Compliance by Design

Translating regulatory requirements into a guided, auditable workflow

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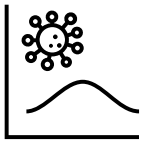
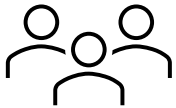
CRICOS 00026A TEQSA PRV12057

What I stepped into



Just post-lockdown

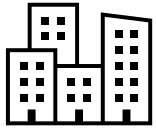


New team



IBC responsibility





120+ certs across 6 facility types

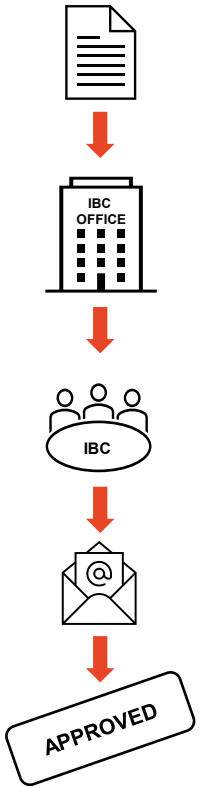


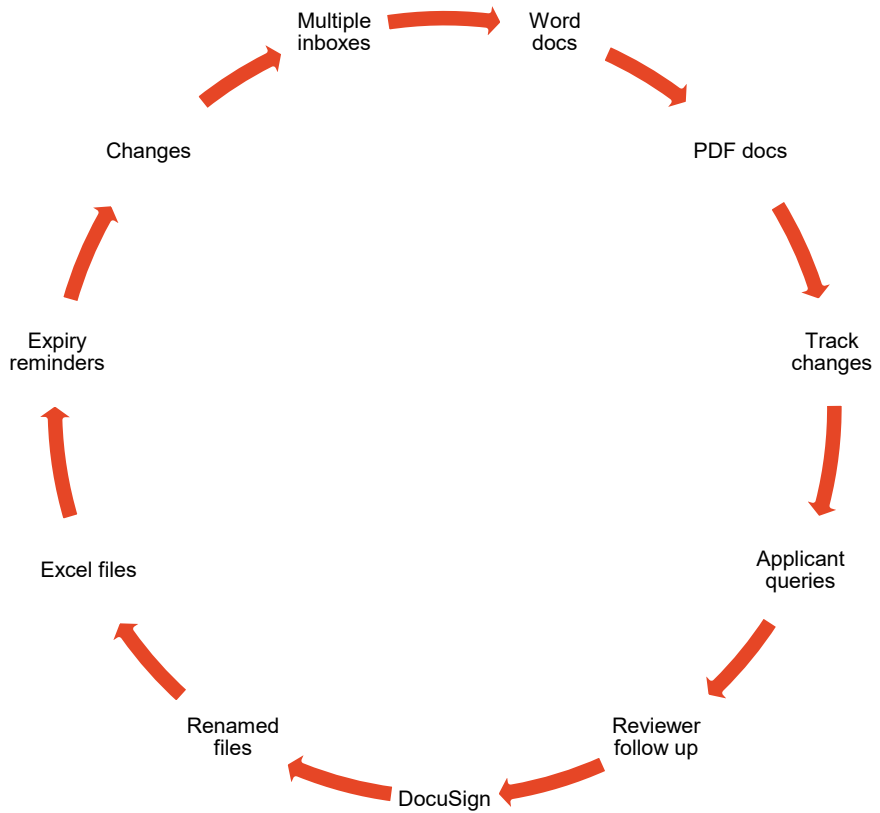
200+ live NLRD + 5000 Exempts



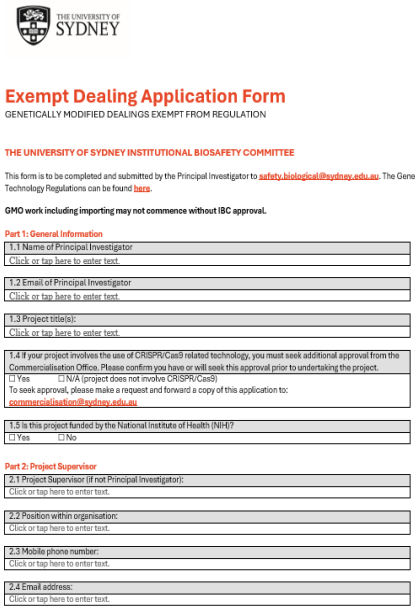
More complex applications

Perceived workflow vs actual workflow





The old forms were not broken



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Exempt Dealing Application Form

GENETICALLY MODIFIED DEALINGS EXEMPT FROM REGULATION

THE UNIVERSITY OF SYDNEY INSTITUTIONAL BIOSAFETY COMMITTEE

This form is to be completed and submitted by the Principal Investigator to safety.biological@sydney.edu.au. The Gene Technology Regulations can be found here.

GMO work including importing may not commence without IBC approval.

Part 1: General Information

1.1 Name of Principal Investigator
Click or tap here to enter text.

1.2 Email of Principal Investigator
Click or tap here to enter text.

1.3 Project title(s):
Click or tap here to enter text.

1.4 If your project involves the use of CRISPR/Cas9 related technology, you must seek additional approval from the Commercialisation Office. Please confirm you have or will seek this approval prior to undertaking the project.
☐ Yes ☐ N/A (project does not involve CRISPR/Cas9) To seek approval, please make a request and forward a copy of this application to: commercialisation@sydney.edu.au

1.5 Is this project funded by the National Institute of Health (NIH)?
☐ Yes ☐ No

Part 2: Project Supervisor

2.1 Project Supervisor (if not Principal Investigator):
Click or tap here to enter text.

2.2 Position within organisation:
Click or tap here to enter text.

2.3 Mobile phone number:
Click or tap here to enter text.

2.4 Email address:
Click or tap here to enter text.



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IBC Ref. Number (IBC Use Only)

NLRD Application Form

NOTIFIABLE LOW RISK DEALING

THE UNIVERSITY OF SYDNEY INSTITUTIONAL BIOSAFETY COMMITTEE

This form is to be completed and submitted by the Principal Investigator to safety.biological@sydney.edu.au. The Gene Technology Regulations can be found here.

GMO work including importing may not commence without IBC approval.

Part 1: General Information

1.1 Name of Principal Investigator
Click or tap here to enter text.

1.2 Email of Principal Investigator
Click or tap here to enter text.

1.3 Project title(s):
Click or tap here to enter text.

1.4 Is this application to replace an existing or expiring NLRD?
☐ Yes (Go to question 1.5) ☐ No (Go to Question 1.7)

1.5 Expiring NLRD approval number/s:
Click or tap here to enter text.

1.6 Please confirm that all work covered under your expiring NLRD(s) is covered under this new application:
☐ Yes ☐ No (if no, please explain your answer below) Please highlight any significant changes between this application and your expiring application within the body of this application: Click or tap here to enter text.

1.7 If your project involves the use of CRISPR/Cas9 related technology, you must seek additional approval from the Commercialisation Office. Please confirm you have or will seek this approval prior to undertaking the project.
☐ Yes ☐ N/A (project does not involve CRISPR/Cas9) To seek approval, please make a request and forward a copy of this application to: commercialisation@sydney.edu.au

1.8 Is this project funded by the National Institute of Health (NIH)?
☐ Yes ☐ No

Goal: process reliability (not just digitisation)

We joined an existing institutional journey

2022

AEC & HREC plan, tender and evaluate

2023

AEC & HREC contract and platform build

Mar 2024

HREC launch

Nov 2024

AEC launch

2025

AEC and HREC: Monitor, evaluate and improve

Nov 2025

IBC invited to the F1 party



Oh, the possibilities

WE COULD BUILD…A GUIDED REGULATORY CONVERSATION…

- Lookups
- Conditional questions
- Guidance
- Warnings
- Validation
- Linked dealings
- Milestones
- Automated notifications



Potential to build a form that was a guided regulatory conversation

Translating regulation into system logic

REGULATION

What must be established?

INTERPRETATION

What information would establish it?

QUESTIONS

How do we ask without supplying the answer?

SYSTEM

When does the form show, link, warn, stop or escalate?

Each regulatory requirement had to become a question, decision or system response

One regulatory question becomes many decision points

Example: GM mouse



Does the proposed work meet Schedule 3, Part 1, item 1.1(a)?

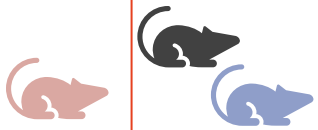
To determine this, the form must assess:

- Animal eligibility
- Nature of the genetic modification
- Potential selective or survival advantage
- Infectious-agent potential
- Source and method of generation
- Associated organisms
- Downstream dealings
- Transport and disposal

A single dealing could trigger 30 fields, 15 logic checks and links to other dealings

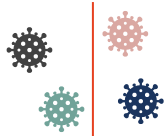
One project can involve multiple linked dealings

NLRD 1.1(a)
GM mice



Will another GMO be introduced into this host?
Yes → create a link

NLRD 2.1(l)
Generate lentivirus



Will this GMO be introduced into a host?
Yes → create a link

NLRD 2.1(m)
Combined dealing



Select the host and vector dealings + assess risks of combination

The system needed to recognise the relationship without merging distinct regulatory dealings

Guide the thinking, do not replace it

PROMPT

Relevant issues and requirements

EXPLAIN

Regulatory terms and concepts

ESCALATE

Uncertainty or potential ineligibility

PRESERVE

Expert assessment and judgement

The form supports assessment; it does not determine compliance

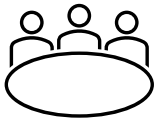
Testing



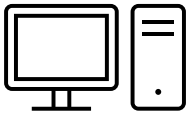
Users



IBC Office



IBC



F1 & ICT

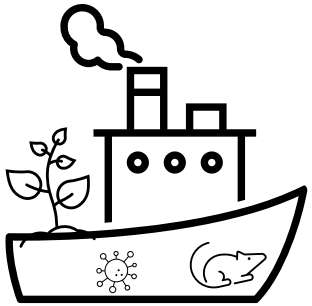
- Security & privacy
- Logic – common & unusual pathways
- Linked dealings
- Warnings
- Dropdowns
- Output documents
- Email templates
- Back-end administration
- Data migration
- Reporting & audit trail

Launch

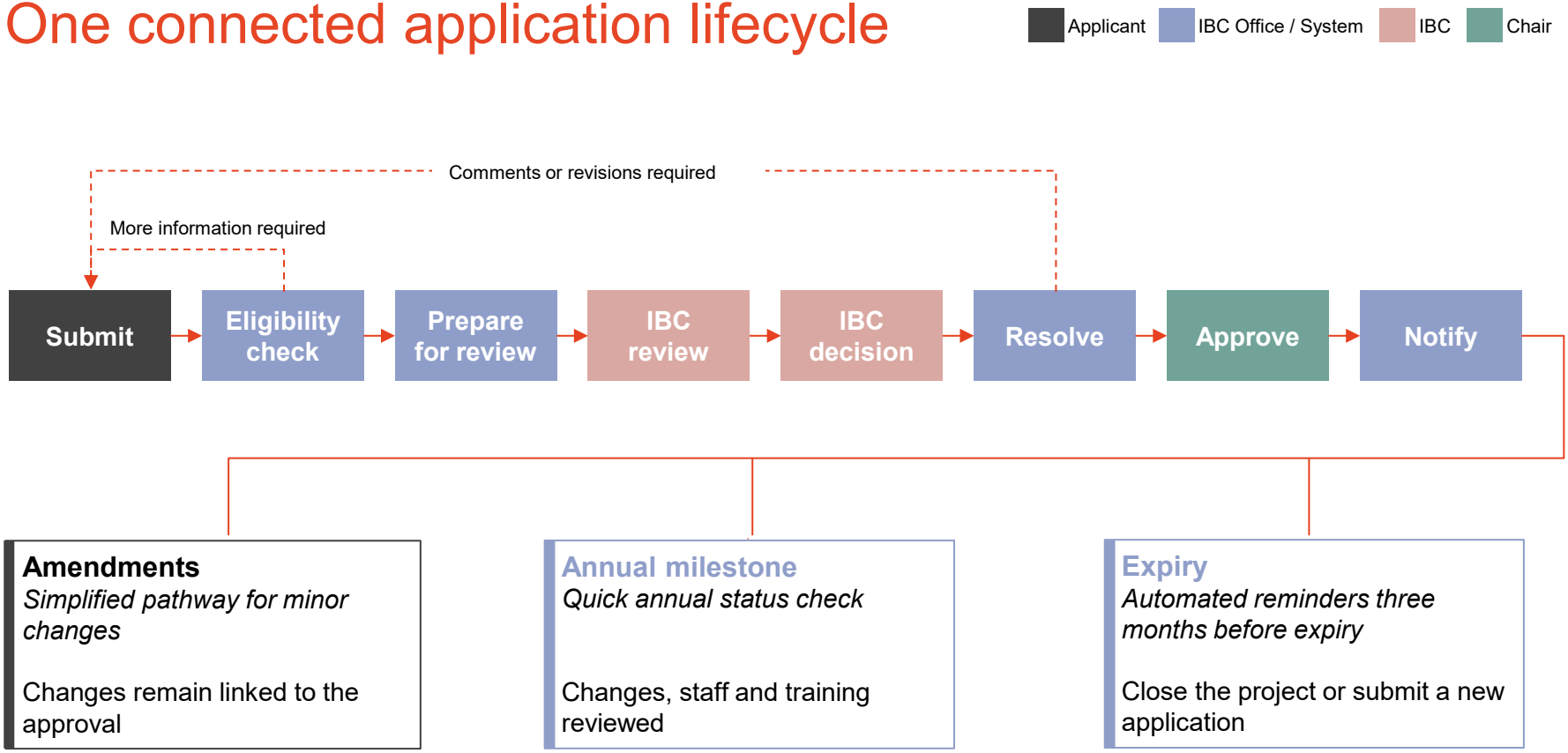
- Communications
- Data migration
- Knowledge Based Articles
- SOP development

→ **April 2026** – Exempt Dealing Form launched

→ **July 2026** – NLRD Form launched



One connected application lifecycle



One record connects submission, review, decisions and post-approval oversight



Design Build Test Launch Refine

The human change

APPLICANTS

- More guided questions
- More reasoning before submission
- Transition support

IBC MEMBERS

- New review interface
- Changed review workflow
- Trust, but verify, the logic

IBC OFFICE

- More triage and data-quality work
- Less document handling
- Ongoing logic maintenance

INSTITUTION

- System support and governance
- Records, archiving and reporting
- Continuous maintenance and improvement

Training supports every part of the change

Early outcomes and lessons

Early outcomes

- Exempt and NLRD workflows launched
- Applications, reviews and records connected
- Conditional logic and linked dealings operational
- Improved traceability, with 20 Exempt dealings identified and closed

Currently evaluating

- User experience after a larger number of submissions
- Whether application quality and completeness improve
- Effects on review and processing time
- Administrative workload and where it has shifted
- Recurring gaps identified through real cases

Lessons so far

- Establish design principles early
- Treat logic and testing as dedicated workstreams
- Involve users early and repeatedly
- Maintain a decision catalogue
- Expect the form to evolve

Launch established the foundation

Evidence will shape what comes next.

Thanks

- Dr. Christopher Denes & Lan Le (IBC Office)
- A. Prof. Mary Byrne (IBC Chair)
- A. Prof. Megan Steain (IBC Deputy Chair)
- Digital Sydney
- USYD AEC & HREC
- USYD ICT team
- Testers & users
- OGTR Team

Questions?



Health, Safety & Wellbeing
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Migration and amendments

Migration



- Transfer core approval data
- Retain the original signed RoA
- Transition activity into the platform when further action is required

Change control



- Amendments do not amend an RoA
- Changes are assessed as administrative, within scope or requiring new approval
- Work does not commence until written advice is issued