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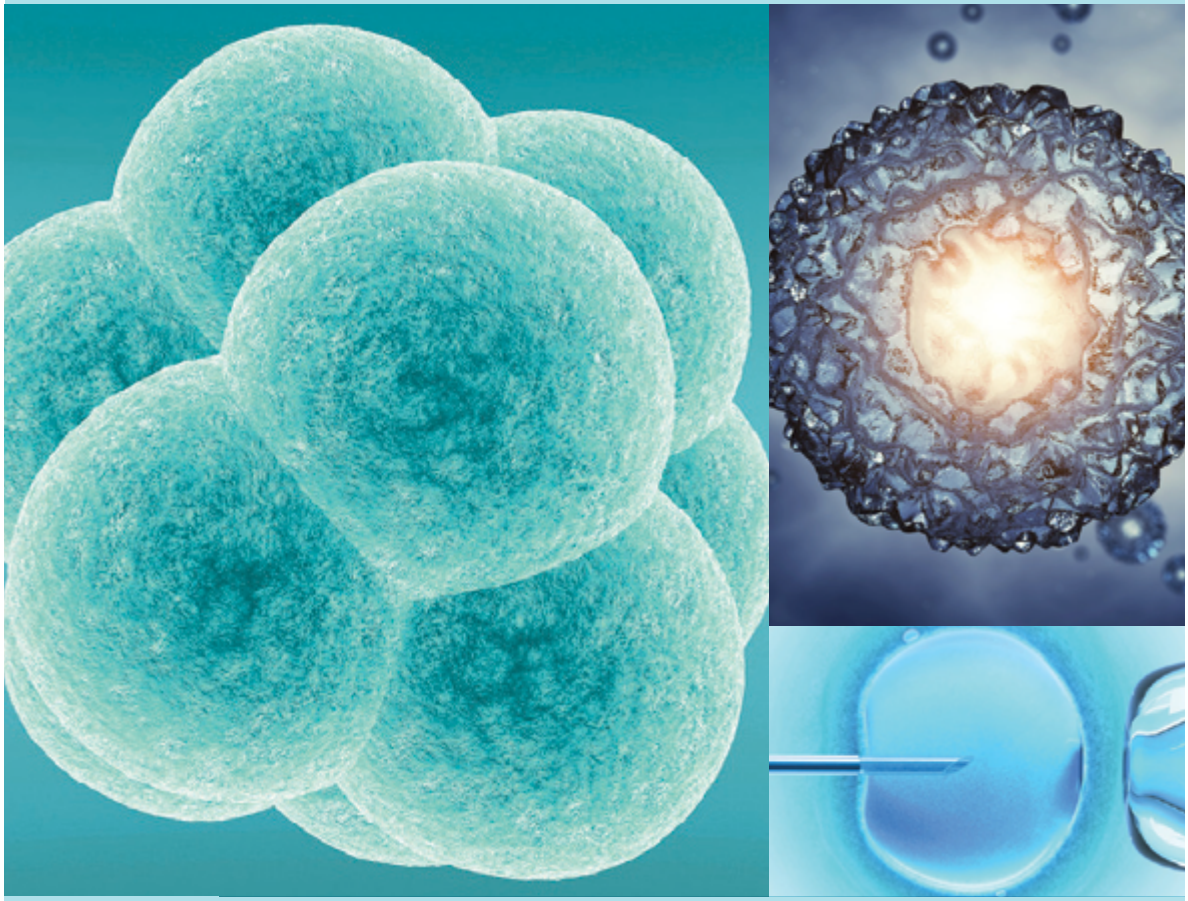
NHMRC Embryo Research Licensing Committee

Report to the Parliament of Australia

For the period 1 September 2022 to 28 February 2023



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P: (02) 6217 9000

Australian Government
National Health and Medical Research Council

NHMRC

The Hon Mark Butler MP
Minister for Health and Aged Care
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to present to you the 41st biannual report from the National Health and Medical Research Council's (NHMRC) Embryo Research Licensing Committee (ERLC) which, in accordance with section 19(3) of the *Research Involving Human Embryos Act 2002* (the RIHE Act), reports on the operation of the RIHE Act and the licences issued under it.

This report is for the period 1 September 2022 to 28 February 2023 and describes the activities ERLC has undertaken during this reporting period, including associated monitoring and compliance activities.

ERLC met once during this reporting period and issued a licence for the generation and study of a novel *in-vitro* model of human blastocysts, referred to as 'iBlastoids'. ERLC varied six licences which included working with a licence holder to meet licence closure requirements on four licences. As of 28 February 2023, there were four general licences issued under the RIHE Act.

During this period, ERLC also implemented a national mitochondrial donation licensing scheme. Amendments to the RIHE Act and the *Prohibition of Human Cloning for Reproduction Act 2002* to enable the staged introduction of mitochondrial donation in Australia came into effect on 1 October 2022. ERLC is the responsible authority for licensing research and specialised training in mitochondrial donation techniques, and licensing and overseeing a suitable IVF clinic to deliver mitochondrial donation as part of a clinical research trial. There were no mitochondrial donation licences issued during the reporting period.

Yours sincerely

Professor Dianne Nicol
Chairperson, NHMRC Embryo Research Licensing Committee
24 April 2023

Telephone
+6102 6217 9000
16 Marcus Clarke Street,
Canberra ACT 2601

info@nhmrc.gov.au
nhmrc.gov.au

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Introduction

Legislative framework

The Commonwealth *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and *Research Involving Human Embryos Act 2002* (the RIHE Act) were developed to address community concerns, including ethical concerns, about scientific developments in relation to human reproduction and the use of human embryos in research activities. The legislation prohibits human cloning for reproductive purposes and a range of other practices relating to reproductive technology. It also regulates research activities that involve the use of human embryos created by assisted reproductive technology (ART) or by other means. There are strong penalties for non-compliance with the legislation.

The RIHE Act established the Embryo Research Licensing Committee (ERLC) of the National Health and Medical Research Council (NHMRC) as a Principal Committee of NHMRC. One of the functions of ERLC is to consider applications for licences to conduct research involving human embryos. As required under section 29 of the RIHE Act, ERLC maintains a publicly available database containing information about licences issued. This database can be accessed on the NHMRC website at www.nhmrc.gov.au.

The *Mitochondrial Donation Law Reform (Maeve's Law) Act 2022* came into effect on 1 October 2022. The Act amends the PHCR and RIHE Acts to allow mitochondrial donation (an assisted reproductive technology technique that might help prevent certain rare mitochondrial diseases) to be used in research and training activities and for human reproductive purposes subject to the outcome of clinical trials. ERLC is the responsible authority for the mitochondrial donation licensing scheme and will administer three new licence types in the initial stage of scheme implementation.

Reporting to Parliament

Section 19(3) of the RIHE Act requires ERLC to table twice yearly reports in either House of Parliament on or before 30 June and 31 December each year and at any other time as required by either House of Parliament. The reports must include information about the operation of the RIHE Act and about licences issued under this Act.

This is the 41st Parliamentary Report of ERLC, which covers the period 1 September 2022 to 28 February 2023.

Further information

Further information about this report and the issue of licences can be obtained by contacting:

Director, Governance, Regulation and Secretariat Support
Research Quality and Priorities Branch
NHMRC
GPO Box 1421
CANBERRA ACT 2601

Telephone: 02 6217 9000
Email: embryo.research@nhmrc.gov.au
Website: www.nhmrc.gov.au

Membership of ERLC

ERLC was established in May 2003 under the RIHE Act. The nine-member committee is responsible for making statutory decisions as outlined in the RIHE Act.

Members are appointed by the Minister for Health and Aged Care, according to the process prescribed in the RIHE Act. Appointments are on a part-time basis for a period not exceeding three years, with members eligible for reappointment.

ERLC appointments for the 2021–2024 triennium commenced on 30 September 2021.

The membership of ERLC is detailed at **Appendix A**.

Functions

Established as a Principal Committee of NHMRC, the functions of ERLC are to:

- consider general and mitochondrial donation applications for licences to conduct research involving human embryos
- issue (subject to conditions) or not issue such licences
- maintain a publicly available database containing information about licences issued
- monitor licensed activities and ensure compliance with the legislation through the appointment of inspectors and take necessary enforcement action, such as cancelling or suspending licences
- report to the Parliament of Australia on the operation of the RIHE Act and the licences issued under this Act
- perform such other functions as are conferred on it by the RIHE Act or any other relevant law.

Operation of ERLC

Committee meetings

During the reporting period ERLC met out-of-session on 7 September 2022 and held a formal committee meeting on 4 November 2022.

New licences issued

One licence was issued in the reporting period. On 19 October 2022, ERLC issued Licence 309729 to Monash University. The licence permits Monash University to generate and study a novel *in-vitro* model of human blastocysts ('iBlastoids'). Licence 309729 authorises the creation and characterisation of iBlastoids, which are human embryos (and human embryo clones) that are generated by reprogramming adult skin cells *in-vitro* into a three-dimensional cluster of cells that resemble a blastocyst and has the potential to develop up to the stage at which the primitive streak appears. Licence 309729 commenced on 19 October 2022 for a period of three years.

Variations to existing licences

The RIHE Act empowers ERLC to vary any licence issued under the Act. Variations to licences may either be requested by the licence holder or initiated by ERLC. Variations may be of an administrative nature (e.g., change to site address) or may relate to aspects of the authorised activities (e.g., number of embryos used).

During the reporting period ERLC varied six licences. Further information about variations to licences approved during the reporting period is at **Appendix B**.

Expiry of licences

Three general research licences and one general training licence expired in the reporting period (refer table below). The final activity reports for these licences are included in this report.

Licence	Holder	Expiry Date
309702B	Genea Limited	14 February 2023
309703	Genea Limited	14 February 2023
309710	Genea Limited	14 February 2023
309726	Genea Limited	14 February 2023

Progress of licensed activities

Licence holder reports

Licence holders are required to report every six months on the progress of their licensed activities. The following reports on the progress of licensed activities are provided here as received from the licence holders.

Current licences

Licence number	**309718**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device.
Progress of licensed activity to date	Over the lifetime of the project, clinically unsuitable abnormally fertilised eggs and excess-declared ART blastocysts have been used to develop an automated vitrification instrument (Gavi) for freezing of oocytes, zygotes/cleavage stage and blastocyst stage embryos. After the product development process, the instrument and associated consumables are CE[1] marked products and are commercially distributed across several regions. The Gavi system has approved protocols for freezing of oocytes, zygotes/ cleavage stage and blastocyst stage embryos. Further optimisations for the different developmental stages may be required as post market surveillance data is continuously monitored, and commercial success ascertained.

1 CE mark affirms compliance with the legislation applicable in the European Economic Area.

Licence number	**309719**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos for the development of improved IVF culture media
Progress of licensed activity to date	The current projects are centred around developing new products for inclusion within the Gems media suite. These projects, which vary widely depending on the product in question, are ongoing; some having utilised excess ART embryos already and some progressing to a stage where they are likely to do so. The use of clinically excess ART embryos in product development is essential. Animal models play a large part in progressing new media, but as their response is not always a true representation of how human embryos will respond, it is important to have a stage between animal model experiments and clinical use, improving confidence in the new products before subjecting patients to those new innovations.

Licence number	**309727**
Licence holder	Melbourne IVF Pty Ltd
Licence title	Comprehensive chromosomal analysis of human preimplantation embryos
Progress of licensed activity to date	During this reporting period, identification and recruitment of eligible patients commenced, however no patients chose to participate and therefore no embryos were used.

Licence number	**309729**
Licence holder	Monash University
Licence title	The generation and study of a novel in-vitro model of human blastocysts ('iBlastoids')
Progress of licensed activity to date	We have commenced recruiting participants who have consented to the requirements outlined in this licence. To date, 6 participants have been recruited as donors to derive skin fibroblasts. We have obtained biopsies from three donors and have since established 3 fibroblast lines from the different donors and have initiated the first series of experiments. These first experiments indicated that further optimization will be required. This is expected as the initial material (skin fibroblasts) is different from the one used for our discovery. Thus, we will continue optimizing our protocols for these new skin fibroblasts.

Expired licences (during the reporting period)

Licence number	**309702B**
Licence holder	Genea Limited
Licence title	Development of methods for preimplantation genetic and metabolic evaluation of human embryos
Progress of licensed activity to date	There has been no activity under licence 309702B over the last 6-month reporting period. Under the licence, Genea was able to investigate and improve techniques for the development of molecular diagnostic test to be applied to human embryos. This licence closed on 14 February 2023.

Licence number	**309703**
Licence holder	Genea Limited
Licence title	Development of human embryonic stem (ES) cells
Progress of licensed activity to date	Under research licence 309703 human embryonic stems cell lines with known genetic conditions were able to be established. Subsequent studies on these stem cell line and cells differentiated from them advanced knowledge of developing models for understanding disease mechanisms. Furthermore, collaborations with pharmaceutical groups provided insight into new development pathways for treatments of the genetic conditions. This licence closed on 14 February 2023.

Licence number	**309710**
Licence holder	Genea Limited
Licence title	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions
Progress of licensed activity to date	Under research licence 309710 human embryonic stems cell lines were able to be established. Subsequent studies on these stem cell line and cells differentiated from them advanced knowledge of developing models for understanding cell differentiation models, such as the development of smooth muscle and neural cells. Such understanding may in the future lead to the development of treatment treatments as varied as Parkinson's Disease and tissue replacement technologies. This licence closed on 14 February 2023.

Licence number	**309726**
Licence holder	Genea Limited
Licence title	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)
Progress of licensed activity to date	Nil reported outcomes as training under this licence did not proceed due to COVID-19. This licence closed on 14 February 2023.

Licensed use of excess ART embryos

The following table shows the use of excess ART embryos under licence, as at 28 February 2023.

Current research licences

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 28 February 2023	Embryos used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	345	259	0
309719	Genea Limited	Use of excess ART embryos for the development of improved IVF culture media	640	58	0
309727	Melbourne IVF Pty Ltd	Comprehensive chromosomal analysis of human preimplantation embryos	100 (maximum of 200 excess ART embryos may be removed from cryostorage and thawed to obtain the 100 embryos)	0	0
Total for current research licences			**1,085**	**317**	**0**

Expired research licences (during the reporting period)

Licence number	Licence holder	Licence title	Embryos authorised to be used under licence	Embryos used in licensed activity up to 28 February 2023	Embryos used during the reporting period
309702B	Genea Limited	Development of methods for preimplantation genetic and metabolic evaluation of human embryos	220	58	0
309703	Genea Limited	Development of human embryonic stem (ES) cells	300 (plus, up to 20 inner cell masses which may be transferred from 309702A or 309702B)	249 (plus 12 embryos first used in 309702A and then transferred to 309703)	0
309710	Genea Limited	Derivation of human embryonic stem cells from embryos identified through preimplantation genetic diagnosis to be affected by known serious monogenic conditions	500	304	0

Expired training licences (during the reporting period)

Licence number	Licence holder	Licence title	Embryos per trainee authorised to be used under licence[2]	Number of active authorised trainees at 28 February 2023	Embryos used in licensed activity up to 28 February 2023 (total, all trainees)[3]	Embryos used during the reporting period (total, all trainees)
309726	Genea Limited	Use of excess ART embryos for training in an alternate biopsy method (day five hatch and biopsy)	25	15	0	0

Licensed use of human eggs

The following table shows the use of human eggs under licence, as at 28 February 2023.

Current research licences

Licence number	Licence holder	Licence title	Eggs authorised to be used under licence	Eggs used in licensed activity up to 28 February 2023	Eggs used during the reporting period
309718	Genea Limited	Use of excess ART embryos and clinically unusable eggs for validation of an IVF device	1,000	407	0
Total for current licences			**1,000**	**407**	**0**

2 The Special Conditions of each licence permit this number of embryos to be removed from cryostorage and thawed in order to obtain a smaller number of suitable embryos for the training activity.

3 Reflects the total number of embryos removed from cryostorage across the period of the licence, noting that the total number of embryos authorised for use under each licence is dependent on the total number of authorised trainees and fluctuates as authorised trainees are added or removed from the licence.

Licensed use of 'other embryos'

The following table shows the use[4] of 'other embryos' under licence, as at 28 February 2023.

Current research licences

Licence number	Licence holder	Licence title	'Other embryos' authorised to be used under licence[5]	'Other embryos' used in licensed activity up to 28 February 2023	'Other embryos' used during the reporting period
309729	Monash University	The generation and study of a novel in-vitro model of human blastocysts ('iBlastoids')	117,010* *initially assessed as showing basic morphological features of an iBlastoid	353	353
Total for current licences			**117,010**	**353**	**353**

4 Use is defined in the RIHE Act as: "**use** includes develop, or development, as the case requires"; for licence number 309729 this includes the creation of an iBlastoid for the activities authorised under that licence.

5 ERLC, as the regulator, made a decision based on the principles of statutory interpretation that iBlastoids come within the definition of a human embryo under the RIHE Act, and therefore require regulation and oversight as 'other embryos'. This decision relates to work undertaken under Licence 309729 issued to Monash University and further information can be found at: https://www.nhmrc.gov.au/about-us/news-centre/nhmrc-statement-iblastoids

Monitoring compliance with the legislation

NHMRC is committed to ensuring that individuals and licence holder organisations comply with both the RIHE Act and the PHCR Act. The legislation establishes a monitoring and compliance framework, which involves the appointment of inspectors and the conduct of a range of monitoring and compliance activities. Further information about the monitoring and compliance activities NHMRC undertakes on behalf of ERLC can be found on the NHMRC website at: www.nhmrc.gov.au/research-policy/embryo-research-licensing.

Monitoring activities

NHMRC inspectors did not conduct any on-site licence inspections during the reporting period. Monitoring discussions were held with one licence holder following their notification of multiple licence closures.

Throughout the period inspectors continued to monitor information provided by licence holders through legislated 6-monthly reports to ERLC and to correspond with licence holders as needed.

Communication and awareness

ERLC considers that providing opportunities for communication and awareness between stakeholders assists with compliance under the legislation and with individual licence conditions.

General information for both applicants and licence holders can be accessed on NHMRC's website at www.nhmrc.gov.au. The NHMRC website contains more information about embryo research licensing, including copies of the RIHE and PHCR Acts, standard conditions that apply to all licences (unless a particular standard condition is specifically excluded by the Special conditions for a licence), application forms and detailed instructions, checklists, and other explanatory materials.

Individuals and organisations considering applying for a licence under the RIHE Act are strongly encouraged to contact ERLC, noting that NHMRC responds to all queries received.

Information exchange visits

No information exchange visits were conducted during this reporting period.

Appendix A: Membership of the Embryo Research Licensing Committee

Members of ERLC for the 2021–2024 triennium are:

Professor Dianne Nicol, Tasmania (Chair)
A person with expertise in a relevant area of law

Associate Professor Bernadette Richards, Queensland
A member of the Australian Health Ethics Committee (AHEC)

Professor Lynn Gillam AM, Victoria
A person with expertise in research ethics

Professor Sarah Robertson, South Australia
A person with expertise in a relevant area of research

Professor Stephen Robson, Australian Capital Territory
A person with expertise in assisted reproductive technology

Dr Carol Wicking, Queensland
A person with expertise in consumer health issues relating to disability and disease

Ms Cal Volks, Victoria
A person with expertise in consumer issues relating to assisted reproductive technology

Ms Louise Johnson, Victoria
A person with expertise in the regulation of assisted reproductive technology

Professor Patrick Tam, New South Wales
A person with expertise in embryology

Appendix B: Variations to licences

During the reporting period, ERLC varied licences as follows:

Licence No.	Organisation	Date of variation	Brief description of variation
309702B	Genea Limited	30 November 2022	Licence extension to 14 February 2023
309703	Genea Limited	30 November 2022	Licence extension to 14 February 2023
309710	Genea Limited	30 November 2022	Licence extension to 14 February 2023
309726	Genea Limited	30 November 2022	Licence extension to 14 February 2023
309718	Genea Limited	15 December 2022	Licence variation to reflect staffing and editorial changes
309719	Genea Limited	15 December 2022	Licence variation to reflect staffing and editorial changes

Appendix C: Glossary of Common Terms

Term	Description
AHEC	Australian Health Ethics Committee (a Principal Committee of the National Health and Medical Research Council).
Application for a licence	Application form for a licence to conduct research activities permitted under section 20(1) of the *Research Involving Human Embryos Act 2002.*
ART	Assisted reproductive technology.
ART embryo	A human embryo that was created by assisted reproductive technology for use in the assisted reproductive technology treatment of a woman.
Blastocyst	A 5-to-7-day-old embryo that has an outer layer of cells and a fluid filled cavity in which there is a cluster of cells called the inner cell mass.
Chromosomal analysis	Test to look at the number of chromosomes present in a sample of cells, and to identify genetic abnormalities as the cause of a condition or disease.
Cryostorage	The storage of biological material (e.g., cells, tissues, or organs) at ultralow or freezing temperatures to preserve them for future use.
Embryonic stem cell	An undifferentiated cell that is a precursor to many different cell types, obtained from a preimplantation embryo, usually at blastocyst stage.
ERLC	The Embryo Research Licensing Committee of the National Health and Medical Research Council.
Excess ART embryo	An ART embryo that is excess to the needs of the woman for whom it was created and her spouse (if any) at the time the embryo was created, as determined in writing by section 9 of the *Research Involving Human Embryos Act 2002.*
Gamete	A human sperm or egg (ovum or oocyte).
HREC	A human research ethics committee.
Human embryo clone	A human embryo that is a genetic copy of another living or dead human.
iBlastoid	Human embryos (and human embryo clones) generated through the reprogramming of adult skin cells *in-vitro,* into a three-dimensional cluster of cells that resemble a blastocyst and has the potential to develop up to the stage at which the primitive streak appears.
Information Exchange Visit	A pre-arranged visit by NHMRC inspectors to provide information about the legislation to interested stakeholders.
Inspection	An inspection of records, documents, and premises to ensure compliance with licence conditions and the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002.*
IVF	*In vitro* fertilisation.

Term	Description
Mitochondrial donation	Mitochondrial donation is an assisted reproductive technology that, when combined with in vitro fertilisation (IVF), has the potential to allow women whose mitochondria would predispose their potential children to mitochondrial disease, to have a biological child who does not inherit that predisposition. There are a number of different mitochondrial donation techniques; each involves combining the nuclear DNA from a male and a female with healthy mitochondrial DNA from a donor egg to create an embryo.
Monitoring and compliance activities	Activities conducted to monitor and assess compliance requirements with licence conditions, under the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning for Reproduction Act 2002.*
NHMRC	National Health and Medical Research Council.
Oocyte	An immature egg cell.
Other embryos	*Other embryos* is the term used in the *Research Involving Human Embryos Act 2002* to refer to human embryos created by processes other than fertilisation of a human egg by a human sperm.
Preimplantation genetic diagnosis	A procedure used prior to implantation to detect serious genetic conditions, diseases, or abnormalities, to which the gamete providers are known to be at risk, to carry or to be predisposed.
Primitive streak	An elongated band of cells that forms along the axis of a developing fertilised egg on day 15 of human development, marking the start of gastrulation.
Proper Consent	Consent obtained in accordance with the *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2017*, issued by NHMRC.
Skin fibroblasts	A connective-tissue cell that secretes molecular collagen proteins into the extracellular matrix to form the structural framework of dermal tissue.
Somatic Cell Nuclear Transfer (SCNT)	A laboratory technique used to create a human embryo clone involving removing the nucleus of a human egg and replacing it with the genetic material from a somatic cell (such as a skin cell or fibroblast) or stem cell line.
Zygote	A cell formed by the fertilisation between two gametes.

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