



For “The Cutting Edge of Biology: What is the Current State of Capabilities and what are the impacts on the BWC” (December 3, 2018, Geneva, Switzerland)

Biotechnology innovation: progress, concerns and our recent efforts with governance

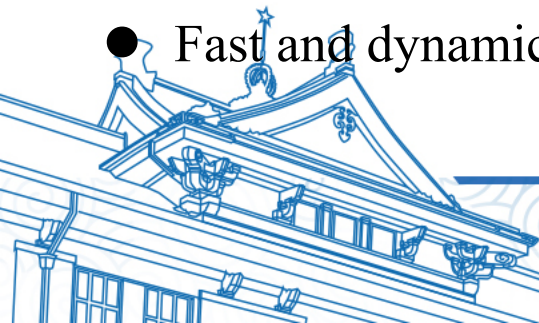
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(<http://tjusa.tju.edu.cn/>)





- Darwin evolution is now being superseded by technological revolution
- Advances in Biology, Chemistry, Physics, Computation, Robotics & AI, and Space sciences are changing/reshaping our relationship with our mother nature
- “*Optimistic for technology*” vs. “*Pessimistic on governance*”
- Science and technology innovation always outpace the regulatory measures
- Fast and dynamic changes of the technologies

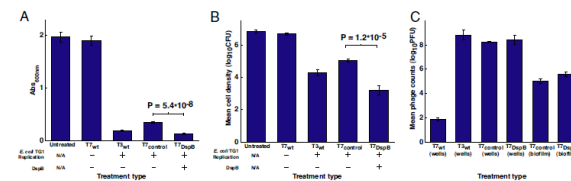
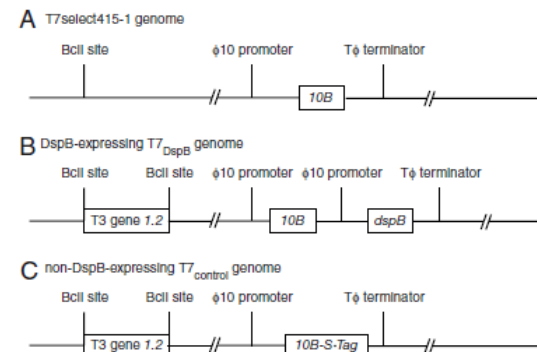
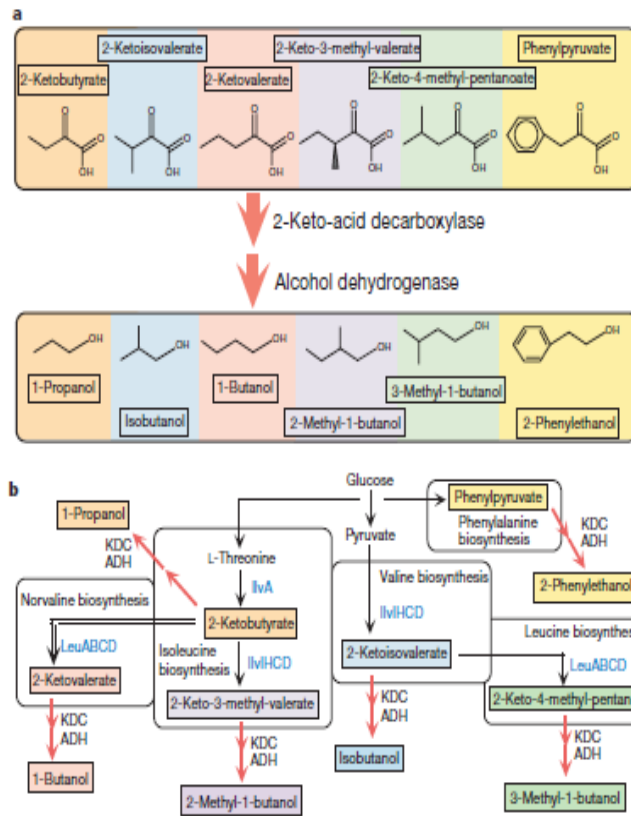
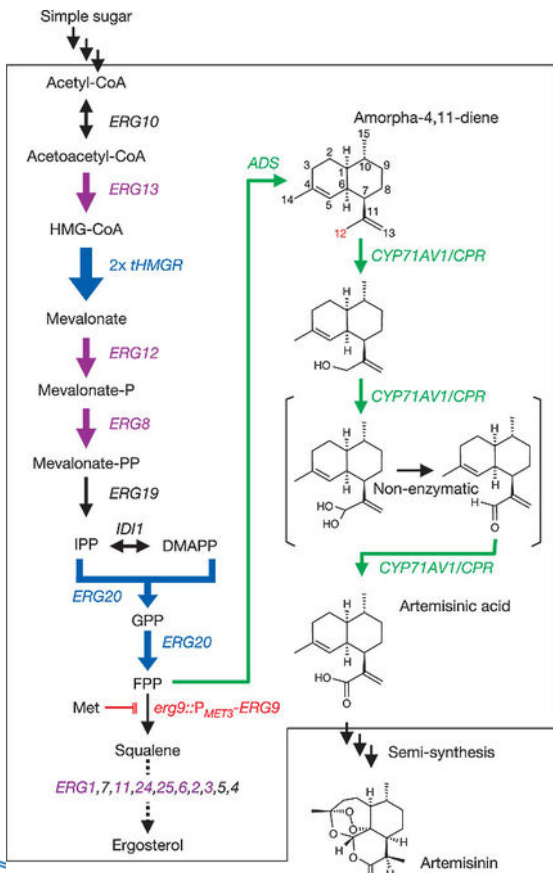


Synthetic biology revolutionized traditional biotechnology industry

Biopharmaceuticals production

Sustainable chemicals

Gene Therapy



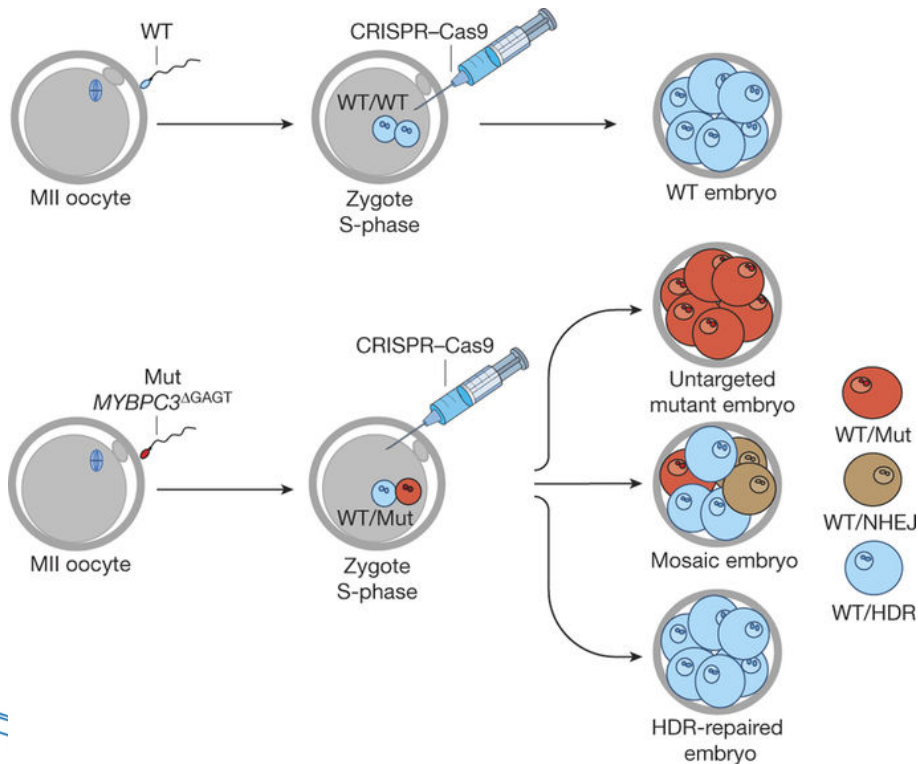
Atsumi, *et al.*, *Nature* 451.7174 (2008): 86.

Ro, *et al.*, *Nature* 440.7086 (2006): 940.

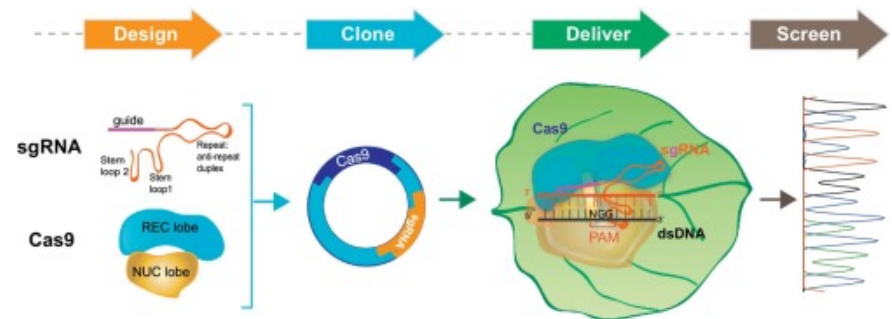
Lu, *et al.*, *PNAS* 104.27 (2007): 11197-11202.

Genome Editing provided revolutionary solutions for genome editing of cells

Correction of a disease gene mutation



Generation of novel disease-resistant crops



Artificial design and chemical synthesis of a horsepox virus genome

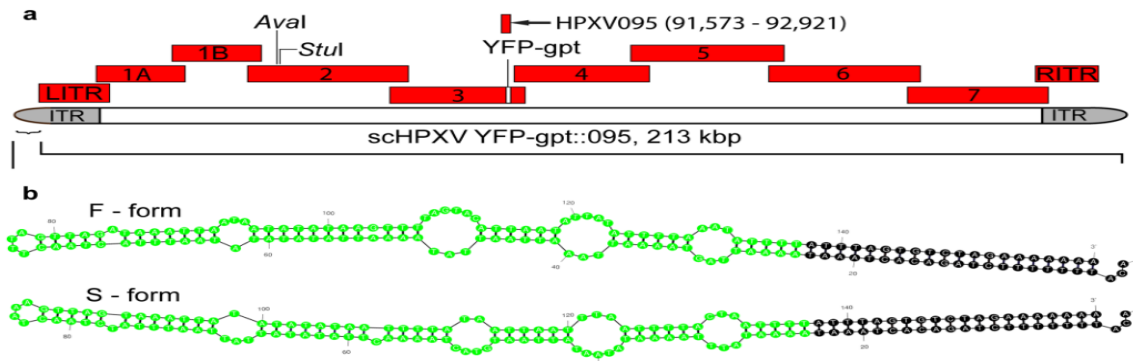


Fig 1. Virus design strategy.

Benefit: a novel replication-proficient smallpox vaccine

Misuse or destructive use: development of horsepox virus with high fatality rate

Noyce et al., (2018 Jan 19) *PLoS ONE* 13(1):e0188453

Traditional ways to deal with the infectious agents challenged!

Ethic concerns for CRISPR/Cas9 (New genome editing methods)



Fig 1. Dogs with Duchenne muscular dystrophy

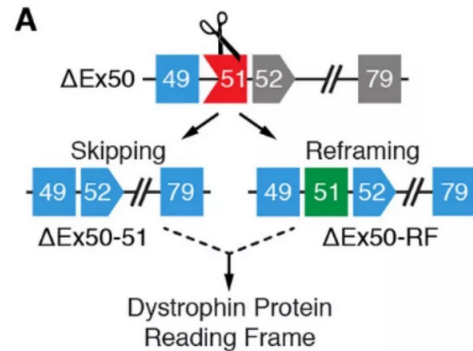


Fig 2. Delivering CRISPR gene editing components (**by direct injection**) to skeletal muscle cells of four dogs to repair related genes.

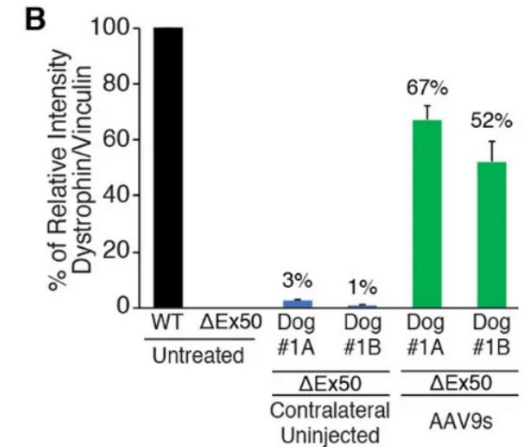


Fig 3. The treated dogs showed improved muscle histology

1. Problem with application, Superman or X Man ?
2. High cost of adeno-associated viruses, a deliver vector for delivering CRISPR component, will it be the privilege for the rich NOWDAYS?



Increased investment and R&D activity

Synthetic Biology National Key Program (2018-2022) > ~50-60 projects

Green energy

Electric energy cells
Plant breeding
Photosynthesis
Biomass utilization

Biomedical engineering

Synthetic vaccines
Cancer diagnosis
Tumor therapy
Biomedical imaging

Chassis engineering

Microbial chassis
Fungal chassis
Plant chassis

Technology development

DNA synthesis
DNA storage

Natural products

Plant products Microbial products
Non-cellular biosynthetic systems

Environmental engineering

Detection of pollutants
Degradation of pollutants
Bloom-forming algae

Safety? Ethic ? Safeguard?

Benefits and risks amplified



- **Balance of research innovation vs. governance**
- **Difficulty to separate between “good use” and potential “bad use”**
- **Challenges with governance: materials vs. information**
- **Technologies ready for potential misuse**
 1. Synthetic virus bacteria with broad infection spectrum and capability
(current international measures insufficient)
 2. Targeted human damage (by genome editing)
 3. Engineered insects
 4. Human modification (by genome editing)





“Safety Management Guidelines for Biotechnological R&D”



Issued by Ministry of Sciences
and Technology of China on
July 12, 2017

Ethics Committee formed under Synthetic
biology Society of China - 2018

Education program - 2018

Tianjin University: “*Biosafety and ethics
relevant to biotechnology*” – undergraduates

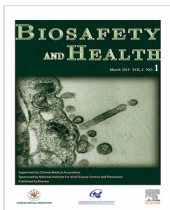
Huazhong University of Sciences and

Technology: “*Ethics of Synthetic Biology*” -
MS and PhD program



BIOSAFETY AND HEALTH

Biosafety and Health (B&H) is an open access, peer-reviewed journal sponsored by the Chinese Medical Association, edited by the National Institute for Viral Disease Control and Prevention, Chinese Center for Disease Control and Prevention (China CDC). B&H aims to publish original research findings and thoughts in any aspect connected with public health and biosafety. In this area, it is one of the few English-language journals with independent intellectual property rights which are hosted by Chinese research and educational institutions. B&H is on the mission to build and maintain a platform for scientists to publish their breakthrough research findings and communicate worldwide, and thereby to advance basic and applied sciences.



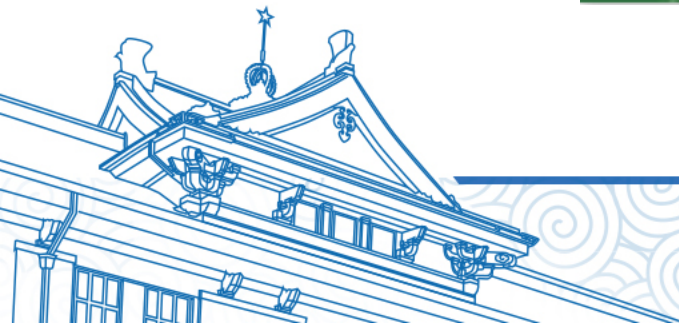
Author Benefits

- Global readership
- Open Access Journal
- International editorial board and outstanding editorial group
- Exempts the Article processing charge (APC) of the first year (March 2019-March 2020)

Editors in Chief



- Two new English journals
 《*Journal of Biosafety and Biosecurity*》 and 《*Biosafety and Health*》 launched in China.
- Attention will be paid to **risk analysis and solution related to cutting edge biology.**





“Ethical and regulatory framework of synthetic biology in China”

(2018-2022) (funded by MOST)

Project goals:

- (1) Establish ethical norms for synthetic biology research, propose specific market access norms and government regulatory policy recommendations;
- (2) Propose effective laboratory research and safety management norms and implementation methods
- (3) Establish public channels of communication and public participation
- (4) Develop intellectual property mechanisms relevant to synthetic biology

“Ethical governance of synthetic biology”

Funded by National Social Science Foundation of China



“International Workshop on Biosafety Laboratory Management and Technologies”

Wuhan, China. Oct 15-25, 2018 (Organized by CAS and MFA of China)



24 scientists and lab managers

22 countries (*Bangladesh, Brazil, Bulgaria, Cambodia, Cameroon, Croatia, Congo, Egypt, Ethiopia, Hungary, Laos, Latvia, Malaysia, Mauritius, Myanmar, Nepal, Nigeria, Pakistan, Poland, Sri Lanka, Tanzania, Uzbekistan*)





1 What is your opinion on risks of dual-use biotechnology?

All responded with “yes, we can see potential risks with dual-use biotechnology”.

2 Is governance of dual-use biotechnology necessary (in your country and in the world)?

All responded with “Yes”.

3 How this has been done in your country so far?

They felt very little governance in the countries.

4 Could it be done better in your country (or in the world)?

All responded with “yes”, but a portion of them felt attention from the governments is not enough currently.

5 If any, what types of resistance you expect when doing so?

No resistance because no action yet! However, they all emphasize the leading roles of governments

6 What you think are the most important factor(s) in governing the dual-use biotechnology?

Government, regulation, mandatory education

International agreement will encourage the governments to act





天津大学生物安全战略研究中心
Tianjin University Center for Biosafety Research and Strategy (CBRS)

Thanks!

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科学技术部、卫生部关于印发《人胚胎干细胞研究伦理指导原则》的通知

Ministry of Science and Technology and the Ministry of Health 《the Ethical Guiding Principles for Human Embryonic Stem Cell Research》

人胚胎干细胞研究伦理指导原则

第一条 为了使我国生物医学领域人胚胎干细胞研究符合生命伦理规范，保证国际公认的生命伦理准则和我国的相关规定得到尊重和遵守，促进人胚胎干细胞研究的健康发展，制定本指导原则。

第二条 本指导原则所称的人胚胎干细胞包括人胚胎来源的干细胞、生殖细胞起源的干细胞和通过核移植所获得的干细胞。

第三条 凡在中华人民共和国境内从事涉及人胚胎干细胞的研究活动，必须遵守本指导原则。

第四条 禁止进行生殖性克隆人的任何研究。

Article 4 Any research on reproductive cloning is prohibited.

第五条 用于研究的人胚胎干细胞只能通过下列方式获得：

- (一) 体外受精时多余的配子或囊胚；
- (二) 自然或自愿选择流产的胎儿细胞；
- (三) 体细胞核移植技术所获得的囊胚和单性分裂囊胚；
- (四) 自愿捐献的生殖细胞。

第六条 进行人胚胎干细胞研究，必须遵守以下行为规范：

(一) 利用体外受精、体细胞核移植、单性复制技术或遗传修饰获得的囊胚，其体外培养期限自受精或核移植开始不得超过14天。

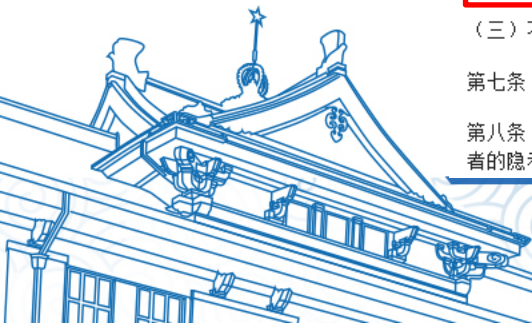
(二) 不得将前款中获得的已用于研究的人囊胚植入人或任何其他动物的生殖系统。

Article 6 Human blastocysts that have been used for research should not be implanted into the reproductive system of humans or any other animal.

(三) 不得将人的生殖细胞与其他物种的生殖细胞结合。

第七条 禁止买卖人类配子、受精卵、胚胎或胎儿组织。

第八条 进行人胚胎干细胞研究，必须认真贯彻知情同意与知情选择原则，签署知情同意书，保护受试者的隐私。





涉及人的生物医学研究伦理审查办法 国家卫生计生委

Ethical examination method for biomedical research involving people

National Health and Family Planning Commission

第十八条 涉及人的生物医学研究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；

Article 18 Biomedical research involving persons shall conform to the following ethical principles

- (1) Allowing subject to withdraw from the study unconditionally at any stage;
- (2) First, the subject's personal safety and health rights should be given priority, followed by scientific and social interests. The research risk and benefit ratio should be reasonable, and strive to make the subjects avoid harm as much as possible;
- (3) The principle of free and compensation. Subjects should be selected fairly and reasonably. No fees should be charged for participants to participate in the study. Appropriate compensation should be given for the reasonable expenses incurred by the subjects during the course of the test;

第六章 法律责任

第四十五条 医疗卫生机构未按照规定设立伦理委员会擅自开展涉及人的生物医学研究的，由县级以上地方卫生计生行政部门责令限期整改；逾期不改的，由县级以上地方卫生计生行政部门予以警告，并可处以3万元以下罚款；对机构主要负责人和其他责任人员，依法给予处分。

Article 45 If a medical and health institution fails to establish an ethics committee to carry out biomedical research involving persons without authorization, the local health and family planning administrative department at or above the county level shall order it to rectify within a time limit;

第四十七条 项目研究者违反本办法规定，有下列情形之一的，由县级以上地方卫生计生行政部门责令限期整改，并可根据情节轻重给予通报批评、警告；对主要负责人和其他责任人员，依法给予处分：

Article 47 If the project researcher violates the provisions of these measures, the local health and family planning administrative department at or above the county level shall be ordered to rectify within a time limit, and may be given criticism and warning according to the seriousness of the case; the principal responsible person and others Responsible personnel shall be punished according to law:

- (一) 研究项目或者研究方案未获得伦理委员会审查批准擅自开展项目研究工作的；
- (二) 研究过程中发生严重不良反应或者严重不良事件未及时报告伦理委员会的；
- (三) 违反知情同意相关规定开展项目研究的；
- (四) 其他违反本办法规定的情形。

- (1) The research project or research project has not been reviewed and approved by the ethics committee to carry out the project research work without authorization;
- (2) Serious adverse reactions or serious adverse events occurred during the research process were not reported to the ethics committee in time;



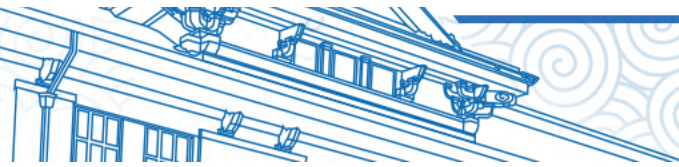


Response of National Health and Wellness Committee and the Ministry of Science and Technology on the incident “Immune AIDS Gene Editing Baby”

原标题：国家卫生健康委员会 科学技术部关于“免疫艾滋病基因编辑婴儿”有关信息的回应

我们高度关注11月28日第二届国际人类基因编辑峰会有关“免疫艾滋病基因编辑婴儿”信息，相关部门正在进行调查核实。我们始终重视和维护人民的健康权益，开展科学研究和医疗活动必须按照有关法律法规和伦理准则进行，对违法违规行为坚决予以查处。

Chinese government always attach importance to and safeguard the people's health rights and interests. Scientific research and medical activities must be carried out in accordance with relevant laws, regulations and ethical standards, and any activities that violated laws or regulations must be thoroughly investigated and definitely punished.





Response of Chinese scientific community on the incident “Immune AIDS Gene Editing Baby”

Chinese Academy of Medical Sciences

声明强调，我们反对在缺乏科学评估的前提下，违反法律法规和伦理规范，开展以生殖为目的的人类胚胎基因编辑临床操作。在发展迅速的基因编辑技术研究和应用中，学术共同体更应强调遵循技术和伦理规范，开展负责任的医学研究与应用，维护国家科学形象，维护人类生命的基本尊严，维护学术共同体的集体荣誉。

Chinese Academy of Sciences

近日，国内外媒体爆出免疫艾滋病基因编辑婴儿诞生的消息，对此中国科学院学部高度重视。作为负责组织和领导学部科学道德和学风建设工作的专门委员会，中国科学院学部科学道德建设委员会发表如下声明：我们高度关注此事，坚决反对任何个人、任何单位在理论不确定、技术不完善、风险不可控、伦理法规明确禁止的情况下开展人类胚胎基因编辑的临床应用。我们愿意积极配合国家及有关部门和地区开展联合调查，核实有关情况，并呼吁相关调查机构及时向社会公布调查进展和结果。

The Chinese scientific community has announced a serious statement to express the clear stance and firm attitude and opposed any words and deeds that challenge scientific ethics. The Chinese scientific community will resolutely defend the will of scientific spirit and scientific ethics, and never change the determination to defend the Chinese government's regulations on stem cell clinical research and regulations and the insistence that science and technology will always benefit mankind and serve the society's sustained and healthy development.

Chinese Academy of Engineering

在学术与技术上，该项“研究”没有先进性，并且对技术的应用严重失当。

在伦理与道德上，在严重缺乏科学评估验证，安全性存在不可预知风险的情况下，贸然开展以生殖为目的的人类生殖细胞基因编辑临床操作，严重违背了基本伦理规范和科学道德。

在法律与法规上，该项“研究”违反了国家相关部门出台的关于基因相关研究的系列政策、法规和管理办法，实施了明令禁止的技术操作。

National Research Foundation of China

近日来，媒体报道的关于贺建奎副教授“人类胚胎基因编辑婴儿”的工作引起国内外学术界和社会广泛忧虑。如果该情况被核实，国家自然科学基金委员会对其做法给人类可能造成的后果表示极度担忧，对其严重违反我国现行法律法规和科学伦理的不负责任行为予以严厉谴责。



Chinese enterprise self-discipline initiative

自律倡议书

近日，有关“基因编辑婴儿”相关信息引发了国内外科学界及生命行业的高度关注与极大担忧。

作为负责任的生命科学研究和技术应用机构，我们完全拥护国家有关部门对涉事方的调查和问责，强烈呼吁同行共同坚守伦理规范，决不把推动科技进步当成突破底线的借口。

为此，我们积极倡议建设健康的行业生态。倡议内容如下：

1. 加强法规意识，主动遵守贯彻。

我们必须严格遵守与生命科学研究、生物技术创新等相关的法律、法规和政策，主动遵守，完全贯彻，积极支持和配合监管部门的指导与管理。

2. 强化伦理意识，提升行业认知。

我们必须不断通过教育强化从业者的科学精神与伦理意识，带头深入学习、交流、研究、完善相关伦理规范，提升行业总体伦理认知。

3. 提升行业自律，承担社会责任。

我们必须在创新发展中避免急功近利，加强行业自律，带头承担社会责任，共同推进行业健康发展。

生命科学和产业的发展既需要政府的监管和科研推动，更需要从业机构的自律与担当。我们欢迎有责任感的机构加入这一行列，互相监督互相帮助，共同维护行业和产业应有的健康氛围，珍惜科研和产业资源，珍视社会公众信任，让生命科技真正造福人类！

本“自律倡议书”参与企业名单如下（共32家，排名不分先后）：

华大基因集团、诺禾致源、贝瑞基因、迪安诊断、吉因加、明码生物、微基因、量化健康、锐翌生物、裕策生物、元码基因、仁东医学、思勤医疗、思路迪、基准医疗、艾吉泰康、微健康基因、金准基因、中大基因、基因慧、瑞奥康晨、百迈客、安诺优达、迈维代谢、艾德生物、海普洛斯、获硕贝肯、岩之澜医学、聚道科技、美吉生物、翊圣生物、吉诺思美。

BGI, along with 31 other biotech companies released the Self-Discipline Proposal:

As a responsible life science research and technology application organization, we fully support the investigation and accountability of the relevant departments by the relevant state departments, and strongly urge peers to adhere to the ethical standards. Never promote the advancement of science and technology as an excuse to break through the bottom line.



