Genome Editing and RNA Technologies

Self-assessment form

FLINDERS INSTITUTIONAL BIOSAFETY COMMITTEE

Under the amended Gene Technology Regulations 2001, the regulatory status of the following gene technology techniques has changed:

- Genome editing techniques such as CRISPR/Cas, TALENS and zinc finger nucleases (ZFNs)
- Oligonucleotide-directed mutagenesis
- RNA interference techniques
- Techniques resulting in null progeny
- Engineered gene drives

To ensure your research is compliant with the amended Regulations, please complete this self-assessment and submit to the IBC's register. In some cases additional applications to the IBC will be required where notified throughout this form.

Researcher's Details
Name:
Phone:
Email:

Question 1:

Which of the following techniques with changed regulatory status do you propose to use?

☐ Site-directed nuclease (SDN) techniques (e.g. CRISPR/Cas, TALENs, ZFNs, meganucleases) **– Proceed to section 1 on page 2 of this form**

☐ Oligonucleotide-directed mutagenesis (ODM) / site-directed mutagenesis **– Proceed to section 2 on page 3 of this form**

☐ Base editing, prime editing or other genome editing techniques that are not SDN technologies **– Proceed to section 3 on page 3 of this form**

☐ Engineered gene drives **– Proceed to section 4 on page 3 of this form**

☐ Production of an organism derived from a GMO, or modified by gene technology, that could be considered not a GMO for any reason (e.g. if the offspring have not inherited traits as a result of gene technology, or if the genetic modification is no longer present) **– Proceed to section 5 on page 3 of this form**

☐ Introduction of RNA, including RNA interference technologies **– Proceed to section 6 on page 4 of this form**

SECTION 1: Site-directed nuclease techniques

Which of the following nucleic acid repair mechanisms will the SDN technique involve?

☐ Unguided repair (non-homologous end joining) – no nucleic acid template supplied to guide genome repair through homology-directed recombination **– Proceed to Section 1, part (i) below**

☐ Homology directed repair – template nucleic acid encoding desired change and with homology with the target site used to create a targeted change, or to insert nucleic acid **– Proceed to Section 1, part (ii) below**

Section 1, part (i) – Unguided repair / non-homologous end joining

Please select which of the options below applies for introduction of the Cas nuclease and guide RNAs:

☐ An expression cassette or plasmid will be used for the transient expression of the Cas nuclease and guide RNAs

Please briefly summarise your work in an email to the IBC for recording on the register of dealings (email: ibcadmin@flinders.edu.au).

☐ Cas nuclease is introduced to the host directly, with or without a guide RNA to target a genomic region of interest (no expression cassette or plasmid)

Where option (b) is selected: This application of SDN technologies is deregulated. No application is required. Please submit this form for recording on the IBC register.

Section 1, part (ii) – Homology directed repair

IBC approval is required prior to commencement of this research. The work may constitute an exempt dealing, notifiable low risk dealing or licence dealing depending on the nature of the dealings being undertaken. If you require assistance determining which dealing type applies, please contact the IBC before starting your application (email: ibcadmin@flinders.edu.au; ph. 08 72218353).

SECTION 2: Oligonucleotide-directed mutagenesis (ODM) / site-directed mutagenesis

IBC approval is required prior to commencement of this research. The work may constitute an exempt dealing, notifiable low risk dealing or licence dealing depending on the nature of the dealings being undertaken. If you require assistance determining which dealing type applies, please contact the IBC before starting your application (email: ibcadmin@flinders.edu.au; ph. 08 72218353).

SECTION 3: Base editing, prime editing or other genome editing techniques that are not SDN technologies

IBC approval is required prior to commencement of this research. The work may constitute an exempt dealing, notifiable low risk dealing or licence dealing depending on the nature of the dealings being undertaken. If you require assistance determining which dealing type applies, please contact the IBC before starting your application (email: ibcadmin@flinders.edu.au; ph. 08 7221 8353).

SECTION 4: Engineered gene drives

Engineered gene drives constitute licenced dealings under the amended *Gene Technology Regulations*. A licence application to the Office of the Gene Technology Regulator must be prepared and submitted to the IBC. Please contact the IBC before starting your application (email: ibcadmin@flinders.edu.au; ph. 08 7221 8353).

SECTION 5: Production of an organism derived from a GMO, or modified by gene technology, that could be considered not a GMO for any reason

Please describe your work in an email to the IBC for further advice on whether or not an application is required (email: ibcadmin@flinders.edu.au).

SECTION 6: Introduction of RNA, including RNA interference technologies

Does or could the introduction of the RNA involve any of the following?:

- Alteration of the host organism's genome sequence by the introduction of the RNA
- Use of viral vectors to introduce the RNA
- Translation of the RNA into a polypeptide
- The potential to give rise to an infectious agent

☐ If yes to **any** of the items above:

IBC approval is required prior to commencement of this research. The work may constitute an exempt dealing, notifiable low risk dealing or licence dealing depending on the nature of the dealings being undertaken. If you require assistance determining which dealing type applies, please contact the IBC before starting your application (email: ibcadmin@flinders.edu.au; ph. 08 72218353).

☐ If no to **all** items above:

Please briefly summarise your work in an email to the IBC for recording on the register of dealings (email: ibcadmin@flinders.edu.au).