Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence number: DIR 206

Licence holder: Western Sydney Local Health District

Clinical trial for the treatment of mycobacterial infections using bacteriophages

Issued: 10 February 2025

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form part of a nationally consistent regulatory system controlling activities involving genetically modified (GM) organisms.

This licence is issued by the Gene Technology Regulator (the Regulator) in accordance with the *Gene Technology Act 2000* and, as applicable, corresponding State law.

The Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of GM organisms into the Australian environment.

Other agencies that also regulate GM organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Water and the Environment. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

Further Information on Licence DIR 206

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator (OGTR) website or by telephoning the Office on 1800 181 030.

Interpretations and Definitions

1. In this licence:
   (a) unless defined otherwise, words and phrases used in this licence have the same meaning as they do in the Act and the Gene Technology Regulations 2001;
   (b) words importing a gender include every other gender;
   (c) words in the singular number include the plural and words in the plural number include the singular;
   (d) expressions used to denote persons generally (such as "person", "party", "someone", "anyone", "no-one", "one", "another" and "whoever"), include a body politic or corporate as well as an individual;
   (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;
   (f) where a word or phrase is given a particular meaning, other grammatical forms of that word or phrase have corresponding meanings;
   (g) specific conditions prevail over general conditions to the extent of any inconsistency.
2. In this licence:

   'Act' means the *Gene Technology Act 2000* (Commonwealth) or the corresponding State law under which this licence is issued.

   'Analytical facility' means a laboratory in Australia accredited to undertake testing of human diagnostic Samples, such as a medical testing laboratory accredited by the National Pathology Accreditation Advisory Council (NPAAC).

   'Clinical trial site' means a medical facility in Australia such as a clinical trial facility and associated Pharmacy, which are notified in writing to the Regulator for the purposes of conducting this clinical trial.

   'Decontaminate' (or ***'Decontamination'***) means, as the case requires, kill the GMOs by one or more of the following methods:

   (a) chemical treatment;
   (b) autoclaving;
   (c) high-temperature incineration; or
   (d) a method approved in writing by the Regulator.

   Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

   'External service provider' means a person engaged by the licence holder solely in relation to transport, storage and/or disposal of the GMOs, and who is not undertaking any dealings with the GMOs that are not for those purposes.

   'GM' means genetically modified.

   '*GMO'* means the genetically modified organisms that are the subject of the dealings authorised by this licence.

   'HITH' means "hospital-in-the-home": the provision of medical care by a medical professional outside a clinical setting, including the home, workplace or school of a participant.

'NLRD' is a Notifiable low risk dealing. Dealings conducted as an NLRD must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.

'OGTR' means the Office of the Gene Technology Regulator.

'Personal information' has the same meaning as in the *Privacy Act 1988*. Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

(a) whether the information or opinion is true or not; and

(b) whether the information or opinion is recorded in a material form or not.

'Pharmacy' means a location within the Clinical trial site, where authorised staff store, prepare, and dispense medications in a medical environment.

'Regulations' means the Gene Technology Regulations 2001 (Commonwealth) or the corresponding State law under which this licence is issued.

'Regulator' means the Gene Technology Regulator.

'Risk group 1 organism' means an organism that satisfies the criteria in AS/NZS 2243.3:2010 for classification as Risk Group 1.

'Sample' means any biological material collected from a treated trial participant for analysis as part of the trial.

'Storage facility' means a third-party facility offering logistical services and distribution of clinical supplies.

'TGA' means that part of the Department of Health and Aged Care that administers the Therapeutic Goods Act 1989, or the relevant delegate of the Secretary exercising powers under that Act.

'The Special Access Scheme (SAS)' allows certain health practitioners to access therapeutic goods (such as medicines, medical devices or biologicals) that are not included in the Australian Register of Therapeutic Goods (ARTG) for a single patient.

General conditions and obligations

Holder of licence

3. The licence holder is Western Sydney Local Health District (WSLHD).

Remaining an Accredited Organisation

4. The licence holder must, at all times, remain an accredited organisation.

Validity of licence

5. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension, or after the licence has been cancelled or surrendered.

Note: Although this licence has no expiry date, the duration of preparation and administration of the GMOs is restricted in accordance with Condition 24.

Persons covered by this licence

6. The persons covered by this licence are:
   (a) the licence holder, and any employees, agents or External service providers of the licence holder; and
   (b) the project supervisor(s); and

(c) other persons who are, or have been, engaged or otherwise authorised by the licence holder or the project supervisor to conduct any of the dealings authorised by this licence.

Note: This includes any medical professionals engaged as part of the trial to treat participants as part of HITH.

7. To the extent that any activity by a trial participant may be considered to be a dealing with the GMO as described in Attachment A for purposes of the Act, that dealing is authorised by this licence.
8. The licence holder must keep a record of all persons covered by this licence, and must keep a record of the contact details of the project supervisor(s) for the licence.

Note: Where External service providers are used, it is sufficient to record the company name and the position or job title of the person(s) conducting the dealing.

9. The licence holder must provide information related to the persons covered by the licence when requested to do so in writing by the Regulator and must provide the information within a time period stipulated by the Regulator.

Description of GMOs covered

10. The licence authorises specified dealings in respect of the GMOs identified and described in **Attachment A**.

Dealings authorised by this licence

11. The licence holder and persons covered by this licence may conduct the following dealings with the GMOs:
    (a) import the GMO;
    (b) conduct the following experiments with the GMOs:
        i) grow or culture the GMO
        ii) prepare the GMO for administration to clinical trial participants;
        iii) administer the GMO to clinical trial participants by injection or infusion, endobronchial lavage, nebuliser, or topical application;
        iv) collect samples from trial participants;
        v) analyse the samples described in 11(b)iv);
    (c) transport the GMOs;
    (d) dispose of the GMOs;

    and may possess, supply, use or store the GMO for the purposes of, or in the course of, any of these dealings.

12. Supply of the GMOs for the purposes of dealings to any other person or organisation not covered by this licence is only authorised by this licence if the Regulator provides prior written approval to the licence holder.

Note: For approval to be granted, the receiving person or organisation must have an appropriate authorisation to conduct dealings with the GMOs. This is likely to be an NLRD or a licence issued by the Regulator.

13. This licence does not apply to dealings with the GMOs conducted as an NLRD or pursuant to another authorisation under the Act.

Conditions imposed by the Act

Note: The Act mandates the following 3 conditions.

Informing people of licence conditions (section 63)

14. The licence holder must inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:
    (a) the particular condition, including any variations of it; and
    (b) the cancellation or suspension of the licence; and
    (c) the surrender of the licence.

Note: No particular conditions of this licence apply to trial participants; therefore, Condition 14 does not apply to trial participants.

Monitoring and audits (section 64)

15. If a person is authorised by this licence to deal with the GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Additional information to be given to the Regulator (section 65)

16. The licence holder must inform the Regulator, if they become aware of:
    (a) additional information about any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or
    (b) any contraventions of the licence by a person covered by the licence; or
    (c) any unintended effects of the dealings authorised by the licence.

Note 1: For the purposes of this condition:
(a) The licence holder is taken to have become aware of additional information if they were reckless as to whether such information existed; and
(b) The licence holder is taken to have become aware of contraventions, or unintended effects, if they were reckless as to whether such contraventions had occurred, or such unintended effects existed.
Note 2: Contraventions of the licence may occur through the action or inaction of a person.
Note 3: Additional information includes any changes at a Clinical trial site, which might increase the likelihood of unintentional exposure of people or release of the GMO into the environment.

Informing the Regulator of any material changes of circumstance

17. The licence holder must immediately, by notice in writing, inform the Regulator of:
    (a) any relevant conviction of the licence holder occurring after the commencement of this licence;
    (b) any revocation or suspension after the commencement of this licence, of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment;
    (c) any event or circumstances occurring after the commencement of this licence that would affect the capacity of the licence holder to meet the conditions in it.
18. The licence holder must provide information related to the licence holder's ongoing suitability to hold a licence when requested to do so in writing by the Regulator, and must provide the information within a time period stipulated by the Regulator.

Further conditions with respect to informing persons covered by the licence

19. If a particular condition, including any variation of it, applies to an External service provider covered by this licence, the licence holder must not permit that person to conduct any dealings unless the person has been informed of the condition, including any variation of it.

Note: Information required under Condition 19 may be provided to External service providers who are engaged solely for storage and transport of the GMO through labelling of the outermost container of the GMOs in accordance with Condition 38(a).

20. If a particular condition, including any variation of it, applies to a person with respect to any dealing, other than to an External service provider, the licence holder must not permit a person covered by this licence to conduct that dealing unless:
    (a) the licence holder has obtained from the person a signed and dated statement that the person:
        (i) has been informed by the licence holder of the condition and, when applicable, its variation; and
        (ii) has understood and agreed to be bound by the condition, or its variation; and
        (iii) has been trained in accordance with sub-condition 20(b) below; and
    (b) the licence holder has trained that person in a manner which enables them to conduct the dealings in accordance with the conditions of this licence.

Note: This includes any medical professionals engaged as part of the trial to treat participants as part of HITH.

21. The licence holder must notify all persons covered by the licence, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.
22. The licence holder must ensure that a copy of the licence is readily available to all persons covered by the licence, other than External service providers, who are conducting dealings with the GMO.

Note: The licence may be made available electronically.

Limits and control measures

23. The GMO may only be administered to participants eligible under Special Access Scheme categories A and B.
24. The preparation and administration of the GMO must be completed within 5 years from the date of issuing of the licence.

Preparation and administration of the GMOs

25. Administration of the GMOs to trial participants must not commence prior to approval by a Human Research Ethics Committee.
26. The following activities must occur within a Clinical trial site or under the HITH program:
    (a) preparation of the GMO for administration to trial participants; and
    (b) administration of the GMO to trial participants.
27. Administration of the GMO via endobronchial lavage must only be conducted within a clinical site.
28. Administration of the GMO using a nebuliser must only be conducted within a clinical site or at the homes of participants.

Conditions relating to trial participants

29. The licence holder must notify each trial participant, from whom Personal information relevant to the administration and/or enforcement of the licence is collected by the licence holder, that such Personal information may be disclosed to the Regulator.
30. Before administering the GMO to any trial participant, the licence holder must obtain written agreement from the trial participant or their carers that:
    (a) Trial participants will not donate blood or organs for 60 days after the final administration of the GMO;
    (b) When treated under the HITH program, adult trial participants or carers will collect any waste potentially contaminated with the GMO in zip lock bag (e.g. tissues or bandages) for disposal at the next HITH visit; and
    (c) Carers present in the room at the time of administration will wear personal protective equipment (PPE) identical to the person administering the GMO.
31. The licence holder must ensure that each trial participant treated under the HITH program is provided with zip-lock bags or a container for storing disposable materials likely to contain the GMO (e.g. bandage or tissue).

Conditions related to the conduct of the dealings

32. Conditions that apply to dealings with GMOs do not apply to Samples collected from trial participants, or other materials or waste, that are reasonably expected not to contain the GMO. The licence holder must provide to the Regulator upon request, a written justification for this expectation.
33. The licence holder must ensure that dealings are only conducted in a manner which:
    (a) does not compromise the health and safety of people; and
    (b) minimises the exposure of persons conducting the dealings to the GMO, other than intended exposure of trial participants.

    Note: The licence holder may achieve this by only engaging or otherwise authorising persons to conduct dealings who are required to adhere to appropriate standards and guidelines. For example, standards developed by the National Pathology Accreditation Advisory Council for pathology practices, the Australian Guidelines for the Prevention and Control of Infection in Healthcare, Guidelines for Good Clinical Practice and the National Safety and Quality Health Service (NSQHS) Standards.

34. The licence holder must ensure that procedures are in place to account for the GMO from import to destruction/export, and records must be made available to the Regulator on request.

Work practices at Clinical trial sites or under the HITH program

35. The licence holder must ensure that the following work practices and behaviours, where applicable, are followed during administration of the GMO:
    (a) the GMO must be administered by a medical professional qualified to carry out the procedure;
    (b) while conducting dealings with the GMO, the medical professional must wear PPE including gloves, a gown, a face mask, and eye protection;
    (c) under the HITH program, the GMO must be administered to trial participants in a closed room in which all surfaces are able to be Decontaminated, and a spill kit must be readily available for use;
    (d) carers present during the administration must wear identical PPE to the person administering the GMO;

(e) when administering the GMO, impermeable absorbent membranes (such as a “bluey”) of appropriate size must be used to ensure any spillage of GMO is contained.
(f) Following administration, surfaces in the room likely to be contaminated with the GMO must be decontaminated with an appropriate chemical disinfectant that is effective against the GMOs.

Transport, storage and disposal of the GMOs

36. Unless covered by an NLRD, the licence holder must ensure that transport of the GMOs is conducted only for the purposes of, or in the course of, another dealing permitted by this licence, for supply in accordance with Condition 12, or for export.
37. For the purposes of import or export, and transport between the border and a Clinical trial site, the licence holder must ensure the GMO is packaged, labelled, stored and transported consistent with IATA shipping classification 3245 or 3373.
38. The licence holder must ensure that transport and storage of the GMOs within a Clinical trial site, transport of Samples to an Analytical facility and, unless conducted according to condition 37, follows these sub-conditions:
    (a) GMOs must be contained within sealed, unbreakable primary and secondary containers, with the outer packaging labelled to indicate at least:
        i) that it contains GMOs; and
        ii) the contact details for the licence holder; and
        iii) instructions to notify the licence holder in case of loss or spill of the GMOs; and
    (b) procedures must be in place to ensure that GMOs are accounted for and that a loss of GMOs during transport or storage or failure of delivery can be detected; and
    (c) access to the GMOs is restricted to authorised persons for whom Conditions 19 and 20 have been met (i.e. the GMOs are within a locked unit or an area which has restricted access). This includes situations where containers are left for collection in a holding area, or left unattended prior to decontamination; and

    Note: All stored GMOs remain the responsibility of the licence holder.

    (d) if the GMO is being transported or stored with a coolant (e.g. dry ice, liquid nitrogen or any other coolant) which will release a gas, a mechanism to allow the escape of the gas must be included. If water ice is used as a coolant then the outer packaging should be constructed so as to prevent any leakage. All containers must be able to withstand the temperatures to which they will be subjected; and

    Note: When transporting and storing with coolants, it is preferable for coolants to be used outside of the secondary container.

    (e) a consolidated record of all GMOs being stored under this condition is maintained and made available to the Regulator upon request.
    (f) for the purposes of transport entirely within a building, and the GMOs are accompanied by authorised persons for whom Condition 19 or 20 has been met, Conditions 38(a)ii), 38(a)iii) and 38(b) do not apply.
39. The licence holder must ensure that all GMOs and waste reasonably expected to contain the GMOs are Decontaminated:
    (a) prior to disposal, unless the method of disposal is also a method of Decontamination; and
    (b) before or upon suspension, cancellation or surrender of the licence, unless covered by another authorisation under the Act, or exported; and

(c) by autoclaving, chemical treatment, high-temperature incineration or any other method approved in writing by the Regulator.

40. Where transport is conducted by External service providers for the purpose of destruction, the licence holder must ensure that the GMO, or waste reasonably expected to contain the GMO, enters the clinical waste stream for decontamination.

Note: In the event of a spill during transport by an External service provider, compliance with relevant State or Territory legislation and regulations to manage clinical or biohazardous spills is sufficient.

Contingency plans

41. If there is a spill or an unintentional release of the GMOs at a Clinical trial site or under the HITH program, the following measures must be implemented:
    (a) the GMOs must be contained to prevent further dispersal; and
    (b) persons cleaning up the GMO must wear appropriate PPE; and
    (c) the exposed area must be decontaminated with an appropriate chemical disinfectant effective against the GMOs; and
    (d) any material used to clean up the spill or PPE worn during clean-up of the spill must be decontaminated; and
    (e) the licence holder must be notified as soon as reasonably possible.

Reporting and Documentation

*Note: The following licence conditions are imposed to demonstrate compliance with other conditions and facilitate monitoring of compliance by staff of the OGTR. Notices and reports may be emailed to OGTR.M&C@health.gov.au. A summary of notification and reporting requirements is provided at **Attachment B**.*

42. At least 14 days prior to first administering the GMO at each Clinical trial site, or within a timeframe agreed to in writing by the Regulator, the licence holder must provide the Regulator with a Compliance Management Plan for that Clinical trial site, specifying:
    (a) the name, address and description of the Clinical trial site, including any associated Pharmacy/Storage area/Analytical facilities;
    (b) the role and contact details of key persons responsible for the management of the trial at the site or at the HITH location;
    (c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures;
    (d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 16, 17, 44 and 45;
    (e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings;
    (f) the person(s) or class of persons administering the GMO, including nurses or private nurses engaged to conduct follow up care to trial participant under the HITH program;
    (g) the expected date of first administration;
    (h) how compliance with Condition 33 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO.

Note: For the purpose of finding out whether the Act has been complied with, an OGTR inspector may, if entry is at a reasonable time, enter a facility occupied by the licence holder or a person covered by the licence and exercise monitoring powers.

43. For each new participant treated, the licence holder must provide the Regulator the following information as soon as practicable:
    (a) the type of bacterial infection to be treated;
    (b) the location in Australia where the follow up care of the participant will take place;

    Note: The suburb and the State or Territory in which the follow up care will occur is sufficient information for the purpose of this condition.

    (c) the mode of administration used;
    (d) where, within the clinical site or under the HITH program (home, school or workplace), the GMO is expected to be administered.
44. For each Clinical trial site, the licence holder must notify the Regulator, in writing, of the end of the clinical trial, no later than 30 days after:
    (a) the final dose being administered; or
    (b) the decision that no further participants will be treated at that site or by HITH from that site.
45. The licence holder must inform the Regulator as soon as reasonably possible:
    (a) in the event of a loss or spill of the GMO;
    (b) in the event of the exposure of a person other than a trial participant or animals, to the GMO; and
    (c) if a trial participant has not followed the procedures described in the instructions provided by the licence holder.
46. Upon request from the Regulator, the licence holder must provide any signed records or documentation collected under a condition of this licence, within a time period stipulated by the Regulator.

Attachment A

DIR No: 206

Title: *Clinical trial of the treatment of mycobacterial infections using bacteriophages*

Organisation Details

Postal address: Western Sydney Local Health District
5 Fleet St
North Parramatta
NSW 2151

Phone No: (02) 9840 3000

GMO Description

GMOs covered by this licence:

Bacteriophages genetically modified as listed in Table 1 below.

Parent Organisms:

Common Name: Bacteriophages

Scientific Name: Bacteriophages

Modified traits:

Categories: Human therapeutic

Description: The bacteriophages are modified to make the bacteriophages lytic. Modifications are listed in Table 1.

Table 1. Nucleic acid responsible for conferring the modified traits

Genetic modifications	
Source, identity, nature of modification	**Modified trait description**
Deletion of repressor gene	Prevents lysogenic lifecycle

Trial participants and route of administration of the GMOs

Trial participants will have multidrug-resistant mycobacterial infections. Administration will be by intravenous injection, direct instillation, or topical application. Administration via nebuliser will be conducted only in clinical sites or within the homes of participants. Administration via endobronchial lavage will be conducted only in clinical sites.

Attachment B – Summary of reporting requirements

Prior to the commencement of the trial	**Condition**	**Timeframe for reporting**
A written Compliance Management Plan for each Clinical trial site: (a) the name, address and description of the Clinical trial site, including any associated Pharmacy/Storage area/Analytical facilities; (b) the role and contact details of key persons responsible for the management of the trial at the site or at the HITH location; (c) that the Institutional Biosafety Committee (IBC) associated with the site (if any) has been notified of the trial and have been consulted regarding site specific procedures; (d) the proposed reporting structure for the trial at the site and how the reporting structure enables the licence holder to become aware of all reportable events including but not limited to Conditions 16, 17, 44 and 45; (e) details of how the persons covered by the licence (for that type of dealing) will be informed of licence conditions applicable to them and how they will be trained to safely conduct the dealings; (f) the person(s) or class of persons administering the GMO, including nurses or private nurses engaged to conduct follow up care to trial participant under the HITH program. (g) the expected date of first administration; (h) how compliance with Condition 33 will be achieved in relation to preparation of participant Samples for analysis subsequent to administering the GMO.	42	At least 14 days prior to the first administration of the GMO at each Clinical trial site, or a timeframe agreed to in writing by the Regulator
Information to be provided at any time during the clinical trial	**Condition**	**Timeframe for reporting**
Any additional information related to the health and safety of people and the environment associated with the dealings covered by the licence, or any unintended effects of the dealings authorised by the licence	16(a), (c)	Immediately
Information related to any contravention of the licence by a person covered by the licence	16(b)	Immediately
Any relevant conviction of the licence holder	17(a)	Immediately
Any revocation or suspension of a licence or permit held by the licence holder under a law of the Commonwealth, a State or a foreign country	17(b)	Immediately
Any event or circumstances that would impact the licence holder capacity to meet the licence conditions	17(c)	Immediately
For each new participant treated (a) the type of bacterial infection to be treated; (b) the location in Australia where the follow up care of the participant will take place; (c) the mode of administration used; (d) where, within the clinical site or under the HITH program (home, school or workplace), the GMO is expected to be administered.	43	As soon as practicable
Provide notification to the Regulator, in writing, of the final GMO administration of the last trial participant at each Clinical trial site	44	Within 30 days of the decision to cease GMO

		administration at that particular Clinical trial site.
Any loss or spill of the GMO, or exposure of a person other than the trial participant to the GMO	45(a),(b)	As soon as reasonably possible
Any event where a trial participant has not followed the procedures described in the instruction provided by the licence holder	45(c)	As soon as reasonably possible
Information to be provided on request by the Regulator		
Information related to the persons covered by the licence	9	Within a timeframe stipulated by the Regulator
Information related to the licence holder's ongoing suitability to hold a licence	18	Within a timeframe stipulated by the Regulator
Copies of signed and dated statements and training records	20	Within a timeframe stipulated by the Regulator
A consolidated record of all GMOs being stored	38(e)	Within a timeframe stipulated by the Regulator
Any signed records or documentation collected under a condition of this licence	46	Within a timeframe stipulated by the Regulator