



Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

Model Form - Record of Assessment
Notifiable Low Risk Dealings (NLRDs)

As of 1 September 2011, the Gene Technology Amendment Regulations 2011 (Commonwealth) amend the Gene Technology Regulations 2001. These changes will affect the way Institutional Biosafety Committees (IBCs) record their assessment of Notifiable Low Risk Dealings (NLRDs). The new regulation 13B(a) requires an IBC that has assessed a proposal as being a NLRD to make a record of its assessment, in a form approved by the Regulator, and specifies the information that this record must contain.

IBCs **must** make a NLRD record of assessment (RoA). IBCs have the option of using this model form to make a RoA of a NLRD as required by 13B(a) of the Regulations. Alternately, IBC may choose to record this information using a different recording system/format. However, it is important to note that, at a minimum, all the information specified in 13B(a) must be included in the RoA. If the record contains all the information specified in Regulation 13B(a)(i)-(x), then this record will be considered to be in a form approved by the Regulator.

A document titled *Guidance for making Records of Assessment of NLRDs* has been prepared to assist IBCs with preparing RoAs of NLRDs (Reg 13B). It is strongly encouraged that the guidance document is used in conjunction with this model form to ensure accurate and comprehensive information is recorded.

Regulation 13B (a)	
(i) What is the identifying name or title of the proposed dealing (as given by the person or organisation proposing to undertake the dealing)?	
(ii) Describe the dealing to be undertaken: <i>(Consider the breadth and scope of the all activities in relation to the dealings including any importation, transport, storage or disposal of the GMO – refer to Section 10 of the Gene Technology Act 2000 for a definition of “deal with” in relation to dealing with a GMO)</i>	
(iii) Is the proposed dealing an NLRD in Part 1 or Part 2 of Schedule 3	Yes <input type="checkbox"/> <i>If the proposed dealing is NOT listed in either Part 1 or Part 2 the dealing is either exempt or should be a Dealing Not Involving Intentional Release (DNIR) i.e. a licensable dealing. This RoA is not required for exempt or licensable dealings.</i>

Regulation 13B (a)	
(iv) If yes to the above question, what kind of dealing is it? (As mentioned in the relevant Part of Schedule 3) <i>(As the NRLD may involve a number of scheduled dealings, all the kinds should be listed)</i>	Which Part?
(v) Date of IBC assessment <i>(Preferably in dd/mm/yyyy format)</i>	
(vi) List the persons (or classes of persons) considered by the IBC to have appropriate training and experience to undertake the dealing	
(vii) List the facilities (or classes of facilities) the IBC considers to be of the appropriate physical containment level and type for the dealing	
(viii) Record the name of the IBC that assessed the proposal	
(ix) Record the name of the person or accredited organisation that submitted the proposal	
(x) Record the name of the person or accredited organisation proposing to undertake the dealing	

IBC Chair or delegate with authority to sign

Printed name:	Signature:
Job title:	Date:

**Post-Assessment Checklist for
Record of Assessment of Notifiable Low Risk Dealings (NLRDs)**

As required by regulation 13B(b), the IBC **must** give a copy of the record of assessment of NLRDs to the person or accredited organisation that submitted the proposal to the IBC. The IBC can choose to use this post-assessment section (or an alternative system) to demonstrate that this has occurred.

Regulation 13B (b)	
<p>Have you given a copy of the record of assessment to the person or accredited organisation that submitted the proposal to the Committee?</p>	<p>Yes <input type="checkbox"/></p> <p>..... (printed name)</p> <p>..... (job title)</p> <p>..... (signature of IBC representative) (date)</p>

<p>I (the person/organisation that submitted the NLRD proposal) have received a copy of the Record of Assessment</p>	<p>..... (printed name)</p> <p>..... (signature) (date)</p>
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