



Cannabis Research – using cannabis for medicinal cannabis research and medical research

Reference: Policy Circular #02/17

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1. Purpose

This policy has been developed to provide advice on the use of cannabis cultivated and produced under the *Narcotic Drugs Act 1967* (the Act) for research purposes.

Cannabis produced under both cannabis research licences and medicinal cannabis licences can be used for research, but in simple terms:

- cannabis research licences allow research into the horticultural and infrastructure aspects of cultivating and producing medicinal cannabis
- medicinal cannabis licences can supply cannabis to holders of manufacture licences under the Act for the purposes of the development of drugs and medicines for use in clinical trials, and
- both types of licence can supply cannabis to preliminary research on medicinal cannabis product development by a holder of a manufacture licence.

2. Background

Activities authorised under a cannabis research licence are outlined in section 9D of the Act, with additional discussion on what research cannabis produced under such licences can be used for under section 9H.

Separately, activities authorised under a medicinal cannabis licence are outlined in section 8E of the Act, with additional discussion on supplying cannabis produced under such a licence for manufacturer and research in relation to medicinal cannabis products further laid out under section 10J.

Importantly, the relationship between a medicinal cannabis licence and a manufacture licence is the aspect of the regulatory framework that allows for human therapeutic supply and subsequently precludes the use of cannabis produced under a cannabis research licence to be used in human clinical trials.

These different aspects of the regulatory framework has led to some confusion over what cannabis cultivated and produced under a cannabis research licence can be used for, what cannabis produced under a medicinal cannabis licence can be used for, and what research means in this context.

3. Allowable research

The following table outlines where cannabis produced under the various licences can be used for research.

It is important to remember that the only pure research that can be undertaken by a cannabis licence holder is by a cannabis research licence holder for horticultural and infrastructure research. All other research relating to medicinal cannabis requires the further involvement of a manufacture licence holder under the Act.

Research activity	Cannabis research licence	Medicinal cannabis licence
strain development	Yes	No
growing conditions	Yes	No
Harvest, destruction, and drying processes	Yes	No
Physicochemical analysis ¹	Yes	Yes
pre-clinical pharmacological research ²	Yes	Yes
Toxicology (<i>in-vitro</i> studies) ²	Yes	Yes
<i>in-vivo</i> studies (animal models) ²	Yes	Yes
product development (in-vitro /physicochemical) ²	Yes	Yes
stability assessment ²	Yes	Yes
Clinical trials ²	No	Yes

¹: partnering with a suitable laboratory for assay, see [Policy Circular #1 - cannabis cultivation and production licences - testing of cannabis and cannabis resin](#)

²: partnering with a ND Act manufacture licence holder

4. Further information

Further information can be found by following the below links:

- Office of Drug Control
<https://www.odc.gov.au/>
- Narcotic Drugs Act 1967
<https://www.legislation.gov.au/Details/C2016C01132>
- Narcotic Drugs Regulation 2016
<https://www.legislation.gov.au/Details/F2016C01047>
- Narcotic Drugs Amendment Bill 2016 – Explanatory memorandum
<https://www.legislation.gov.au/Details/C2016B00010/Download>