*This application form should be completed for Notifiable Low Risk Dealings and exempt dealings associated with an NLRD, as categorised in the Commonwealth Gene Technology Regulations 2001 and in the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019. Completed applications should be submitted electronically to the Biosafety Officer:* [*ibcadmin@flinders.edu.au*](mailto:ibcadmin@flinders.edu.au)*.*

***Please note:*** *Applicants must complete and submit a risk assessment with this application form. See* [*section 5*](#_5) *of this form for further information.*

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| **OFFICE USE ONLY** | **Application ID** |  |
| **Date of IBC approval** |  |
| **Approval expiry date** |  |
| **Dealing type** |  |

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| 1 | General Information | | | | | |
| Project Title: **(to be reported to OGTR)** | | |  | | | |
| **Organisation(s) where the dealing will be conducted (name all applicable)** | | | |  | | |
| **Has this dealing been approved by or is currently being reviewed by another IBC?** | | | | Yes  No *If yes, please submit relevant approval notice and record of assessment and complete following details* | | |
| **Other IBC name** | |  |
| **Dealing ID** | |  |
| **Does this application replace another approved dealing?** | | | | Yes  No *If yes, complete following details* | | |
| **Dealing ID** | |  |
| **Name of the approving IBC** | |  |
| **Category of dealing** | | Exempt  PC1 NLRD  PC2 NLRD  DNIR |
| 1.1 | | Project Supervisor / Chief Investigator Details | | | | |
| **Name** | | | | |  | |
| **Organisation/ Employer** | | | | |  | |
| **Telephone** | | | | |  | |
| **Email address** | | | | |  | |
| **Has the Project Supervisor/ Chief Investigator previously submitted an application to this IBC?** | | | | | Yes  No *If no, please provide a brief outline below of relevant experience and qualifications in relation to GMO work* | |
| 1.2 | | Preferred Contact Person details | | | | |
| **Same as above** | | | | |  | |
| **Preferred Contact Person** | | | | |  | |
| **Organisation/ Employer** | | | | |  | |
| **Telephone** | | | | |  | |
| **Email address** | | | | |  | |
| **Has the Preferred Contact Person previously submitted a dealing application to this IBC?** | | | | | Yes  No *If no, please provide a brief outline below of relevant experience and qualifications in relation to GMO work* | |

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| 2 | Summary of the dealing types | | | |
| Refer to the Schedules in the Gene Technology Regulations 2001, available online at [**https://www.legislation.gov.au/Details/F2019C00781**](https://www.legislation.gov.au/Details/F2019C00781) to determine the correct type(s) of dealing(s). Indicate all that apply. | | | | |
| Exempt Dealing Category *(Schedule 2 Part 1)*  *Please also select the relevant host/vector system category from Schedule 2 Part 2 below.* | | 2  3  3A  4  5 | ***A dealing is an exempt dealing if it:*** *a) is a kind mentioned in Schedule 2 Part 1; &  b) does not involve a genetic modification other than a modification described; &  c) does not involve an intentional release of the GMO into the environment; &  d) does not involve a retroviral vector that is able to transduce human cells* | |
| Exempt Dealing Host/Vector System Category *(Schedule 2 Part 2)*  *Please also select the relevant exempt dealing category from Schedule 2, Part 1 above.* | | 1   2   3   4   5  6  7  8  9  10 | | *Please select relevant exempt host vector systems in* [*Section 4.1*](#_About_the_GMOs) *of this form.* |
| Notifiable Low Risk Dealing – PC1 *(Schedule 3 Part 1)* | | 1.1(a)  1.1 (c) | | *A dealing is not a notifiable low risk dealing if it: a) is also a dealing of a kind mentioned in Part 3 of Schedule 3; or b) involves an intentional release of the GMO into the environment.*  *A dealing that is not an exempt dealing or a notifiable low risk dealing must be authorised under an OGTR licence.* |
| Notifiable Low Risk Dealing – PC2 *(Schedule 3 Part 2.1)* | | 2.1(a)  2.1(aa)  2.1(b)  2.1(c)  2.1(d)  2.1(e)  2.1(f)  2.1(g)  2.1(h)  2.1(i)  2.1(j)  2.1(k)  2.1(l) Part (iii)  A or  B  2.1(m) Part (iv)  A or  B | |
| Notifiable Low Risk Dealing – PC3  *(Schedule 3 Part 2.2)*  *If YES please contact Biosafety Officer before proceeding further* | | 2.2 | |

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| 3 | About the dealing | | |
| *Please ensure that the information provided, including the description, accurately includes all aspects of the dealing. Investigators should ensure that information about* ***all storage and proposed transport, including importation or exportation, decontamination and disposal of GMOs*** *is included as these aspects of a dealing also require approval.*  *Please include the aims of the proposed dealing, method of producing GMOs and their use. If more than one type of dealing is included on this application, please ensure that the work associated with each dealing type is clearly identified and outlined.* | | | |
| **Proposed commencement date** | | |  |
| **3.1 Description of the dealing** | | | |
| *Only dealings that are listed on an approval notice can be undertaken. Therefore, please ‘check’ the dealings that will be undertaken.*  *NOTE: A dealing includes the possession, supply or use of the GMO, for the purposes of, or in the course of, a dealing mentioned in any of activities listed.*  *\*As defined in the Gene Technology Act 2000:  thing, includes a substance, and a thing in electronic or magnetic form.* | | Conduct experiments with the GMO | |
| Make, develop, produce or manufacture the GMO | |
| Breed the GMO | |
| Propagate the GMO | |
| Use the GMO in the course of manufacture of a thing\* that is not the GMO  *If yes, complete following details* Is the thing\* subject to regulation by other agencies (e.g. Food Standards Australia, Australian Pesticides and Veterinary Medicines Association, Therapeutic Goods Administration)  Yes ⮚ Agency        No | |
| Grow, raise or culture the GMO | |
| Import the GMO  *If yes, complete following details*  Is an Import Permit required?  Search BICON for further information: <https://bicon.agriculture.gov.au/BiconWeb4.0/>  Yes ⮚ DAWR Import Permit ID        No | |
| Transport the GMO | |
| Dispose of the GMO | |
| Store the GMO | |
| Does this dealing involve:  Human Ethics Committee approval ⮚ Approval no:       or  pending  Animal Ethics Committee approval ⮚ Approval no:       or  pending  Radiation  Carcinogenic / hazardous substances  Security Sensitive Biological Agents  Import of biological materials from an overseas location  If YES please see [**Appendix 1**](#_APPENDIX_2_–) for further instructions. | |

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| 3.2 Lay Summary- please include a short summary of the project using lay language |
|  |
| 3.3 Description of work– please include details of how all dealings checked in box 3.1 above, including transport, storage and disposal will be conducted. |
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| 3.4 Benefits of the work(no more than 200 words/15 lines of text) |
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| 4 | | | About the GMOs | |
| **4.1 For Exempt Dealings please select all hosts and vectors that apply from the list below** Only complete this section for exempt dealings DIRECTLY associated with the Notifiable Low Risk Dealing described in this application. For stand-alone exempt dealings, complete an exempt dealing application from the Flinders University biosafety website. | | | | |
| Item | Class | Host (select all that apply) | | Vector (select all that apply) |
| 1 | Bacteria | *Escherichia coli* K12, *E. coli* B, *E. coli* C or *E. coli* Nissle 1917 – any derivative that does not contain:  (a) generalised transducing phages; or (b) genes able to complement the conjugation defect in a non‑conjugative plasmid | | Non‑conjugative plasmids  lambda bacteriophage  lambdoid bacteriophage  Fd, F1 or M13 bacteriophage  None (non‑vector systems) |
| 2 | Bacteria | *Bacillus* – asporogenic strains of the following species with a reversion frequency <10–7: (a) *B. amyloliquefaciens* (b) *B. licheniformis* (c) *B. pumilus* (d) *B. subtilis* (e) *B. thuringiensis* | | Non‑conjugative plasmids  Other plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of *Bacillus*  None (non‑vector systems) |
| 3 | Bacteria | *Pseudomonas putida* strain KT2440 | | Non‑conjugative plasmids  None (non‑vector systems) |
| 4 | Bacteria | The following *Streptomyces* species: (a) *S. aureofaciens* (b) *S. coelicolor* (c) *S. cyaneus* (d) *S. griseus* (e) *S. lividans* (f) *S. parvulus* (g) *S. rimosus* (h) *S. venezuelae* | | Non‑conjugative plasmids  Plasmids SCP2, SLP1, SLP2, PIJ101 and derivatives  Actinophage phi C31 and derivatives  None (non‑vector systems) |
| 5 | Bacteria | *Agrobacterium radiobacter*  *Agrobacterium rhizogenes* (disarmed strains only)  *Agrobacterium tumefaciens* (disarmed strains only) | | Disarmed Ri or Ti plasmids  None (non‑vector systems) |
| 6 | Bacteria | Any of the following:  *Allorhizobium* species  *Corynebacterium glutamicum*  *Lactobacillus* species  *Lactococcus lactis*  *Oenococcus oeni* syn. *Leuconostoc oeni*  *Pediococcus* species  *Photobacterium angustum*  *Pseudoalteromonas tunicata*  *Rhizobium* species  *Sphingopyxis alaskensis* syn. *Sphingomonas alaskensis*  *Streptococcus thermophilus*  *Synechococcus* species strains PCC7002, PCC7942 and WH8102  *Synechocystis* species strain PCC 6803  *Vibrio cholerae* CVD103‑HgR  *Zymomonas mobilis* | | Non‑conjugative plasmids  None (non‑vector systems) |
| 7 | Fungi | Any of the following:  *Kluyveromyces lactis*  *Neurospora crassa* – laboratory strains  *Pichia pastoris*  *Saccharomyces cerevisiae*  *Schizosaccharomyces pombe*  *Trichoderma reesei*  *Yarrowia lipolytica* | | All vectors  None (non‑vector systems) |
| 8 | Slime moulds | *Dictyostelium* species | | *Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2  None (non‑vector systems) |
| 9 | Tissue culture | Any of the following if they cannot spontaneously generate a whole animal: (a) animal or human cell cultures (including packaging cell lines); (b) isolated cells, isolated tissues or isolated organs, whether animal or human; (c) early non-human mammalian embryos cultured *in vitro* | | Plasmids  Replication defective viral vectors unable to transduce human cells  polyhedron minus forms of the baculovirus *Autographa californica* nuclear polyhedrosis virus (ACNPV)  None (non‑vector systems) |
| 10 | Tissue culture | Either of the following if they are not intended, and are not likely without human intervention, to vegetatively propagate, flower or regenerate into a whole plant: (a) plant cell cultures; (b) isolated plant tissues or organs | | Disarmed Ri or Ti plasmids in *Agrobacterium radiobacter*, *Agrobacterium rhizogenes* (disarmed strains only) or *Agrobacterium tumefaciens* (disarmed strains only)  Non‑pathogenic viral vectors  None (non‑vector systems) |

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| 4.2 Complete the table below to describe the GMOs used in the Notifiable Low Risk Dealing.*Please see* [*Appendix 2*](#_APPENDIX_3_–) *for examples of how to complete this table.* | | | | | |
| **Common Name of Parent Organism** | **Scientific Name of Parent/ Host Organism\***  *\*the organism that you propose to genetically modify.*  *This includes host cells/cells lines/and viral vectors (for viruses include the family).* | **Vector(s) and Method of Transfer.**  *Provide copies of references or vector maps for novel vectors or methods of transfer. For dealings involving viral vectors provide details of each of the plasmids to be used. Also include packaging and/or helper cell line details as required.* | **Exempt Host/**  **Vector System (Y/N)** | **Identity and Function of Nucleic Acid and Organism of Origin**  *Attach more pages if required.* | **Dealing Type**  *Must list specific Schedule – e.g. Schedule 3, Part 1, 1.1 (a)* |
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| 4.3 Class of modified trait and Gene(s) Responsible (insert details where applicable) | |
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| 1. Abiotic stress resistance |  |
| 1. Altered agronomic characteristics |  |
| 1. Altered biocontrol characteristics |  |
| 1. Altered bioremediation characteristics |  |
| 1. Altered biosensor characteristics |  |
| 1. Altered horticultural characteristics |  |
| 1. Altered nutritional characteristics |  |
| 1. Altered pharmaceutical characteristics |  |
| 1. Altered physical product characteristics |  |
| 1. Altered physiological characteristics |  |
| 1. Antibiotic resistance |  |
| 1. Antigen expression |  |
| 1. Attenuation |  |
| 1. Bacterial resistance |  |
| 1. Disease resistance |  |
| 1. Fungal resistance |  |
| 1. Growth factor expression |  |
| 1. Herbicide tolerance |  |
| 1. Immuno -modulatory protein expression |  |
| 1. Oncogene |  |
| 1. Pest resistance |  |
| 1. Pesticide resistance |  |
| 1. Protein expression |  |
| 1. Reporter/marker gene expression |  |
| 1. Virus resistance |  |
| 1. Other, describe |  |

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| 5 | Risk assessment | |
| For applications involving GMO microorganismsPlease indicate the relevant Risk Group(s) (as per *AS/NZS 2243:3 Safety in Laboratories*) for all microorganisms involved in this dealing. Select all that apply.You can obtain access to the Standard via SAI Global when on campus:<http://www.saiglobal.com/online/autologin.asp> | | No microorganisms  Risk Group 1 microorganisms Risk Group 2 microorganisms Risk Group 3 microorganisms Risk Group 4 microorganisms |
| For applications involving cell linesI [the applicant] confirm that: The cell line(s) used in the application are GMO(s); **OR**  The cell line(s) used in the application are not GMO(s). Was a viral vector or infective particle used in the production of the cell line?  Yes  No \*\* Please be aware that cell lines produced with early retroviral vectors (including lentiviral vectors) may secrete infectious particles\*\* | | |
| **For Notifiable Low Risk Dealings, a risk assessment for the dealings must be submitted with this application.**  **Please complete the risk assessment form available on the** [**Flinders University Biosafety website**](https://staff.flinders.edu.au/research/integrity/biosafety) **(Resources & forms):** <https://staff.flinders.edu.au/content/dam/staff/research/ebi/biosafety/risk-assessment-form.pdf> | | |

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| 6 | Persons undertaking the dealing | | | | |
| *The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This* includes persons beyond the persons conducting the research, such as persons involved in importation, transportation and disposal of GMOs*.*  **Note: Appropriate training for personnel undertaking research includes** successful completion of Biosafety Training, reading the Biosafety Manual and completing a Physical Containment (PC) facility induction for all PC facilities where you will be undertaking work. | | | | | |
| **List all persons known to be involved at the time of writing this application -** *d*etails of additional persons can be added later by notifying the IBC via email. | | | | | |
| **Name** | | **Category**  **Research Staff/ Student/ Other** | **Biosafety Training completed?** | | |
| **Yes/ No** | **If yes, when (year) & where (organisation)?** | **If no, what measures are in place to ensure all personnel are adequately trained before commencing the dealing?** |
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| 7 | Facilities to be Used | | | |
| *All facilities to be used must be authorised. Please list all facilities intended to be used at the time of writing this application – details of additional facilities can be added later by notifying the IBC via email.*  Note: If you have any questions regarding any facilities or “local contact persons”, please contact the Biosafety Officer: [ibcadmin@flinders.edu.au](mailto:ibcadmin@flinders.edu.au) | | | | |
|  | | **Facility 1** | **Facility 2** | **Facility 3** |
| **Organisation/Site** | |  |  |  |
| **OGTR Certified?** | | Yes  No | Yes  No | Yes  No |
| **OGTR Certification No.** | |  |  |  |
| **Room Number(s)** | |  |  |  |
| **Building** | |  |  |  |
| **Type of facility & PC level** | |  |  |  |
| **Local contact person** | |  |  |  |
|  | | **Facility 4** | **Facility 5** | **Facility 6** |
| **Organisation/Site** | |  |  |  |
| **OGTR Certified?** | | Yes  No | Yes  No | Yes  No |
| **OGTR Certification No.** | |  |  |  |
| **Room Number(s)** | |  |  |  |
| **Building** | |  |  |  |
| **Type of facility & PC level** | |  |  |  |
| **Local contact person** | |  |  |  |

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| 8 | Storage Locations | | | |
| *All storage locations used must be authorised. Storage of GMOs outside of a certified PC facility is permitted, but must be authorised by the IBC. Unauthorised storage of GMOs is an offence under the Act.* | | | | |
|  | | **Location 1** | **Location 2** | **Location 3** |
| **Organisation/Site** | |  |  |  |
| **OGTR Certified?** | | Yes  No | Yes  No | Yes  No |
| **OGTR Certification No.** | |  |  |  |
| **Room Number(s)** | |  |  |  |
| **Building** | |  |  |  |
| **Storage location**  **(e.g. locked -80 freezer in corridor; fridge # 1, etc.)** | |  |  |  |

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| 9 | Project Supervisor Declaration | | | | |
| Please ensure you understand each statement and your responsibilities and then sign the application form (electronic signatures accepted). | | | | | |
| I have read, considered and understand my responsibilities under the Gene Technology Act 2000 and agree to undertake the dealing outlined in this application in accordance with the relevant Office of the Gene Technology Regulator guidelines and regulations (including, but not limited to all disposal, transport and storage) <http://www.ogtr.gov.au> | | | | | |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work are appropriately trained and are aware of and follow the relevant guidelines and regulations. | | | | | |
| I have considered the potential risks that the conduct of this dealing could pose to people and/or the environment and will implement appropriate actions and precautions to minimise these risks. | | | | | |
| Where a GMO is received from sources outside the institution responsible for the project, I will take steps to confirm its identity. | | | | | |
| In the event of an unintentional release of a GMO I am aware that I must put into place the appropriate responses to contain the release and I will inform the IBC as soon as practicable of any incidents, accidents or unintentional releases involving GMOs. | | | | | |
| I am aware that breaches of the legislation are serious matters and that penalties could include loss of OGTR Accreditation status for the organisation, imprisonment and/or substantial fines. | | | | | |
| Name | |  | Signature |  | Date |

|  |  |
| --- | --- |
| 10 | **Comments for the IBC** – e.g. use this section to list any attachments to the application |
|  | |

**Please submit this application form, together with the Risk Assessment (for NLRDs) and any other required documentation to the IBC via email:** [**ibcadmin@flinders.edu.au**](mailto:ibcadmin@flinders.edu.au)

***Please retain a copy of your completed application for your own records.***

# APPENDIX 1: – Approvals/Notifications/Compliance Checklist

| Note that if your dealing involves any of the following, you must also carry out the action required.  **Where approval is required, it is your responsibility to obtain that approval.** |
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| --- | --- |
| **Does the dealing involve:** | **Action required:** |
| **Animals, animal tissues or animal cells?** | **You must obtain approval from an Animal Welfare Committee.**  At Flinders:  <https://staff.flinders.edu.au/research/integrity/animal-ethics>  Animal Ethics Officer telephone: 8201 5962  Email: [animal.welfare@flinders.edu.au](mailto:animal.welfare@flinders.edu.au) |
| **Human subjects, tissues, body products or personal information?** | **You must obtain approval from a Human Research Ethics Committee.**  At Flinders:  [Southern Adelaide Clinical Human Research Ethics Committee](http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/salhn+research/undertaking+research/southern+adelaide+clinical+human+research+ethics+committee)  Email: [Health:SALHNofficeforresearch@sa.gov.au](health:SALHNofficeforresearch@sa.gov.au) |
| **Radioactive substances or ionizing radiation?** | **At Flinders you must notify the Radiation Safety Officer:**  <https://staff.flinders.edu.au/workplace-support/whs/contact-whs> |
| **Microorganisms, chemicals or equipment listed in the** [**Defence and Strategic Goods List**](https://dsgl.defence.gov.au/Pages/Home.aspx)**?** | If your goods are listed in the Defence and Strategic Goods List and you are planning to send any goods or associated information or publications overseas (including electronically), please **seek advice regarding permit requirements**.  Flinders contact:  Dr Jess Hall – [defence.exports@flinders.edu.au](mailto:defence.exports@flinders.edu.au); ph. 72218353 |
| **Security Sensitive Biological Agents?** | If your dealing involves microorganisms or toxins listed as [Security Sensitive Biological Agents](http://www.health.gov.au/ssba), please **contact the IBC for further advice before submitting any applications**.  Email: [ibcadmin@flinders.edu.au](mailto:ibcadmin@flinders.edu.au) |
| **Carcinogenic substances (scheduled)?** | **You must follow the *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice*.**  At Flinders, contact the Work Health & Safety Unit for advice.  Telephone: 8201 3024 |
| **Hazardous substances?** | **At Flinders, you must comply with the Hazardous Chemicals Safety Management Procedures:**  <http://www.flinders.edu.au/ppmanual/health-safety/workplace-substances-management.cfm> |
| **Import of biological materials from overseas?** | **A Department of Agriculture import permit may be required.** Search the BICON database for import conditions for your goods: <https://bicon.agriculture.gov.au/BiconWeb4.0/>  For shared-use permits held by the University for commonly imported items, please view the list of available permits and apply via [ServiceOne](https://serviceone.flinders.edu.au/) > Research Services > Importing, exporting or transporting biological goods > I am applying to use a University-held permit.  For items not covered by shared-use permits, a permit must be arranged through the Department of Agriculture by the researcher where required. Assistance can be provided by Dr Jess Hall – [biosecurity@flinders.edu.au](mailto:biosecurity@flinders.edu.au) |

# APPENDIX 2 – Examples of how to complete [Section 4.2](#_4.2_For_Notifiable) of this application

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| --- | --- | --- | --- | --- | --- |
| ***For Notifiable Low Risk Dealings, complete table below to describe source(s) and type (s) of DNA.*** | | | | | |
| **Common Name of Parent Organism** | **Scientific Name of Parent/ Host Organism**  *The parent organism means the organism that you propose to genetically modify. It also includes intended host cells, e.g. tissue culture cells or host animal cells transduced by a vector.* | **Vector(s) and Method of Transfer.**  *Provide copies of references or vector maps for novel vectors or methods of transfer. For dealings involving viral vectors provide details of each of the plasmids to be used. Also include packaging and/or helper cell line details as required.* | **Exempt Host/**  **Vector System (Y/N)** | **Identity and Function of Nucleic Acid and Organism of Origin**  *Attach more pages if required* | **Dealing Type** |
| Zebrafish | *Danio rerio* | Plasmid microinjected into embryos | No | Expression of green fluorescent protein (GFP) from *Aequorea victoria* | Schedule 3, Part 2, 2.1(a) |
| Mouse | *Mus musculus* | Standard non-conjugative plasmid expression vector microinjected into embryos | No | Expression of bacterial neomycin resistance gene (*neo*) and knock-out of Vitamin D receptor gene (*Vdr/Nr1i1*) | Schedule 3, Part 1, 1.1(a) |
| Human cultured cells | Human cell line (HEK-293) | Replication defective human adenoviral vector | No | Expression of green fluorescent protein (GFP) from *Aequorea victoria* | Schedule 3, Part 1, 1.1(c) |
| Thale cress | *Arabidopsis thaliana* | Non tumorigenic disarmed Ti plasmid via vacuum infiltration | No | Expression of pigment related genes (*chm*, *var1* and *var2*) from *Arabidopsis* species | Schedule 3, Part 2, 2.1(b) |
| Escherichia | *Escherichia coli* (pathogenic strains) | Standard non-conjugative cloning vector pUC, pBluescript by electroporation | No | Expression of defective virulence genes from *E. coli* | Schedule 3, Part 2, 2.1(d) |
| Human cultured cells | Human cell line (fibroblast cell line) | Replication defective human adenoviral vector | No | Expression of wild type and mutant oncogenes isolated from *Homo sapiens* | Schedule 3, Part 2, 2.1(j) |
| Escherichia | *Escherichia coli* K12 | Standard non-conjugative plasmids | Yes (>25 L) | Expression of insulin gene from *Homo sapiens* | Schedule 3, Part 2, 2.1(f) |