UNIVERSITY
OF WOLLONGONG
AUSTRALIA

WHS Unit

# REDCap Biosafety User Guide

# Contents

# 1. Introduction

This REDCap Biosafety User Guide provides instructions for staff and students regarding how to:

- Access the REDCap Biosafety database, including creating a REDCap account
- Create a Biosafety Project
- Complete a Biological Record form
- Complete an Application/Registration
- Submit an Application/Registration
- Determine the status of an application
- Use the REDCap Reports tool
- Complete or end a Biosafety Project
- Submit Annual Reports or Amendment Requests
- Nominate a Data Access Group

# 2. The role of the Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC), on behalf of UOW, co-ordinates compliance with the relevant legislation and standards and provides advice on risks associated with infectious organisms, biohazardous materials, genetically modified organisms and materials requiring quarantine containment. These regulations cover the import/export, transport, storage and handling of biological materials.

# 3. Biosafety Applications

If your research, teaching or service activities involve biological materials, you must submit a Biosafety Application via REDCap for review by the Institutional Biosafety Committee (IBC).

Depending on the nature of the work and the microorganisms involved, the application will fall into one of two categories:

- **Notification**

  For low-risk activities involving Risk Group 1 biological materials. A risk assessment will also need to be attached to the application.

- **Approval**

  For higher-risk activities, including those involving Risk Group 2 biological materials and GMOs. The application must also include relevant risk assessments, safe work procedures and research protocols.

For further information regarding the classification of biological materials and whether the Biosafety Application is for Notification or Approval purposes, refer to the UOW Biosafety and Gene Technology webpage.

# 4. The REDCap Biosafety Database

The REDCap Biosafety Database is an online platform to manage biological material details, biosafety applications and related documents, such as annual reports and amendment requests.

In REDCap Biosafety, a project's biosafety information is stored within a **Biosafety Project**. A **Biosafety Project** contains the **Application Registration** form and **Biological Record** details, approval details and **Annual Reports**.

To submit an application to the IBC, the following needs to be completed within REDCap Biosafety:

- Create a **Biosafety Project**
- Enter the project's biological materials information in the **Biological Record** form
- Complete the **Application/Registration** form, including selecting the relevant Facility Manager/s and Head of School for Approval and attaching relevant risk assessments, safe work procedures and other applicable documentation.
- Submit the **Application/Registration** form

REDCap Biosafety is also used to determine the status of an application, complete or end a Biosafety Project as well as submitting Annual Reports and Amendment Requests.

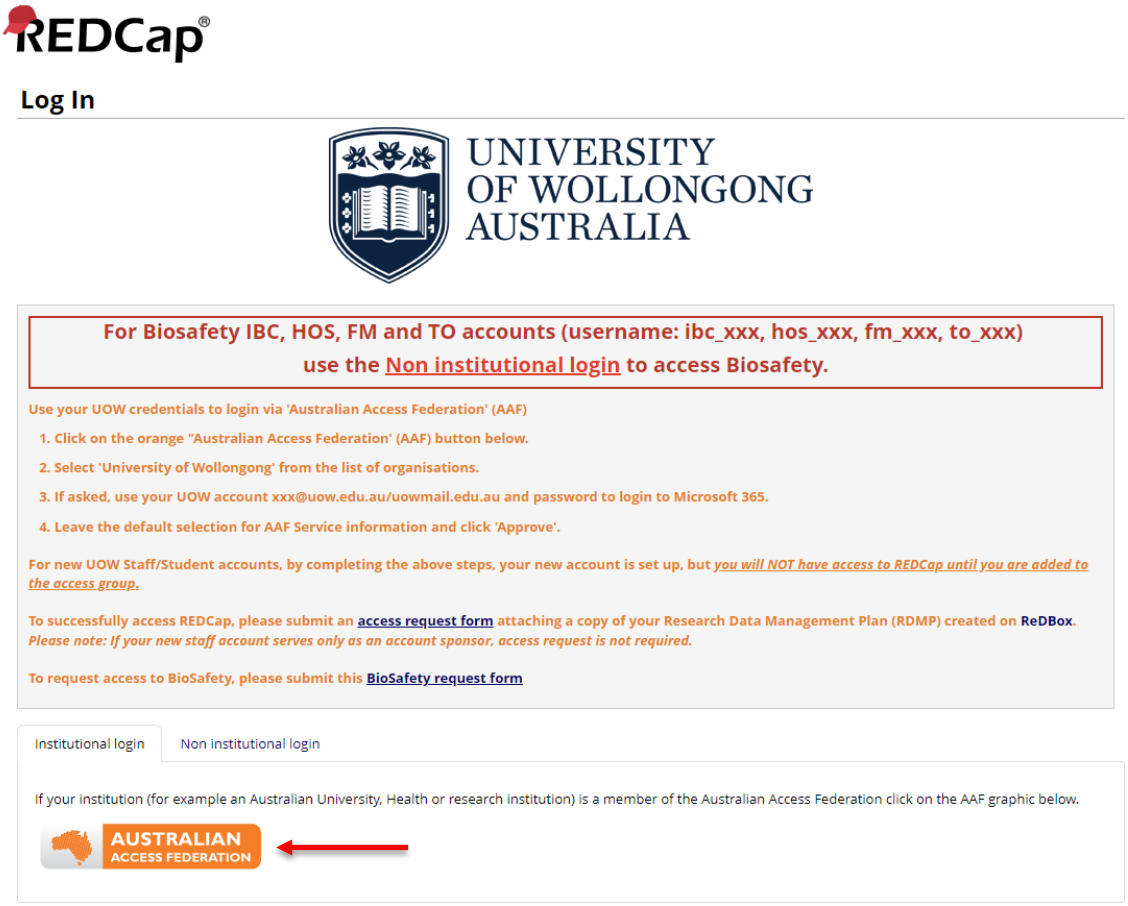
The sections following provide guidance on how to complete the above activities within REDCap Biosafety.

# 5. Accessing REDCap Biosafety

## 5.1 CREATE A REDCAP ACCOUNT

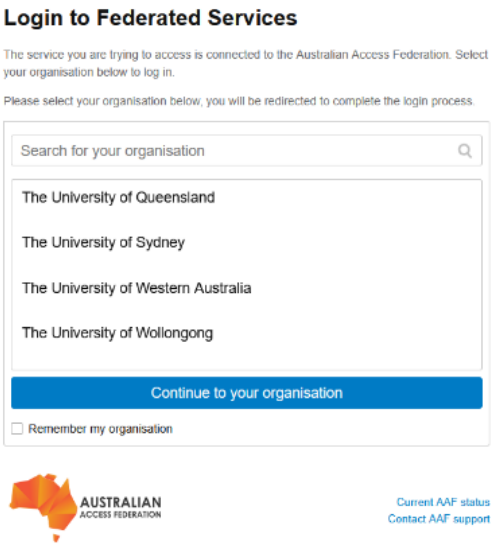
In order to access REDCap Biosafety, users will need to create a REDCap account first. If you already have an account, proceed to section 5.2, otherwise follow the steps below:

5.1.1 Access the REDCap Homepage via:
https://redcap.uow.edu.au/redcap/redcap_v15.0.9/index.php?pid=940



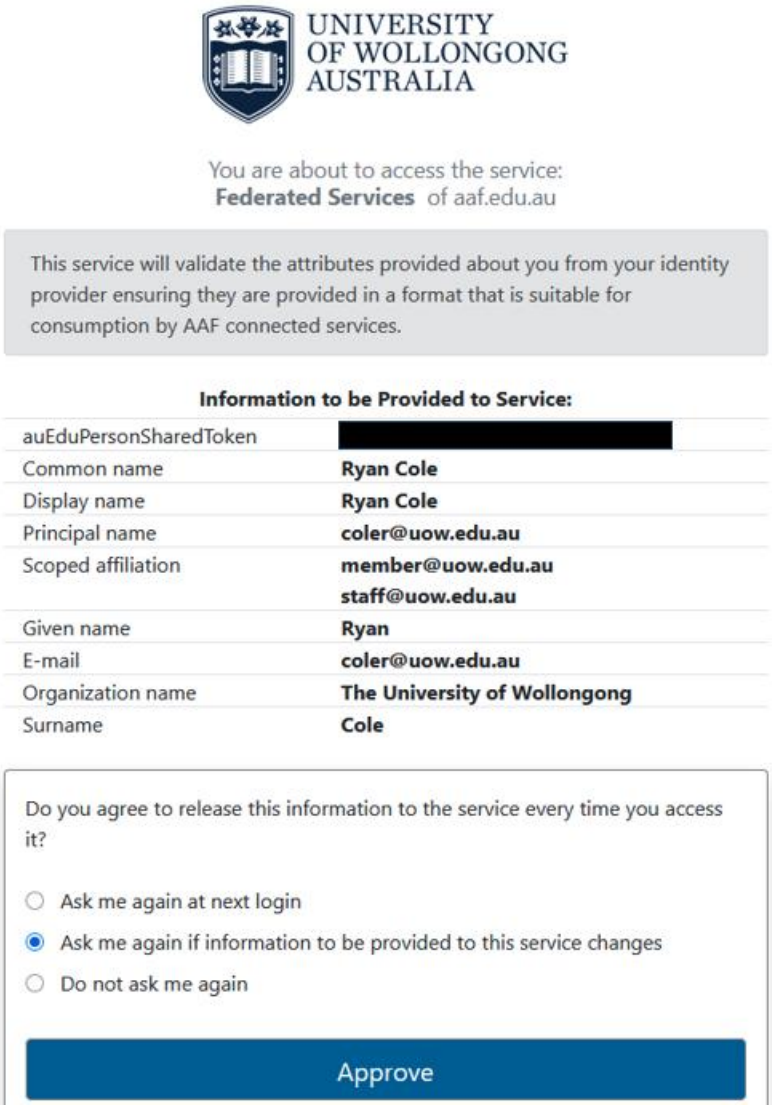

5.1.2 Use your UOW Credentials to login via 'Australian Access Federation (AAF)':

- Click on the orange 'Australian Access Federation (AAF)' icon.
- Select 'University of Wollongong' from the list of organisations.




- If asked, use your UOW account xxxxx@uow.edu.au/uowmail.edu.au and password to login to Microsoft 365.

- Leave the default selection for AAF Service information and select ‘Approve’.

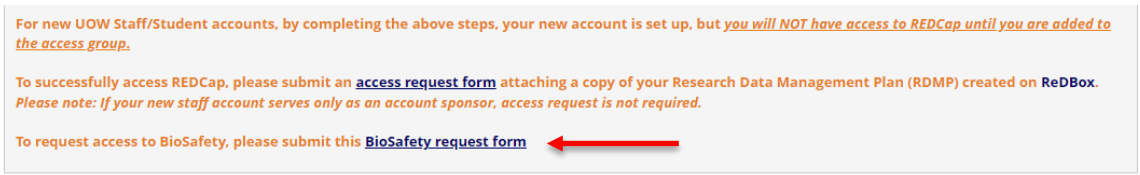



- You will receive email notification when your account has been successfully set-up.

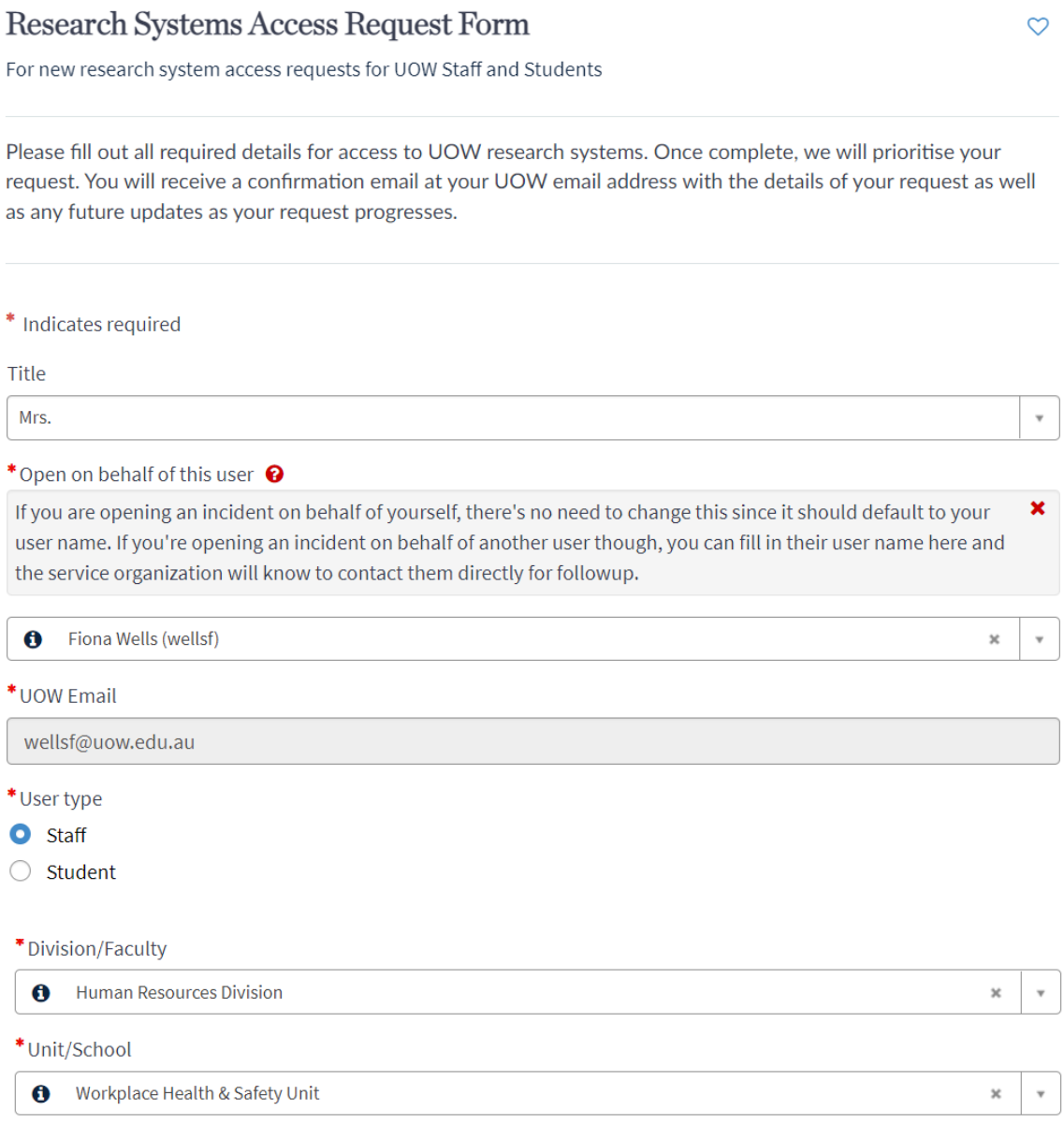
## 5.2 SET-UP ACCESS TO UOW BIOSAFETY

5.2.1 Once the REDCap account has been set-up, access the REDCap Homepage via https://redcap.uow.edu.au/redcap/redcap_v15.0.9/index.php?pid=940.

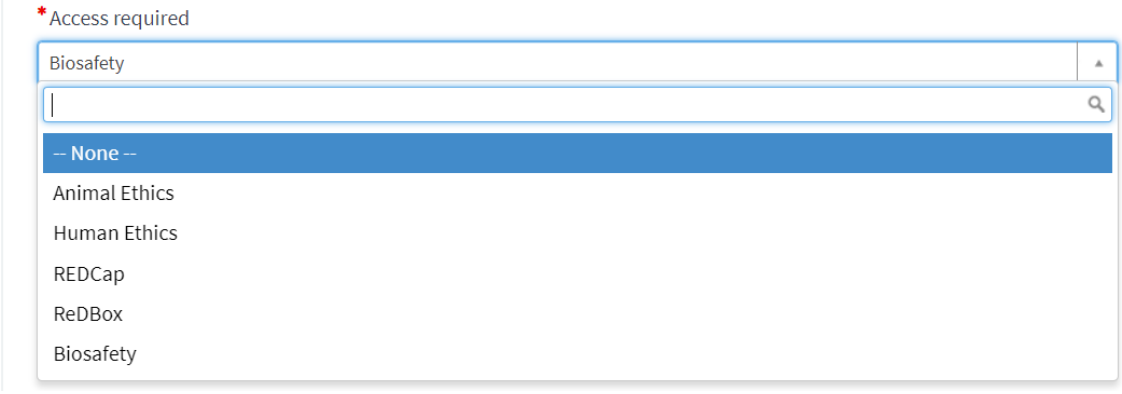
5.2.2 Request access to REDCap Biosafety using the Research Systems Access Request Form. Access to this form can also be obtained by selecting the 'Biosafety request form' link located at the bottom of the UOW REDCap homepage.



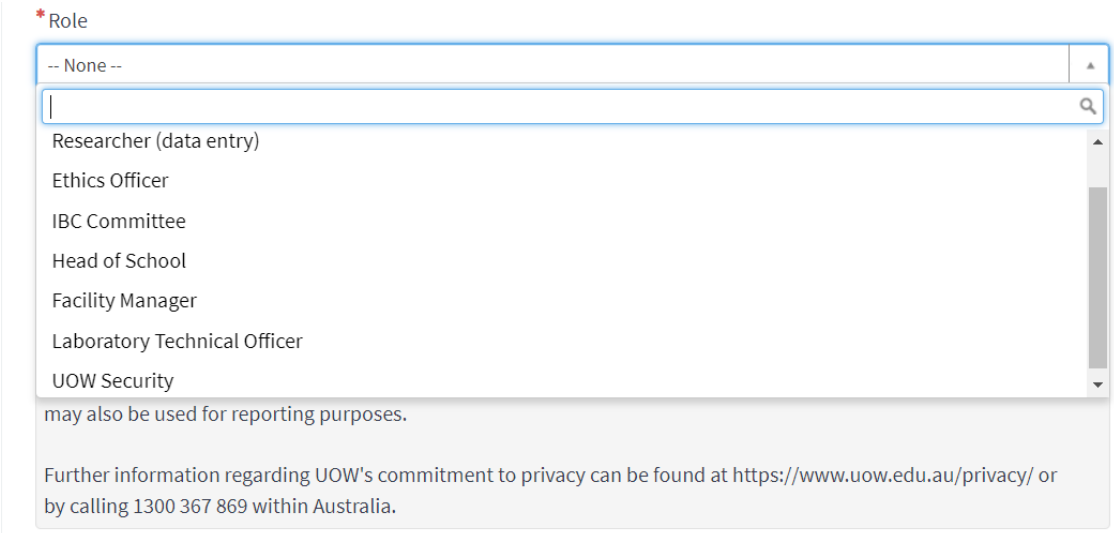

5.2.3 Complete and submit the Research Systems Access Request Form. An example is provided in the sections below.



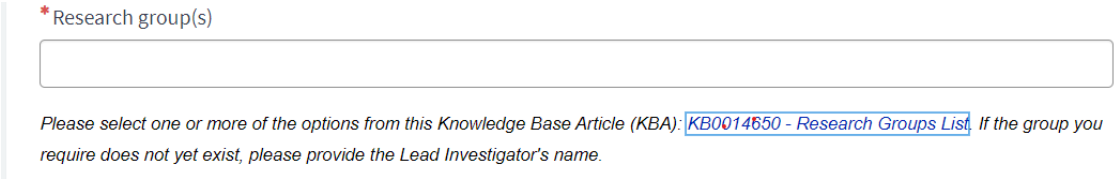
5.2.4 For access to REDCap Biosafety, select Biosafety in the 'Access required' field.




5.2.5 You will then be prompted to select your role when accessing REDCap Biosafety. If you are a researcher, select 'Researcher (data entry)'.
*Note: If you require access to REDCap Biosafety for two purposes (i.e., two roles), for example, researcher and IBC Member, two separate access request forms will need to be submitted, as each role will require different logins.*




5.2.6 If you selected 'Researcher (data entry)' as your role, you will then be prompted to list the relevant research group/s. The Knowledge Base Article – Research Groups List provides a list of current research groups in the REDCap Biosafety Database. If the group you require does not yet exist, please provide the Lead Investigator's name in the space provided.




5.2.7 You will then be prompted to upload your Biosafety and GMO Training Certificates.

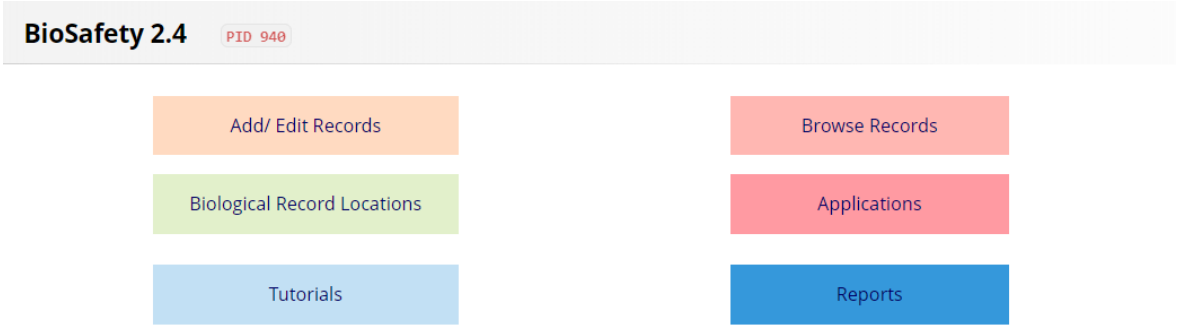
5.2.8 Once all the required fields have been completed, selected **Submit**.

5.2.9 You will receive an email once your access request has been approved.

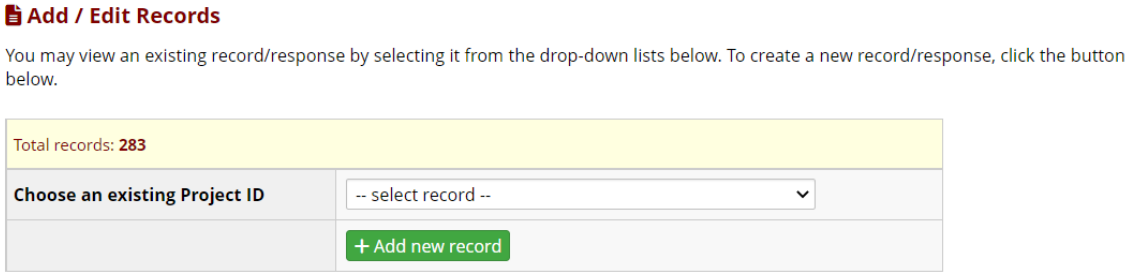
# 6. Creating a Biosafety Project

**6.1** Login to REDCap Biosafety.

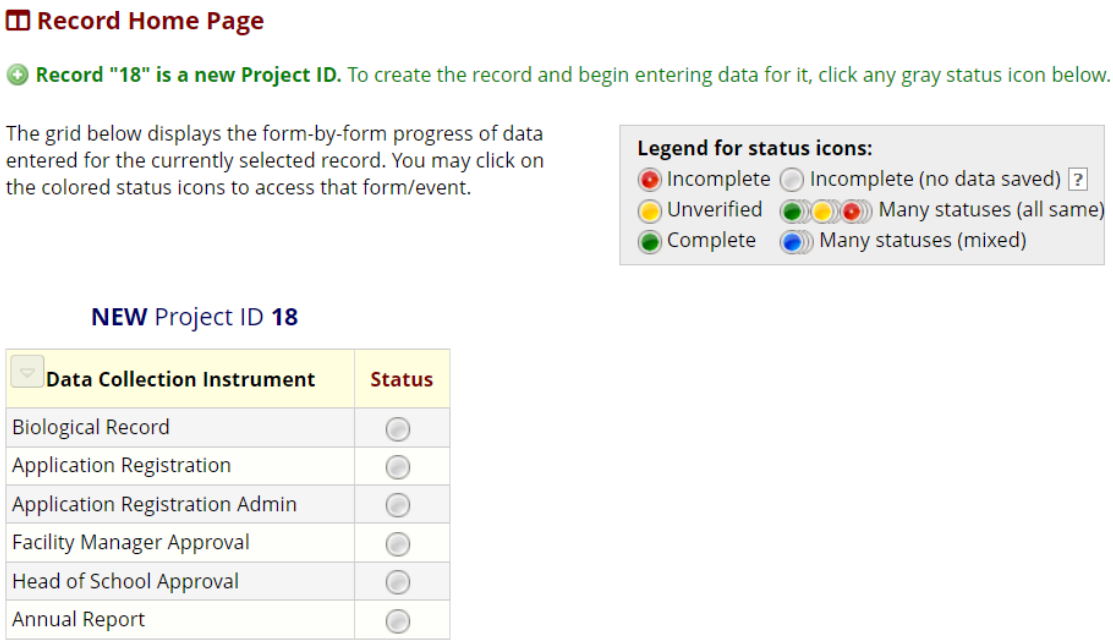
**6.2** From the Homepage, select **Add/Edit Records** to create a new Biosafety Project



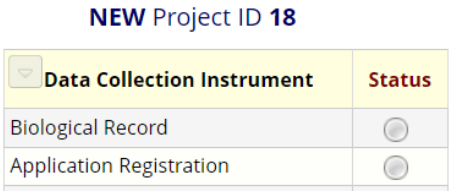

**6.3** Select **+ Add new record**



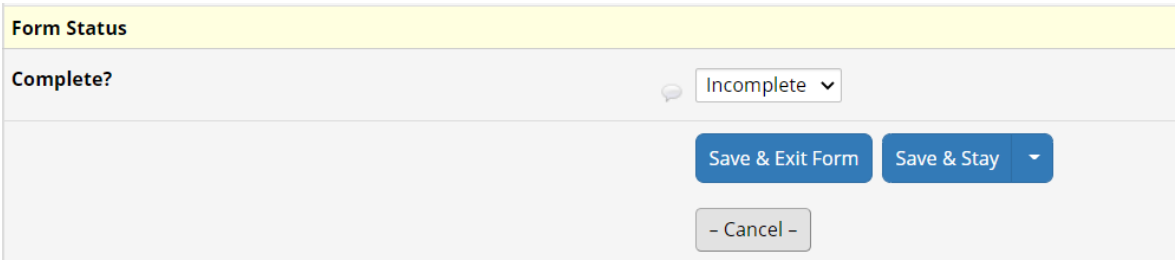

**6.4** The **Record Home Page** will then display details of the Biosafety Project just created.



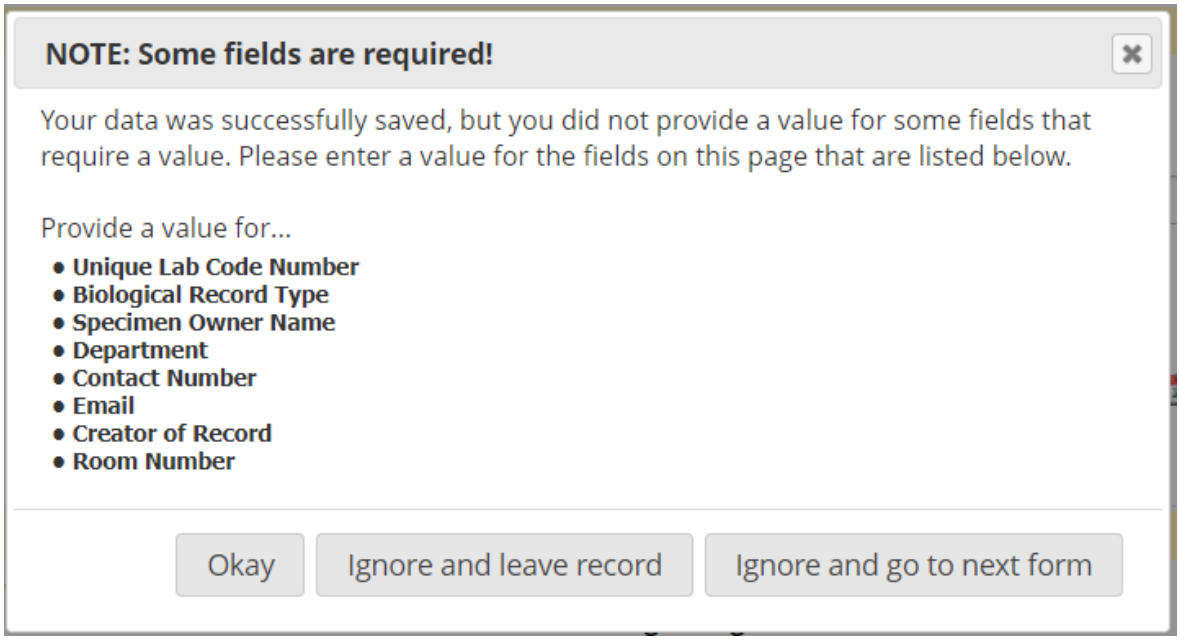
**6.5** Partially complete either the **Biological Record** or **Application Registration** to save the Biosafety Project. Select the grey radio button adjacent to **Biological Record** or **Application Registration** to open either form.



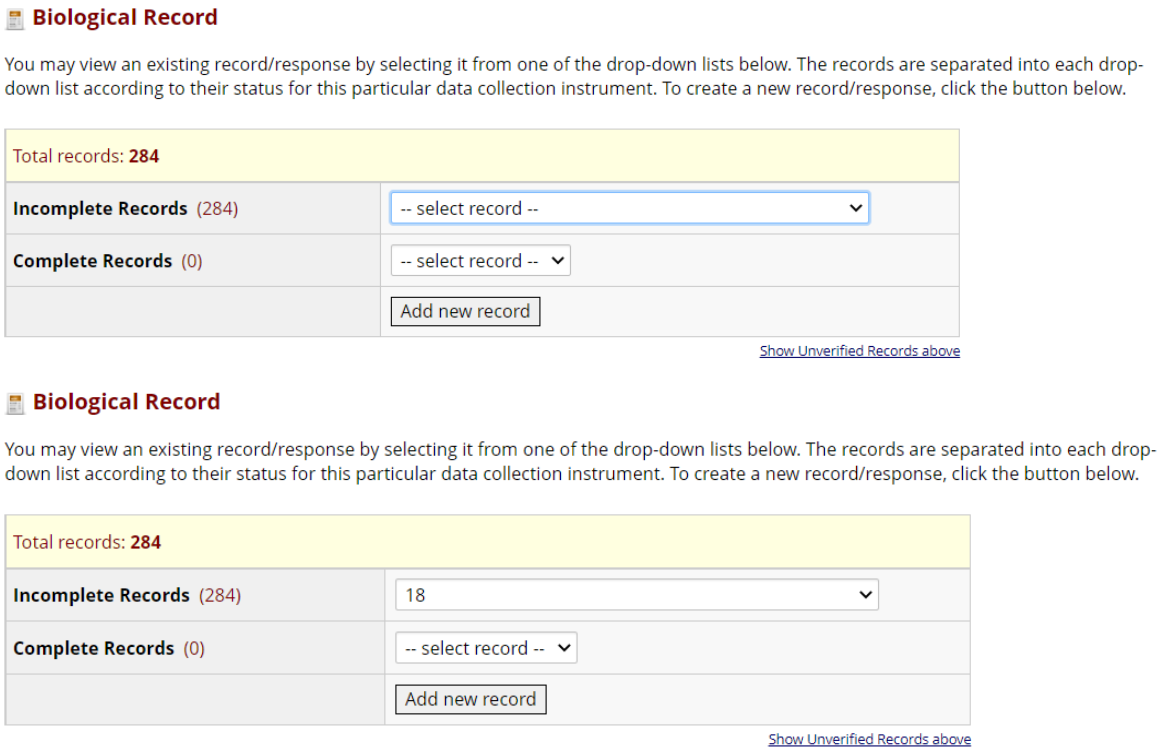

Complete at least one detail on either form and then select **Save and Exit Form** located at the bottom of the form.




**6.6** A pop-up may appear warning you of incomplete fields. Select **Ignore and leave record**.



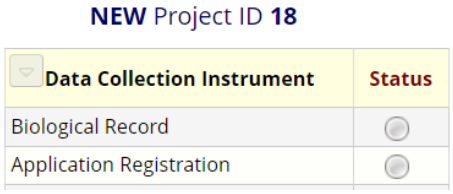

**6.7** You will then be taken to the Record page. Check the **Incomplete Records** dropdown to confirm your Biosafety Project was successfully saved. If successful, the **Project ID** number will appear in the Incomplete Records list and can be selected.




# 7. How to complete a Biological Record form

A Biological Record captures information about organisms being used in teaching and research. It includes the organism's biological classification, biological details, storage and usage locations, and owner/creator details. Each **Biological Record** represents a specific organism, or group of samples from the same organism. Different strains should be recorded in separate records.

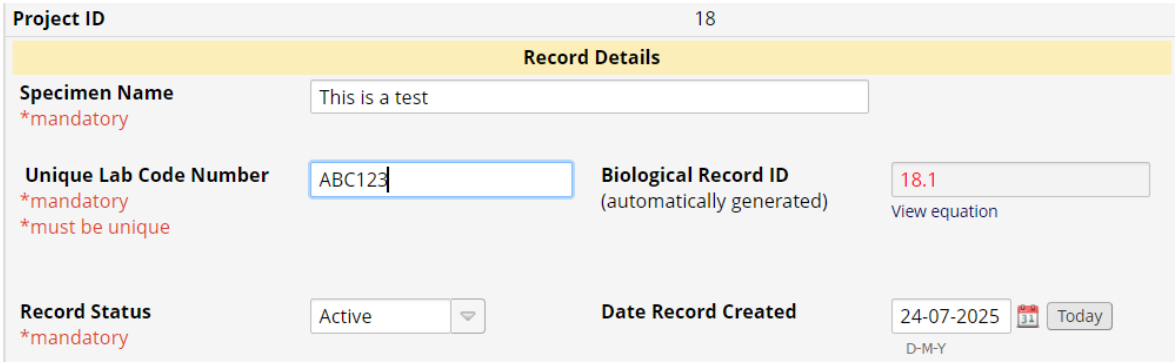
To begin, open an existing Biosafety Project, or create a new one. Then, select the grey radio button adjacent to **Biological Record** to open the **Biological Record** form.




A Biological Record contains the following sections:

## 7.1 RECORD DETAILS

The **Record Details** section contains the biological materials' identifying information, such as its name and unique lab code number. This section also contains the field **Record Status** which classifies the biological material as Active, Destroyed, Relocated or Inactive.




## 7.2 BIOLOGICAL MATERIAL CLASSIFICATION

The **Biological Material Classification** contains information regarding the classification of the biological material.

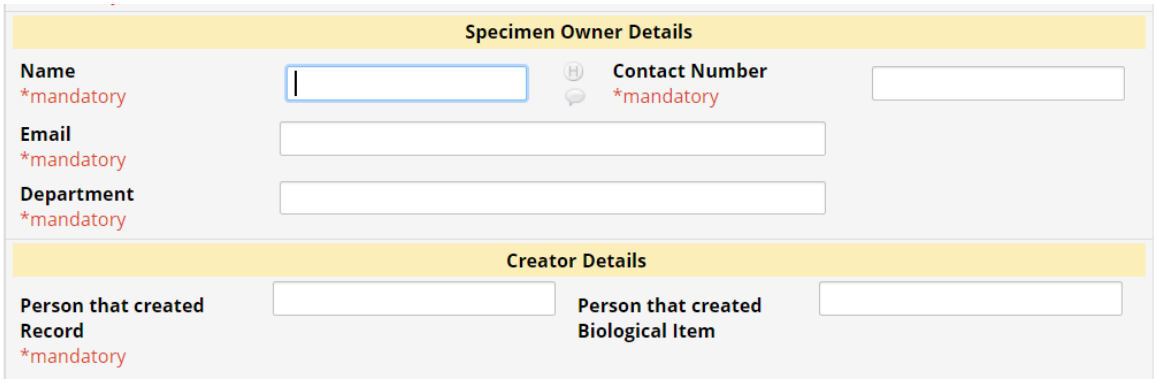

Additional sections will be displayed in the form when **Approved Arrangement Site Required** or **GMO** are set to **Yes**.

Additionally, when the **Record Type** is selected, the system may request additional information in the **Sub-Type** field. For example,

- If Biological Sample – Human is selected, then the sub-type options are Fixed Tissue, Fresh Tissue, Bodily Fluid, Cell Line, Fecal Matter.
- If Biological Sample – Microbial is selected, then the sub-type options are Bacterial, Viral, Fungal.

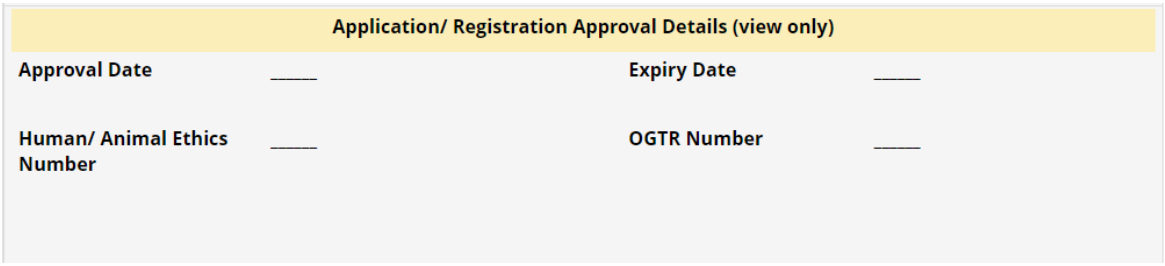
## 7.3 SPECIMEN OWNER AND CREATOR DETAILS

Complete **Specimen Owner Details** and **Creator Details** in the relevant fields provided.



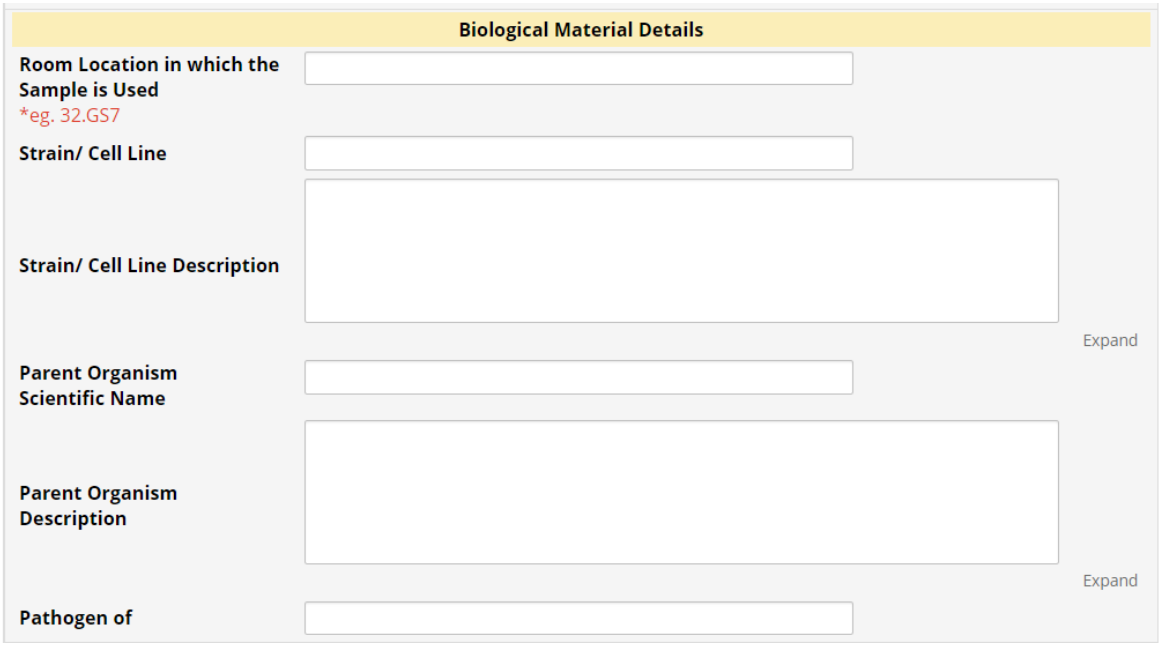

## 7.4 APPLICATION / REGISTRATION APPROVAL DETAILS (VIEW ONLY)

The **Application / Registration Approval Details (view only)** auto populates to display the current status of your application. It is for information purposes only.



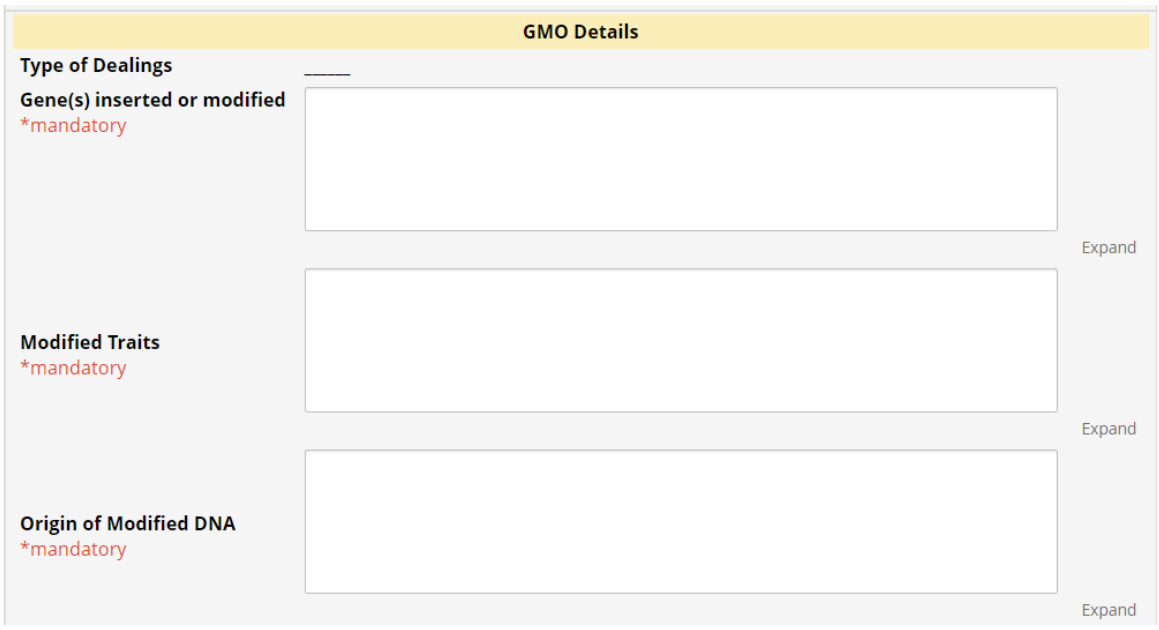

## 7.5 BIOLOGICAL MATERIAL DETAILS

The **Biological Material Details** section enables the user to enter additional details regarding the biological material, including the room where the sample is going to be used.



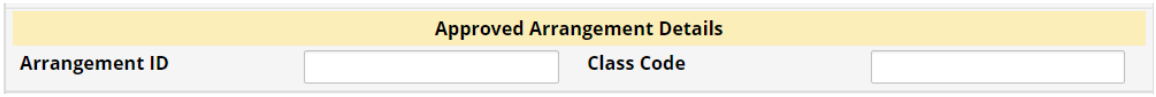
## 7.6 GMO DETAILS

The **GMO Details** section is only visible when the **GMO** field in **Biological Material Classification** is set to **Yes**. Complete the relevant details as prompted for any GMO materials.




## 7.7 APPROVED ARRANGEMENT DETAILS

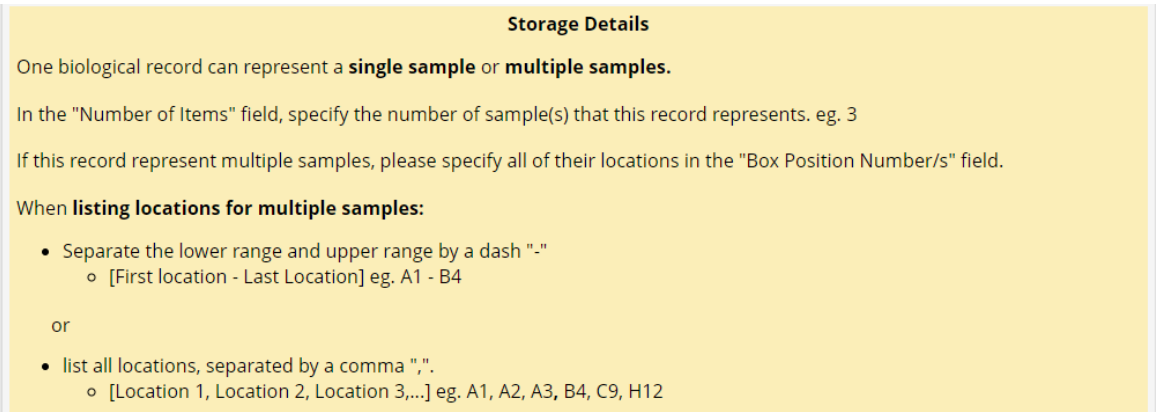
The **Approved Arrangement Details** section is only visible when **the Approved Arrangement Site Required?** section is set to **Yes**. Complete the relevant details as prompted.



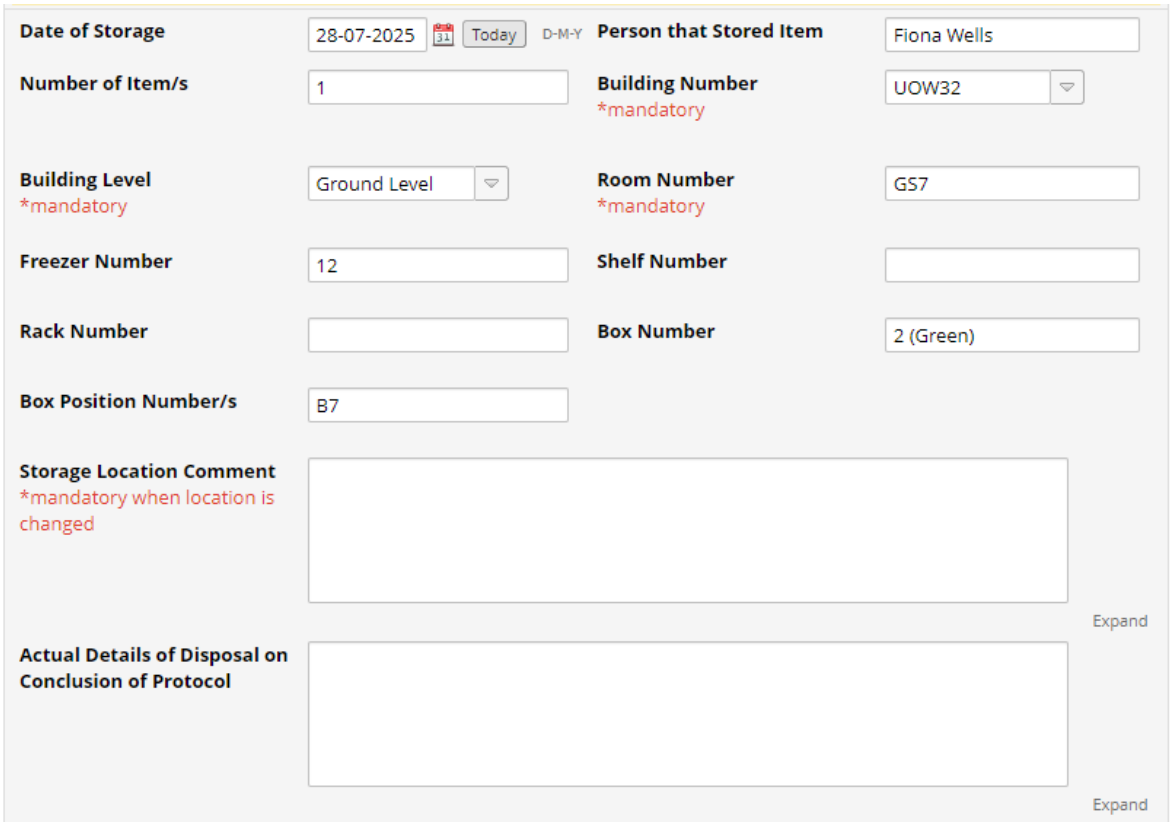

## 7.8 STORAGE DETAILS

The **Storage Details** section allows the user to specify the exact storage location of their sample/s.

The form provides some explanatory text regarding the location of samples and how to express the information.



An example of completed storage details is provided below.

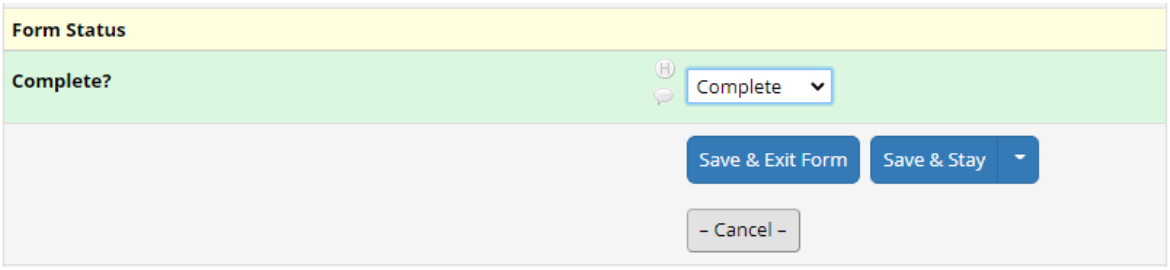



## 7.9 COMMENTS

The **comments** section allows for any additional information and the inclusion of attachments related to the biological material/s.

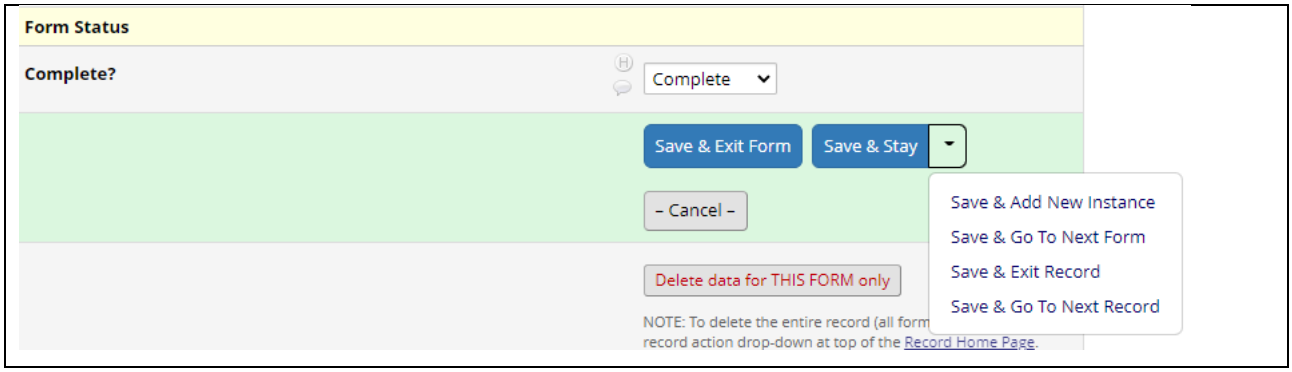

## 7.10 FORM STATUS

If all of the **Biological Record** details have been entered, change the **Complete?** status to **Complete**, otherwise leave as **Incomplete**.




## 7.11 SAVING THE BIOLOGICAL RECORD

To **save** the **Biological Record**, choose one of the following **Save options**:




- **Save & Exit Form** – to return to the current Biosafety Project page.
- **Save & Stay** – to stay on the current record
- **Save & Add new instance** – to create another Biological Record for your biological material. Note, in REDCap an instance refers to a data record.
- **Save & Go To Next Form** – to go to the current Biosafety Project's Application/Registration form
- **Save & Exit Record** – to go to the Record Home Page which allows you to select another Biosafety Project
- **Save & Go To Next Record** – to go to the next Biosafety Project

# 8. How to complete an Application/ Registration

The **Application/Registration form** contains project information, biological material details, storage details, as well as any attachments relevant to the work to be conducted, such as Risk Assessments and Safe Work Procedures.

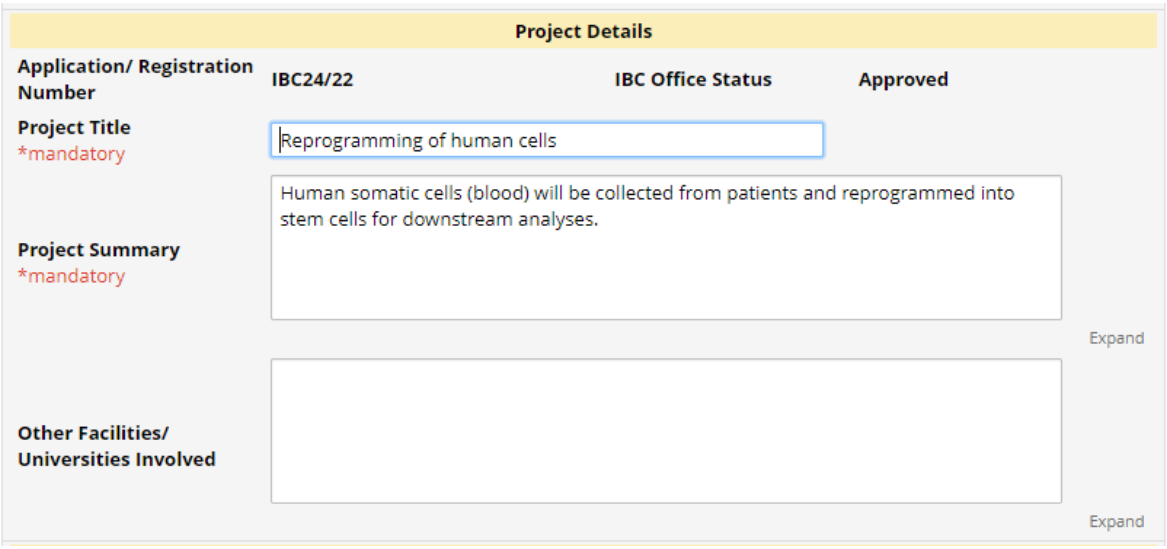
The information provided on the **Application/Registration** form is used by the IBC during the approval process.


To begin, open an existing **Biosafety Project**, or create a new one.

Then, select the grey radio button adjacent to **Application Registration** to open the **Application Registration** form.

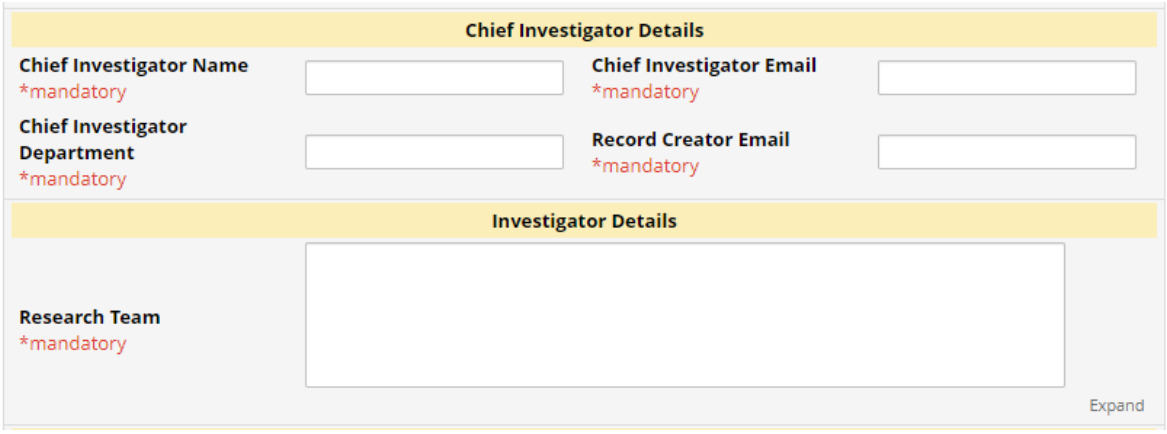
## 8.1 PROJECT DETAILS

Complete details as prompted. Note, details for **Application/Registration Number** and **IBC Office Status** will be generated following IBC Review.




## 8.2 CHIEF INVESTIGATOR AND INVESTIGATOR DETAILS

Complete details as prompted.



## 8.3 PROJECT CLASSIFICATION

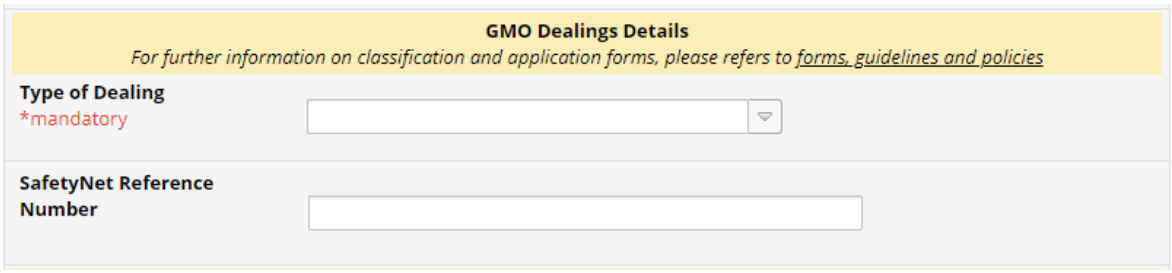
Project Classifications are automatically marked No. Change to Yes as relevant.


Additional fields may need to be completed, depending on the **Project Classification** selected. For example;

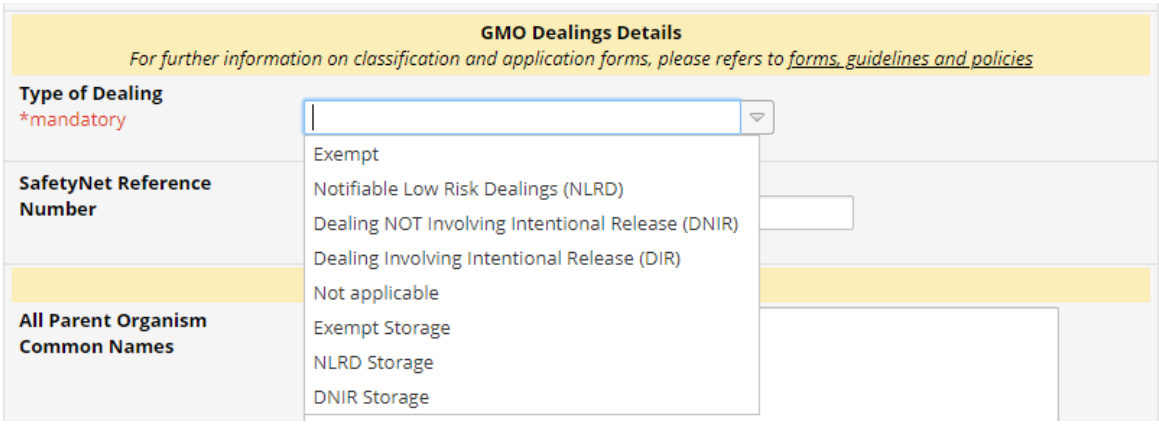
- When **Approved Arranged Site Required?** is changed to **YES**, the **Approved Arrangement Details** section is displayed.
- When **GMO** is changed to **YES**, the **GMO Dealings Details** section is displayed.
- When **Security Sensitive Biological Agents** is changed to **Yes**, the **Security Sensitive Biological Agents Approval** section is displayed
- When **Defense Trade Approval Required** is changed to **Yes**, the **Defence Trade Approval** section is displayed
- When **Bio-hazardous Material** is changed to **Yes**, the **Bio-hazard Material Details** section is displayed

## 8.4 GMO DEALINGS DETAILS

The **GMO Dealings Details** section is displayed when **GMO** is set to **Yes** in the **Project Classification** section.

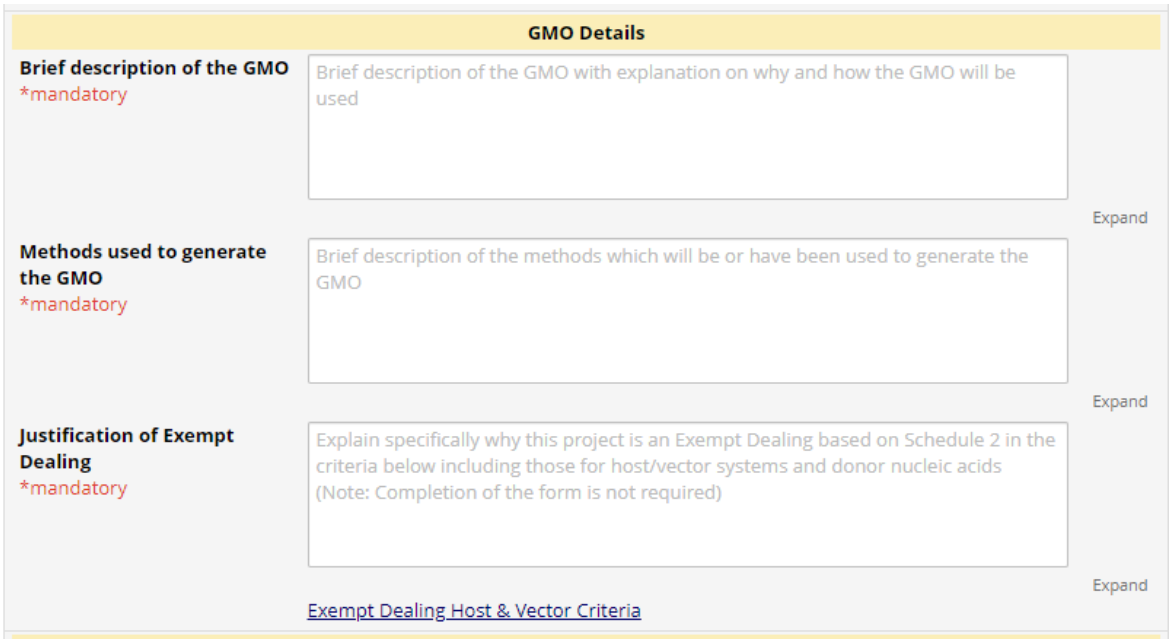



Select the **Type of Dealing** from the drop-down list.



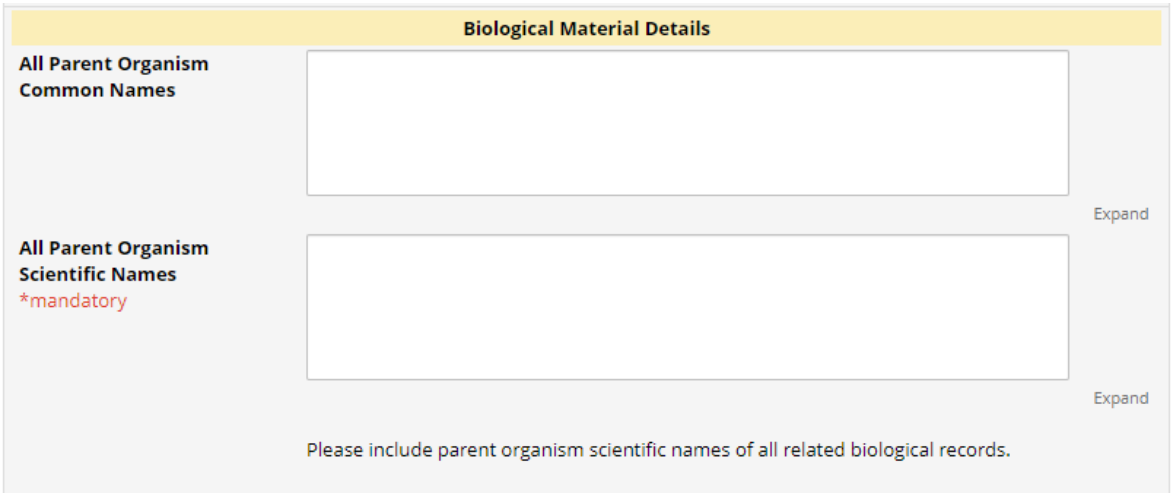

Additional sections and fields will be displayed depending on the **Type of Dealing** selected.

Below is an example for **Exempt Dealing**.

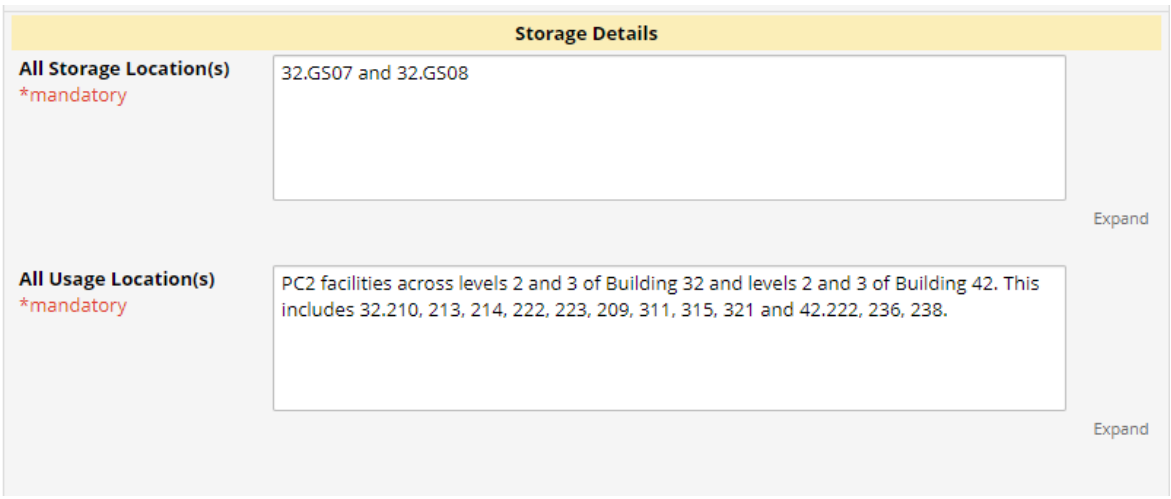
## 8.5 BIOLOGICAL MATERIAL DETAILS

Include details of all biological materials involved in the project.



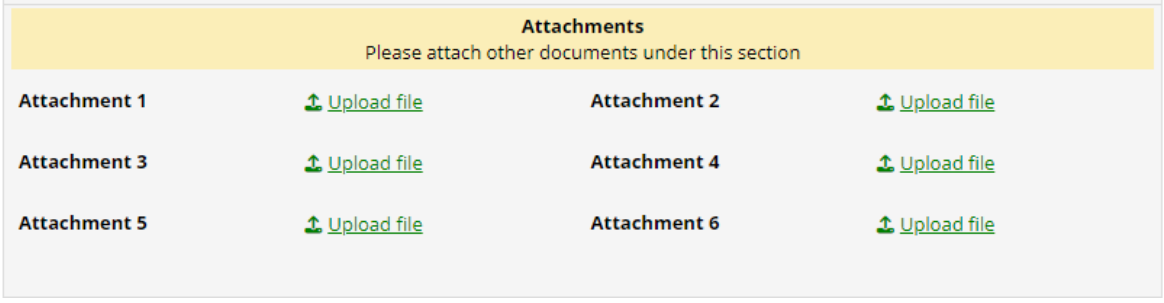

## 8.6 STORAGE DETAILS

Include the building and room numbers of the biological material's storage and usage locations.



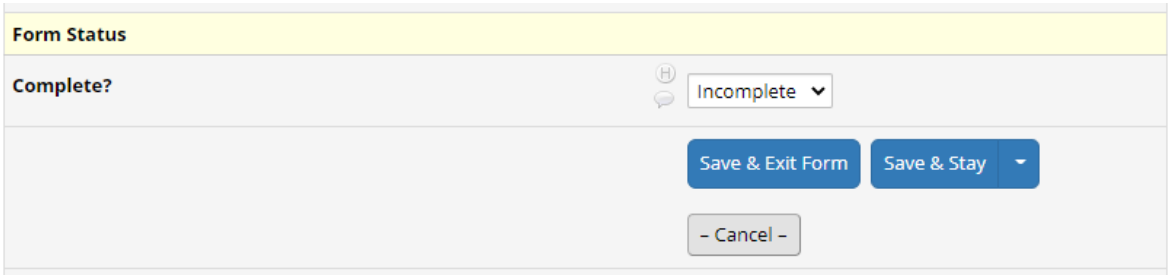

## 8.7 ATTACHMENTS

Upload your Risk Assessments, Safe Work Procedures, Research Protocol and any other relevant documents in this section, as required.



## 8.8 SAVING THE APPLICATION

To save the Application/Registration without submitting it, leave the **Form Status** at **Incomplete** and select **Save & Exit Form**.




## 8.9 SUBMITTING THE APPLICATION

If all details have been completed and you are ready to submit the application to the IBC, please refer to **Section 9 – Submitting an Application/Registration** following.

# 9. Submitting an Application / Registration

Before submitting your **Biosafety Application/Registration**, make sure that:

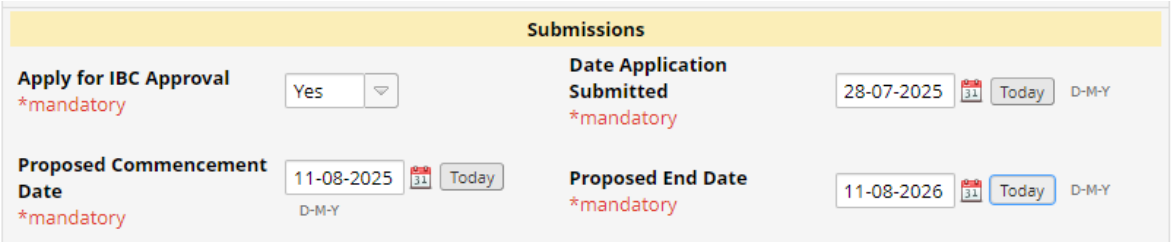
- The **Biological Records** describe all biological materials associated with the **Biosafety Application/Registration**.
- The **Application/Registration** includes:
    - All researchers involved in the project
    - The correct Chief Investigator email and Record Creator email
    - All biological materials and their storage locations
    - All documents required for the classification of the biological material
    - The correct Project Classification

To submit the **Biosafety Application/Registration** form, complete the following sections:

## 9.1 SUBMISSIONS

Complete the details in the **Submissions** section of the **Application/Registration**

- Set **Apply for IBC Approval** to **Yes**.
- Set the **Date Application Submitted** to **Today**
- Choose a **Proposed Commencement Date**
- Choose a **Proposed End Date**

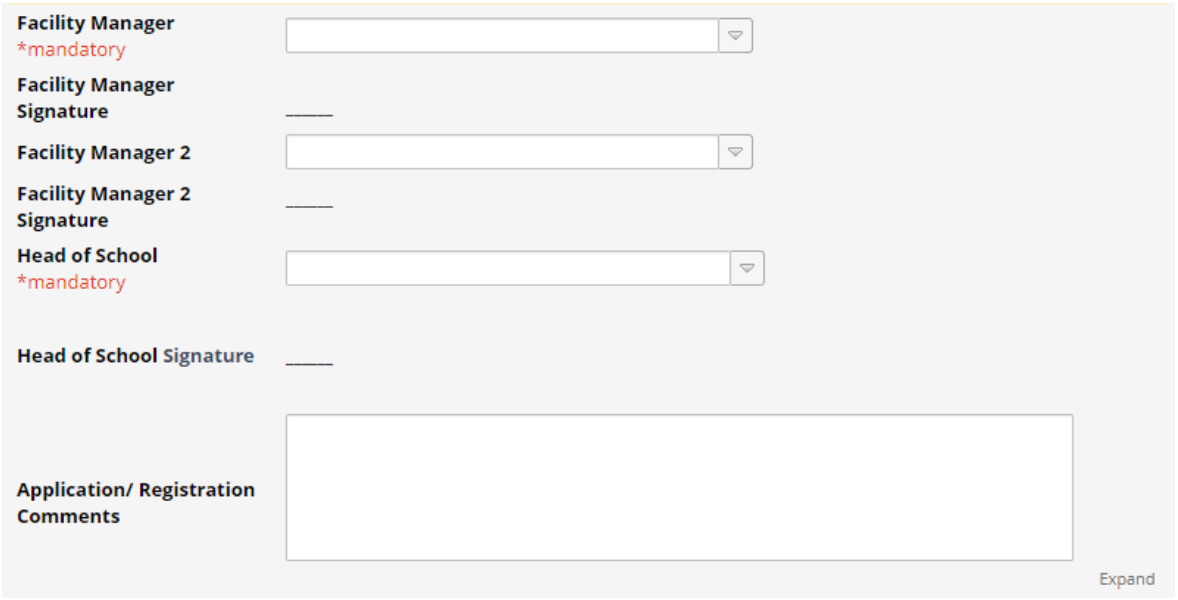


## 9.2 FACILITY MANAGER AND HEAD OF SCHOOL APPROVAL

9.2.1 Select the **Facility Manager/s** for your biological materials to notify them of your application.

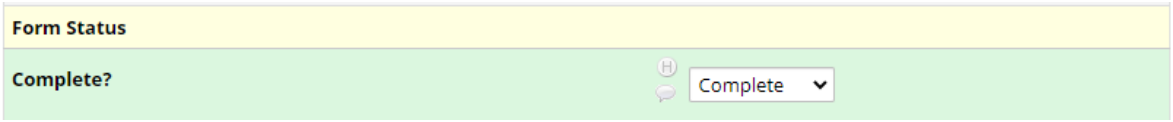
9.2.2 Select the **Head of School** for your biological materials to notify them of your application.

9.2.3 Low risk projects, such as Risk Group 1 or Exempt Dealings do not require Head of School Approval. In the Head of School field **Not Required** can be selected in these instances.




## 9.3 SET THE APPLICATION TO COMPLETE

Once you have reviewed the application and all details have been entered correctly, set the **Form Status** to **Complete**.




## 9.4 SAVE THE APPLICATION AND SUBMIT TO THE IBC

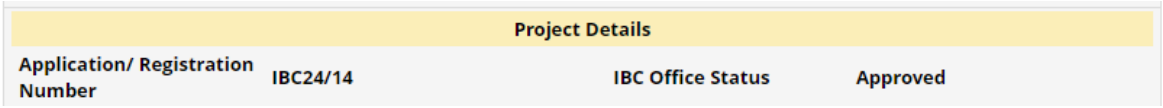
Select **Save and Exit Form or Save and Stay** to submit your application to the IBC.

You will receive an automatically generated email from uow-biosafety@uow.edu.au as your application moves through the approval process – Facility Manager – Head of School – IBC to advise whether your application has been approved or rejected at each stage.

# 10. Determining the status of an application

Once the Facility Manager/s and Head of School have approved the application and marked the **Form Status** as **Complete**, the grey radio buttons adjacent to **Facility Manager Approval** and **Head of School Approval** will be green.


Once the application has been approved by the IBC and processed by the WHS Advisor (Science) the **Application Registration Admin** radio button will be green and the **IBC Office Status** in the **Project Details** section of the **Application Registration** will display **Approved**.




The Chief Investigator will also receive notification from the IBC regarding the outcome of their application.

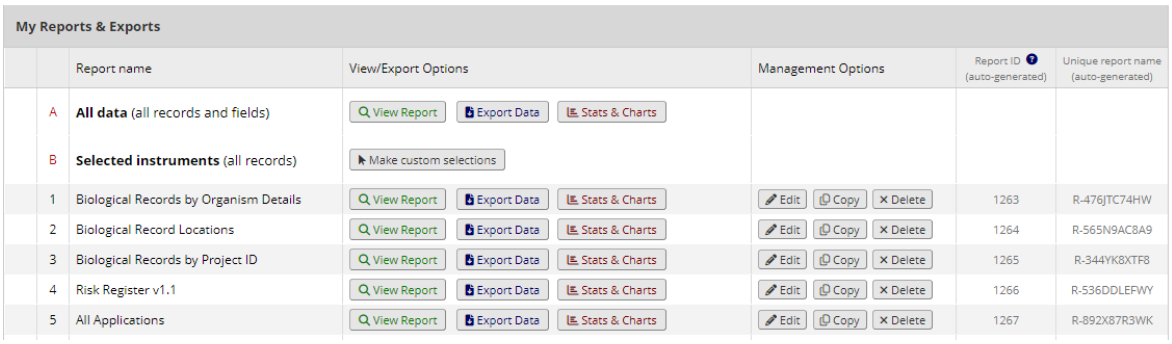
# 11. The REDCap Reports Tool

The **REDCap Reports tool** produces reports using data from your **Biological Records** and **Application/Registrations**.

The reports can assist in helping you keep track of your Biosafety Applications, biological records, or to locate a particular one. You will only be able to see data from your own groups on the report and users outside of your group will not be able to see your data.

To access reports, select **Reports** from the Project Home page.


You will then be taken to a list of all available reports.




Below is an example of the report **Biological Record Locations**, which displays detailed information about where each biological record is used and stored.

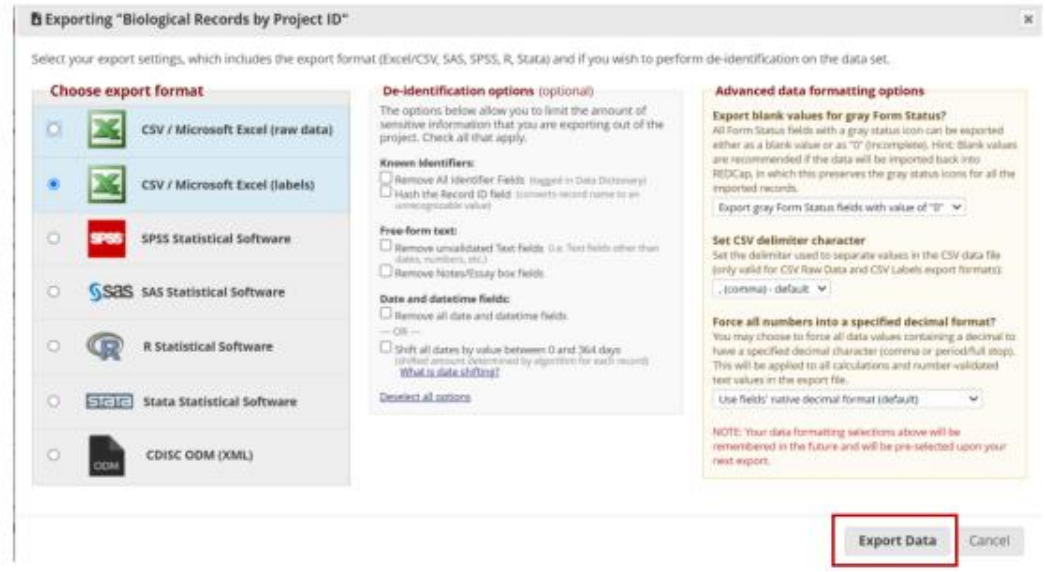
| Project ID record_id | Unique Lab Code Number lab_code_number | Specimen Name specimen_name | Parent Organism Scientific Name parent_organism_scientific_name | Record Status record_status | Room Location in which the Sample is Used usage_location | Building Number building_number | Level building_level | Room Number room_number | Free Num |
|---|---|---|---|---|---|---|---|---|---|
| JY1 | JY657 | cherry GST (stop) | Escherichia coli | Active (1) | 32.315 | UOW32 - IHMRI (2) | | GS7 | 12 |
| JY1 | JY658 | cherry TDP (stop)2 | Escherichia coli | Active (1) | 32.315 | UOW32 - IHMRI (2) | | GS7 | 12 |
| JY1 | JY659 | cherry A4V (stop) | Escherichia coli | Active (1) | 32.315 | UOW32 - IHMRI (2) | | GS7 | 12 |
| JY1 | JY660 | cherry | Escherichia coli | Active (1) | 32.315 | UOW32 - IHMRI (2) | | GS7 | 12 |

The report also contains filters and a search bar which can help narrow down the report data displayed.

Alternatively, you can also export the data as a spreadsheet to do your own custom queries.

- Select **Export Data**


- Then check **CSV/Microsoft Excel (labels)** as your export format.
- Then select **Export Data**



# 12. Completing or Ending a Biosafety Project

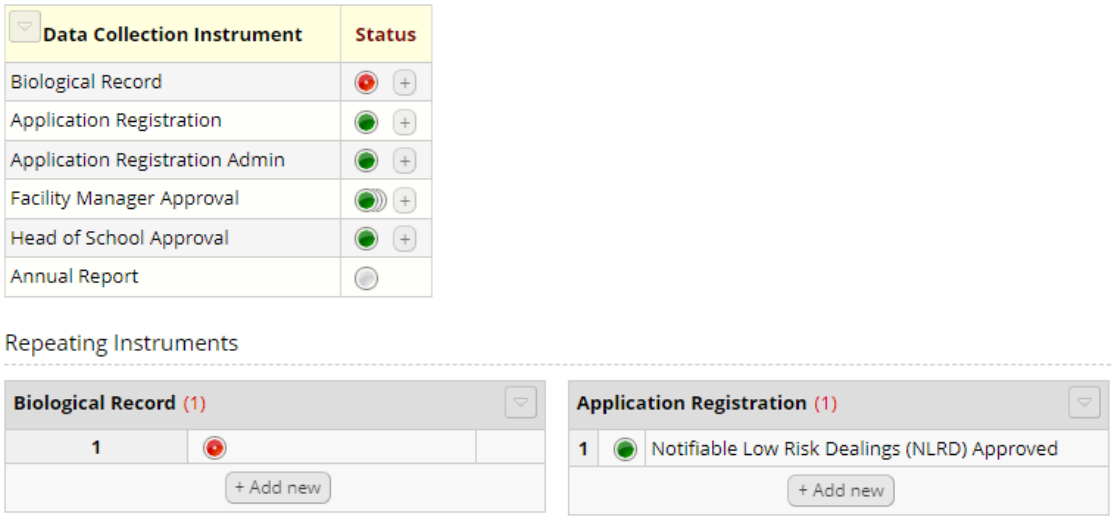
All biological materials must be under an active Biosafety Application/Registration to be stored or handled at UOW. When your **Application/Registration** expires, you can either:

- Submit a **final report** detailing the disposal of the biological materials.
- Submit a **Storage Application** form to store the biological materials for later use
- Renew your **Application/Registration** to continue working with the biological materials.

## 12.1 DISPOSAL OF BIOLOGICAL MATERIALS

12.1.1 Login to REDCap Biosafety

12.1.2 Go to your **Biosafety Project** with a completed **Application/Registration**




12.1.3 Complete the **Final Report**, detailing the disposal of biological materials.

12.1.4 Upload the **Final Report** to the **Annual Report** section of the Project.

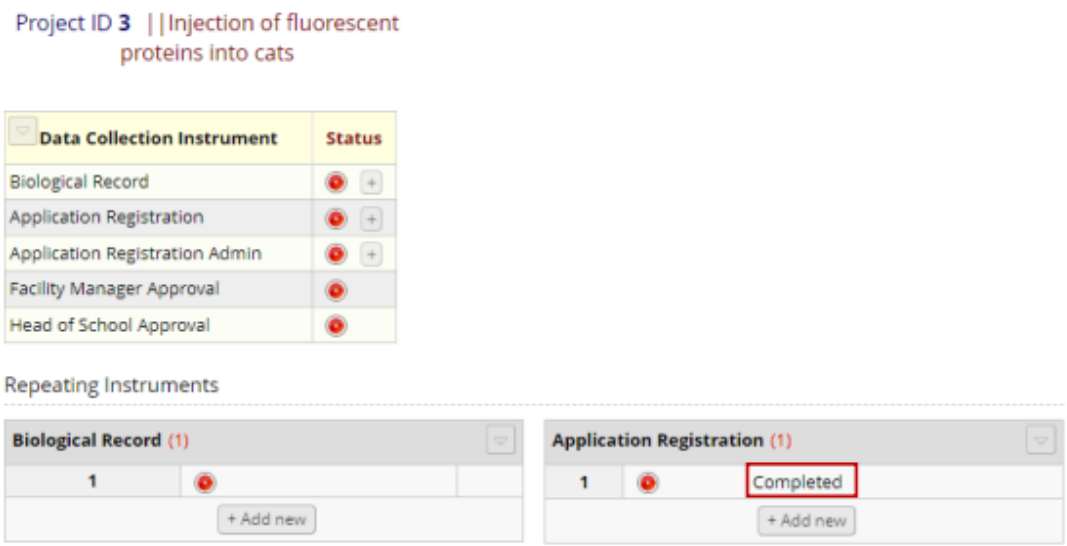
12.1.5 Your **Final Report** will be reviewed at the next IBC Meeting.

## 12.2 APPLY FOR STORAGE

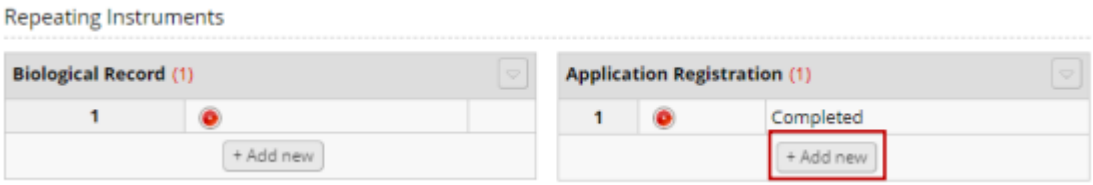
12.2.1 Login to REDCap Biosafety

12.2.2 Complete and submit your **Final Report**.

12.2.3 Go to your **Biosafety Project** with a completed **Application Registration**.

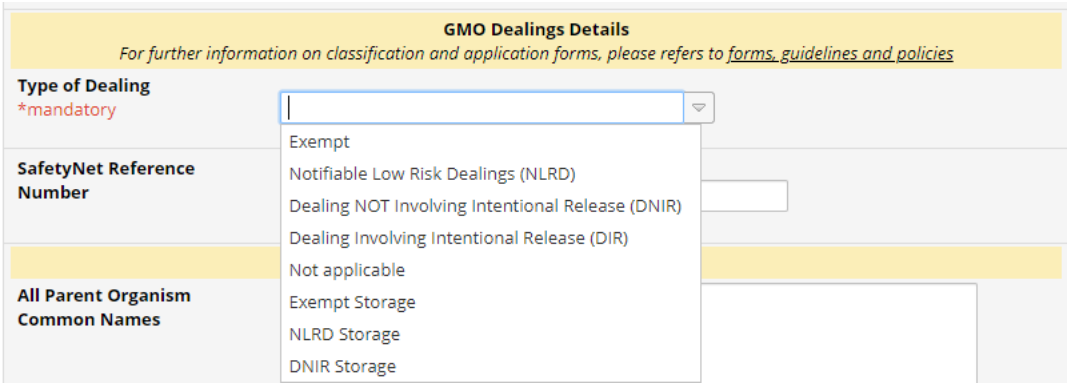



12.2.4 Create a new **Application/Registration** under the same **Biosafety Project**.

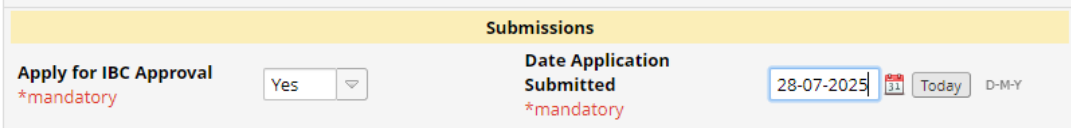



12.2.5 Complete the **Application/Registration** form as per Sections 8 and 9 of this User Guide. The following sections are of note:

- For **GMO Dealings Details**, select the appropriate storage application option and fill out the details.

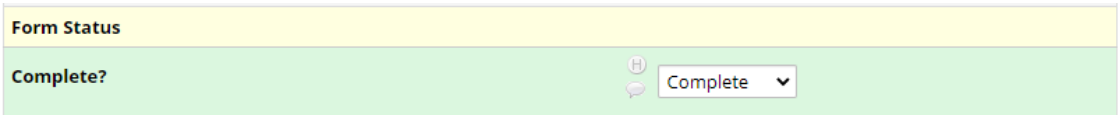



- In the **Submissions** section of the form, remember to select **Yes** for **Apply for IBC Approval**.




- In the **Facility Manager/s and Head of School Approval** section of the form, remember to select a Facility Manager/s and Head of School for approval.

12.2.6 Once you have reviewed the application and all details have been entered correctly, set the **Form Status** to **Complete**.

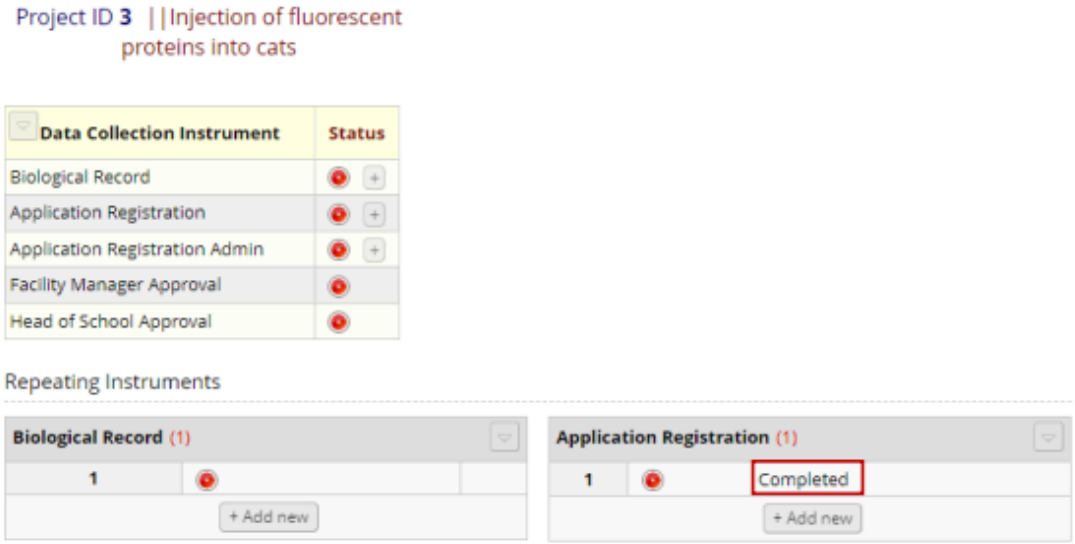



12.2.7 Select **Save and Exit Form** or **Save and Stay** to submit your application to the IBC. You will receive an automatically generated email from uow-biosafety@uow.edu.au as your application moves through the approval process – Facility Manager – Head of School – IBC to advise whether your application has been approved or rejected at each stage.

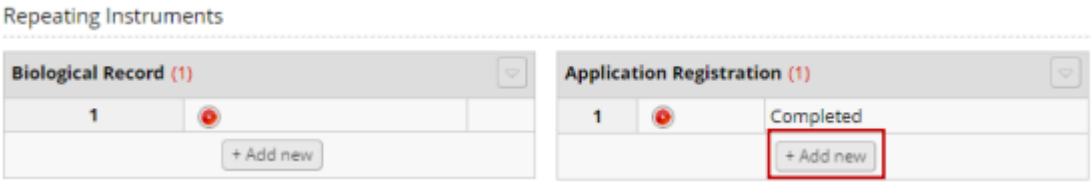
## 12.3 RENEW YOUR APPLICATION/REGISTRATION

12.3.1 Login to REDCap Biosafety

12.3.2 Go to your **Biosafety Project** with a completed **Application/Registration**.

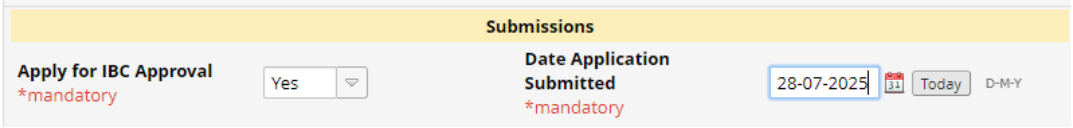



12.3.3 Create a new **Application/Registration** under the same **Biosafety Project**.



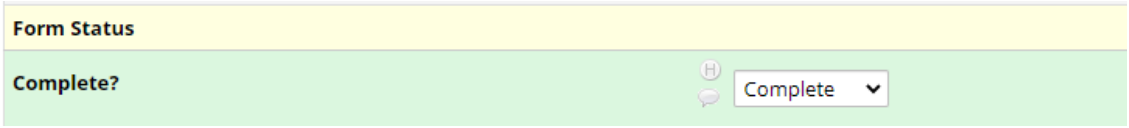

12.3.4 Complete the **Application/Registration** form as per Sections 8 and 9 of this User Guide. The following sections are of note:

- In the Attachments section of the form, In the **Submissions** section of the form, remember to select **Yes** for **Apply for IBC Approval**.



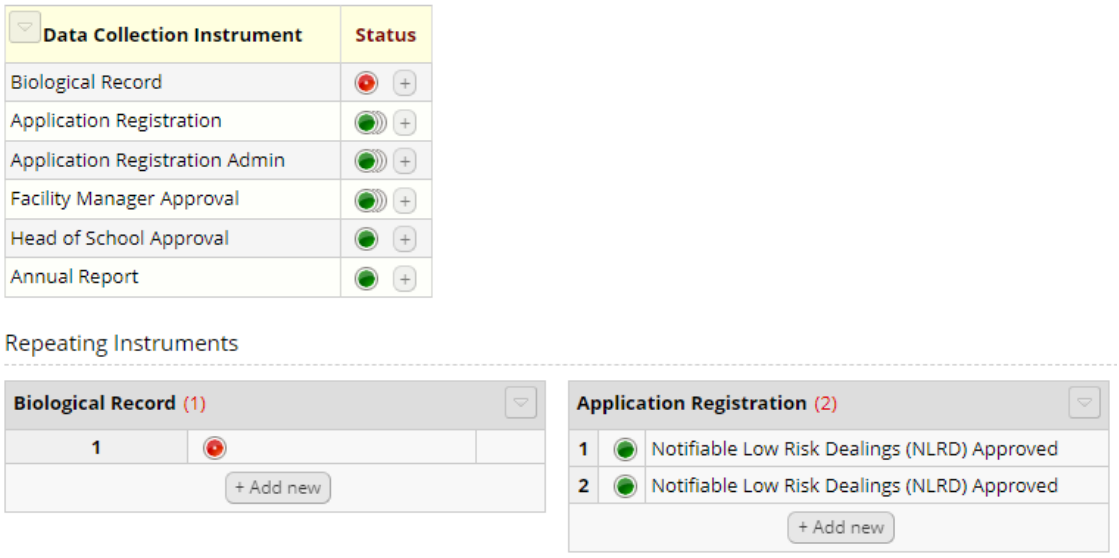

- In the **Facility Manager/s and Head of School Approval** section of the form, remember to select a Facility Manager/s and Head of School for approval.

12.3.5 Once you have reviewed the application and all details have been entered correctly, set the **Form Status** to **Complete**.




12.3.6 Select **Save and Exit Form** or **Save and Stay** to submit your application to the IBC. You will receive an automatically generated email from uow-biosafety@uow.edu.au as your application moves through the approval process – Facility Manager – Head of School – IBC to advise whether your application has been approved or rejected at each stage.

12.3.7 On the Biosafety Project **Record Home page**, the new **Application/Registration** form will appear as a second instance under the original **Application/Registration**.




# 13. Amendments and Annual Reports

## 13.1 SUBMITTING AN ANNUAL REPORT

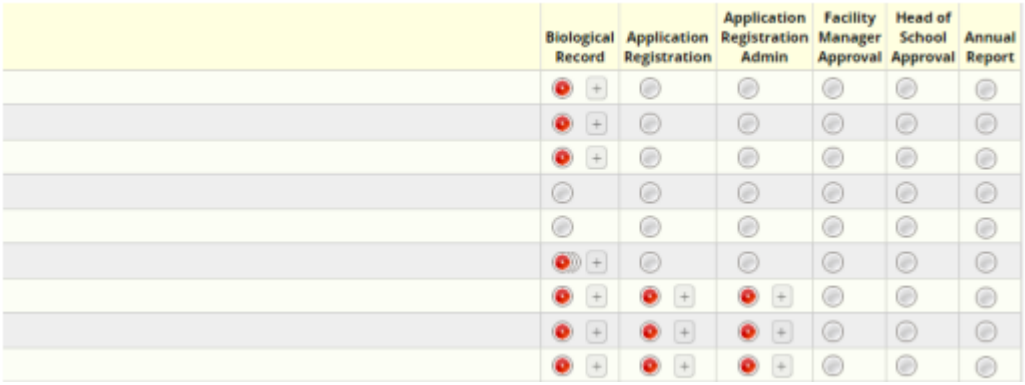
13.1.1 Complete the Annual Report form.

13.1.2 Login to REDCap Biosafety

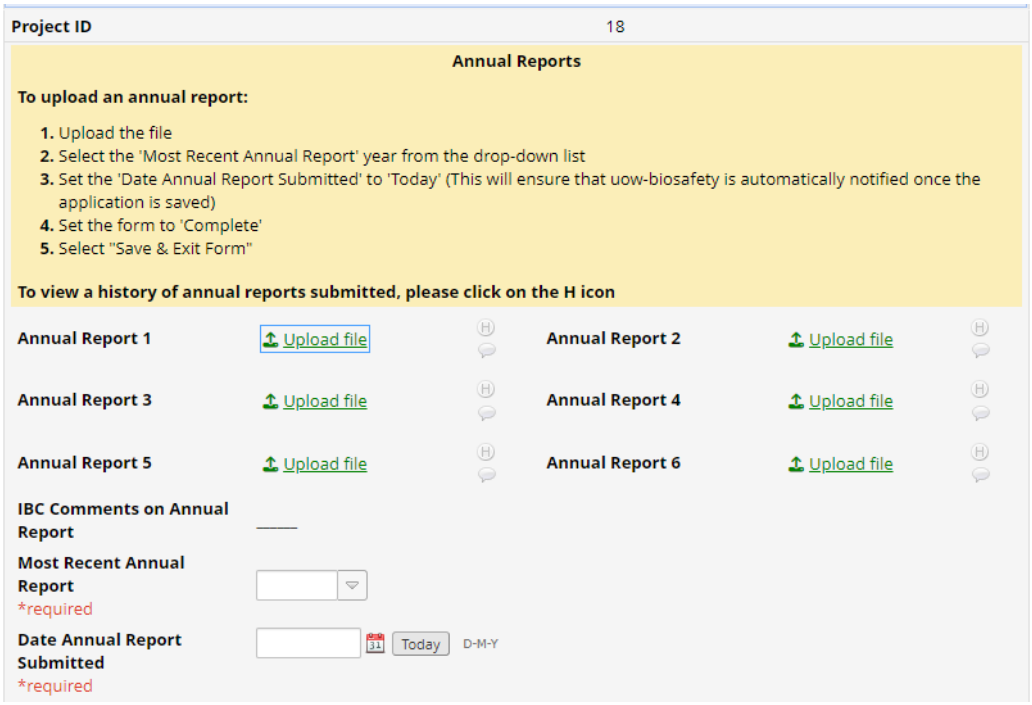
13.1.3 Select **Browse Records**.

13.1.4 In the **Record Status Dashboard**, identify your applications requiring Annual Reports by their Project ID or Project Title.

13.1.5 Select the radio button in the Annual Report column for the relevant application.

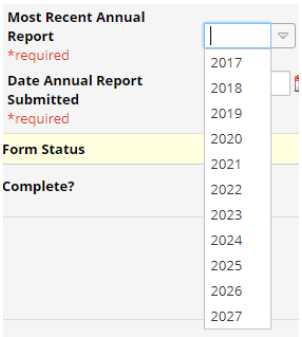



13.1.6 The **Annual Reports** form will then be displayed.



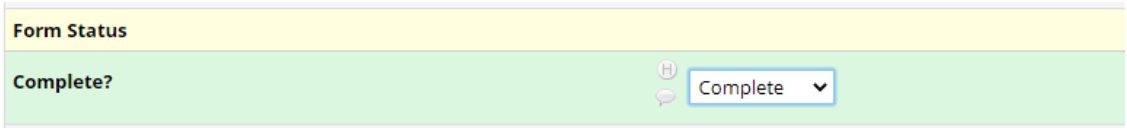

13.1.7 Select **Upload file**, navigate to the relevant annual report file, and click the **Upload file** button.

13.1.8 Select the **Most Recent Annual Report** year from the drop-down list.

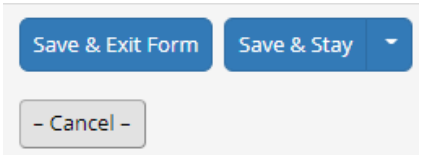


13.1.9 Set the **Date Annual Report Submitted** to **Today**.


13.1.10 Set the **Form Status** to **Complete**.




13.1.11 Select **Save and Exit Form**.




## 13.2 SUBMITTING AN AMENDMENT REQUEST

Any changes to an approved project must be submitted to the IBC for review. This includes:

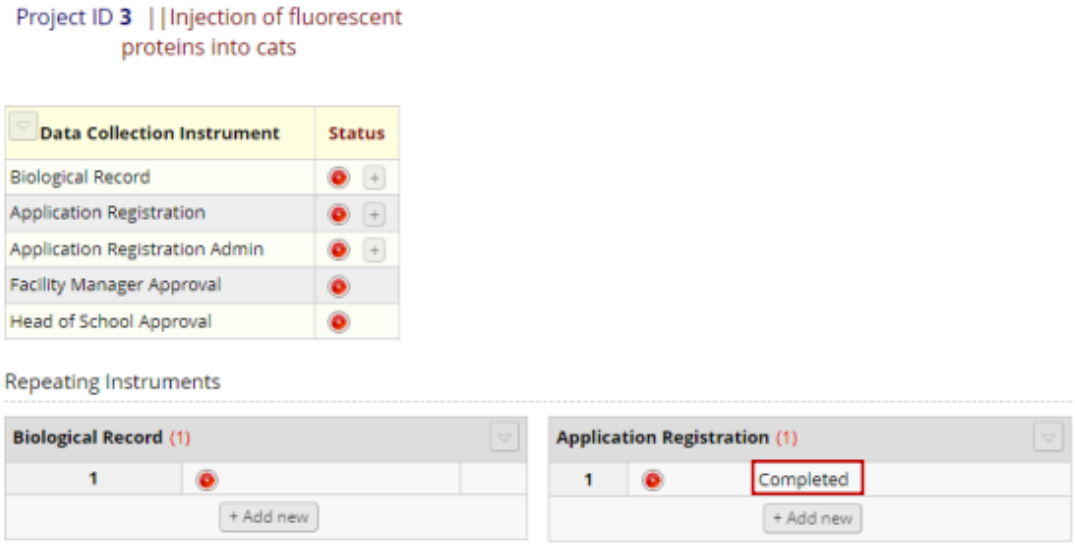
- Adding similar GMOs
- Changes to facility conditions or research conditions
- Updates to GMO storage locations

**Note:** Any changes to research personnel can be addressed as part of the annual reporting requirements.

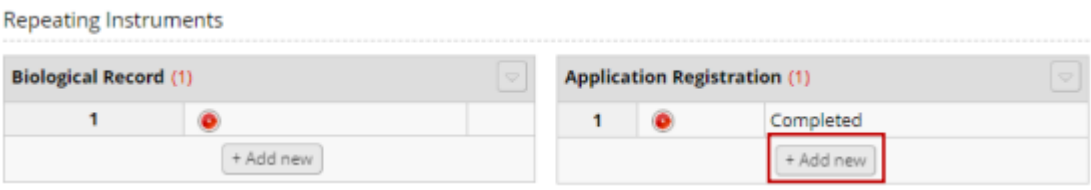
**For changes to Biosafety Applications, including Exempt Dealings, NLRD, DNIR and DIR, the amendment process is as follows:**

13.2.1 Login to REDCap Biosafety

13.2.2 Go to your **Biosafety Project** with a completed **Application/Registration**.

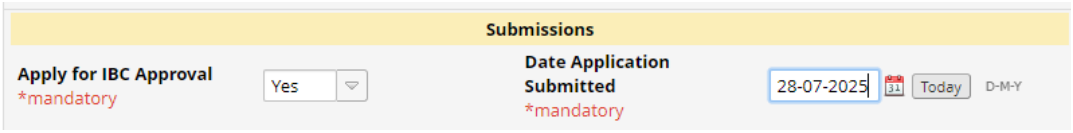


13.2.3 Create a new **Application/Registration** under the same **Biosafety Project.**



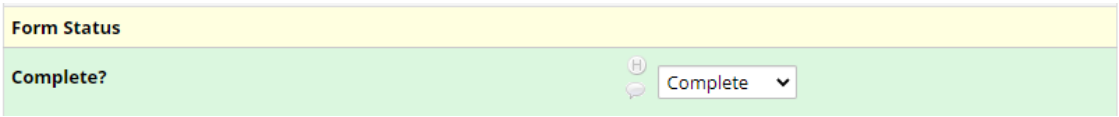

13.2.4 Complete the **Application/Registration** form as per Sections 8 and 9 of this User Guide. The following sections are of note:

- In the **Submissions** section of the form, remember to select **Yes** for **Apply for IBC Approval**.




- In the **Facility Manager/s and Head of School Approval** section of the form, remember to select a Facility Manager/s and Head of School for approval.
- In the Attachments section, Attach any new or updated documents where relevant
  - For DNIR Licenced Dealings: Complete and attach the Application to vary or surrender a DNIR licence
  - For DIR Licenced Dealings: Complete and attach the Application to vary or surrender a DIR licence

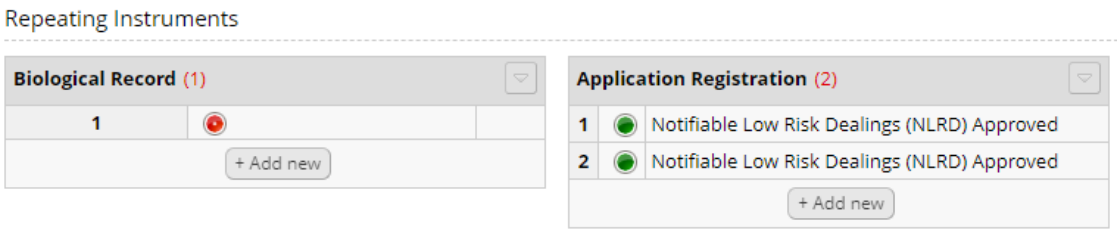
13.2.5 Once you have reviewed the application and all details have been entered correctly, set the **Form Status** to **Complete**.




13.2.6 Select **Save and Exit Form** or **Save and Stay** to submit your application to the IBC.

You will receive an automatically generated email from uow-biosafety@uow.edu.au as your application moves through the approval process – Facility Manager – Head of School – IBC to advise whether your application has been approved or rejected at each stage.

13.2.7 On the Biosafety Project **Record Home page**, the new **Application/Registration** form will appear as a second instance under the original **Application/Registration**.

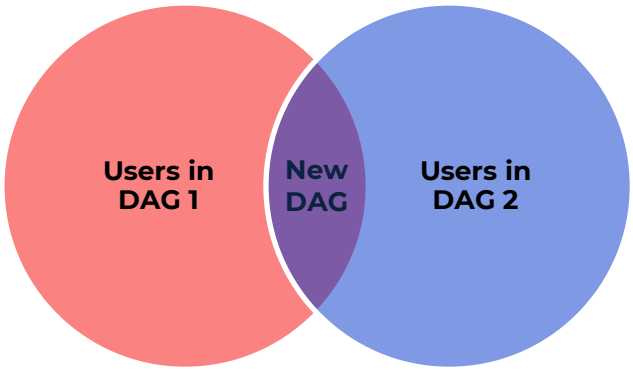


# 14. Data access groups

Data Access Groups (DAGs) restrict viewing of data within REDCap. Users assigned to one or many DAGs should only be able to view data from their groups but not any others. Users assigned to a group will only be able to see records created by users within their group.

Users can nominate their DAGs when initially setting up access to REDCap Biosafety using the Research Systems Access Request Form. Afterwards, please send any requests to modify a user's DAGs to uow-biosafety@uow.edu.au.

A BioSafety Record can only belong to one DAG. If you need to transfer your BioSafety Record between your DAGs, please email uow-biosafety@uow.edu.au. If you need to transfer your BioSafety Record to another user's DAG, you would need to acquire the new DAGs owner and Ethics permission.




If a new project includes researchers from multiple labs (and subsequently multiple DAGs), the best practice would be to create a new DAG for the BioSafety Record of that project, then add the participating researchers to the new DAG. To request the creation of a new DAG, please email uow-biosafety@uow.edu.au with the name of the new DAG, and the list of users to be added to the new DAG.

# 15. Version Control

| VERSION NO. | DATE RELEASED | APPROVED BY | AMENDMENT |
|---|---|---|---|
| 1 | September 2025 | Senior Manager, WHS | Exiting documents previously developed by the Researcher Development and Integrity Team, reviewed, updated and combined into one REDCao Biosafety User Guide. |