

The “He JianKui (贺建奎) Incident”: Summary of Facts and Concerns

Olivia Ngan

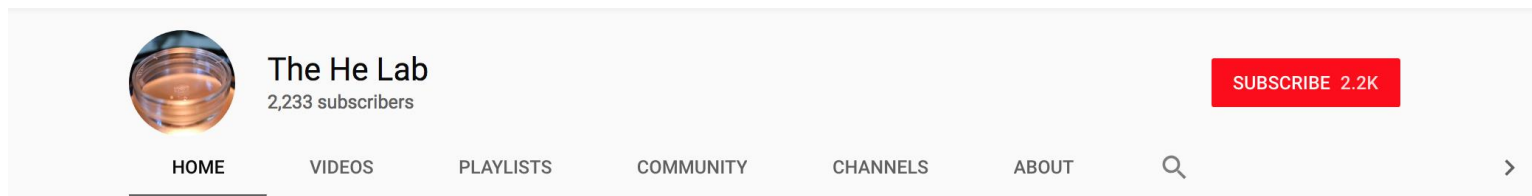
Post-doctoral Fellow

CUHK Centre for Bioethics

The Chinese University of Hong Kong

Outline

- Key events after He JianKui's breaking the news of his work
- Reaction and current consensus from the scientific community, professional society in germline genome editing



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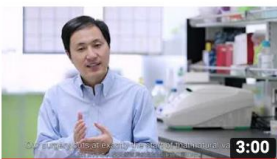
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Gene Surgery in Embryos: An Embryologist Explains How ...

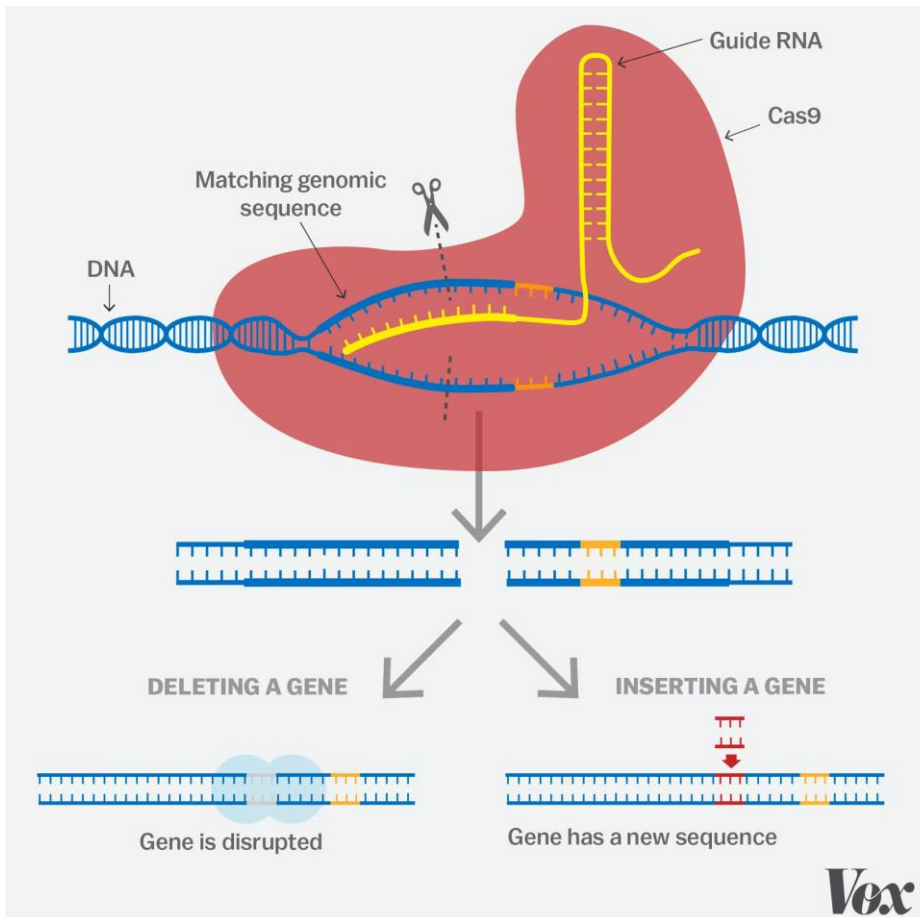
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CRISPR Technology

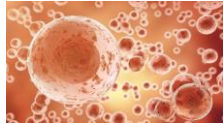


CRISPR is a simple yet powerful tool for editing genomes.

It allow genetic material to be added, removed, or altered at particular locations in the genome.

Potential applications include correcting genetic defects, treating and preventing the spread of diseases and improving crops.

Timeline of “CRISPR-related events”

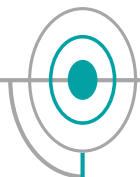


Scientists showed that CRISPR could be used to edit the genomes of cultured mouse cells or human cells



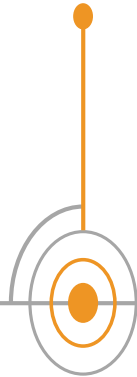
Produce customized dogs with double the amount of muscle mass by deleting a gene

2012



CRISPR was discovered

2013



2014



First monkeys engineered with targeted mutations using CRISPR

2015



CRISPR to edit the genes of various crops to make them more nutritious

2016



Timeline of “CRISPR-related events”



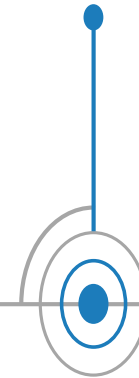
- Gene editing in embryos intended for pregnancy **has not previously been reported**.
- CRISPR is remarkably accurate at editing the genes that it is supposed to edit, but it can also cause **off-target mutations**.
- No one has previously tried editing embryos that develop into humans, because the science **is not yet precise enough to guarantee the results**.
- He **shocked the world** by making the world’s first genome-edited babies



2018



2018



Dr He posted a video-clip online announcing his work on the world first-gene-edited baby using CRISPR



What has he done?



About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos

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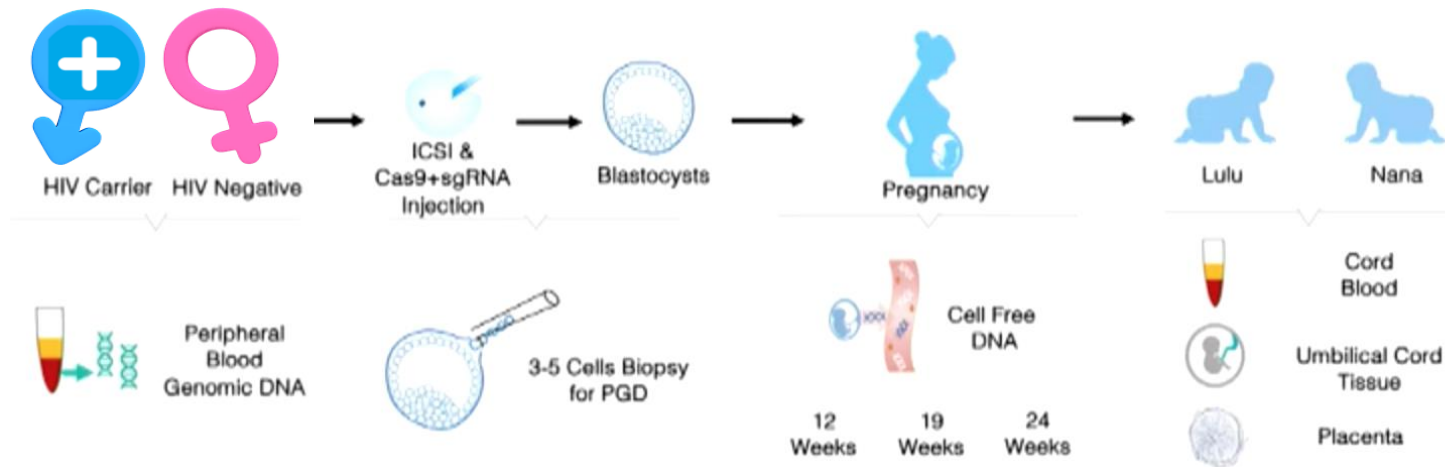


The He Lab
Published on Nov 25, 2018

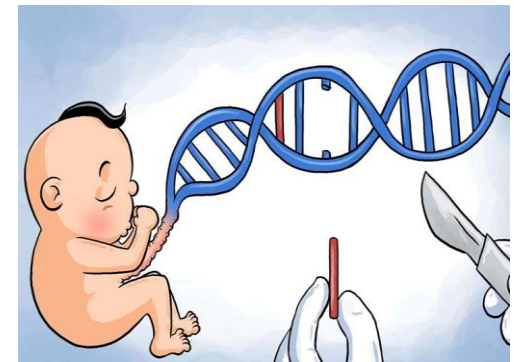
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- Former professor, Southern University of Science and Technology, Shenzhen, China
- He **claimed** he impregnated a woman with embryos that had been edited to disable the genetic pathway HIV uses to infect cells, using CRISPR

JK's Study Design

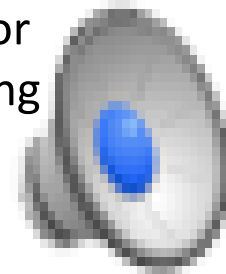


- March 2017 to November 2018
- 8 couples enrolled; 1 dropped out; 30 eggs; 70% edited
- Recruited through HIV AIDS support group
- The pregnancy was normal and closely monitored by ultrasounds and blood test.
- Whole genome sequencing were used to check the status of Twins and JK claimed the surgery worked safely as intended.



He made some “heroic” statements

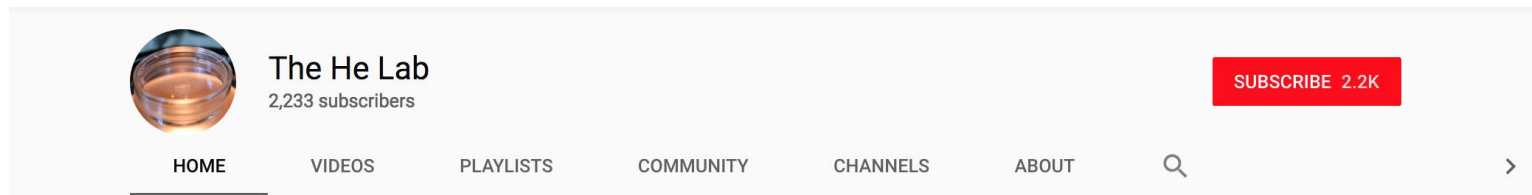
- “A gene surgery that couples save a child from a lethal genetic disease like cystic fibrosis or from life threatening disease like HIV doesn't't just **give that little boy or girl an equal chance at a healthy life.**”
- “**We heal a whole family**”
- “**I cannot think of a gift more beautiful** and wholesome for society than giving another couple a chance to start a loving family”



“I understand my work will be controversial, but I believe families need this technology. And I'm willing to take the criticism for them,” he said.

Five principles JK suggested

In another video, JK and his team came up with 5 **Ethical Principles for Therapeutic Assisted Reproductive Technologies** justifying the pressing need of their work.



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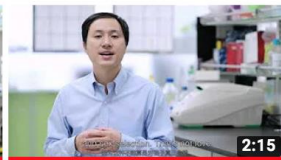
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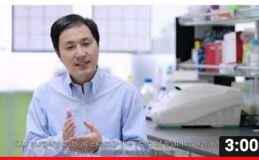


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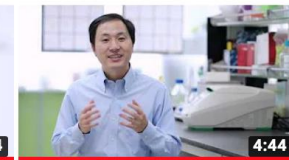
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PERSPECTIVE

Draft Ethical Principles for Therapeutic Assisted Reproductive Technologies

He Jiankui,^{1*} Ryan Ferrel,¹ Chen Yuanlin,¹ Qin Jinzhou,^{1,2} and Chen Yangran¹

Abstract

The germline gene-editing field has several detailed preclinical research guidelines but lacks concise and plain-language ethics statements on ultimate clinical uses. The general public deserves a clear vision of the future to gauge the field's ultimate intentions and have meaningful input and discussion about its progress. We propose the identification of a core set of fundamental human values to frame, guide, and restrict clinical applications that communities around the world can share and localize based on religious beliefs, culture, and public-health challenges.

Introduction

More than seven million children are born every year with lethal or debilitating diseases of genetic or partially genetic origin.¹ Gene surgeries, including CRISPR² gene editing and mitochondrial donation techniques, promise new therapeutic strategies during *in vitro* fertilization (IVF) to cure or prevent these diseases before a child can suffer.

The potential utility and, for some, the controversy of gene editing to treat unborn children, including the availability and effectiveness of preimplantation genetic diagnosis for many genetic diseases, has prompted scientific societies and other worldwide organizations to publish a raft of guidelines about permissible preclinical research.³ Guidelines for ultimate clinical practices, however, remain less defined. What should be our proposed ethics and actual red lines?

A clear vision of the future, succinctly stated in plain language, is needed for the public to gauge the field's eventual intentions and have meaningful conversations about how gene surgery may or may not affect their family, friends, and neighbors.

Surveys conducted in 2018 of >2,500 Americans³ and 4,000 Chinese⁴ show the general public of both countries are generally receptive to gene surgery in human embryos—if the sole purpose is to treat serious diseases.

Respondents rejected enhancements, with the notable example of increasing intelligence being opposed by about 80% of Americans and 70% of Chinese respondents. Despite contrasting regulatory frameworks—the United States passed a law in 2015 explicitly to prohibit any applications,⁵ whereas China maintains a ministerial guideline⁶ drafted in response to cloning concerns⁷ over 15 years prior to the emergence of CRISPR—a cross-cultural ethical divide did not emerge in the American and Chinese surveys. Support for therapeutic uses of gene surgery in embryos was high, even among a majority of highly religious Americans.

On the other hand, many survey respondents also reported they were relatively uninformed about the gene-editing field. So, current public views on gene surgery may be forming based on widely shared personal ethics toward medicine and mercy. This is an open invitation for the scientific community to support the public in making informed decisions about gene surgery's clinical utility, limitations, risks, regulatory needs, and future role in society.

Open Dialogue

Open dialogue has helped shape regulations and advance cultural attitudes in the field of IVF and other assisted reproductive technologies (ART) for >40 years. As a result, initial worries and warnings around eugenic application

*Clustered Regularly Interspaced Short Palindromic Repeats.

¹Department of Biology, Southern University of Science and Technology, Shenzhen, P.R. China; ²Department of Human Reproductive Medicine Center, Third Affiliated Hospital, Shenzhen University, Shenzhen, China.

Five principles JK suggested

1. Mercy for families in need (悲悯之心)

A broken gene, infertility, or a preventable disease should not extinguish life or undermine a loving couple's union.

For a few families, early gene surgery may be the only viable way to heal a heritable disease and save a child from a lifetime of suffering.

2. Only for serious disease, never vanity (有所为更有所不为)

Gene surgery is a serious medical procedure that should never be used for aesthetics, enhancement, or sex selection purposes — or in any way that would compromise a child's welfare, joy, or free will. No one has a right to determine a child's genetics except to prevent disease.

Gene surgery exposes a child to potential safety risks that can be permanent. Performing gene surgery is only permissible when the risks of the procedure are outweighed by a serious medical need.

3. Respect a child's autonomy (探索你自由)

A life is more than our physical body and its DNA. After gene surgery, a child has equal rights to live life freely, to choose his or her occupation, to citizenship, and to privacy. No obligations exist to his or her parents or any organization, including paying for the procedure.

4. Genes do not define you (生活需要奋斗)

Our DNA does not predetermine our purpose or what we could achieve. We flourish from our own hard work, nutrition, and support from society and our loved ones. Whatever our genes may be, we are equal in dignity and potential.

5. Everyone deserves freedom from genetic disease (促进普惠的健康权)

Wealth should not determine health. Organizations developing genetic cures have a deep moral obligation to serve families of every background.

PERSPECTIVE

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He Jiankui,^{1*} Ryan Ferrell,¹ Chen Yuanlin,¹ Qin Jinzhou,^{1,2} and Chen Yangran¹

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Open dialogue has helped shape regulations and advance cultural attitudes in the field of IVF and other assisted reproductive technologies (ART) for >40 years. As a result, initial worries and warnings around eugenic applications in making informed decisions about genetic utility, limitations, risks, regulatory needs, and their role in society.

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For a few families, early gene surgery may be the only viable way to heal a heritable disease and save a child from a lifetime of suffering.
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Gene surgery is a serious medical procedure that should never be used for aesthetics, enhancement, or sex selection purposes — or in any way that would compromise a child's welfare, joy, or free will. No one has a right to determine a child's genetics except to prevent disease.
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- 5. Everyone deserves freedom (每个人都有追求健康的权利)**
Wealth should not determine health. Organisms have a deep moral obligation to serve families of every background.

Retracted from the journal due to a lack of full disclosure - conflicts of interest by authors

“We decided to publish this commentary after peer review in expedited fashion because we felt it **added an unusual and interesting viewpoint from a Chinese research team**, in contrast to the dozens of official guidelines and reports grappling with germline editing issued over the past few years,” said Kevin Davies, PhD, executive editor of The CRISPR

Two days after the video...



At the conference

Health & Environment

Unrepentant Chinese scientist He Jiankui apologises for sparking global controversy, but says he is proud of his achievement

- Speaking at international conference in Hong Kong, academic says couples who took part in experiment gave informed consent
- Scientist reveals second woman may be pregnant, but does not give details

 Elizabeth Cheung
Alice Shen
Karen Zhang
Published: 2:00pm, 28 Nov, 2018



Two days after the video, he attended the summit.

He was proud of what he had done, saying he intended to engineer babies who would not be vulnerable to H.I.V. infection.

在香港舉行的一個基因組編輯國際會議上，科學家賀建奎說，「事實上，對於這個具體案例，我感到自豪。」

Questions from the audience

Why HIV? Why CCR5? What is the medical needs?



What is the ethical reviews process?



What is the informed consent process?
Who conducted? Who reviewed? What did the consent procedure include?



Questions from the audience

- **Scientific Validity?**

- Technology is not proven safe
- Off-target mutations are likely to happen

- **Why HIV CCR5?**

- Prevalent in developing countries
- A global health challenge
- JK sees there's a medical need to prevent HIV in this regard, although sperm washing is effective enough

Why HIV? Why CCR5?
What is the medical
needs?



Questions from the audience

- JK claimed 4 people reviewed the consent, US professor, China academics etc
- After one month, JK and another prof involved in the consent procedures
 - Line-by-line; question any question.
 - Private discussion

Consent documents has been made it publicly available in his lab website



What is the informed consent process?
Who conducted? Who reviewed? What did the consent include?

JK's Study Design- Informed Consent



南方科技大学
SOUTH UNIVERSITY OF SCIENCE AND TECHNOLOGY OF CHINA

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Research

The He lab is focused on developing advanced genomic tech the quality and practicality of personalized medicine.

One key focus includes developing a single molecule genom for accurate, fast, and inexpensive prenatal and cancer diag single molecule sequencers were placed in Chinese hospital.

We are also studying the safety and feasibility of preventing diseases using genome editing ("gene surgery") early in life, embryos. For several years, we have been evaluating key saf germline editing with CRISPR/Cas9, including off-target eff monkey, and nonviable human embryos. We developed a w sequencing protocol and bioinformatics pipeline to detect a We are also investigating different techniques to reduce clir mosaicism. In tandem with scientific research, we are keenl engaging patient communities and regulators for discussing and restrict the ethical use of gene surgery early in life.

"Writing" Genomes

Off-target and mosaicism are two major safety concerns of g editing using CRISPR/Cas9 system. We evaluated the off-ta mouse, monkey and nonviable human embryos. We have developa a whol genome deep sequencing protocol to detecting off-targets. We are also working to improve the efficiency of genome editing in embryos, and reduce the mosaicism.

Information about the clinical trial of Lulu and Nana:

[Birth of twins with gene edited for HIV resistance](#)

[Informed consent](#)

[Second informed consent](#)

[Ethical approval](#)

Article 1 Why conducting this research?

1. The theoretical basis of the experiment: **Based on the human assisted reproductive technology, with the core of the CRISPR / Cas9 gene editing technology, gene editing of the CCR5 gene in the embryo would knock out the CCR5 gene. It would help these CCR5 gene editing babies to obtain the genotype of the Northern European to naturally immunize against HIV-1 virus;**

Method: Based on the human assisted reproductive technology, early embryos were injected with trace amounts of Cas9 RNP after intracytoplasmic sperm injection (ICSI) during normal IVF treatment. Cas9 RNP (Cas9 protein and optimized optical sgRNA) can act on the CCR5 gene, so as to prevent the newborn from the AIDS by editing the CCR5 gene and hindering the HIV-1 virus from invading the (CD4+) T cell. With the help of Preimplantation Genetic Screening or preimplantation genetic diagnosis (PGS / PGD), high-throughput whole genome sequencing, early pregnancy screening and other rigorous techniques could reduce the probability of birth defects, deformed children, etc., and decrease the risk of off-target issues and other risks. This technique may be able to produce IVF baby naturally immunized against AIDS (Referred to as baby) [See Annex I: Technical Procedure Flow Chart]

2. **Technical Objectives: The main objective of this project is to produce infants who have the ability to immunize against HIV-1 virus.**

JK's Study Design- Informed Consent

Article 7 Who is responsible for the cost of participating in the research?

1. The costs incurred in this clinical trial are paid by He Jiankui laboratory at the South University of Science and Technology under the project fund. The coverage details are as follows:
 - (1) IVF outpatient costs, COH costs, embryo laboratory culture costs;
 - (2) Round-trip transportation costs (limited to high-speed rail second-class seat or economy class airfare);
 - (3) Accommodation costs: 350 RMB / day / person;
 - (4) Lost work allowance: 200 RMB / person;
 - (5) Pregnancy detection and monitor costs: Villus puncture, amniotic fluid test, B-ultrasound etc. (For details, please refer to Attachment 4: Project Examination. I understand and agree with my legal wife to do the above tests.)
 - (6) The cost of awaiting medical treatment at the designated medical institution one month prior to the birth and the post-natal recovery at the designated medical institution within 28 days after birth, as well as the rent and nursing fees (200RMB / day);
 - (7) Insurance: The project team will buy Ping An Group's A-Star health insurance for the newborn baby.
2. Based on the calculation of the average costs of such a procedure, the project team commits to pay total cost of **280,000 RMB per couple**. Any cost beyond this limit will be the responsibility of the volunteers. Any costs incurred during the trial but unrelated to the research, including but not limited to the treatment of other diseases and travel accident will be the responsibility of the volunteers.

JK's Study Design- Informed Consent

Article 3 Possible risks and precautions.

1. With the existing knowledge, the additional operations proposed in this project will not put the mother at risk of contracting HIV and other infectious diseases. In case of any disputes over rights and obligations during the project period between you and the medical institution, the contract signed shall prevail, and the project team is not responsible for this.
2. In order to ensure normal embryo development, in vitro fertilization and incubation phase injection of trace substances is at the trace amount (pg level, that is 10^{-10} – 10^{-12} g). It does not guarantee that gene editing will play its role. It is normal if the infants do not have the capacity of natural Immunity to AIDS. The project team does not assume legal responsibility in this situation.
3. The primary risk of gene editing (DNA-targeted CRISPR-Cas9 endonuclease) is the off-target effect of generating extra DNA mutations at sites other than the intended target. This is due to that the technique can cause nonspecific cleavage, resulting in mutations in non-targeted genomic sites. **PGD, whole genome-wide sequencing, amniocentesis and peripheral blood test of mothers in different stages of pregnancy after transplantation will minimize the possibility of substantial injury.** Therefore, this project team is not responsible for the risk of off-target which is beyond the risk consequences of the existing medical science and technology.

JK's Study Design- Informed Consent

6. Neonatal malformations, congenitally deficiency, suffering from common genetic diseases belong to the scope of natural risk of natural reproduction, the project team does not assume legal responsibility.
1. This research project will likely help you produce HIV-resistant infants. It is beyond the scope of the research project to test the HIV-related effects of maternal infection during the research period, and the risk is borne by volunteers. HIV resistance in infants is based on a health certificate issued by a post-natal medical institution obstetric.
2. The project team purchases Ping An Group's Anxingbao insurance for babies born.

Guidelines in China

- **Several other points**

- 1) The Chinese Government prohibits the genetic manipulation of human gametes, zygotes, and embryos for reproductive purposes.
 - Legal violation
- 2) HIV carriers are not allowed to have assisted reproductive technologies'
- 3) 14 days embryo rule

What is the ethical reviews process in China?




JK's Study Design- Ethics Approval

According to information listed on China's Clinical Trial Registry website, the study was sponsored by the **Southern University of Science and Technology (南方科技大学)** and **Shenzhen HarMoniCare Women and Children's Hospital (深圳和美妇儿专科医院)**.

The Ethics Certificate was also obtained from the hospital on March, 2017

点, 在国际日益竞争激烈的基因编辑技术应用中脱颖而出; 这将是超越 2010 年获得诺贝尔奖的体外受精技术领域的开创性研究, 将为无数的重大遗传性疾病的治疗带来曙光。

医学伦理委员会审批意见:
符合伦理规范, 同意开展。

主任委员 (签章):  日期: 2017 年 3 月 7 日

深圳和美妇儿专科医院
医学伦理委员会审查申请书

项目名称	CCRS 基因编辑	项目起止时间	2017 年 3 月—2019 年 3 月		
项目类别	A.新技术、新项目 () B.第二、三类医疗技术 () C.科研项目 (✓) D.移植医学 () E.器官移植 () F.其他 (请注明)				
1/2	1. 申请人 (项目负责人) 信息				
姓名	性别	男	学历	博士	电话
					18688955436
目前主要研究方向	基因组学				
申请理由:	<p>CCRS(C-C chemokine receptor type 5)是 ccr5 基因编码的一种蛋白质, 定位于白细胞表面, 作为趋化因子的受体而与免疫系统相关, 在 T 细胞与特定组织和靶器官结合过程中发挥作用, 具有调控 T 细胞和单核细胞或巨噬细胞系的迁移、增殖与免疫的功能, 主要表达于记忆性的静止期 T 淋巴细胞、单核细胞、未成熟的树突状细胞等的细胞膜上。人群调查和实验研究结果表明, CCR5Δ32 缺失的个体拥有正常的免疫功能和炎症反应, 并且对多种病毒感染表现出显著的抵御能力; 因此, 作用于 CCR5 的基因编辑或将有效阻断霍乱、天花或艾滋病毒感染。</p> <p>近期我国科学家利用 CRISPR-Cas9 破坏乙肝病毒, 基因治疗对罕见病带来希望, 2017 年 2 月, 美国国家科学、工程与医学研究院首次批准用于重大疾病治疗的胚胎编辑实验研究的伦理申请, 这将为无数的重大遗传性疾病的治疗带来曙光。</p> <p>本研究拟采用 CRISPR-Cas9 技术对胚胎进行编辑, 通过胚胎植入前遗传学检测和孕期全方位检测可以获得具有 CCR5 基因编辑的个体, 使婴儿从植入母亲子宫之前就获得了抗霍乱、天花或艾滋病的潜力。</p> <p>在早期预实验中, 我们已经设置了严格基因编辑质控标准, 从安全性角度全面评估 CCR5 基因在胚胎编辑的可行性: 1. 采用细胞系和动物模型 (小鼠, 猴子) 对选定的 CCR5 基因进行严格的早期试验研究, 特别是选择人类的近亲-猴子作为模式动物, 采用 CRISPR-Cas9 对其胚胎编辑, 采用多种方法来综合评价执行过基因编辑的猴子的健康状态、生理状态及其神经行为, 以找出由于基因组编辑而导致的任何相关疾病, 同时分离经过基因编辑的胚胎干细胞, 检测其经过基因编辑后增殖及分化是否异常; 2. 采用多种手段减少脱靶事件和嵌合体问题, 例如使用高保真 CAS9 蛋白和选择最佳 sgRNA, 结合全基因组扩增和全基因组二代测序是检测脱靶事件和嵌合体问题, 同时开发生物信息学方法, 准确评价脱靶是否存在潜在危害; 3. 在动物模型中检测基因编辑带来的多代影响, 探究基因编辑后裔的健康状态。</p> <p>基于以上研究和实验结果, 本研究拟通过辅助生殖技术实现人类胚胎的体外受精, 采用 CRISPR-Cas9 基因编辑技术对受精卵的 CCR5 基因进行基因编辑, 与正常受精卵对比, 比较胚胎形态学差异; 同时, 采用单细胞转录组学研究方法, 比较基因编辑后的胚胎与正常发育胚胎在转录组发育的差异, 另一方面通过 PGS/PGD 技术, 对植入前胚胎结合单细胞全基因组测序技术进行严格的遗传学诊断和筛查, 再次确认基因编辑成功, 全面评估脱靶及嵌合体问题, 选择目标胚胎进行移植; 在孕早期阶段, 在全基因组水平对早期及中期羊水筛查胎儿是否正常, 最终生产 CCR5 突变的健康孩子。</p> <p>我们期望, 建立完善的基因手术治疗严格行业质量控制标准, 占领整个基因编辑相关治疗技术门槛的制高点。</p>				

JK's Study Design- Informed Consent

- **The hospital and the university** linked to a controversial experiment purporting to have created the world's first genetically-edited babies **denied their involvement**.
- The public statement:
 - The University and the Department were **unaware** of the research project and its nature.
 - The research was **conducted outside** of the campus and **was not reported** to the University nor the Department.
- The University formed an independent committee to investigate this incident

Chinese hospital denies approving gene-edited babies experiment

Tuesday, November 27, 2018 1 comment

Like 0

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关于贺建奎副教授对人体胚胎进行基因编辑研究的情况声明

2018-11-26 综合新闻

今日，有媒体报道贺建奎副教授（已于2018年2月1日停薪留职，离职期为2018年2月—2021年1月）对人体胚胎进行了基因编辑研究，我校深表震惊。在关注到相关报道后，学校第一时间联系贺建奎副教授了解情况，贺建奎副教授所在生物系随即召开学术委员会，对此研究行为进行讨论。根据目前了解到的情况，我校形成如下意见：

- 一、此项研究工作为贺建奎副教授在校外开展，未向学校和所在生物系报告，学校和生物系对此不知情。
- 二、对于贺建奎副教授将基因编辑技术用于人体胚胎研究，生物系学术委员会认为其严重违背了学术伦理和学术规范。
- 三、南方科技大学严格要求科学研究遵照国家法律法规，尊重和遵守国际学术伦理、学术规范，我校将立即聘请权威专家成立独立委员会，进行深入调查，待调查之后公布相关信息。

Reaction from the Chinese Scholars

The Genetics Society of China and the Chinese Society for Stem Cell Research issued a joint statement saying: “We strongly condemn it for the extreme irresponsibility, both scientifically and ethically.”

Society

Chinese scientists condemn ‘crazy’ and ‘unethical’ gene-editing experiment

- More than 120 researchers sign open letter criticising He Jiankui after he claimed to have been responsible for world’s first gene-edited babies



Alice Shen

Published: 11:30pm, 26 Nov, 2018 ▾

Reaction from the Chinese Scholars

- *“We are **opposed to any clinical operation of human embryo genome editing for reproductive purposes** in violation of laws, regulations, and ethical norms **in the absence of full scientific evaluation.**”*
- *On the same day, the Chinese national health commission ordered the Guangdong health commission initiated an investigation.*

Two months later

January, 2019

The investigation team of Guangdong Province

The investigation team of Guangdong Province

The government investigation found that

- JK, starting from 2016, had deliberately evaded supervision, used unsafe and ineffective methods, and forged ethical review materials.
 - To circumvent the regulations, JK got blood from HIV-negative volunteers.
- Dr. He had raised funds on his own “in pursuit of personal fame and fortune.”

The activities seriously violated ethical principles and scientific integrity and breached relevant regulations of China, according to the investigation.

「該行為嚴重違背倫理道德和科研誠信，嚴重違反國家有關規定，在國內外造成惡劣影響」新華社說。

Gene editing

Second woman carrying gene-edited baby, Chinese authorities confirm

Police to investigate He Jiankui after last year's claim to have altered the DNA of twin girls



▲ He Jiankui faces a police investigation in China over his claim to have created gene-edited babies. Photograph: Mark Schiefelbein/AP

Agence France-Presse

Tue 22 Jan 2019 01:10 GMT

Investigators in Guangdong province will hand over suspected **crimes to the public security** agency, the news report said without elaborating.

The report did not say what **punitive measures** the government intends to take against He and his team.

What then?

Latest

Southern University of Science and Technology Public Statement

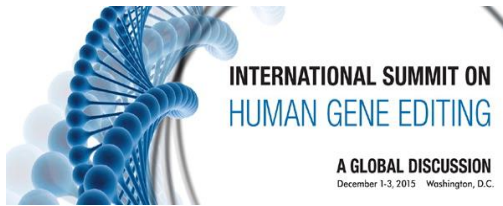
Jan 21, 2019 **Latest News**

The Guangdong Province Investigation Task Force has completed a preliminary investigation of the gene-edited baby incident. Based on the conclusion of the task force and after deliberation, Southern University of Science and Technology (SUSTech) hereby makes the following statement:

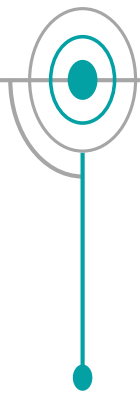
Effective immediately, SUSTech will rescind the work contract with Dr. Jiankui He and terminate any of his teaching and research activities at SUSTech.



Timeline of “CRISPR-related events”

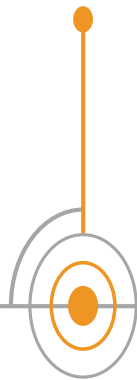


April 2015

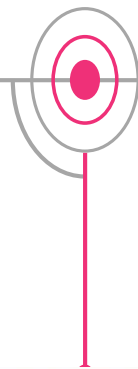


CRISPR on human embryo by a Chinese research team

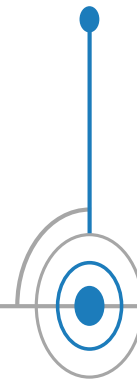
December 2015



November 2018



December 2018



Surprised, not surprised?

[Protein Cell](#). 2015 May; 6(5): 363–372.

Published online 2015 Apr 18.

doi: [10.1007/s13238-015-0153-5](https://doi.org/10.1007/s13238-015-0153-5)

PMCID: PMC4417674

PMID: [25894090](https://pubmed.ncbi.nlm.nih.gov/25894090/)

CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes

[Puping Liang](#),[#] [Yanwen Xu](#),[#] [Xiyi Xia](#),
[Xiaowei Xie](#), [Yuxi Chen](#), [Yujing Li](#),
[Canquan Zhou](#),[✉] and [Junjiu Hua](#)

► [Author information](#) ► [Article no](#)

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News & Comment > News > 2018 > September > Article

NATURE | NEWS

Chinese scientists genetically modify human embryos

Rumours of germline modification prove true — and look set to reignite an ethical debate.

David Cyranoski & Sara Reardon

22 April 2015



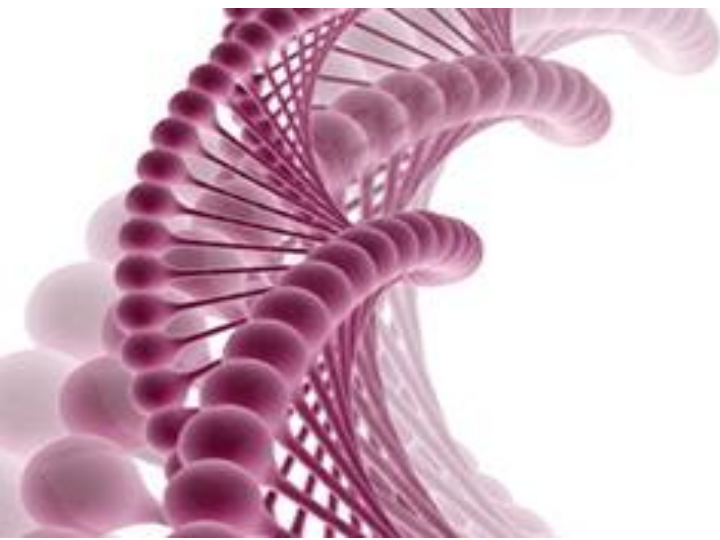
INTERNATIONAL SUMMIT ON HUMAN GENE EDITING

A GLOBAL DISCUSSION

December 1-3, 2015 Washington, D.C.

It would be irresponsible to proceed with any clinical use of germline editing unless and until (i) the **relevant safety and efficacy** issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad **societal consensus** about the appropriateness of the proposed application.

The international community should strive to **establish norms concerning acceptable uses** of human germline editing and to harmonize regulations, in order to discourage unacceptable activities while advancing human health and welfare.



SECOND INTERNATIONAL SUMMIT ON³³ HUMAN GENOME EDITING

November 27-29, 2018 The University of Hong Kong

THE ACADEMY OF SCIENCES OF HONG KONG
THE ROYAL SOCIETY
U.S. NATIONAL ACADEMY OF SCIENCES
U.S. NATIONAL ACADEMY OF MEDICINE

Germline genome editing could become acceptable in the future if these risks are addressed and if a number of additional criteria are met. These criteria include strict **independent oversight**, a **compelling medical need**, an absence of reasonable alternatives, a plan for long-term follow-up, and attention to societal effects.


Progress over the last three years and the discussions at the current summit, however, suggest that it is time to define a rigorous, responsible translational pathway toward such trials.



COMMENT • 13 MARCH 2019

Adopt a moratorium on heritable genome editing

Eric Lander, Françoise Baylis, Feng Zhang, Emmanuelle Charpentier, Paul Berg and specialists from seven countries call for an international governance framework.

Eric S. Lander , Françoise Baylis , Feng Zhang , Emmanuelle Charpentier , Paul Berg , Catherine Bourgain , Bärbel Friedrich , J. Keith Joung , Jinsong Li , David Liu , Luigi Naldini , Jing-Bao Nie , Renzong Qiu , Bettina Schoene-Seifert , Feng Shao , Sharon Terry , Wensheng Wei  & Ernst-Ludwig Winnacker 



Scientists and ethicists from seven nations called for a moratorium on gene-editing experiments designed to alter heritable traits in human babies.

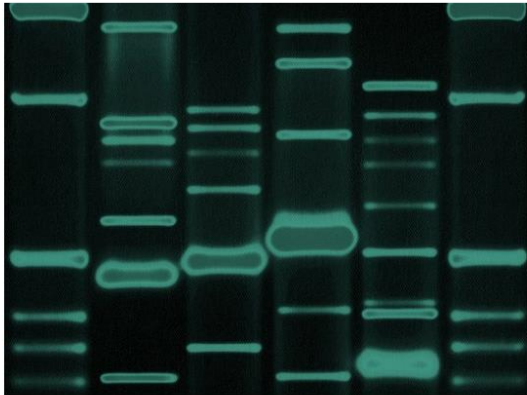
- First, that the risks of gene editing are simply **too uncertain** and potentially large to proceed.
- Secondly, the deeply controversial nature and potential social impact of altering human DNA means researchers need **“broad societal consensus”** before proceeding.

Venture Capitals

- There has been growing interest in proposals for genetic enhancement of humans

JASON PONTIN IDEAS 08.07.18 08:00 AM

THE GENETICS (AND ETHICS) OF MAKING HUMANS FIT FOR MARS



MIT Technol. Rev

The DIY designer baby project funded with Bitcoin

Cryptocurrency, biohacking, and the fantastic plan for transgenic humans.

by Antonio Regalado February 1, 2019

Brief reflection

- Are germline genome editing techniques *inevitable* advances?
- Should we be worried about the era of human genome editing?
- How should we approach the technology? Should we decide based on a societal, ethical, legal consensus?



Next..

- **Professor Alastair V. Campbell**
 - *Ethical Reflections on Germline Genome Editing*
- ***Prof. Alexandre Erler***
 - Regulating Germline Genome Editing: Some Key Ideas in the Debate