

Department of Health and Aged Care Office of the Gene Technology Regulator

OGTR Online Services Portal NLRD Form Guide

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Accessing the NLRD Form

1. To access a new or existing NLRD form, from the home page, select [Services] followed by the [Notifiable Low Risk Dealings] service tile.

Home > Services				
Services				
Please select the service you would like to complete from the tiles submissions.				
Please select a service below				
ааа 				
Notifiable Low Risk Dealing (NLRD)				

- 2. This will take you to the Notifiable Low Risk Dealings (NLRDs) dashboard.
 - Draft submissions will be visible on this page (the default view is five Submissions).
 - For accessing draft submissions, see the section <u>Accessing draft or completed</u> <u>submissions</u>.
- 3. Select [New submission] to begin a new Submission for reporting NLRDs. This will open a new NLRD form.





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Form information

You can view information about the form, including timeframes, acknowledgements of receipt of applications and privacy on the "Information" page.

You can also view and/or print a "checklist" showing the information required to complete the form.



Submission Number

Upon selecting "Next" from the Information page, your submission number will be generated and will appear above the left-hand menu. It can be noted down for reference, if needed. Once the number is generated, you can return to this draft submission at any time from the Draft Submissions dashboard.





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Confidential Commercial Information (CCI)

At this stage, information that is, or may be subject to a CCI application cannot be submitted via the portal. If you believe your submission needs to include CCI, please contact the OGTR before completing the submission.

1. Select "No" to the question "Will this submission contain any Confidential Commercial Information"

Confidential Commercial Information
Will this submission contain any Confidential Commercial Information (CCI) •
Previous Save and Next

2. Select "Save and Next" to move to the "Proposed NLRD" page.

Adding a new NLRD

1. On the "Proposed NLRD" page select the button "Add a new NLRD"

Submission Number: SUB-000121			
Information			
Confidential Commercial Information	r		
		This submission requires at least one NLRD and cannot have more than 20 NLRD	Add a new NLRD
Proposed NLRD		IBC NLRD Identifier 🛧 IBC Assessment Date Project Title	IBC Name
Contact Details	L		
Declaration			



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NLRD Details

When you first open the "Add a new NLRD" sub-form, you will see your organisation name at the top of the screen, under the heading "Name of the organisation giving notice of the dealing". This is the organisation you are currently representing.

- 1. Enter details in the following mandatory fields:
 - a. Name of the IBC that assessed this dealing

Note: If your IBC isn't shown here, this means it has not been connected to your organisation in our database. Please contact the OGTR to discuss.

- b. IBC Identifier
- c. IBC Assessment Date

Note: If this date is outside of the allowable assessment date for the current reporting period, you will be asked to explain why.

Name of the organisation giving notice of the dealing	
Test Organisation	
Name of the Institutional Biosafety Committee (IBC) that assessed this dealing *	
If the IBC you wish to select does not appear in the drop-down list, please email the OGTR or phone on 1800 181 030 to make sure all IBC's accertance your organisation have been reported.	essed by
Test Institutional Biosafety Committee	~
IBC NLRD Identifier *	
NLRD-1234	
IBC Assessment Date *	
08/01/2023	

2. Enter details of "Organisation(s) proposing to undertake this dealing" by selecting the [Add Organisation] button, this will display the "Add Organisation proposing to undertake this dealing" sub-form.



Add an accredited organisation from the look-up list:

1. Answer "Yes" to the question "Do you wish to add an accredited organisation" and search for an accredited organisation name using the magnifying glass.

Do you wish to add an accredited organisation?		
💽 Yes 🗌 No		
Name of accredited organisation proposing to undertake this deal	ng *	
Click the magnifying glass to search		
The accredited organisation did not appear when I searched		
The accredited organisation did not appear when I searched		



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2. Type the name of the organisation into the search bar and press enter or click the magnifying glass to search.

Note: To search for an organisation you must start typing the first characters of the organisation's name. If the organisation name starts with "The" you will need to search using the term "The"

Lookup records	×
	Test Q
Choose one record and click Select to continue	
✓ Organisation Name ↑	
Test Organisation	
	Select Cancel Remove value

- 3. Once you have found the relevant organisation, tick the box next to the organisation name and choose [Select] to add the name.
- 4. You will return to the "Add Organisation proposing to undertake this dealing" sub-form, select [Add] to add the organisation to the NLRD record.

Do you wish to add an accredited organisation?	
Name of accredited organisation proposing to undertake this dealing * Click the magnifying glass to search	
Test Organisation	x Q
The accredited organisation did not appear when I searched	
Add Cancel	

Manually add an accredited organisation:

If the organisation did not appear when you searched for it, you may need to add it manually.

1. Answer "Yes" to the question "Do you wish to add an accredited organisation" and select "The accredited organisation did not appear when I searched"



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2. Manually enter the name of an accredited organisation

 Name of accredited organisation proposing to undertake this dealing
Click the magnifying glass to search
The accredited organisation did not appear when I searched
Name of organisation proposing to undertake this dealing *
ACT Organisation
Add Cancel

3. Select [Add] to add the organisation to the NLRD details

Add a non-accredited organisation

- 1. Select "No" to the question "Do you wish to add an accredited organisation"
- 2. This will allow you to enter the name of a non-accredited organisation.
- 3. Select [Add] to add the organisation to the NLRD details.

Do you wish to add an accredited organisation? Yes No Name of non-accredited organisation/person proposing to undertake this dealing *? Other Organisation Add Cancel	The name of an individual should only be entered here if the NLRD is actually being undertaken by an individual who is not associated
Reminder: You can add multiple organisations, in cases of collaborative research for example, by repeating the above steps (see below image). You can use any combination of the above methods for one NLRD record.	
Organisation(s) proposing to undertake this dealing * 😯	tion
Name of Organisation 🛧	_
ACT Directorate	
Other Organisation	

Reminder:



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NLRD Details continued

- 1. Enter details in the following mandatory fields:
 - a. Project Title
 - b. GMO Details

Project Title *
This is a project title
GMO Details *
Please provide the genus and species (where known) and for please separate by a comma, or semi colon.
These are GMO details
Dealing Type
Please tick all Schedule 3 classifications below that apply to the Where applicable, NLRD subtypes will be automatically select OGTR on 1800 181 030 or ogtr.applications@health.gov.au

c. Dealing Type (Select one or many as applicable)

Note: If the dealing type has a mandatory subtype that requires manual selection, the form will provide guidance on this as shown in the image below.



Reminder: Dealing types selected here must match your IBC Record of Assessment (RoA).

2. Once all mandatory fields are complete, select [Save and close], located at the bottom of the screen.



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- Continue adding NLRDs by repeating the above steps, or view/filter the NLRD grid (see details about the NLRD grid below) to check you have recorded all NLRDs that you intend to report.
- 4. To move on to entering "Contact Details", select [Save and Next].

Drafting & coming back to NLRDs

If at any point you do not wish to continue entering details about an NLRD, you may select [Save and close]. However, the 'NLRD Details' sub-form cannot be saved unless **all mandatory fields have been completed.** If you have saved an NLRD record, you can still edit the details of that NLRD after saving and closing the record.



The NLRD Grid

This is a view of all the NLRD records in your submission. It shows useful information about your NLRDs (as shown in the below image). From this view, you can do the following by selecting the arrow next to the relevant NLRD record:

- Edit NLRD records
- Delete NLRD records
- Clone NLRD records (see below for further details)

Note: The grid can be sorted by any of the available columns, by clicking on that heading.

IBC NLRD Identifier	IBC Assessment Date	Project Title	IBC Name	
NLRD5	02/07/2023	Project Title	Test Institutional Biosafety Committee	Edit Delete
NLRD4	01/07/2023	This is a project title	Test Institutional Biosafety Committee	Clone



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The NLRD grid is limited to displaying 10 NLRD records on each page. Pages can be scrolled through by selecting the arrows below the grid

NLRD13	02/07/2023	Proj Title	Test Institutional Biosafety Committee	
NLRD14	02/07/2023	Project Titles	Test Institutional Biosafety Committee	
NLRD15	02/07/2023	Project Title	Test Institutional Biosafety Committee	
NLRD5	02/07/2023	Project Title	Test Institutional Biosafety	



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Adding multiple similar NLRDs using the Cloning tool

Cloning NLRDs allows you to copy some of the details of a specific record. Not all details can be copied; those that are often repeated across different records can be. Some of the available fields are selected by default when you select the 'clone' option and some fields, such as 'GMO Details' and 'Project Title' cannot be copied from one record to another at all.

- 1. To clone an NLRD, select [Clone] from the dropdown next to an individual record. The form will prompt you to complete the following fields:
 - a. The number of NLRDs you wish to create
 - b. Which fields you would like to copy to the newly created records.

How many NLRDs would you like to create from the selected record?				
A maximum of 20 NLRDs in total can be attached to the submission, including the one being copied				
Please select the fields to copy into each new NLRD:				
	Name of the Institutional Biosafety Committee (IBC) that assessed this dealing			
	IBC Assessment Date			
	Reason why the NLRD was not reported within the required period			
	Organisation(s) proposing to undertake this dealing			
	Dealing Type			
	Clone Cancel			

- 2. Select [Clone] at the bottom of the form
- 3. You can only have a maximum of 20 NLRDs per submission, including the record you are trying to clone. If the amount you enter results in the total number of records in the form being greater than 20, you will see the following error. In this case, select a lower number of NLRDs to clone.





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- 4. Any NLRDs that have been cloned will require additional information to be entered. The relevant NLRDs will be marked with an exclamation mark next to the IBC NLRD Identifier.
 - Once you have edited an NLRD to include the required information, the exclamation mark will disappear.
 - The form location tile will also indicate if any NLRDs are incomplete

	IBC NLRD Identifier
A	



Contact Details

On the contact details page, you are required to enter the details of the Application Contact for the submission.

1. Click on the magnifying glass to open the search window

person from your organisation you would like to nominate as a contact for this
person from your organisation you would like to nominate as a contact for this
ring glass to search
Q
ontact name does not appear when searched, please contact the OGTR by 1800 181 030 (ask to speak to the Application Entry Point section) or email <u>plications@health.gov.au</u>
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2. In the new window, type a name, or part of a name into the search bar, and press enter or click the magnifying glass to search.

		- \ <u>-</u>
Lookup records	×	R R
		sc 🔰
	Jamie Q	jo 🖌
Choose one record and click Select to continue		ne
✓ Full name		re
Jamie Bloggs		<i>"ו"</i>
		Ca
		re
		da
		th
		th
		th
	Select Cancel Remove value	th

Reminder: To find someone in the list of contacts, they will need to already be recorded as an "Nominated Contact" in OGTR records. If a contact does not appear in the list, please follow the instructions on the page to have them added.

1



3.

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Choose o	record and click Select to continue
~	Full name
	Jamie Bloggs
	Select Cancel Remove value

Once you have found the correct contact, tick the box next to their name and choose [Select] to add the contact.

4. Back on the "Contact Details" page, you will see the name of the contact is now showing in the Contact Name box. You can now move on to the next page.

Contact Name *		
Please select the person from your organisation you would like to nominate as a contact for this submission.		
Click the magnifying glass to search		
Jamie Bloggs	×Q	

Saving a draft submission

If at any point you wish to exit the form, you can close the browser or navigate back to the "Services" page using the tabs at the top of the page.

Home	Services
Home →	Notifiable Low Risk Dealing (NLRD) Reporting Form



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The [Save and Close] button can be used to exit a submission with incomplete information on a page, saving the information you have entered until that point. However, you will be unable to progress the form using [Save and Next] until all required information on the page has been completed.

	IBC NLRD Identifier 🛧	IBC Assessment Date	Project Title	IBC Name
	NLRD-1234	11/01/2023	Project Title	Test Institutional Biosafety Committee
Pr	revious Save and Close	Save and Next		

When you access a draft submission, it will open from the last save point. Completed form tabs before this will be green.

Note: You will need to navigate through the form using the "Save and Next" buttons at the bottom of the screen, not by clicking on the chevron icons on the left-hand side of the page.



How the menu appears with no tabs marked as "completed"

How the menu appears when some tabs are marked as "completed"

How the menu appears when all tabs are marked as "completed" and the form is ready for submission.



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Declaration page

On the Declaration page, you will be required to make a legal declaration prior to submitting. You will have the opportunity to decide how to make this declaration, i.e. hard copy signature or a declaration checkbox.

Electronic declaration

- 1. To make a declaration electronically:
 - a. select 'No' to the question "Do you need to have this report signed in hard copy?"

Declaration		
Do you need to have this report signed in hard copy? *? Yes No		

b. Ensure the nominated contact shown in bold in the first paragraph is correct

Note: In this example, that contact is Jamie Bloggs.

c. Ensure that your name, as the person making the declaration, is shown in the declaration text.

Note: This may or may not be the same person as the Nominated Contact. In this example, the logged in user, who is the person making the declaration is **Jane Doe**

	Nominated Contact
	The nominated contact for this submission is Jamie Bloggs A copy of the submission will be sent to the: • Submitter of this form • Nominated contact • Organisation primary contact • Organisation secondary contact
Person making the declaration	 Jane Doe, declare that: I am a person authorised to submit this form; to the best of my knowledge, the information supplied on this form and any other attachment(s) is not false or misleading; I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the <i>Gene Technology Act 2000</i> and corresponding state law; by including my name on this form it is deemed to be my signature for the purpose of this form.

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d. To make the declaration shown on the screen, select the checkbox "I agree to this declaration".



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Hard-copy declaration

- 1. To make a declaration in hard copy:
 - a. Select 'Yes' to the question "Do you need to have this report signed in hard copy?"



- b. Select [Print hard copy]
- c. A PDF copy of your form will be downloaded

1. Print and Sign Click the print button bellow to generate a hard copy version of this reporting form. Please ensure that your browser allows for pop-ups in order to print the hard copy. Print hard copy
Submission Number: SUB-000064
Creating submission document. Your download should start shortly

2. The PDF has information about the submission, such as the date the document was generated and the Submission ID:

	Australian Government Department of Health and Aged Care Office of the Gene Technology Regulator	Document generated on: 22/05/2023 at 15:14 AEST/AEDT Submission reference: SUB-000064					
Notifiable Low Risk Dealing (NLRD) Reporting Form							

3. The PDF must be signed and uploaded to submit the form. **Note:** You must change the file name for the signed copy that you upload, this helps to ensure that the unsigned copy is not accidentally uploaded.



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a. Ensure the PDF is signed in the necessary place and upload the document by selecting "Upload file"

Lagree to this declaration *	2. Upload signed hard copy *	
Signature: Name:	 Files you upload must be: *.xls,*.xls,*.pdf,*.doc,*.docx,*.jpg,*.jpeg,*.tif,*.tiff,*.png, or *.zip format no larger than 5MB each no larger than 50MB in total 	
Position:		
Date:	Upload file	

Submitting the form

1. Once you have completed the declaration, select [Submit]



- 2. At this point, the form will check to ensure that all reporting requirements are still met:
 - a. For example, if you have had the form open for some time and the IBC assessment date is now outside of the allowable assessment date for the current reporting period, you will not be able to submit the form.
 - b. In this instance, the form will show an exclamation mark next to the NLRDs that require updating. You will need to navigate back through the form and provide required information in order to submit the form.
- 3. If all form requirements are met, you may see a status bar (shown in below image). If submission is successful, it will no longer be available on the "Draft submissions" tab.

Notifiable Low Risk Dealing (NLRD) Reporting Form Submission Number: SUB-000221					
	Information	Declaration			
		Do you need to have this report signed in hard copy? * ?			
	Confidential Commercial Information				
		Please wait 50%	A copy of the submission will		
	Proposed NLRD	Organisation printing contact Organisation secondary contact			

Following Submission

Following submission of a form, the following contacts will receive an acknowledgement of receipt email containing a copy of the PDF receipt:

- Primary contact
- Secondary contact (where one is recorded for the organisation)
- Nominated application contact



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• Person that submitted the form

If any issues are identified with your submission, the OGTR will contact you. Additionally, if you need to contact the OGTR regarding your submission, your form submission email will contain a reference number you can refer to.

Following submission, individual NLRD records will be assigned OGTR identifiers. They can be viewed on the "NLRD" tab of the "Services" page. See below for further guidance.

Accessing draft or completed submissions

Submission records are only used while a submission is being drafted. After submission the record will no longer appear on the "Draft submissions" tab in a service.

"Draft submissions" tab - shows forms that have not yet been submitted.

"NLRDs" tab – shows individual NLRDs and limited information about them including status, OGTR identifier and expiry date.

Completed NLRD form submission will generate NLRD records that appear on the NLRDs tab.

Information about using the dashboards can be found in the "OGTR Online Services Portal User Guide".