# Guidelines for Moderna’s mRNA Access Program

**Section 1: Overview**

The Doherty Institute has recently partnered with Moderna on their mRNA Access program, which is designed to facilitate access to Moderna’s mRNA technology to express antigens of choice for pre-clinical testing of vaccine candidates. All Doherty Institute staff are eligible to apply to an internal review panel using the process provided in Section 2. The panel will rapidly review each application for quality, feasibility and duplication. Successful applicants can then apply directly to Moderna using the mRNA Access portal (details provided upon success) to order mRNA vaccine material.

mRNA Access includes a two-step process:

1. Initial testing of unformulated (naked) mRNA to confirm expression in cell-lines
2. If successful expression is confirmed, you can apply for further testing of LNP-formulated mRNA in vitro and in vivo (murine only) models

Researchers are limited to the following quantity of unformulated and LNP-formulated mRNA per sequence requested:

* 200ug of unformulated mRNA
* 2mg of LNP-formulated mRNA

If the preclinical work shows promise, we may be able to engage in a separate process with Moderna about clinical analysis.

Each applicant should be aware of the requirements and responsibilities in Section 3. It is essential to review these to ensure your application will be eligible and able to be executed correctly.

The public facing website can be found here: <https://mrna-access.modernatx.com/>

Please contact Mason Littlejohn Mason.Littlejohn@unimelb.edu.au to discuss further.

**Section 2: Internal application process**

Please submit a 1-2 page document with the following information clearly highlighted:

1. Name of Principal Investigator
2. Department within the Doherty Institute
3. Pathogen target (see Appendix 1)\*
4. Description of the antigen
5. Rationale: why is this unique or interesting?
6. Brief description of the plan for preclinical testing of the vaccine candidate

\* This is the currently permitted pathogen list for mRNA Access. If you have a proposal for mRNA vaccines against a different pathogen, please discuss with Mason.

There will be a series of calls/rounds based on demand. The first round will close on 15 June 2022. Please forward applications to Mason Littlejohn Mason.Littlejohn@unimelb.edu.au

When applying directly to Moderna using the mRNA Access Portal, you will be asked for the amino acid sequence for the requested mRNA vaccine, as well as a detailed Workplan for your proposed activities. Again, we remind you to read and acknowledge the requirements laid out in Section 3.

Moderna have the right to decline any request. We do not expect fees for these materials, but this is subject to change.

You may be required to develop a short summary report at the conclusion of the Workplan.

**Section 3: Researcher responsibilities and requirements**

Researchers must agree to and abide by the following:

1. To use Moderna mRNA only to conduct the research outlined in the Workplan
2. To provide updates through the Request Portal on any proposed changes or updates to such research activities
3. To use for investigational use in murine immunogenicity models and/or laboratory in vitro studies and not to be used in humans
4. Not to use materials directly or indirectly for commercial purposes
5. Not to modify the material except as expressly outlined in the Workplan
6. Not to derivatise, reverse engineer, deconstruct or evaluate the material in an attempt to determine the structure, sequence or composition of any such Moderna materials
7. Not to transfer materials to a third party or subject materials to any rights of a third party (outside UoM)
8. Not use for the purposes of any “head-to-head” comparisons with other mRNA products, including experimental and commercially available materials
9. The formulated mRNA is only available following completed testing of unformulated mRNA to confirm viability of the antigen.

In addition, researchers must:

* Use materials in accordance with handling and storage requirements
* Promptly (within 30 days) destroy unused Moderna materials following completion of Workplan
* Maintain records in a good scientific and detailed manner to properly reflect all work done and results achieved
* Provide manuscript, abstract or other presentations to Moderna for review 30 days prior to the submission date

IP implications

* Improvements/inventions made during this process to the University’s background IP will be owned solely by the University of Melbourne
* Any modifications, improvements or adaptations to Moderna’s background IP will be owned by Moderna
* Arising inventions or improvements will be owned jointly in equal share.

**Appendix 1: Permitted Pathogen List**

* Alkhurma virus
* Andes virus
* Bacillus anthracis (anthrax)
* Balamuthia mandrillaris
* Barmah Forest virus (BFV)
* Brucella species (brucellosis)
* Burkholderia mallei (glanders)
* Burkholderia pseudomallei (melioidosis)
* Cache Valley virus
* Caliciviruses
* California encephalitis
* Campylobacter jejuni
* Canine Distemper (Morbilli)
* Cedar virus (Henipa)
* Chapare virus
* Chikungunya virus
* Chlamydia psittaci (Psittacosis)
* Clostridium botulinum toxin (botulism)
* Coccidioides spp.
* Coxiella burnetii (Q fever)
* Crimean-Congo haemorrhagic fever virus
* Cryptosporidium parvum
* Cyclospora cayatanensis
* Deer Tick Virus
* Dengue virus
* Eastern equine encephalitis (EEE)
* Ebola virus
* Echovirus
* Entamoeba histolytica
* Enterovirus A71
* Enterovirus D68
* Francisella tularensis (tularemia)
* Giardia lamblia
* Guanarito virus
* Hantaan virus
* Hantaviruses causing Hanta Pulmonary syndrome
* Hazara virus
* Hendra virus
* Hepatitis A virus
* Hepatitis E (HEV)
* Hookworm (N. americanus)
* HPIV (1 or 3)
* Human Immunodeficiency Virus (HIV)
* Human T-cell leukaemia virus (HTLV-1)
* Influenza virus A Pandemic
* Japanese encephalitis virus (JE)
* Junin virus
* Kyasanur Forest virus
* Kumasi virus
* LaCrosse encephalitis virus (LACV)
* Lassa virus
* Leishmaniasis
* Leptospirosis
* Listeria monocytogenes
* Lujo virus
* Machupo virus
* Malaria
* Marburg and Ravn virus
* Menagle virus
* Meningocococcal meningitis
* Microsporidia
* MERS-CoV
* Monkeypox/Smallpox
* Mojiang virus
* Naegleria fowleri
* Nipah virus
* Omsk Hemorrhagic Fever virus
* O'nyong-nyong virus
* Phlebovirus
* Powassan virus
* Punta Toro virus
* Rabies virus
* Rhinovirus C
* Ricin toxin (Ricinus communis)
* Rickettsia (Spotted fevers)
* Rift Valley fever virus
* Salmonella (typhoid/paratyphoid fever)
* SARS-CoV-1
* SARS-CoV-2
* Schistosomiasis (S. Mansoni)
* Semliki Forest virus (SFV)
* SFTS virus
* Shigella species
* Sin Nombre virus
* Sosuga virus
* St. Louis encephalitis virus (SLEV)
* Staphylococcus enterotoxin B (SEB)
* Toxoplasma gondii
* Tuberculosis, including drug-resistant TB
* Venezuelan equine encephalitis (VEE)
* Vibrio (pathogenic)
* West Nile virus (WNV)
* Western equine encephalitis (WEE)
* Yellow fever virus (YFV)
* Yersinia pestis (plague)
* Zika virus