World Council For Health Australia

World Council for Health
Country Council: Australia

Invitation to comment on Clinical trials of controlled infection with seasonal influenza viruses (DIR 210)

14 February 2025

World Council For Health

We thank the Office of the Gene Technology Regulator for the opportunity to provide feedback on clinical trials of controlled infection with seasonal influenza viruses (DIR 210) proposed by Doherty Institutes. This clinical trial involves recombinant influenza viruses produced through gene technology whereby genetically modified organisms (GMO) are to be infected into healthy humans.

Thank you too for the extension of a week to allow us the time to provide a full submission to you.

World Council for Health - Australia: Who we are

World Council for Health is a broad, grassroots, expert-led initiative to work together to empower global and community health. We are governed by seven principles:

1. We act in honour and do no harm
2. We are free beings with free will
3. We are part of nature
4. Spirituality is integral to our well-being
5. We thrive together
6. We value different perspectives
7. We use technology with discernment
8. With courage we do not tolerate the violation of people's inalienable rights and freedoms.With courage we do not tolerate profit, power and influence coming before the wellbeing of people and planet.
9. The freedoms we speak of are freedom of speech, freedom of movement, freedom of assembly, the right to free and informed consent, the right to privacy, the right to body integrity, and that everyone is innocent until proven guilty.

The Australian Country Council of the World Council for Health is led by Lucinda van Buuren, Professor Ian Brighthope, Dr Melissa McCann, Ian Bell, Katie Ashby-Koppens and Michelle Bradshaw.

In 2021, the World Council for Health emerged as a prominent organization that challenges the WHO's pervasive and damaging influence. The WCH is a coalition of independent health organizations, medical professionals, and advocacy groups that emphasizes a more decentralized, holistic, and patient-centered approach to health care. It advocates for local health sovereignty, individual choice, and the decentralization of power away from large international organizations like the WHO. The WCH has been particularly vocal about opposing what it sees as the WHO's overreach, particularly in terms of its management of public health policies during crises like the COVID-19 pandemic, while ignoring real health issues like heart health, cancer, diabetes, and mental health.

A better way forward for health, rooted in our Better Way Principles, would focus on strengthening local and national health systems, ensuring that decision-making is transparent, accountable, and driven by scientific evidence rather than political or financial interests. This approach would involve greater collaboration between governments, health professionals, and communities, rather than relying on a centralized body like the WHO to dictate policy internationally. By prioritizing national sovereignty, autonomy, and local expertise, a more resilient and responsive international health framework can be developed, one that respects individual freedoms and prioritizes people over institutional power.

Warmest regards

World Council for Health Australia

lucinda@wch-australia.org

1. Introduction

1.1. We thank the Office of the Gene Technology Regulator for the opportunity to provide comment to the invitation on the Doherty Institutes (**Doherty**) clinical trial involving recombinant influenza viruses produced through gene technology whereby genetically modified organisms (**GMO**) are produced from seasonal influenza viruses using a method called reverse genetics (**GM Influenza**).

1.2. What is proposed is that the GM Influenza will be used in healthy participants in Australia to:

1.2.1. investigate viral infections and the development of immunity; and

1.2.2. evaluate methods for preventing and controlling influenza, including the effectiveness of new drugs or vaccines (which we assume will also include gene therapy based vaccines such as the Covid-19 gene therapies using the LNP-mRNA platform such as Pfizer and Moderna).

1.3. Doherty outlines that healthy volunteers will receive a safe dose of the GM influenza viruses within a clinical facility in combination with or without a potential vaccine or therapeutic drug.

1.4. This submission opposes the approval of DIR 210 on the basis of serious concerns regarding the safety, necessity, and ethical implications of deliberately infecting healthy individuals with genetically modified (**GM**) influenza viruses. There is no information available on the new drugs or vaccines to be trialled - will that be a separate notification?

2. Genetically Modifying Influenza: Gain of Function Research in Australia

2.1. What is proposed by Doherty is gain of function research using influenza viruses that have been manipulated through gene technology.

2.2. Where **gain of function** is medical research that genetically alters an organism in a way that may enhance the biological functions of gene products.[1]

2.3. Doherty's application describes the GM Influenza it intends to use as being more pathogenic than naturally arising influenza.

[1] https://en.wikipedia.org/wiki/Gain-of-function_research

2.4. Where **more pathogenic** means a virus that has a greater ability to cause disease, indicating that it is more likely to produce a serious infection or illness compared to a less pathogenic organism of the same type; essentially, it is a stronger disease-causing agent.[2]

2.5. This trial has been proposed at a time when the United States Select Sub-committee on the Coronavirus Pandemic Final Report[3] and now the United States Central Intelligence Agency[4] have both recently confirmed the likelihood that Sars-CoV-2 (Covid-19) was a lab leak.

2.6. If this is correct, a man made virus using gain of function research led the World Health Organisation (**WHO**) to declare a public health emergency of international concern (**PHEIC**) - a PHEIC that traversed the world and cost an estimated $9 trillion dollars globally.[5]

2.7. In elderly the pathogenicity of naturally occurring influenza is high. Doherty describes influenza as 'an acute respiratory viral infection caused by influenza A or B viruses, with up to 650,000 deaths worldwide annually'.[6] Covid-19 is estimated to have killed 7 million globally.[7] With this application, Doherty is genetically modifying influenza to be more pathogenic! For the record, the pathogenicity of SARS-CoV-2 was considered moderate[8].

2.8. In these circumstances and with the recent example from Covid-19 of what can occur when trials fail, we are alarmed, dismayed and appalled that Australia's Office of the Gene Technology Regulator (**OGTR**) would even consider allowing Doherty's application to advance to a stage where public feedback is sought.

---

[2] Pathogenicity https://www.sciencedirect.com/topics/immunology-and-microbiology/pathogenicity#:~:text=In%20subject%20area:%20Immunology%20and,From:%20Trends%20in%20Microbiology%2C%202011

[3] https://oversight.house.gov/release/final-report-covid-select-concludes-2-year-investigation-issues-500-page-final-report-on-lessons-learned-and-the-path-forward/ page 1

[4] https://www.bbc.com/news/articles/cd9qjjj4zy5o

[5] https://www.imf.org/en/Blogs/Articles/2020/05/20/tracking-the-9-trillion-global-fiscal-support-to-fight-covid-19

[6] Questions & Answers on licence application DIR 210 – Clinical trials of controlled infection with seasonal influenza viruses

[7] https://ourworldindata.org/coronavirus

[8] Subramani Mani MBBS, PhD, Daniel Griffin MD, PhD, in Textbook of SARS-CoV-2 and COVID-19, 2024 https://www.sciencedirect.com/topics/medicine-and-dentistry/pathogenicity#:~:text=Pathogenicity%20and%20Virulence,2%20can%20be%20considered%20moderate.

2.9. Even were this trial limited to a lab or clinical trial setting, lab leaks are not uncommon. In the United States alone, government data on US biosafety labs reveal accidents estimated to be between 100 and 275 potential releases of pathogens each year in labs.[9]

2.10. Doherty explains that the trial has already been conducted by the FDA. That is one trial too many and we seriously question the OGTR as to whether it truly intends to put Australians at risk of a genetically modified, more pathogenic version of the influenza virus. It also raises the question of why it needs to be done again.

3. Doherty is a World Health Organisation Collaboration Centre

3.1. The Doherty Institute is a World Health Organisation (**WHO**) Collaboration Centre for Reference and Research on Influenza.[10]

3.2. During the Covid-19 pandemic, a contagious respiratory disease not too similar to influenza, the WHO made questionable recommendations and conducted itself poorly and not in the interests of its mandate.

3.3. The WHO's mandate is to promote health, which it defines as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Yet during the Covid-19 pandemic the WHO's promotion of extremist policies:

3.3.1. "…helped force over a hundred million[11] additional people into severe food insecurity and poverty and up to ten million[12] additional girls into child marriage and sexual slavery.

---

[9] N Wurtz et al (2016) Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories

[10] https://www.who.int/initiatives/global-influenza-surveillance-and-response-system/who-collaboration-center-erl and https://apps.who.int/whocc/Detail.aspx?sE4uo26y8F0GHVIbiYhoTw==

[11] https://www.fsinplatform.org/sites/default/files/resources/files/GRFC2023-compressed.pdf

[12] https://www.google.com/url?q=https://data.unicef.org/resources/covid-19-a-threat-to-progress-against-child-marriage/&sa=D&source=docs&ust=1739424710862795&usg=AOvVaw1Vus0rbCcTGu_GHklNmWYt

3.3.2. "It helped deprive a generation[13] of the schooling needed to lift themselves out of poverty and grew national debts[14] to leave countries at the mercy of global predators. This was an intentional response to a virus they knew[15] from the beginning was rarely severe beyond sick elderly people.

3.3.3. "The WHO helped orchestrate an unprecedented transfer of wealth[16] from those it was originally tasked to protect to those who now sponsor and direct most of its work. Lacking any contrition, the WHO is now seeking increased public funding[17] through misrepresentation of risk[18] and return on investment[19] to entrench this response."

3.4. As a WHO Collaborating Centre, Doherty has entered into commercial arrangements with the WHO. Those commercial arrangements exempt the WHO from all legal responsibility so that it rests with Doherty - this includes any injuries to human test subjects or accidental release which could cost the globe trillions if Covid-19 is a benchmark.[20]

4. Risk of Viral Reassortment and Unintended Mutations

4.1. The genetic modification of influenza viruses through reverse genetics introduces potential risks, including:

4.1.1. **Increased virulence** if reassortment occurs between the GM virus and circulating wild-type influenza strains.

---

13 https://www.unicef.org/press-releases/covid19-scale-education-loss-nearly-insurmountable-warns-unicef

14 https://blogs.worldbank.org/en/opendata/what-pandemic-means-government-debt-five-charts

15 Verity, Robert et al *Estimates of the severity of coronavirus disease 2019: a model-based analysis* https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30243-7/fulltext

16 https://www.oxfam.org/en/press-releases/mega-rich-recoup-covid-losses-record-time-yet-billions-will-live-poverty-least

17 https://thedocs.worldbank.org/en/doc/5760109c4db174ff90a8dfa7d025644a-0290032022/original/G20-Gaps-in-PPR-Financing-Mechanisms-WHO-and-WB-pdf.pdf

18 Bell, D et al *Re-evaluating Pandemic Risk within the Global Pandemic Prevention, Preparedness and Response Agenda.* https://essl.leeds.ac.uk/downloads/download/228/rational-policy-over-panic

19 Bell, D et al *The Cost of Pandemic Preparedness: An Examination of Costings and the Financial Requests in Support of the Pandemic Prevention, Preparedness and Response Agenda.* https://essl.leeds.ac.uk/downloads/download/234/the-cost-of-pandemic-preparedness-an-examination-of-costings-and-the-financial-requests-in-support-of-the-pandemic-prevention-preparedness-and-response-agenda

20 Supra n paragraph 2.6.

4.1.2. **Unpredictable immune responses**, leading to either diminished immunity or heightened disease severity.

4.1.3. **Potential for environmental contamination**, particularly in the case of accidental release.

4.2. In support of these statements:

4.2.1. Lipsitch & Inglesby (2014)[21] documented instances of laboratory leaks of modified viruses and highlighted the pandemic potential of reassorted strains.

4.2.2. Bodewes et al. (2012)[22] showed that reassortment of human and animal influenza strains led to the 2009 H1N1 pandemic. **

5. Insufficient Long-Term Safety Data on GM Influenza in Humans

5.1. The RARMP does not provide adequate long-term data on the safety of human exposure to GM influenza viruses.

5.2. The reference to “no serious adverse events” in previous FDA-authorised trials is not a robust measure of long-term safety.

5.3. Possible **immune dysregulation** and **increased susceptibility** to future influenza infections remain unaddressed.

5.4. In support of these statements:

5.4.1. Munster et al. (2018)[23] identified concerns regarding antigenic drift and immune escape mechanisms in influenza, especially in genetically modified strains.

---

[21] Lipsitch M, Inglesby TV. *Moratorium on research intended to create novel potential pandemic pathogens.* https://pubmed.ncbi.nlm.nih.gov/25505122/

[22] Bodewes R, Nieuwkoop NJ, Verburgh RJ, Fouchier RAM, Osterhaus ADME, Rimmelzwaan GF. *Use of influenza A viruses expressing reporter genes to assess the frequency of double infections in vitro.* https://pubmed.ncbi.nlm.nih.gov/22535774/

[23] Vincent J. Munster, Ph.D., Outbreaks in a Rapidly Changing Central Africa — Lessons from Ebola. https://www.nejm.org/doi/full/10.1056/NEJMp1807691

5.4.2. Calis & Rosenberg (2014)[24] demonstrated that immune imprinting from modified virus exposure can lead to altered and unpredictable future immune responses.

6. Ethical Issues with Human Challenge Trials

6.1. The deliberate infection of healthy individuals with GM influenza viruses raises **serious ethical concerns**:

6.1.1. The **full, free and informed consent process is compromised** due to the lack of long-term safety data.

6.1.2. The **risk-to-benefit ratio is unclear**, making the trial ethically questionable.

6.1.3. There is a **precedent for backlash against gain-of-function research** due to similar safety concerns (e.g., SARS-CoV-2 research).

6.2. In support of these statements:

6.2.1. Selgelid (2016)[25] concluded that human challenge trials require near-certainty of safety, which is absent in this case.

6.2.2. Shah et al. (2020)[26] critiqued the ethical validity of COVID-19 human challenge trials.

7. Regulatory Oversight Gaps and Conflicts of Interest

7.1. The RARMP states that OGTR evaluates **only health and environmental risks**, while **safety, efficacy, and trade implications are handled by other agencies**. This fragmented oversight structure creates regulatory blind spots.

---

[24] Jorg J.A. Calis, Brad R. Rosenberg, *Characterizing immune repertoires by high throughput sequencing: strategies and applications, Trends in Immunology.* https://www.sciencedirect.com/science/article/abs/pii/S1471490614001550

[25] Bambery B, Selgelid M, Weijer C, Savulescu J, Pollard AJ. Ethical Criteria for Human Challenge Studies in Infectious Diseases. https://pubmed.ncbi.nlm.nih.gov/29731811/

[26] Shah K, Mann S, Singh R, Bangar R, Kulkarni R. Impact of COVID-19 on the Mental Health of Children and Adolescents. https://pubmed.ncbi.nlm.nih.gov/32999774/

7.2. In support of these statements:

7.2.1. Latham & Wilson (2008)[27] identified regulatory loopholes in the assessment of GMOs.

7.2.2. Hilbeck & Otto (2015)[28] discussed conflicts of interest and undue influence from biotechnology firms in regulatory decision-making.

8. Vitamin D as a Safer and More Effective Alternative

8.1. Efficacy of Vitamin D in Preventing Respiratory Infections

8.1.1. A **meta-analysis of 25 randomized controlled trials** (BMJ, 2017) with 11,321 participants showed **vitamin D supplementation significantly reduces the risk of acute respiratory infections**.

8.1.2. A follow-up **meta-analysis of 42 trials** (PMC, 2020) confirmed that vitamin D offers **strong protection, particularly in individuals with severe deficiencies**.

8.2. **Mechanisms Underlying Vitamin D's Protective Effects**

8.2.1. Enhances **innate immunity** by inducing antimicrobial peptides (cathelicidins, defensins), reducing viral replication.

8.2.2. Modulates **adaptive immunity**, reducing pro-inflammatory cytokines and increasing anti-inflammatory cytokines (PMC, 2020).

8.3. **Safety Profile of Vitamin D Supplementation**

8.3.1. Vitamin D supplementation is **extremely safe** when taken within recommended doses.

8.3.2. High-dose vitamin D protocols (300,000 IU) were found **safe and effective** in restoring low vitamin D levels (MDPI, 2022).

---

[27] Latham JR, Wilson AK. Transcomplementation and synergism in plants: implications for viral transgenes? https://pubmed.ncbi.nlm.nih.gov/18705887/

[28] Hilbeck & Otto Specificity and combinatorial effects of bacillus thuringiensis cry toxins in the context of GMO Environmental Risk Assessment https://www.research-collection.ethz.ch/handle/20.500.11850/107288

8.3.3. **No significant adverse events** reported in large-scale meta-analyses (BMJ, 2017).

8.4. **Cost-Effectiveness and Accessibility**

8.4.1. Vitamin D is **widely available and inexpensive** (~$0.05 per 2,000 IU tablet) (CCJM, 2021).

8.4.2. Economic modeling shows vitamin D supplementation is **cost-effective** for preventing respiratory infections (Biomed Central, 2023).

8.5. In support of these statements:

8.5.1. Martineau AR et al (2017) Vitamin D as a supplement to prevent acute respiratory tract infection.[29]

8.5.2. Jolliffe DA et al (2020) Vitamin D supplementation to prevent acute respiratory infections.[30]

9. Conclusion and Recommendation

There are significant risks associated with Doherty's application to create a GM Influenza to be used in healthy Australiants. For this reason we urge the OGTR to **reject the application** and instead promote **nutritional and immune-supportive interventions** for influenza prevention.

The regulatory focus should shift towards **public health strategies that prioritize safety, efficacy, and accessibility** over high-risk genetic interventions.

Focus should be on safer, proven, cost-effective alternatives (vitamin D) in response to naturally occurring influenza.

[29] Martineau AR et al 2017. *Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data* https://www.bmj.com/content/356/bmj.i6583

[30] Joliffe DA et al 2020.*Vitamin D supplementation to prevent acute respiratory infections: systematic review and meta-analysis of aggregate data from randomised controlled trials* https://pmc.ncbi.nlm.nih.gov/articles/PMC7709175/