

Instructions on Reporting Requirements for Notifiable Low Risk Dealings (NLRDs)

Purpose

This document has been prepared to assist persons or accredited organisations in the completion of the NLRD form to meet their reporting requirements to the Gene Technology Regulator (the Regulator).

Definitions

Record of Assessment (RoA): is required for proposed dealings which have been assessed to be NLRDs by an Institutional Biosafety Committee (IBC).

NLRD form: is the form approved by the Regulator which is to be used to provide a subset of information from the RoA to the Regulator.

Person: refers to individuals or non-accredited organisations undertaking or intending to undertake NLRDs.

Requirements of the NLRD Reporting Process

- a person or accredited organisation must provide the Regulator with a completed NLRD form for dealings assessed to be NLRDs by an IBC. The form must be provided to the Regulator in a report for the financial year (for accredited organisations, this form is part of the annual report).
- a person or accredited organisation that has been given a copy of a RoA by an IBC must keep a copy of the IBC's RoA for 8 years after the date of the assessment.
- a person or accredited organisation cannot vary, transfer or 'renew/extend' a dealing assessed to be a NLRD.
- for a NLRD to be continued past its expiry date, it must be assessed again as a new NLRD (with a new IBC identifier) and notified to the OGTR in the annual report for the reporting period in which the new assessment has been undertaken.
- any intended changes to a NLRD, as detailed in the RoA, may need to be assessed again as a new NLRD (with a new IBC identifier). This is dependent on how the original RoA was written.
- if, as a result of changes, a new NLRD is assessed, it must then be notified to the OGTR in the reporting period in which the assessment has been undertaken.

A copy of the NLRD form is available on the OGTR website. The content and guidance on completion of the NLRD form is detailed on the following page.

Completing the NLRD form

| Fields) | Guide to completing the fields |
|---|--|
| IBC NLRD Identifier | Enter a unique identifier (this can include letters and numerals and other characters), eg. "COL 2011/43" Please do not enter extraneous information in this field such as project titles/purpose. |
| Date of IBC Assessment | This must be a date only (no text) between 21 June 2001 and 30th June of the reporting period (future dates not permitted). Use any date format you wish - the cell will format the date automatically. |
| Name of IBC | This is the IBC used by the organisation. e.g. <i>ABCD Institutional Biosafety Committee</i> . |
| Name of Organisation Notifying Dealing * | Name of the organisation that submitted the NLRD proposal to the IBC. This should also be the organisation that notifies the Regulator. |
| Project Title * (please do not include confidential information) | Brief project title, for listing on OGTR website DO NOT include any CCI information in the title. |
| GMO details | Genus and species (where known) and for viruses, the family. If not known, describe the GMO as best you can. For multiple GMOs, please separate by a comma, or semi colon. |
| PC1 NLRD TYPE (a) – (c) * | Paragraph number(s) relating to the kinds of dealing detailed in Part 1 of Schedule 3 of the Gene Technology Regulations 2001 (as amended). For multiple types, enter each type separated by a comma, eg. "(a), (c)". |
| PC2 NLRD TYPE (a) – (m) * | Paragraph number(s) relating to the kinds of dealing detailed in Part 2 of Schedule 3 of the Gene Technology Regulations 2001 (as amended). For multiple types, enter each type separated by a comma, eg. "(d)(i)(B), (g), (h)(ii)". |
| PC3 NLRD * | Indicate if the dealing is also a dealing described in Part 2.2 of Schedule 3. This field can be filled by indicating “yes” or “PC3”. |
| Has the IBC assessed the proposed dealing to be an NLRD? | Only submit NLRDs to the Gene Technology Regulator in the organisation annual report that have actually been assessed to be a NLRD. (The answer to this should be "Yes".) |

* Fields that will be included in the public list of NLRDs on the OGTR website