（一）任何可能会影响受试者的权利、安全和利益，或者影响到研究实施的方案修改;

（二）进行的研究或研究产品相关的严重的、未预料到的不良事件，以及研究人员、资助者及法规部门对之做出的反应;

（三）任何可能影响研究的利益/风险的新情况的出现;

（四）在研究项目提前终止或暂停或终止的情况下，申请人应向涉人伦理委员会报告暂停或终止的理由，并向涉人伦理委员会提交研究总结报告。

第二十一条 项目研究者在学术期刊发表涉及人的科技研究成果时，应当出具该研究项目经过伦理审查批准的证明文件。

第五章 实验动物福利伦理审查程序

第二十二条 动物伦理委员会审查依据的基本原则:

（一）动物保护原则。审查动物实验的必要性，对实验目的、预期利益与造成动物的伤害、死亡进行综合的评估。禁止无意义滥养、滥用、滥杀实验动物。制止没有科学意义和社会价值或不必要的动物实验；优化动物实验方案以保护实验动物特别是濒危动物物种，减少不必要的动物使用数量；在不影响实验结果的科学性、可比性情况下，采取动物替代方法，使用低等级替代高等级动物、用非脊椎动物替代脊椎动物、用组织细胞替代整体动物、用分子生物学、人工合成材料、计算机模拟等非动物实验方法替代动物实验的原则。

（二）动物福利原则。保证实验动物生存时包括运输中享有最基本的权利，享有免受饥渴、生活舒适自由，享有良好的饲养条件和标准化的生活环境，各类实验动物管理要符合该类实验动物的操作技术规程。

（三）伦理原则。应充分考虑动物的利益，善待动物，防止或减少动物的应激、痛苦和伤害，尊重动物生命，制止针对动物的野蛮行为、采取痛苦最少的方法处置动物；实验动物项目要保证从业人员的安全；动物实验方法和目的符合人类的道德伦理标准和国际惯例。

（四）综合性科学评估原则

1、公正性。动物伦理委员会的审查工作应该保持独立、公正、科学、民主、透明、不泄密，不受政治、商业和自身利益的影响。

2、必要性。各类实验动物的饲养和应用或处置必须有充分的理由为前提。

3、利益平衡。符合当代社会公认的道德伦理价值观，兼顾动物和人类利益；在全面、客观地评估动物所受的伤害和应用者由此可能获取的利益基础上，负责任地出具实验动物或动物实验伦理审查报告。

第二十三条 动物伦理委员会应依据实验动物福利伦理审查的基本原则，兼顾动物福利和动物实验者利益，在综合评估动物所受的伤 害和使用动物的必要性基础上进行科学评审，并出具评审意见。

第二十四条 涉及实验动物的科研项目负责人为伦理审查申请人，在申请伦理审查时应当向动物伦理委员会提交下列材料:

（一）伦理审查申请表;

（二）研究项目方案，包括项目负责人信息、项目意义、必要性、项目中有关实验动物的用途、饲养管理或实验处置方法、预期出现的对动物的伤害、处死动物的方法、项目进行中涉及动物福利和伦理问题的详细描述等;

（三）遵守实验动物福利伦理原则的声明;

（四）需要提交的其他相关材料。

第二十五条 动物伦理委员会审查程序

（一）项目负责人向动物伦理委员会提交科研伦理审查申请;

（二）校伦理委员会办公室对申请进行形式审查，移交动物伦理委员会。动物伦理委员会可根据具体情况采取会议评审或函审。必要时，可邀请申请者或其他合适的研究人员进行说明;

（三）不大于最小风险的研究项目；对已批准的项目方案做较小修改，不影响研究风险受益比；跟踪审查；开展各类科研项目申报前的审查等，可以进行快速审查。校伦理委员会办公室指定 2 名委员为项目评审的主审委员，主审委员对项目进行初审，提出初审意见。必要时，也可一次性聘用相关人员作为临时委员协助评审。当主审意见一致并为同意时，该申请将在审查例会上快速通过或由分委员会主任审核通过；当主审意见为作必要修正后同意时，申请人根据要求修正并再次交由主审委员审核，主审意见一致并为同意时，该申请将在审查例会上快速通过或由分委员会主任审核通过；主审委员意见不一致或出现不同意时，由分委员会主任召集进行会议审查。分委员会以投票表决的方式作出决定，最少到会委员人数应超过半数成员。如无法协商一致，应根据少数服从多数的原则做出审查决定。

（四）其他风险较大的项目，须以会议形式进行评审，到会委员及决定方式同上。

（五）评审决议应由主任签发。对于否定性的决议，应有明确的解释。

（六）校伦理委员会办公室以书面方式向项目负责人传达伦理审查决议。

第二十六条 有下列情况之一的，不能通过动物伦理委员会的评审:

（一）申请者的实验动物相关项目不接受或逃避伦理评审的;

（二）不提供足够举证的或申报审查的材料不全或不真实的;

（三）缺少动物实验项目实施或动物伤害的客观理由和必要性的;

（四）从事直接接触实验动物的生产、运输、研究和使用的人员未经过专业培训或明显违反实验动物福利伦理原则要求的;

（五）实验动物的生产、运输、实验环境达不到相应等级的实验动物环境设施国家标准的; 实验动物的饲料、笼具、垫料不合格的;

（六）实验动物保种、繁殖、生产、供应、运输和经营中缺少维护–动物福利、规范从业人员道德伦理行为的操作规程，或不按规范的操–作规程进行的; 虐待实验动物，造成实验动物不应有的应激、疾病和 死亡的;

（七）动物实验项目的设计或实施不科学。没有利用已有的数据对实验设计方案和实验指标进行优化，没有科学选

用实验动物种类及品系、造模方式或动物模型以提高实验的成功率。没有采用可以充分利用动物的组织器官或用较少的动物获得更多的试验数据的方法；没有体现减少和替代实验动物使用的原则；

（八）动物实验项目的设计或实施中没有体现善待动物、关注动物生命，没有通过改进和完善实验程序，减轻或减少动物的疼痛和痛苦，减少动物不必要的处死和处死的数量。在处死动物方法上，没有选择更有效的减少或缩短动物痛苦的方法；

（九）活体解剖动物或手术时不采取麻醉方法的；对实验动物的生和死处理采取违反道德伦理的、使用一些极端的手段或会引起社会广泛伦理争议的动物实验；

（十）动物实验的方法和目的不符合我国传统的道德伦理标准或国际惯例或属于国家明令禁止的各类动物实验；动物实验目的、结果与当代社会的期望、与科学的道德伦理相违背的；

（十一）对人类或任何动物均无实际利益并导致实验动物极端痛苦的各种动物实验；

（十二）对有关实验动物新技术的使用缺少道德伦理控制的，违背人类传统生殖伦理，把动物细胞导入人类胚胎或把人类细胞导入动物 胚胎中培育杂交动物的各类实验；以及对人类尊严的亵渎、可能引发社会巨大的伦理冲突的其它动物实验；

（十三）严重违反实验动物福利伦理审查原则的其它行为的。

第二十七条 对实验动物伦理审查决议有异议时，申请者可以补充新材料或改进后再行申请。

第二十八条 动物伦理委员会对批准的动物实验项目应进行日常监督检查，发现问题时应明确提出整改意见，严重者应立即做出暂停该项目动物实验的决议。在项目研究结束时，申请人应当向伦理委员会办公室提交总结等相关材料。

第六章 运作

第二十九条 审查决定：研究者或研究利益相关方对伦理审查委员会的审查决定有不同意见，可以提交复审，与伦理委员会及其办公室沟通交流。

第三十条 利益冲突管理：遵循利益冲突政策，与研究项目存在利益冲突的委员/临时委员应主动声明并退出该项目审查的讨论和决定程序。伦理审查委员会应审查研究人员与研究项目之间的利益冲突，必要时采取限制性措施。

第三十一条 保密：伦理委员会委员/临时委员对送审项目的文件负有保密责任和义务，审查完成后，及时交回所有送审文件与审查材料，不得私自复制与外传。

第三十二条 协作：所有与受试者保护的相关部门应协助伦理委员会工作，明确各自在伦理审查和研究监管中的职责，保证学校承担的所有涉及人的生物医学研究项目都提交伦理审查，受试者的健康和权益得到保护；保证开展研究中

所涉及的组织机构利益冲突、审查委员和研究人员的个人利益冲突得到最大限度的减少或消除；有效的报告和处理违背法规与方案的情况；建立与受试者、研究者或研究利益相关方有效的沟通渠道，对其所关心的问题和诉求做出回应。

第三十三条 质量管理：伦理审查委员会接受上级卫生行政部门、药品监督管理部门等监督管理；接受独立的、外部的质量评估或认证。伦理委员会对检查发现的问题采取相应的改进措施。

第三十四条 监督管理：伦理委员会向学校、上级卫生行政部门等报告年度伦理审查工作情况。对伦理审查委员会违反法规的“批准”决定，校务会可要求伦理审查委员会重审，或中止所批准的研究项目。

第七章 附则

第三十五条 本章程由温州肯恩大学伦理委员会负责解释。

第三十六条 本章程自颁布之日起施行。

（此页无正文）

温州肯恩大学办公室　　2021年10月22日印发

Regulations of Wenzhou-Kean University Ethics Committee (Interim)

Chapter I. General

Article 1. In accordance with the Measures for the Ethical Review of Biomedical Research Involving Human Subjects, Regulations for Ethical Review of Biomedical Research Involving Human Subjects, Regulations for the Management of Laboratory Animals and relevant national laws, regulations, and international practices, these Regulations are hereby formulated in order to: regulate Wenzhou-Kean University to carry out relevant experiments involving human subjects and animals, respect and protect the legal rights and interests of human subjects, safeguard the welfare of animals, and standardize the ethical review and professional behavior of practitioners, in combination with actual situation of research work in the University.

Article 2. Wenzhou-Kean University Ethics Committee (hereinafter referred to as the Ethics Committee) is a deliberative body that coordinates, regulates, and guides the University's ethical governance.

Article 3. All departments (colleges) and individuals of the University engaged in research activities involving human subjects and experimental animals shall apply for the ethical review in advance. After the permission from the Ethics Committee, the research activities could proceed under the supervision and inspection of the Ethics Committee.

Article 4. The ethical review process shall comply with national laws and regulations, relevant rules and regulations of the University, as well as recognized bioethics principles. The ethical review process shall be independent, objective, fair and transparent.

Chapter II. Organization

Article 5. The Ethics Committee is the highest deliberative body for the University ethics matters. There are two sub-committees responsible for special

ethical review and supervision. They are the Institutional Review Board and the Laboratory Animal Ethics Committee. The office of the Ethics Committee is located in the Office of Research and Sponsored Programs, with equipment to store the review process data.

Article 6. The Ethics Committee is composed of experts in the fields of biomedicine, law, ethics, and sociology, as well as representatives of relevant teachers, students, and social individuals. The Institutional Review Board is composed of several members, including one director and two deputy directors. The Laboratory Animal Ethics Committee is composed of several members, including one director and one deputy director. The director and deputy director are elected by the committee members of the Ethics Committee through consultation and introduced to the University Administration Meeting for consideration and final decision.

Article 7. The members of the two sub-committees each serve a term of 5 years and could be re-elected. When the committee members need to be replaced for a certain reason, the adjustment shall be proposed by the meeting of the directors of the sub-committees of the Ethics Committee and reported to the University Administration Meeting for consideration and final decision.

Article 8. The University supports and guarantees the operation of the Ethics Committee in terms of funding and other aspects.

Chapter III. Work Responsibility

Article 9. The Ethics Committee shall formulate articles of related regulations, related reviewing procedures, supervision systems, professional training plans, etc., and conduct regular publicity of national policy, law, and ethical principles.

Article 10. The director of each subcommittee shall be responsible for convening regular meetings, organizing project ethics review activity, and issuing or authorizing review decisions.

Article 11. The Institutional Review Board shall be responsible for the ethics

review and supervision of the University's research projects involving human subjects. For any type of medical research project involving human subjects carried out in a medical unit, the director of the project shall apply to the medical unit for ethical review.

Article 12. The Laboratory Animal Ethics Committee shall be responsible for the ethics review and supervision of relevant experimental animal research projects carried out by the University.

Article 13. The Ethics Committee shall stop behaviors that violate the ethical principles of humans or animals. For the units and individuals that violate ethical principles, the Ethics Committee has the right to make rectification decisions within a time limit and to put forward suggestions for dealing with serious cases until the termination of the experiment.

Chapter IV. Ethics Review Procedure Involving Humans

Article 14. The scientific and technological research activities involving human subjects shall conform to the following ethics principles:

1. The principle of informed consent. Respect and guarantee subjects' right to decide whether to participate in the research or not; Strictly implement the procedures of informed consent; Prevent the use of deception, inducement, coercion, and other means to push the human subjects to agree to participate in the research; Allow human subjects to unconditionally withdraw from the research at any stage.

2. The principle of risk control. Human subjects' personal safety and health rights are given priority, followed by the scientific and social benefits. The ratio of research risk and profit shall be reasonable and strive to avoid harm to subjects as much as possible.

3. The principle of free and compensation. Subjects shall be selected fairly and reasonably; No fees shall be charged for subjects' participation in research; Reasonable compensation shall be provided for subjects' reasonable expenses during

the experiment.

4. The principle of privacy protection. Effectively protect the subject's privacy. Truthfully inform the subject of the storage, use, and confidentiality measures of the subject's personal information, and shall not disclose the subject's personal information to a third party without authorization.

5. The principle of compensation according to law. Subjects who suffer damages from participating in the research shall receive timely and free treatment, and shall be compensated in accordance with laws, regulations, and mutual agreement.

6. The principle of special protection. Special protection shall be given to subjects from special populations such as children, pregnant women, persons with mental retardation, and patients with mental disorders.

Article 15. The people in charge of a research project involving human subjects is the applicant for ethics review, and the following materials shall be submitted to the Institutional Review Board when applying for ethics review:

1. Application form for ethics review.

2. Research proposal, including principal investigator's information, project significance, project necessity, literature review, pre-clinical research and animal experiment data, experimental plan, and the handling plan of expected possible harm or accidents to humans, animals, nature, and society, etc.

3. Informed consent form of subjects.

4. A letter of commitment to comply with the basic principles of bioethics and accept the supervision and inspection of the university ethics committee.

5. Other relevant materials that need to be submitted.

Article 16. Review procedures of the Institutional Review Board

1. The principal investigator submits the application for research ethics review to the Ethics Committee.

2. The Ethics Committee office conducts a formal review of the application and

transfers it to the Institutional Review Board. The Institutional Review Board may adopt a meeting review or letter review according to the specific situation. If necessary, applicants or other suitable researchers can be invited to explain.

3. In principle, when the research involving vulnerable groups is not involved and the research risk is not greater than the minimum risk, a quick review can be conducted by letter review. The Ethics Committee office appoints two members as the main reviewers for the project review, and the main reviewers conduct a preliminary review of the project and put forward preliminary review opinions. When necessary, relevant personnel can also be hired as temporary committee members to assist in the review. When the main reviewer's opinion is unanimous and agrees, the application will be quickly passed at the regular review meeting or approved by the director of the subcommittee. When the main reviewer's opinion is agreed after making necessary amendments, the applicant shall amend it according to the requirements and submit it to the main reviewer again, and when the committee members review and the main reviewers consistently agree, the application will be passed quickly at the regular review meeting or approved by the director of the subcommittee. When the opinions of the main review members are inconsistent or disagree, the director of the subcommittee will convene a meeting for review. The sub-committee makes decisions by voting, and at least the number of members' presence shall exceed half of the members. If there is no consensus, the review decision shall be made based on the principle of the minority subordinating to the majority.

4. Other major projects or projects with greater risks to the subjects must be reviewed in the form of a meeting, and the committee members and the method of decision-making are the same as above.

5. The review decision shall be signed and issued by the director. For negative decisions, there shall be clear explanations.

6. The university ethics committee office communicates the ethics review decision to the principal investigator in writing.

Article 17. The main content of the review

1. Research plans and supporting documents. The process of signing informed consent, the suitability, and feasibility of documents and plans are paid attention particularly.

2. Scientific design and implementation of research. The suitability of the research design, statistical rationality, the possibility of using the least number of research subjects to obtain reliable conclusions, the reasons for weighing the research subjects and the expected benefits and predicted risks of the relevant community, the reasons for applying the control group, the criteria for premature cancellation of the research subjects, and the criteria for suspension and termination of the research, etc.

3. Recruit research subjects. The population characteristics of the research object; The method of contacting and recruiting the research object; Method of conveying information to the research object or its representatives; Selection criteria of the research object; The exclusion criteria of the research object.

4. Protection of research objects. The qualifications and experience of the researcher; The medical security, medical supervision, and psychological and social support provided to the research object; Measures to be taken when the research object voluntarily withdraws during the research process; Plan for the project participant to obtain the research product after the research; Rewards and compensations of research participant; Regulations on treatment or compensation for damages caused by participation in research by research participants; Arrangements for insurance and compensation.

5. Protection of the privacy of research participants. A description of practitioners who may have access to the personal data of research participants, and measures to ensure the confidentiality and security of the personal information of research participants.

6. Procedures for signing informed consent. Introduce in detail the procedures for obtaining the informed consent, including the person in charge of obtaining the

informed consent, and the adequacy, completeness, and comprehensibility of the written or oral information provided to the research participants or their legal representatives. Provide the reasons for including those who cannot sign informed consent, provide a detailed description of obtaining consent or authorization for the participation of research participants, and ensure that the research participants obtain information about their rights, safety, and welfare during the research process.

7. Community considerations. The influence of research participants extracted from the local community, the steps of community consultation during the research design stage, the community consultation provided during the research process, the research's ability to respond to local medical care and public health needs, the description of the availability and affordability of successful products in relevant communities after research, and the ways in which research participants and relevant communities obtain research results, etc.

Article 18. After the project ethics review is passed, the following situations should be reported to the Institutional Review Board:

1. Research plan needs to be modified.

2. The solicited subject's information, possible subject's information, or informed consent needs to be modified

3. Serious and unexpected adverse events related to the research occur.

4. When encountering unforeseen circumstances and the research work is interrupted.

Article 19. For research projects that have been approved for implementation, the Institutional Review Board shall designate members to conduct follow-up reviews. At the end of the research project, the applicant shall submit the summary and other relevant materials to the Institutional Review Board.

Article 20. The following circumstances or events require follow-up review of research:

1. Any plan modification that may affect the rights, safety, and interests of the

subjects, or affect the implementation of the research.

2. Serious and unanticipated adverse events related to the research carried out or research product, and the reactions of researchers, sponsors, and regulatory authorities to those events.

3. The emergence of any new circumstances that may affect the benefits or risks of the research.

4. In the case of early termination or suspension of the research project, the applicant shall report the reason for the suspension or termination to the Institutional Review Board, and submit a research summary report.

Article 21. When the principal investigator publishes the scientific and technological research results involving human subjects in academic journals, he/she shall present a certification document that the research project has been ethically reviewed and approved.

Chapter V. Procedure for Ethics Review of Laboratory Animals' Welfare

Article 22. The review principles of the Laboratory Animal Ethics Committee:

1. Principle of animal protection. Review the necessity of animal experiments, and conduct a comprehensive assessment of the experiment's purpose, expected benefits, and the injury and death of animals. It is forbidden to raise, abuse, or kill laboratory animals indiscriminately without meaning. Stop animal experiments that do not have scientific significance and social value or are unnecessary. Optimize animal experiment plans to protect experimental animals, especially endangered animal species, and reduce the number of unnecessary animals. Apply the principle of adopting animal substitution methods without affecting the scientific and comparability of experimental results, using low-grade animals instead of high-grade animals, replacing vertebrates with invertebrates, replacing whole animals with tissue cells, and replacing animal experiments with non-animal experimental methods such as molecular biology, synthetic materials, and computer simulations.

2. Principle of animal welfare. Ensure the most basic rights during the survival of experimental animals including transportation; Give animals freedom from hunger and thirst, comfortable life, good breeding conditions, and a standardized living environment; The management of various experimental animals must comply with the operating technical regulations for such experimental animals.

3. Ethical principles. Full consideration shall be given to the interests of animals, be kind to animals, prevent or reduce animal stress, pain, and injury, respect animal life, stop barbaric behavior against animals, and take the least painful method to dispose of animals. Experimental animal projects shall ensure the safety of practitioners. The methods and purposes of animal experiments conform to human moral and ethical standards and international practices.

4. Principles of comprehensive scientific evaluation.

(1) Fairness. The review work of the animal-related ethics committee shall remain independent, fair, scientific, democratic, transparent, non-disclosure, and free from the influence of politics, business, and self-interest.

(2) Necessity. The breeding, application, or disposal of various types of laboratory animals must have sufficient reasons as a prerequisite.

(3) Balance of interests. Comply with the moral and ethical values recognized by contemporary society, and take into account the interests of animals and humans. On the basis of a comprehensive and objective assessment of the harm suffered by animals and the benefits that users may obtain from this, the ethics committee shall responsibly issue the laboratory animals or animal experiment ethics review reports.

Article 23. The Laboratory Animal Ethics Committee shall, in accordance with the basic principles of the ethical review of laboratory animal welfare, take into account animal welfare and the interests of animal experimenters, conduct scientific reviews on the basis of a comprehensive assessment of the injuries suffered by animals and the necessity of using animals, and issue review comments.

Article 24. The people in charge of a research project involving animals is an

applicant for ethics review, and the following materials shall be submitted to the Laboratory Animal Ethics Committee when applying for ethics review:

1. Application form for ethics review.

2. Research project plan, including the information of the principal investigator, the significance and necessity of the project, the use of the experimental animals in the project, the breeding management or experimental disposal methods, the expected harm to the animals, the method of killing the animals, detailed descriptions of animal welfare and ethical issues when the project is in progress.

3. A statement of compliance with the ethical principles of laboratory animal welfare.

4. Other relevant material that needs to be submitted.

Article 25. Review procedure of the Laboratory Animal Ethics Committee.

1. The people in charge of the project shall submit the scientific and technological ethics review application to the Laboratory Animal Ethics Committee.

2. The Ethics Committee office conducts a formal review of the application and transfers it to the Laboratory Animal Ethics Committee. The Laboratory Animal Ethics Committee may adopt a meeting review or letter review according to the specific situation. If necessary, applicants or other suitable researchers can be invited to explain.

3. A quick review can be conducted in the following circumstances: the research projects' risk does not exceed the minimum risk, minor modifications to the approved project scheme do not affect the risk benefit ratio, conduct a follow up review, each type of research project is reviewed before the application. The Ethics Committee office appoints 2 members as the main reviewers for the project review, and the main reviewers conduct a preliminary review of the project and put forward preliminary review opinions. When necessary, relevant personnel can also be hired as temporary committee members to assist in the review. When the main reviewer's opinion is unanimous and agrees, the application will be quickly passed at the regular

review meeting or approved by the director of the subcommittee. When the main reviewer's opinion is agreed after making necessary amendments, the applicant shall amend it according to the requirements and submit it to the main reviewer again, and when the committee members review and the main reviewers consistently agree, the application will be passed quickly at the regular review meeting or approved by the director of the subcommittee. When the opinions of the main review members are inconsistent or disagree, the director of the subcommittee will convene a meeting for review. The sub-committee makes decisions by voting, and at least the number of members' presence shall exceed half of the members. If there is no consensus, the review decision shall be made based on the principle of the minority subordinating to the majority.

4. Other projects with greater risks must be reviewed in the form of a meeting, and the committee members and the method of decision-making are the same as above.

5. The review decision shall be signed and issued by the director. For negative decisions, there shall be clear explanations.

6. The Ethics Committee office communicates the ethics review decision to the principal investigator in writing.

Article 26. One of the following conditions cannot pass the review by the Laboratory Animal Ethics Committee:

1. The applicant does not accept or evade ethical review for the experimental animal-related projects.

2. Failing to provide sufficient evidence or incomplete or untrue materials applied for review.

3. Lack of objective reasons and necessity for the implementation of animal experiment projects or animal injury

4. People who engaged in the production, transportation, research, and use of experimental animals in direct contact have not received professional training or

obviously violated the requirements of the experimental animal welfare ethics principle.

5. Experiments in which the production, transportation, and experimental environment of experimental animals cannot reach the corresponding level of national standards for animal environmental facilities. Feed, cages, and litter for experimental animals are unqualified.

6. Laboratory animal breed conservation, breeding, production, supply, transportation, and operation lack operating procedures for maintaining animal welfare, regulating the ethical behavior of practitioners, or failing to follow the standardized operating procedures. Abuse experimental animals and result in experimental animals Unwanted stress, illness, and death.

7. The design or implementation of animal experiment projects is unscientific. No use of existing data to optimize the experimental design plan and experimental indicators. There is no scientific selection of experimental animal types and strains, modeling methods, or animal models to improve the success rate of the experiment. Failed to adopt methods that can make full use of animal tissues and organs or use fewer animals to obtain more experimental data. Failed to reflect the principle of reducing and replacing the use of experimental animals.

8. The design or implementation of the animal experiment project did not reflect being kind to laboratory animals and paying attention to animal's life. Without improving and perfecting the experimental procedures, alleviate or reduce the pain and suffering of animals, and reduce the number of unnecessary deaths and executions of animals. In terms of the method of killing animals, no more effective method was chosen to reduce or shorten the suffering of animals.

9. No anesthesia is used during the biopsy of animals or during surgery. Experimental animals' life and death are handled by animal experiments that violate ethics. Use extreme methods to cause widespread ethical controversy in society.

10. The methods and purposes of animal experiments do not conform to national

traditional moral and ethical standards or international practice, or belong to various animal experiments prohibited by the state. The purpose and results of animal experiments are contrary to the expectations of contemporary society, and scientific morals and ethics.

11. All kinds of animal experiments that cause extreme pain and harm in laboratory animals with no actual benefits to humans and animals.

12. All kinds of experiments that lack moral and ethical control over the use of new technologies related to laboratory animals, violate the traditional human reproductive ethics, introduce animal cells into human embryos or introduce human cells into animal embryos to breed hybrid animals and other animal experiments that desecrate human dignity and may cause huge ethical conflicts in society.

13. Other acts that seriously violate the principles of ethical review of laboratory animal welfare.

Article 27. If there are objections to the decision of the experimental animal ethics review, the applicant can add new materials or make improvements and reapply.

Article 28. The Laboratory Animal Ethics Committee shall conduct daily supervision and inspection of approved animal experiment projects. When problems are found, rectification opinions shall be clearly put forward. In serious cases, the decision to suspend animal experiments in the project shall be made immediately. At the end of the project research, the applicant shall submit the summary and other relevant materials to the Ethics Committee office.

Chapter VI. Operation

Article 29. Review decision: researchers or research stakeholders who have different opinions on the review decision of the Ethics Committee can submit materials for retrial, communicate with the ethics committee and its office.

Article 30. Conflict of interest management: following the conflict of interest

policy, members or temporary members who have conflicts of interest with the research project shall proactively declare and withdraw from the discussion and decision procedures of the project review. The Ethics Committee shall review the conflict of interest between the researcher and the research project, and take restrictive measures when necessary.

Article 31. Confidentiality: the members of the ethics committee or temporary members have the responsibility and obligation to keep the documents submitted for review of the project confidential. After the review is completed, all submitted documents and review materials shall be returned promptly, and they shall not be copied or transmitted privately.

Article 32. Collaboration: all relevant departments related to the protection of subjects shall assist the Ethics Committee to clarify their respective responsibilities in ethics review and research supervision. Ensure that all biomedical research projects involving people undertaken by the university are submitted for ethics review, and ensure that the health and rights of the subjects are protected. Ensure that the conflicts of interest of the organizations involved in the research, and the personal conflicts of interest of the review committee and the researchers are minimized or eliminated. Effectively report and handle violations of laws and regulations situations. Establish effective communication channels with subjects, researchers, or research stakeholders, and respond to their concerns and demands.

Article 33. Quality management: the Ethics Committee accepts the supervision and management of the health administration department and the drug supervision and management department. Accept independent and external quality evaluation or certification. The Ethics Committee takes corresponding improvement measures for the problems found in the inspection.

Article 34. Supervision management: the Ethics Committee reports the annual ethics review work to the University and the superior health administrative department. For the “approval” decision of the Ethics Committee in violation of the

regulations, the University council may request the Ethics Committee to re-examine or suspend the approved research project.

Chapter VII. Supplementary Provision

Article 35. Wenzhou-Kean University Ethics Committee reserves the right to explain all the terms.

Article 36. These Regulations shall come into force upon promulgation.