**合成生物学伦理治理宣言**

Declaration on the Ethical Governance of Synthetic Biology

**撰稿团队**：

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**发起单位**：

华中科技大学生命伦理学研究中心

电子科技大学科技伦理治理研究中心

中国生物工程学会合成生物学分会

中科院深圳先进技术研究院合成生物学研究所

**Drafted By:**

National Key R&D Program "Research on Ethics, Policies and Regulations of Synthetic Biology" (2018YFA0902400)

Center for Bioethics, Huazhong University of Science and Technology

Center for Ethics and Governance of Science and Technology , University of Electronic Science and Technology of China

Chinese Society for Synthetic Biology

Shenzhen Institutes of Advanced Technology, Chinese Academy of Sciences

**Preface/前言**

Synthetic biology is one of the most promising science and technology in nowadays. It shall solve the global problems such as needs of energy, materials, food, drugs, vaccines, and the prevention and control of infectious diseases, which affect human health and sustainable development all over the world; it shall provide protection for improving the ecological environment and maintaining biodiversity. The purpose of the guidelines is to provide ethical governance codes for the innovation and development of synthetic biology, and to standardize the good and sustainable development strategy of synthetic biology for the benefit of all humankind.

合成生物学是当代最具前景的新兴科技之一，它可能帮助解决全世界面临的能源、材料、食品、药物、疫苗短缺、传染病防控等影响人类健康和可持续发展的问题，并可能为改善日趋恶化的生态环境和生物多样性提供保护方案。本宣言旨在为合成生物学科技创新和发展提供伦理治理指南，规范合成生物学向善、可持续发展，造福全人类。

**Framework/框架**

Declaration on the Ethical Governance of Synthetic Biology consists of ethical principles and governance guidelines. Ethical principles are value consensus, and governance guidelines are the policy and regulatory framework for implementing ethical principles. Ethical principles include trustworthiness, to build a trust relationship between different stakeholders in the innovation system; solidarity, to guarantee synthetic biology development for serving the community with a shared future for mankind, biodiversity and sustainable development; justice, to ensure fair access and distribution, as well as benefit sharing of achievements; respect for person, to respect for human autonomy in S&T development; Species integrity and human dignity, to evaluate human dignity and intrinsic value of life in in S&T intervention.

《合成生物学伦理治理宣言》由伦理原则和治理纲领组成，伦理原则是价值共识，治理纲领是贯彻伦理原则的政策规制框架。伦理原则包括可信 /trustworthiness（建构科技创新体制中不同利益攸关者的信任关系）、共济 /solidarity（保障科技发展增进人类命运共同体的福祉、生物多样性与可持续发展）、公正/justice（确保科技创新的成果公平可及、公正分配、惠益分享）、尊重/respect for person（在科技发展中尊重人的自主性）、尊严/Species integrity and human dignity（在科技干预中权衡人的尊严与生命内在价值）。

Based on the value consensus, formulate the governance guidelines, including Biosafety, Biosecurity, Intellectual Property, Public Engagement, Capacity Building.

在价值共识的基础之上，制定治理纲领，包括生物安全/Biosafety、生物安保 /Biosecurity、知识产权/Intellectual Property、公众参与/Public Engagement、能力建设/Capacity Building。

**Content/正文**

1. **Trustworthiness/可信**
2. **Robustness of Enabling Technologies(确保安全可控)**

Conduct safety assessments of synthetic biology to ensure the robustness and reliability of enabling technologies, to ensure research activities of design and manufacture of the genetic material on living organisms are safe and controllable. Establish an open and transparent mechanism for the cycle of synthetic biology research and technology applications to achieve interpretability, traceability, understandability, and feedback. In addition to basic and applied research, develop biological containment technology measures and safety devices to ensure biosafety and biosecurity.

对合成生物使能技术进行安全评估，保障使能技术的鲁棒性和可靠性，确保设计和制造活有机体的遗传物质的研究活动安全可控。建立合成生物学研究和转化应用全生命周期的公开透明机制，实现可解释性、可追溯性、可理解性、可反馈性。在基础和应用研究之外，研究开发应对生物安全和生物安保的生物遏制技术措施和安全装置。

1. **Risk Prevention (加强风险防范)**

Enhance bottom-line thinking and risk awareness, strengthen potential risk research and judgment in the development of synthetic biology, contribute knowledge of risk perception and assessment. Prospectively conduct risk assessment for the application of synthetic biology in the fields of medicine, food, energy, materials, agriculture, environment; based on the precautionary principle, analyze and evaluate the construction of organisms, the enhanced functionalities, the novelty and complexity of synthetic materials, risks of gene modify wildlife populations, and its corresponding ecological and human health impacts.

增强底线思维和风险意识，加强合成生物学发展的潜在风险研判，积累风险认知和评估的知识。对合成生物学在医药/食品、能源/材料、农业/环境领域的应用研究进行前瞻性风险评估，基于防范原则，分析和评估从无到有构建新型生物体、创造新颖和增强的功能性、合成材料的新颖性和复杂性、基因驱动改造野生生物种群的不确定性风险以及相应的生态环境和人体健康影响。

1. **Dynamic Balancing (保持动态权衡)**

Carry out risk-benefit assessment and judgment on the innovation and application of synthetic biology, weigh expected benefits and potential risks based on core theories and different technical solutions, ensure an acceptable risk-benefit ratio, and promote synthetic biology research on building knowledge and understanding of the nature of life, use of buildings to create major innovative value of social and economic benefits. Based on the reflective balance method, according to the progress of basic and applied research, establish a dynamic balancing evaluation mechanism across disciplines, fields, regions and borders.

对合成生物学创新和应用进行风险-受益评估与判断，基于核心理论和不同技术解决方案权衡预期受益和潜在风险，确保可接受的风险-受益比，充分发挥合成生物学建物致知理解生命本质，以及建物致用创造社会经济效益的重大创新价值。基于反思平衡方法，根据基础和应用研究进展，建立跨学科、跨领域、跨地区、跨国界的动态权衡评估机制。

1. **Accountability (强化责任担当)**

Implement the value concept of responsible innovation, and implement the main responsibility in synthetic biology research. Strengthen self-discipline awareness, strengthen self-restraint in synthetic biology R&D-related activities, actively integrate ethical principles into all aspects of scientific research and technological development, strengthen science integrity, research ethics and behave self-management, establish and improve R&D and application accountability mechanisms, the communication of research results should balance maximization of benefits and minimization of risks. Consciously assume responsibility for science popularization and communication, actively participate in public dialogue, and promote public understanding of science.

贯彻负责任创新的价值理念，落实合成生物学研究和创新中的主体责任。强化自律意识，加强合成生物学研发相关活动的自我约束，主动将伦理原则/准则融入科学研究和技术研发各环节，加强科研诚信、研究伦理和自我管理，建立健全研发和转化应用问责机制，传播研究成果应平衡兼顾效益最大化和风险最小化。自觉承担科学普及和传播责任，积极参与公众对话，促进公众理解科学。

1. **Solidarity/共济**
2. **Public Well-Being (增进共同福祉)**

Adhere to people-oriented, follow the common values of people, and respect the fundamental interests of mankind. The innovation of synthetic biology should pursue public good, give priority to meeting major or urgent social public needs, and actively promote the well-being of disadvantaged groups. Human well-being includes both current and future generations, and requires people to be in good condition both in society and environment. Also, the risks to people and the environment that synthetic biology innovations may cause should be minimized and the benefits maximized.

坚持以人为本，遵循人类共同价值观，尊重人类根本利益诉求。合成生物技术的创新和应用应该追求公共善（public good），优先考虑满足重大或急迫的社会公共需求，积极促进弱势群体的福祉。人的福祉既包含现在世代的人，也包含未来世代的人，要求人在社会和环境中都处于良好状态。同时要将合成生物学创新可能引起的对人和环境的风险最小化、受益最大化。

1. **Sustainable Development (实现可持续发展)**

Synthetic biology should be committed to providing alternative technologies to solve the unsustainable development problems of energy, materials, food, environment, health, data storage and others we faced at the current society, opening up a new era of bio-economics, preserving human digital heritage, responding to unknown epidemic threats. Promote sustainable economic, social and ecological development and build a community with a shared future for mankind.

合成生物学应该致力于提供替代技术来解决当前社会面临的能源、材料、食品、环境、健康、数据存储等不可持续发展问题，开创新的生物经济时代，保存人类数字遗产，应对未知流行病的威胁。推动经济、社会及生态可持续发展，共建人类命运共同体。

1. **Biodiversity Protection(保护生物多样性)**

Fully consider potential positive and negative impacts, apply the organisms and products produced by synthetic biotechnology to help protect biodiversity, to build a community of life on earth, to rescue the loss of species. Strengthen the measurements to the potential threats such as living modified organisms and the escape of genes into environment, take the initiative comprehensively to evaluate the impact of scientific and technological innovation on biodiversity.

充分考虑潜在正面和负面影响，谨慎利用合成生物技术所产生的生物体和产品助力生物多样性保护，共建地球生命共同体，遏制生物多样性丧失。加强防范改性活体以及基因环境逃逸等潜在威胁，主动全方位考虑和评估科技创新对生物多样性的影响。

1. **International Collaboration (加强国际合作)**

Change the thinking of zero-sum game, encourage the international scientific community to carry out extensive exchanges and cooperation, and explore the win-win mechanism of cooperation in competition or competition in cooperation. Jointly face the safety and ethical challenges that synthetic biology may bring, share practices in biosafety, strengthen learning and communication, and establish an international scientific and technological ethics governance cooperation alliance covering early precaution mechanisms and effective supervision systems.

转变零和博弈的思维，鼓励国际科学共同体广泛开展交流与合作，探索竞争中合作与合作中竞争的共赢机制。共同面对合成生物学可能带来的安全和伦理挑战，分享生物安全实践，加强学习与交流，建立涵盖预警机制和有效监管体系的国际科技伦理治理合作联盟。

1. **Justice/公正**
2. **Equitable Access(促进公平可及)**

Adhere to inclusiveness, effectively protect the rights and interests of stakeholders, promote the fair sharing of synthetic biology research outcomes and products in the whole society, promote to justice and equal opportunities. When providing products and services, we should fully respect and help disadvantaged groups and special groups, reduce social structural inequality, and narrow the gap between the rich and the poor.

坚持普惠性和包容性，切实保护各利益相关者的权益，推动全社会公平共享合成生物学的研究成果和预期产品，促进社会公平正义和机会均等。在提供产品和服务时，应充分尊重和帮助弱势群体、特殊群体，减少社会结构不平等，缩小贫富差距。

1. **Benefit Sharing(保障惠益分享)**

Sustainable apply of components of biological diversity and equitable utilize benefits of genetic resources. Facilitate technology transfer, knowledge sharing and capacity building in synthetic biology research for synthetic biological products such as living modified organisms through the exchange and sharing of biological resource data and information, covering the equitable sharing of research processes, research results and technical information, including the needs of residents and local communities.

可持续利用生物多样性组成成分，公平公正地利用遗传资源所产生的惠益。通过生物资源数据和信息交换共享，促进改性活生物体之类的合成生物产品技术转让、知识共享和合成生物学研究能力建设，涵盖研究过程、研究成果和技术资料的公平共享，同时考虑土著居民和当地社区的需求。

1. **Global Justice (维护全球公正)**

Narrowing the existing inequality in the global political and economic order through technological innovation, fully considering the impact of synthetic natural products and biofuels on agricultural cultivation in developing countries, and making full use of synthetic biotechnology to improve global access to vaccines and drugs , to promote global health justice.

通过技术创新缩小现存全球政治和经济秩序不平等，一方面充分考虑合成天然产物和生物燃料对发展中国家农业种植的冲击和影响，另一方面充分利用合成生物技术提高疫苗和药物的全球可及，促进全球健康公正。

1. **Respect for Person/尊重**
2. **Informed Consent (贯彻知情同意)**

The ethical principle of respecting people requires respecting people’s autonomy, effectively guaranteeing the right to know and consent of clinical research subjects. Conduct research activities based on the highest ethical standards with full respect for research subjects. The form of informed consent may vary according to the circumstances of the intervention or research and the level of risk it entails, balancing the needs of research development.

尊重人的伦理原则要求尊重人的自主性，切实保障临床研究受试者的知情权和同意权。在充分尊重研究受试者的前提下，基于最高的伦理标准开展研究活动。知情同意的形式可随干预或科研的情况及其引致的风险大小而异，与科研发展的需求相平衡。

1. **Protection of Personal Information (保护个人信息)**

The ethical principle of respecting people requires the protection of personal information and privacy, handling personal information in accordance with the principles of legality, legitimacy, necessity and integrity, avoiding personal privacy and data leakage, not compromising personal data legitimate rights, establishing privacy security assessment standards and protection schemes. The entire cycle of information collection, transmission, storage, processing, exchange, sharing and destruction runs through privacy and security protection

尊重人的伦理原则要求保护个人信息和隐私，依照合法、正当、必要和诚信原则处理个人信息，避免个人隐私和数据泄露，不得损害个人合法数据权益，构建隐私安全评估标准和保护方案，在数据/信息采集、传输、存储、处理、交换、共享和销毁全生命周期贯穿隐私安全保护。

1. **Respect for Person/尊严**
2. **Human Dignity (维护人的尊严)**

Human dignity is sacred and inviolable, the existence of every human being has value in itself. Under the premise that technology is more and more capable of interfering with the inner nature of human beings, it is necessary to face up to the inherent limitations and fragility, and safeguard the dignity and rights based on intrinsic worth. Ensure the humanization of technology and avoid dehumanization trends.

人的尊严是神圣、不可侵犯的，每一个人的存在本身就是有价值的。在技术越来越有能力干预人的内在本质（inner nature）的前提下，必须正视人固有的有限性和脆弱性，维护基于内在固有价值（inherent worth）的尊严和权利。确保技术的人性化发展，避免去人化（dehumanization）的趋势。

1. **Species Integrity (尊重生命价值)**

Synthetic biology challenges the traditional concept of life, also helps to understand the nature of life. Synthetic biology may transform and synthesize existing organisms of different species through rational design and directed evolution, it shall recognize the intrinsic worth of life with sentience, and carefully maintain the distinction between the value of natural life and artificial life.

合成生物学既挑战传统生命观念，又帮助理解生命本质。合成生物学通过理性设计和定向进化改造、合成现有不同物种生物体，应该承认有感觉能力的生命的内在价值（intrinsic worth），谨慎保持自然生命和人工生命的价值区分。

1. **Biosafety/生物安全**

In view of the possible risks to the environment and public health caused by the interaction between synthetic microorganisms and other organisms as well as environment, biosafety risk assessments of synthetic biology technologies and products should be carried out, and risk assessment principles, procedures and methods system should be established. Possible biosafety risk factors preventive countermeasures shall be set up and maintained, especially strengthen on potential risks assessment, and develop scientific strategies related to human health and ecological environment.

针对合成微生物与环境及其它生物之间相互作用导致对环境和公众健康可能产生的风险，应该开展合成生物学技术和产品的生物安全风险评估，建立健全风险评估原则、程序和方法体系。监测可能生物安全风险因子并建设维护预防应对措施，特别是加强关注与人类健康和生态环境相关潜在风险评估和科学应对策略。

1. **Biosecurity/生物安保**

For highly pathogenic microorganisms, emerging and reemerging pathogenic bacteria or viruses, and pathogens or toxins, chemical agents whose virulence or pathogenicity has been modified or synthesized that may be used for bioterrorism, biological warfare or malicious purposes, biological metabolites, etc., strict supervision and preventive measures should be followed and carried out. Strengthen related research to prevent the malicious use of synthetic biology technology, contain the abuse unitization of biological products, data, knowledge or equipment, speed up the formulation of laws and regulations on synthetic biology biosecurity, safeguard national security.

针对可能被用于生物恐怖袭击、生物战或恶意目的的高致病性病原体、新发或突发致病性细菌或病毒以及毒力或致病性被改造、合成的病原体或毒素、化学制剂、生物代谢产物等，应该采取严格的监管和防范措施。同时加强研究阻止恶意使用合成生物技术，防止生物制品、数据、专业知识或设备被缪用滥用，加快制订应对合成生物学生物安保的法律法规，维护国家安全。

1. **Intellectual Property/知识产权**
2. **Reaffirming the International Consensus on "Balance of Interests"(重申“利益平衡”的国际共识)**

Regardless of the development stage of synthetic biology, the purpose of intellectual property protection should be to promote technological innovation, technology transfer and promotion, and to enhance the production and utilization of knowledge by producers and users that is beneficial to social and economic welfare. Share a balance of rights and obligations.

无论合成生物学处于怎样的发展阶段和状态，知识产权保护机制的目的应在于促进技术创新、技术转让与技术传播,以有利于社会及经济福利的方式去促进技术知识的生产者与使用者的互利，并促进权利与义务的平衡。

1. **Pay Attention to the "Strategic" Nature of Synthetic Biology****(重视合成生物学的“战略性”)**

To protect intellectual property is to protect innovation. The development of synthetic biology is closely related to social development and national security. A specialized intellectual property governance mechanism that conforms to the characteristics and laws of synthetic biology development should be built up, top-level design should be strengthened. The issues of synthetic biology intellectual property governance should be incorporated into a national intellectual property strategy system including of international-country (region)-industry (field)-related institutions, and explore a multiple co-governance mechanism.

保护知识产权就是保护创新，合成生物学发展攸关国家发展和国家安全，应当构建符合合成生物学发展特点和规律的专门化的知识产权治理机制，加强顶层设计，将合成生物学知识产权治理议题纳入国际-国家（地区）-行业/区域-相关机构各层级的知识产权战略体系，探索多元共治机制。

1. **Pay Attention to the "Convergency" of Synthetic Biology(重视合成生物学的“会聚性”)**

The knowledge and achievements related to synthetic biology are diverse, also the protection of related intellectual property rights is complex, even considered as "mystery of intellectual property rights in synthetic biology". Actively explore multi-path protection methods such as patents, copyrights, trade secrets (including technology secrets and business secrets), trademarks, integrated circuit layout designs, geographical indications, genetic resources, and traditional knowledge to achieve adaptive protection and combinative protection, nested protection and spatial protection.

合成生物学相关知识成果具有多样性，相关知识产权保护呈现复杂性，甚至构成“合成生物学知识产权之谜”。应当积极探索综合运用专利、版权、商业秘密（包括技术秘密与经营秘密）、商标、集成电路布图设计、地理标志、遗传资源、传统知识等多路径的保护方式来达成适配性保护、组合性保护、嵌套型保护与立体式保护。

1. **Pay Attention to the "****Subversiveness" of Synthetic Biology(重视合成生物学的“颠覆性”)**

The concept of responsible research and innovation must be implemented for the development of disruptive technology. While continuously expanding the participation of innovative entities, we insist on responsible research on the basic research side and emphasize responsible innovation on the technology application side. Guide science and technology development for good, establish and improve the ethical review mechanism and security review mechanism in the patent licensing system, even the intellectual property system, and clarify the ethical review standards and regulatory rules. Adapt and improve relevant intellectual property legislation, public policies and standards through reflective integration and forward-looking reconstruction.

对颠覆性科技发展要贯彻负责任研究与创新的理念。在不断扩大创新主体参与的同时，在基础研究端坚持负责任研究，在技术应用端强调负责任创新。引导科技向善，建立健全专利授权制度乃至更大范围的知识产权制度中的伦理审查机制和安全审查机制，明确伦理审查标准和监管规则。通过反思性整合与前瞻性重塑，调适和完善相关知识产权立法、公共政策与标准。

1. **Pay Attention to the "Openness" of Synthetic Biology(重视合成生物学的“开放性”)**

Scientifically and reasonably define the boundary between "public domain" and "proprietary domain" in the intellectual property protection mechanism, promote the transformation of knowledge achievements and their legal status from "close/close loop/close source" to "open/open thought/open source", Ensure the continuity and integrity of social innovation. Prevent the abuse of relevant intellectual property rights and maintain fair competition in industrial development. Strengthen international dialogue and cooperation, actively participate in and guide the formulation of international rules, provide and continuously optimize the rule interpretation and roadmap for intellectual property governance of synthetic biology.

科学合理地界定知识产权保护机制中“公共领域”与“专有领域”之间的界限，推动知识成果及其法律状态从“封闭/闭环/闭源”向“共享/开放/开源”转变，保障社会创新的连续性和完整性。防止相关知识产权滥用，维护产业发展中的公平竞争。加强国际对话与合作，主动参与并引导国际规则制定，提供并不断优化合成生物学知识产权治理的解读方案与路线图。

1. **Public Engagement/公众参与**

Ensure the public as the most important stakeholder has a voice in the acceptance of a novel technology, strengthen public education, science popularization, and communication dialogue, foster sense of public ownership and participation, build scientific communication platform and public participation channel that promote public awareness and understanding of biotechnology. The scientific community shall deliver facts and clarify doubts to the public, maintains credibility, enhance the public's awareness of the benefits/risks on the development and application of synthetic biology, as well as their trust in scientific research and experts group.

确保公众作为最重要的利益相关者在接受一种新兴技术方面的发言权，加强公众教育、科学普及和沟通对话，培养公众有份（ownership）参与意识，构建促进公众认知和理解生物科技的科学传播平台和公众参与渠道，科学共同体向公众澄清事实、释疑解惑，保持公信力，增进公众对合成生物学发展与应用的受益/风险认知以及对科学研究与专家系统的信任。

1. **Capacity Building/能力建设**

政府部门、大学、科研院所和媒体机构应该设立可持续的教育培训项目，加强针对以合成生物学为代表的新兴科技的伦理治理以及科学专业精神的教育和培训。在理工医类的本科、研究生教育中纳入科技伦理、工程伦理和医学伦理课程，设置面向文理工医本科生的相关应用伦理专业学位，构建立体化、多层级、多种类、多主体的新兴科技伦理治理能力建设体系。

Government, universities, research institutes and media organizations should set up sustainable education and training programs to strengthen the ethical governance of novel science and technology represented by synthetic biology, as well as the education and promotion of scientific spirit. Set up science and technology ethics, engineering ethics and medical ethics courses in the undergraduate and postgraduate education of science, engineering and medicine, etc. set up relevant applied ethics professional degrees for undergraduates of art, science, engineering and medicine, build up the multi-level, multi-type, multi-subject novel science and technology Ethics governance capacity system.