

Requisition and Reporting System

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1. Purpose

To describe the software and process used to receive sample requisitions and link Protected Health Information (PHI) to clinical reports.

2. Scope

ISO 15189 requires patient PHI to be collected and included on clinical reports, however, OICR does not permit receipt of PHI. A system was designed to a) create requisition forms, b) de-identify samples prior to receipt at OICR, and c) re-associate PHI with clinical results on the final report, which is only visible to the reviewing licensed Geneticist and Clinical Coordinator. This ensures that samples can be appropriately tracked throughout laboratory processing without exposing PHI to OICR staff. OICR engaged independent third parties to conduct a Privacy Impact and a Threats and Vulnerabilities Assessment, addressing audit recommendations prior to implementation of this system.

The purpose of this Standard Operating Procedure (SOP) is to describe the Requisition and Reporting software and to define procedures for its use and maintenance, including account access, study requisition form configuration, email notification management, case history management, user roles and functions, system administration and updates. OICR Web Development maintains two additional SOPs related to this system, covering [Change Management](#) and [Application Deployment](#).

3. Responsibilities

Genomics Management:

Review procedure annually or as required.

Genomics Program Manager and GSI Director:

Act as Administrator for the system, including supervision of system utilization (auditing), study requisition form configuration, user (role) access control, study authorization control

Genome Interpretation Manager:

Supervision of staff interacting with the system at the reporting stage, including licensed Geneticists.

Tissue Portal Staff:

Use of the system at the requisition receipt stage.

Licensed Geneticists:

Use of the system at the report review and release stage.

External Clinical Coordinators:

Use of the system inclusive of requisition submission, clinical report review and case history management.

OICR Web Developers/Genome Sequence Informatics (GSI):

Maintain Github repository and external data archives. Update the system as required and document any updates. Update and follow SOPs related to change management and application deployment.

Study Sponsor or Delegate:

Submission of study and site specific OICR Genomics Requisition System Access Request Forms, monitoring of study specific requisitions.

4. System Description

The [OICR Genomics Requisition Portal](#) is a user role-based secure portal for the submission of test requisitions and associated tissues, including: fresh frozen tissue blocks, fresh frozen laser capture microdissected (LCM) tissues, formalin fixed paraffin embedded (FFPE) tissue sections, buffy coat, EDTA and STRECK blood tubes for OICR Genomics' validated whole genome, whole transcriptome, and targeted ctDNA assays. OICR Genomics complies with the ISO 15189 standard, which requires collection of the following PHI:

- Patient name (first, middle and last) and date of birth
- Specimen collection date
- Referring lab identifier
- Requisitioner name
- Referring physician name (first, middle and last), email address, medical license number, city, phone number, and hospital

The [OICR Genomics Requisition Portal](#) retains all required PHI in an access-restricted database accessible to Clinical Coordinators and licensed Geneticists. PHI must never be transmitted, shipped or communicated in print or via digital platforms such as Slack or email; PHI may only be recorded via study specific requisition forms through the [OICR Genomics Requisition Portal](#).

4.1 User Roles

There are two categories of user roles: global user roles and study specific user roles. A specific user can have from none to all of these user roles.

Global user roles control the Requisition Portal as a whole, permitting users to modify system level pages, emails, and forms. These roles are visible from My Account > Account Settings, in the User Settings area.

There are three global user roles:

- **Global Administrator (no PHI access):** Includes the GSI Director and individuals in IT
 - Assign other users global roles
 - Modify pages on the requisition other than forms
- **Form Administrator (no PHI access):** Includes the Genomics Program Manager and GSI Director, who may:
 - Create and customize specific study requisition form templates
 - Add/remove user access and assign study specific user roles
 - Monitor de-identified sample withdrawals, consent withdrawals, rejected clinical reports, rescinded clinical reports, report progress, and system auditing.
 - Clone existing requisitions after software revision
 - Merge requisition forms
 - Commit forms metadata to GitHub
- **No role (no PHI access):** the default level for all users not granted one of the two other roles.

Global user roles are discussed more in Section 12-14.

Study specific user roles are assigned per form, granting specific permissions to that form alone. These roles ensure tracking of all stages of a requisition lifecycle from sample submission to report generation and sign out. Key activities of each role are defined below.

1. **Requisitioner (full PHI access):** Includes external Clinical Coordinators, who are authorized to view PHI and patient information. Requisitioners may:
 - a. Submit a requisition
 - b. Withdraw a requisition (user entry error)
 - c. Edit a requisition
 - d. Submit notification of consent withdrawal
 - e. Print requisition for inclusion in medical record (includes PHI)
 - f. Print shipping manifest (no PHI)
 - g. Rescind signed out clinical reports to correct PHI and/or non-PHI fields
2. **Accessioner (no PHI access):** Includes Tissue Portal staff, who may:
 - a. Approve a requisition/requisition edit (non-PHI fields)
 - b. Accept a shipment following receipt at OICR
 - c. Download MISO LIMS information
 - d. Review rescinded requisitions and genomic reports for required changes to non-PHI fields (Requisitioner initiated)
 - e. Report privacy breaches
3. **Laboratory (no PHI access):** Includes Cancer Genomics Interpreter (CGI) informatics staff and Medical Laboratory Technicians (MLTs), who may:
 - a. Upload a draft clinical report (no PHI), triggering an email notification to a Sign Out user

- b. Reopen and upload a revised draft clinical report (no PHI), triggering an email notification to a Sign Out user
 - c. Review requisition edits (non-PHI fields)
 - d. Review rescinded requisitions and genomic reports for required changes to non-PHI fields (Requisitioner initiated)
- 4. **Sign Out (full PHI access)**: Includes external Geneticists (ACMG/CCMG) who are authorized to view PHI and patient information. Sign Out users may:
 - a. Review and approve or reject a draft clinical report
 - b. Review requisition edits (PHI and non-PHI fields)
 - c. Approve or reject revisions to rescinded clinical reports
- 5. **Administrator (no PHI access)**: Includes the Genomics Program Manager and GSI Director, who may:
 - a. Create and customize specific study requisition form templates
 - b. Add/remove user access and assign study specific user roles
 - c. Monitor de-identified sample withdrawals, consent withdrawals, rejected clinical reports, rescinded clinical reports, report progress, and system auditing

Study specific user roles are discussed more in Sections 6 through 11.

4.2 Requisition Lifecycle

Requisitions require actions from study-specific user roles to ensure that submission, draft genomic report generation and clinical report sign out occur in a stage-gated process. The general processing stages of a requisition workflow are depicted below (figure 1a).

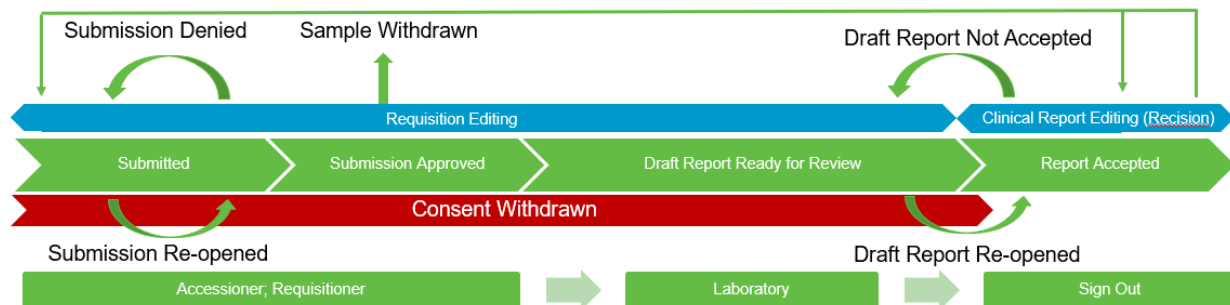


Figure 1a. An overview of a requisition's lifecycle.

In the ideal case, a requisition proceeds as follows:

1. A Requisitioner submits a requisition form with PHI
2. An Accessioner reviews the requisition form (no PHI) and approves the submission
3. A Laboratory user uses the information from the approved requisition form to draft and submit a clinical report (no PHI)
4. The Sign-Out user reviews the clinical report, adds PHI to the report, and submits a signed-out clinical report with PHI
5. The Requisitioner retrieves the signed-out clinical report with PHI from the system.

4.3 Requisition Statuses

A requisition may enter several other states depending on the specific case's needs. For example, an assay may need to be changed in a requisition from a lower coverage to higher coverage. Email notifications alert user roles of tasks that require their attention or to confirm completion of an action/process. Requisition status is always visible within your user dashboard, see [Navigating the OICR Genomics Requisition Portal](#).

Below is a full list of every state that a requisition can be in. The permissible transitions from state to state are outlined in Figure 1b.

- Submitted: A requisition has been submitted by a Requisitioner but has not yet been approved by an OICR Accessioner. Rescinded reports with Requisitioner changes to non-PHI fields may revert to this status state.
- Submission Approved: A requisition has been approved by an OICR Accessioner. Samples may be shipped.
- Submission Denied: An OICR Accessioner has reviewed the submitted requisition and determined an error is present.
- Submission Reopened: A Requisitioner has reopened a previously denied requisition.
- Sample Withdrawn: A Requisitioner has withdrawn a submitted requisition, due to mistaken submission.
- Consent Withdrawn: A Requisitioner has indicated that a patient has withdrawn consent.
- Draft Report Ready for Review: A Laboratory user has uploaded a draft genomic report for review by a Geneticist (Sign Out user).
- Report Accepted, Sign Out Complete: A Geneticist (Sign Out user) has reviewed the draft genomic report and accepted the case analysis. Sign Out is complete and a clinical report may be downloaded by a Requisitioner.
- Draft Report Not Accepted: A Geneticist has not accepted the draft genomic report, revision is required. Laboratory user must update/correct draft genomic and/or QC report and upload copies.
- Sign Out Rescinded with PHI: A requisitioner has rescinded a signed out clinical report due to discovery of an error in PHI by a requisitioner or treating physician.

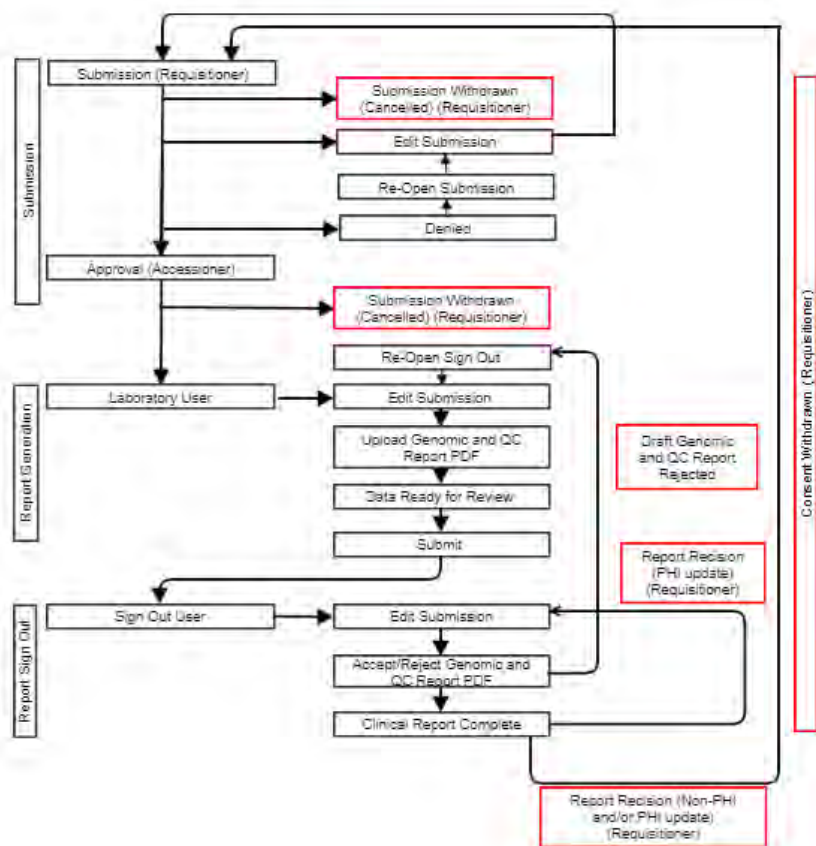


Figure 1b: States that a requisition can enter and how they get there.

4.4 Information Collected for All Study Requisitions

The nature of OICR requisitions require the collection of personal health information (PHI) as well as other non-identifying information about specific cases. All data is maintained behind OICR's firewall on storage encrypted at rest and given the highest level of protection. All internet communications between a user and the [OICR Genomics Requisition Portal](#) are encrypted with Open SSL and visibility is restricted based on user role.

The following is a list of information that is collected for every requisition. A specific study may have more requirements; check the Requisition Portal for the full list. Incomplete requisitions cannot be saved; all fields must be complete. Review this section thoroughly and ensure you have collected all required information.

Required PHI:

- Patient name (first, middle and last),

- Patient Date of birth
- Specimen collection date
- Referring lab identifier
- Referring physician, including first, middle and last name
- Physician email address
- Physician Medical license #
- Physician City
- Physician Phone #
- Physician Hospital.

Required Non-PHI

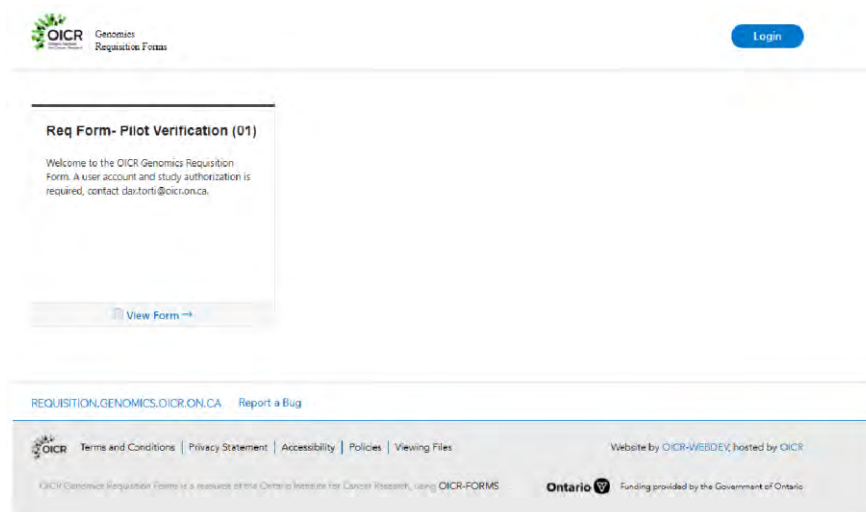
- Study
- Patient study ID
- Patient sample study ID
- Genetic sex
- Consent status (yes/no)
- Site of biopsy
- Primary cancer diagnosis
- Tumour type
- Oncotree code (see below)
- % tumor cellularity/content in marked area: minimum 30%, except for LCM material. Use pathology report estimate.
- % necrosis in marked area: Use pathology report estimate.

4.4.1. OncoTree Codes

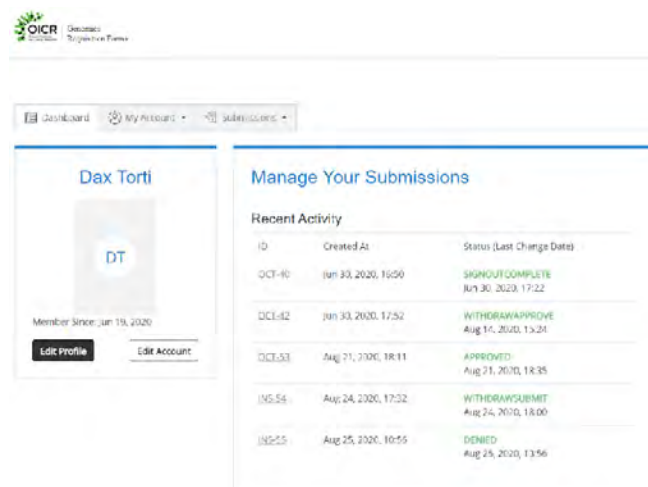
Tumors must be classified using OncoTree codes that are defined at <http://oncotree.mskcc.org/#/home>. Always select the “oncotree_latest_stable” version. OncoTree categorizes tumors by tissue and tumor type. The web interface may be utilized to classify the tumor. Use the respective tumor acronym, i.e. for Fibrolamellar Carcinoma (FLC), enter the code “FLC” on the requisition Oncotree code text field.

5. Navigating the OICR Genomics Requisition Portal

All users begin their session at [OICR Genomics Requisition Portal](#) landing page. Permissions for each study are granted by the Administrator. Clinical Program managers may be granted access to more than one study as required to monitor their team’s respective activities.



5.1 Dashboard



Upon user login, users are directed to their dashboard as seen above. Each menu tab contains the following information:

- Dashboard: All recent activity including submitted requisitions and associated identities (IDs).
- My Account (My Profile): User account information.
- Submissions :
- Manage Forms : Visible to Administrators and Form Administrators

5.2 My Account

My Account displays a drop-down contains information about the current user.

My Profile: Modify the user's first and last name. After making any changes, press 'Save Changes'.

Account Settings: View email address, update password, view global roles, status of the account, selected language, and timezone. After making any changes, press 'Save Changes'.

5.3 Submissions (Requisition Status)

The Submissions tab has a drop-down list of the submitted forms from every requisition form the current user is permitted to view. If a user's role does not permit them access to submissions, there may be no drop-down visible.

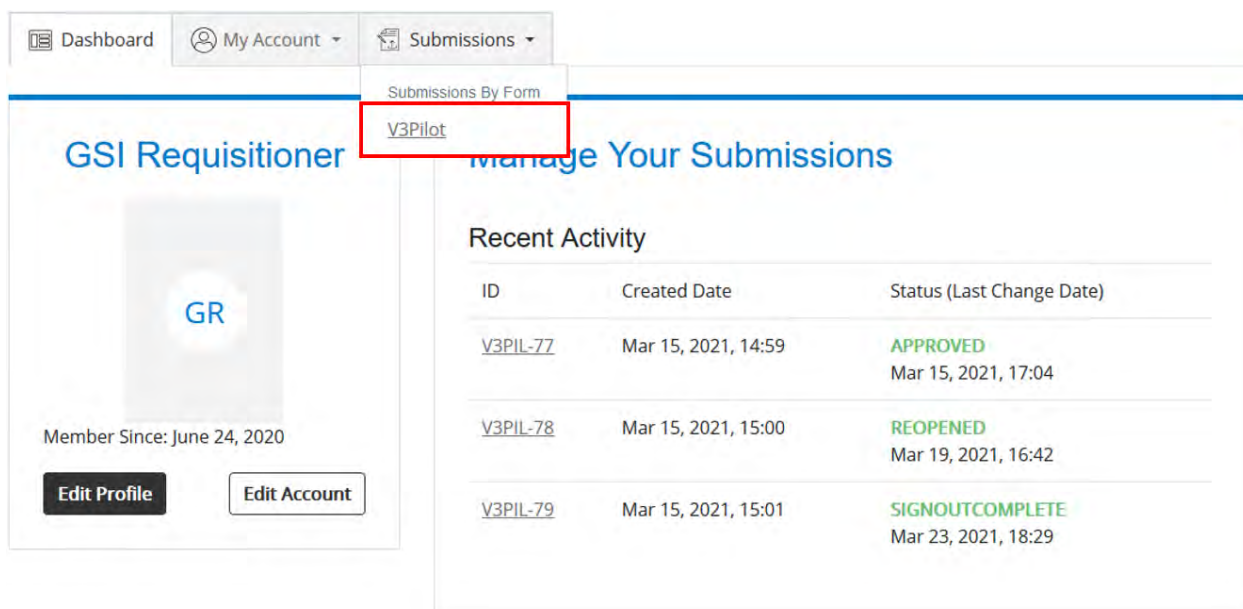
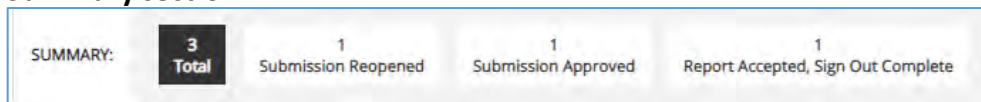


Figure: Selecting the "V3Pilot" requisition form from the Submissions drop-down.

Once a user selects a requisition form from the Submission drop-down, they will see the Study Submissions page.

Summary section



The summary section is an aggregate view of all [requisition status states](#). Note, status state icons will only appear in the "Summary" field after a requisition has reached this status state at least once for a given study form. For a complete list of possible statuses, see Section 4.2. Requisition Lifecycle.

Table with submissions

Filters: Status: All Updated between: mm/dd/yyyy and: mm/dd/yyyy Search: Enter Keywords Clear					
Bulk Actions: -- Select Option -- Apply					
<input type="checkbox"/>	ID	Submitted By	Created Date	Status (Last Change Date)	Actions
<input type="checkbox"/>	V3PIL-79	GSI Requisitioner gsireq0622@gmail.com	March 15, 2021, 15:01	REPORT ACCEPTED, SIGN OUT COMPLETE March 23, 2021, 18:29	View
<input type="checkbox"/>	V3PIL-78	GSI Requisitioner gsireq0622@gmail.com	March 15, 2021, 15:00	SUBMISSION REOPENED March 19, 2021, 16:42	View
<input type="checkbox"/>	V3PIL-77	GSI Requisitioner gsireq0622@gmail.com	March 15, 2021, 14:59	SUBMISSION APPROVED March 15, 2021, 17:04	View

The submissions table contains the status of all study requisitions the user is permitted to view.

- Filter section: filter the requisitions by status, updated date, and keywords
- Bulk Actions: select submissions with the check boxes at the left and use the drop-down to perform a bulk action on all requisitions simultaneously
- Table columns
 - ID: the unique requisition ID. Clicking on the ID of any submission will take the user to the submitted form for review.
 - Submitted by: the name and email address of the requisitioner who submitted the form.
 - Created Date: the date the requisition was submitted
 - Status (Last Change Date): the status of the requisition and date last modified. See "Requisition Lifecycle" for a complete list of statuses.
 - Actions: select the drop-down to perform an action on the requisition appropriate for its status and role.

5.3.1 Requisition Page

The requisition page, accessed through the Study Submissions page, has the full contents of the requisition forms that the user is permitted to view (e.g. a Laboratory User cannot view submissions that are not approved, nor can they view PHI).

V2Pilot-test-delete

Tools ▾

ID

V2PILOT-71
SUBMISSION REOPENED
MARCH 11, 2021, 17:24
[View](#)

V2PILOT-73
SUBMISSION APPROVED
MARCH 11, 2021, 17:15
[View](#)

V2PILOT-72
SUBMISSION APPROVED
MARCH 11, 2021, 17:00
[View](#)

ID: V2PILOT-71

Submission Reopened March 11, 2021, 17:24
Submitted By: Dax Torti (dtorti26@gmail.com)

[Edit Submission](#) [X](#)

[Edit Submission](#)
[Download Requisition](#)
[Download Manifest](#)
[Download Miso](#)

Submission Case History

#	Action	Updated By	Updated At	Comment	Submission
4	Submission Reopened	Dax Torti (dtorti26@gmail.com)	March 11, 2021, 17:24		View Submission
3	Submission Denied	GSI Accessioner (gsiacc0622@gmail.com)	March 11, 2021, 17:08	Issues with data entry, incorrect study ID.	
2	Submitted	Dax Torti (dtorti26@gmail.com)	March 11, 2021, 16:00		
1	Submitted	Dax Torti (dtorti26@gmail.com)	March 11, 2021, 16:00		View Submission

On the left side is a listing of all requisition forms for this study, including the status, last modified date, and Action drop-down from the Study Submissions page. The same set of actions is available at the top right for the form currently in view.

In the center is a specific requisition. The unique requisition ID is at the top, as well as the status, last modified date, and requisitioner.

The submission tab shows the contents of the form as it was submitted. If permitted by role and status, modifications are also made here, including uploading QC and clinical reports.

5.3.1.1 Requisition Case History

The case history contains a date and time stamped audit log of all requisition status changes as performed by all users. All requisition status changes, Accessioner submission denials and rejected draft genomic report notes may be reviewed from the “Case History” tab

1. Select a requisition ID from the study dashboard as seen below.
2. Select the “Case History” tab, as seen below.

Dashboard My Account Submissions ▾

Published Open Qm: July 06, 2020

INSPIRE Requisition

ID: INS-56 [Edit](#) [X](#)

[Withdraw Consent](#) Consent Withdrawn: Aug 27, 2020, 15:00

Submission **Case History**

5.4 Manage Forms

The “Manage Forms” dashboard contains form management configuration options and is available to Administrators of specific forms as well as global Form Administrators.

Form ID	Date	Status
OCT-41	Jun 30, 2020, 17:29	SIGNOUT COMPLETE Jun 30, 2020, 17:38
INS-52	Aug 14, 2020, 16:29	APPROVED Aug 14, 2020, 16:29

6. Study Specific User Accounts

The OICR Genomics Requisition System user accounts, study and access permissions and site-specific study requisition forms are granted/created upon study approval.

6.1 Requesting a User Account/Access Change Request

The Administrator must receive a completed TW-024 OICR Genomics Requisition System Access Request Form from the academic study sponsor, site co-investigator, or their authorized delegate for each authorized account, specifying the user role (Requisitioner or Sign Out) as defined in [Requisition System Processes Associated with User Roles](#). The study sponsor or delegate must also immediately submit a TW-024 OICR Genomics Requisition System Access Request Form for any employee whose employment status or study assignment has changed. All accounts require an institutional email address.

6.2 Account Creation, Password Configuration and Account Agreement Terms

Since the introduction of multi-factor authentication (MFA), this process has changed.

1. The Administrator will add users to a specific study site requisition form following [Configuring Study Specific User Roles](#).

2. The Administrator submits a ticket to OICR IT (helpdesk@oicr.on.ca) requesting the user's password be set to permit MFA. Include the user's name and email address, and the system (Genomics Requisition and Reporting system).
3. The user will receive an email notification "Genomics Requisition Forms-Account Created". Ensure they add requisition.genomics@oicr.on.ca to their email account safe senders list. This email notifies the user that their password will arrive shortly from OICR's IT team.
4. OICR IT will create the user account in Crowd and email a password to the user.
5. Upon first login, the user will be prompted to accept the new account agreement.
6. After accepting the account agreement, the user must complete their basic profile information.
7. The user can then use the Account Settings page to set their password to something more memorable.

6.3 Password Reset

If you have access to the system and wish to reset your password, follow these steps:

1. From the [OICR Genomics Requisition Portal](#), select Login, and select "Forgot your password".
2. Enter your account email address.
3. The portal will display the following notification and the user will receive an email notification with subject header "OICR Genomics Requisition Forms- Reset Your Password".
4. From the notification email, select "Reset your password".
5. Set a new password.

If you have forgotten your password, please email helpdesk@oicr.on.ca and request your password for the OICR Genomics Requisition System be reset.

6.4 User Account and Password Expiry Policies

Accounts that are not accessed for a period >1 year will automatically be deactivated. If your account is deactivated, please contact the Administrator.

Passwords must be reset every year. Users will be prompted to select a new password 1 year from initial account activation.

7. Requisitioner Processes

Requisitioners requisition assays for patients in studies. Only Requisitioners may edit a requisition or rescind a clinical report. Only Requisitioner and Sign Out users (Geneticists) have visibility of PHI fields.

7.1 Submitting a Study Specific Requisition (Requisitioner)

Each requisition form captures critical information, including PHI. Only completed requisition forms may be submitted; if all fields are not complete the requisition may not be submitted. Upon completion of the submission, a study specific requisition ID will be automatically assigned and annotated in all portal email notifications.

Be prepared and have all required information available for entry. More details about what information is required is available under “Information Collected for All Study Requisitions”.

1. To submit a study specific requisition, login to [OICR Genomics Requisition Portal](#).
2. In the upper right-hand corner of the dashboard landing page, select “View Forms”.
3. Select the study specific requisition tile e.g. “Req Form-Pilot Verification (01)”. If the requisition form is “greyed out” and you cannot enter information, you do not have permission to access that particular requisition form; contact the Administrator.
4. Complete the requisition form with information about the case. See Section 4.3 Information Collected for All Study Requisitions for more information. Certain fields, including your account information may be autocompleted.
5. A notification email will be sent to confirm your submission with the subject header “Your requisition was received. Accessioner approval pending”.
6. Before shipping any materials, your requisition must be approved/accepted by OICR. Do not ship samples until your submission is approved.
7. You may review your submission at any time by navigating to your account dashboard and selecting the “Submissions” tab and study specific form, where you can track requisition status.
8. If desired, you can download the requisition for your records. Select the study requisition and from the “Actions” column, select “Download Requisition” for your records. This PDF will contain PHI.


<input type="checkbox"/> ID	Submitted By	Created Date	Status (Last Change Date)	Actions
<input type="checkbox"/> V2PILOT-74	Dax Torti dtortiz26@gmail.com	March 11, 2021, 17:55	SUBMITTED March 12, 2021, 15:09	<div>View</div>
<input type="checkbox"/> V2PILOT-75	Dax Torti dtortiz26@gmail.com	March 12, 2021, 14:17	SUBMISSION REOPENED March 12, 2021, 15:03	<div>Reopen to Edit</div>
<input type="checkbox"/> V2PILOT-71	Dax Torti dtortiz26@gmail.com	March 11, 2021, 16:00	SAMPLE WITHDRAWN March 11, 2021, 17:40	<div>View Submission</div>
<input type="checkbox"/> V2PILOT-73	Dax Torti dtortiz26@gmail.com	March 11, 2021, 17:13	SUBMISSION APPROVED March 11, 2021, 17:15	<div>Withdraw Submission</div>
<input type="checkbox"/> V2PILOT-72	Dax Torti dtortiz26@gmail.com	March 11, 2021, 16:48	SUBMISSION APPROVED March 11, 2021, 17:00	<div>Download Requisition</div>
				<div>Download Manifest</div>
				<div>Download Miso</div>

7.2 Shipping Materials and Manifest Documentation (Requisitioner)

After receiving an email notification with subject “Your requisition was approved. Ship materials to OICR.”, you may ship materials to OICR. Alternatively, the requisition status “Submission Approved” may be monitored directly from your user dashboard.

1. Upon notification of requisition approval, either click on the notification email link or login directly to the [OICR Genomics Requisition Portal](#).
2. On the study submissions page, select the approved requisition, and under the “Actions” column, select “Download Manifest”.
3. The PDF Manifest lists sample information only without PHI, shipping address and date of submission. Specific shipping instructions will be provided by OICR Genomics. Only include the shipment manifest document within a shipment. Requisition PDFs contain PHI and should never be included in a shipment. Materials must be identified with study ID, sample study IDs and respective requisition ID as indicated on shipment manifest form. In the image below, the requisition ID is “V2PILOT-72”.

1 of 1



OICR
Ontario Institute
for Cancer Research

Director: Trevor Pugh, PhD, FACMG
Phone: 647-468-7844

Main contact: Dax Torti, PhD
Phone: 647-260-7938

Hours of Operation: Mon - Fri, 9:00AM - 5:00PM

Ontario Institute for Cancer Research
c/o Tissue Portal Sample Receiving
MaRS Centre, West Tower
661 University Avenue, Suite 6-46
Toronto, Ontario, Canada, M5G 0A3

CAP: 8381376

OICR Genomics Shipment Manifest

ID: V2PILOT-72

Form: V2Pilot-test-delete
Current Status: Submitted

Created At: March 11, 2021, 4:48 PM EST
Updated At: March 11, 2021, 4:48 PM EST
Software Version: req.v.1.1

Instructions:

Include a copy of the shipment manifest only. Do not email or include a copy of the requisition in a shipment. Ensure all shipped materials are de-identified and are clearly labeled with requisition ID (V2PILOT-72), Study, Study ID, and Study Sample ID only. Surgical identifiers and/or procedure dates, nor patient initials are permitted in shipment documentation.

Included Materials:

[] Study Sample ID(s)
 Specimen (Tumour): Pilot-01-02-TD
 Specimen (Blood): adfs

7.3 Editing a Study Specific Requisition Prior to Sign Out (Requisitioner)

If you have erroneously entered information on a requisition, editing a requisition is possible and required. All changes and edits are logged in the Case History. If a clinical report has not been signed out, follow these steps.

1. From your account dashboard navigate to the “Submissions” tab and select the study specific form.
2. From the study specific dashboard or within the requisition itself, select the Action drop-down menu and click “Reopen to edit”.
3. From the action menu, select “Edit submission”.
4. All fields will become editable. When corrections are complete, click “Submit” at the bottom of the requisition. Requisition status will revert to “SUBMITTED”.
5. An email notification will confirm the revision, with the subject “An Existing Requisition Was Edited by a Requisitioner.”
6. OICR Accessioners will review your edited requisition and accept or reject the revised requisition. If your requisition was previously approved and materials shipped to OICR, OICR Accessioners and Laboratory users will correct errors in de-identified records and Sign Out users will review and correct PHI fields at OICR as necessary. Requisition form changes may be reviewed at any time by downloading a copy of any version of the original or edited requisition from the requisition case history, see section [Case History Review](#).
7. The Requisitioner will receive an email with the subject header “Your Requisition Was Approved. Ship Materials to OICR.” Follow instructions within the body of the email if material shipment is pending. If materials were shipped to OICR Genomics after a prior requisition approval, disregard instructions for shipment.

7.4 Withdrawing a Study Specific Requisition (Mistaken Submission) (Requisitioner)

At any time, a requisition may be withdrawn by the Requisitioner in the case of a mistaken submission.

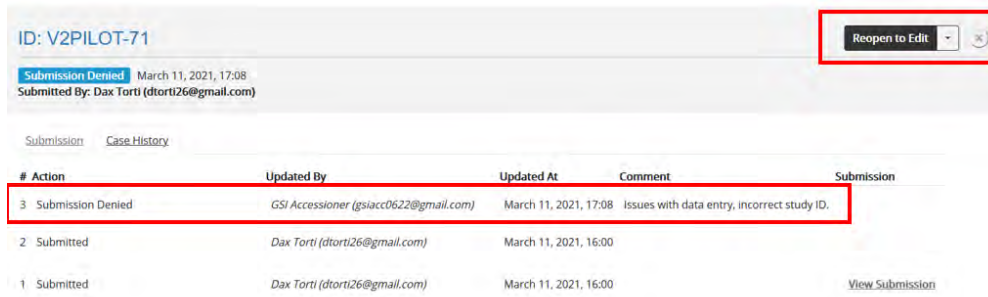
1. From your account dashboard navigate to the “Submissions” tab and select the study specific form.
2. From the “Actions” column, select “Edit Submission” (for submitted and approved requisitions), or “Withdraw Submission” (for submitted, but not yet approved requisitions)
3. From within the requisition form, select “Withdraw submission” and select “sample withdrawn” as seen below. Enter the reason for withdrawal of the requisition in the text field; justification is required. The information will appear in the case history and be visible to other roles. Do not include any PHI in the text field. Click “Submit” at the bottom of form.
4. An email notification will be sent to the Requisitioner and Accessioner with subject “A Requisition Has Been Cancelled (Mistaken Submission).” The requisition status will display “Sample Withdrawn” and the justification will appear within the current requisition version.

- For submitted and approved requisitions, OICR Accessioners will receive an email indicating that the sample should not be processed and will be set aside for return to your institute.

7.5 Re-submitting a Denied (Rejected) Submission (Requisitioner)

If an Accessioner at OICR has rejected your requisition submission due to a data entry error or other discrepancy, please review the case history of the requisition and correct or provide further information to clarify the requisition issue. Do not communicate PHI to OICR staff.

- When you receive a notification email with subject header “Your Requisition Was Denied. Do Not Ship Sample(s)”, review is required. From your account dashboard, navigate to the “Submissions” tab and select the study.
- Select and view the patient requisition “ID” with status “Submission Denied” from the dashboard. Select the “Case History” tab and scroll to the “Action” case log “Submission Denied”. Review the “Comment” section to review corrective recommendations and/or data requiring review, as seen below.



The screenshot shows the OICR Genomics Requisition Portal interface. At the top, the ID is V2PILOT-71. Below this, a status bar indicates "Submission Denied" on March 11, 2021, 17:08, submitted by Dax Torti (dtorti26@gmail.com). A red box highlights a "Reopen to Edit" button. Below the status bar, there are tabs for "Submission" and "Case History". The "Case History" tab is active, showing a table of actions. The table has columns: #, Action, Updated By, Updated At, Comment, and Submission. The first row (highlighted with a red box) shows action 3: "Submission Denied" by GSI Accessioner (gsiaacc0622@gmail.com) on March 11, 2021, 17:08, with the comment "Issues with data entry, incorrect study ID." The second row shows action 2: "Submitted" by Dax Torti (dtorti26@gmail.com) on March 11, 2021, 16:00. The third row shows action 1: "Submitted" by Dax Torti (dtorti26@gmail.com) on March 11, 2021, 16:00, with a "View Submission" link.

#	Action	Updated By	Updated At	Comment	Submission
3	Submission Denied	GSI Accessioner (gsiaacc0622@gmail.com)	March 11, 2021, 17:08	Issues with data entry, incorrect study ID.	
2	Submitted	Dax Torti (dtorti26@gmail.com)	March 11, 2021, 16:00		
1	Submitted	Dax Torti (dtorti26@gmail.com)	March 11, 2021, 16:00		View Submission

- You may directly proceed to re-open the submission from the case history tab by selecting “Reopen to edit”, as seen above, or from the main study dashboard. Requisition status will change from “Submission Denied” to “Submission Reopened”.
- From the submission or case history tab or the main study dashboard, select “Edit Submission”.
- When corrections are complete, click “Submit” at the bottom of the requisition. The requisition process will then begin again at step 4, [9.1 Submitting a Study Specific Requisition \(Requisitioner\)](#). Requisition status will revert to “SUBMITTED”.

7.6 Registering Consent Withdrawal (Requisitioner)

External Clinical Coordinators (Requisitioners) are required to notify OICR Genomics of a patient’s request to withdraw consent. All stages of consent withdrawal occur through the [OICR Genomics Requisition Portal](#). Do not communicate information outside of the Requisition Portal.

- From your account dashboard navigate to the “Submissions” tab and select the study specific form.

2. From the “Actions” column, select “Edit Submission” (for submitted and approved requisitions). or “Withdraw Submission” (for submitted, but not yet approved requisitions).
 - 2.1. Alternatively, the same functions may be initiated directly from the requisition form
3. New fields will appear immediately below. Select “Consent Withdrawn”. Enter the reason for consent withdrawal in the text field. Do not include any PHI because the information will appear in the case history and be visible to other roles. Click “Submit” at bottom of form.

V2Pilot-test-delete

The screenshot shows a web interface for withdrawing a submission. On the left is a sidebar with a list of submissions, including 'V2PILOT-75', 'V2PILOT-76', 'V2PILOT-77', and 'V2PILOT-78'. The main content area is titled 'WITHDRAW [NON-PHI]' and contains the following sections:

- Do you want to withdraw this submission?**: A section with a red-bordered box containing a 'Withdraw Submission' button.
- Please choose the type of withdraw. ***: A section with two radio buttons: 'Sample Withdrawn' and 'Consent Withdrawn'. The 'Consent Withdrawn' button is highlighted with a red box.
- Reason for withdraw? Do not include PHI in your note. This text field will be visible in the requisition case history and visible to all roles. ***: A large text input field with a red border.

4. An email notification with subject “Patient Consent Has Been Withdrawn; Stop Processing Samples and/or Data” will be sent to all roles associated with the study including Requisitioner, Accessioner, Laboratory, Sign Out and Administrator. Contact the Administrator to arrange for return or destruction of materials. Requisition status will state “Withdraw consent”.

7.7 Download a Signed Out Clinical Report PDF (Requisitioner)

Requisitioners will receive an email notification with subject header “A Clinical Report Has Been Signed Out. Case Report Complete. Requisitioner, Download Clinical Report.” When a clinical report is ready for review by a treating physician.

1. Login to the OICR Genomics Requisition System. Select the specific requisition or select “View Submission”.
2. Scroll to the header “Sign Out Report [PHI]” and click on the report of interest to download. The clinical report PDF containing PHI will be downloaded to your computer, typically to the “Downloads” directory for Windows PCs or the download directory specified by your web browser.
3. Share the completed clinical report with the treating physician and/or include in the patient’s medical file.

7.8 Rescinding (Correcting) a Signed Out Clinical Report (Requisitioner)

If a treating physician or a clinical coordinator observes an error in patient information (PHI, non-PHI, or both) on a signed out clinical report, the information may be corrected, and an updated clinical report issued. The Requisitioner must initiate all corrective actions to an erroneous requisition. Versioned copies of the requisition will be available in the case history.

1. To edit a requisition after a clinical report has been signed out, navigate to the respective study dashboard or to the specific requisition and select “Edit to Rescind”.
2. Scroll to the bottom of the requisition and select “Rescind Sign Out”. A new submenu will appear, select whether the error occurs in non-PHI fields, PHI and non-PHI fields, or PHI only fields. A text field will appear, note the affected fields that were changed, but do not disclose PHI. These comments will appear in the case history and be viewable by all users. These comments will assist Accessioners, Laboratory and Sign Out users to review and correct the requested changes.

For further information on correcting each type of requisition, see below.

7.8.1 PHI Correction

If only PHI fields are impacted, the status of the requisition will change from “Report Accepted, Sign Out Complete” to “Sign Out Rescinded with PHI”.

1. Complete steps in section 9.8, steps 1 and 2, selecting “PHI only”.
2. An email will be sent to the requisitioner, administrator and sign out roles “A clinical report has been rescinded by a Requisitioner. Requisitioner, edit requisition PHI and resubmit”. Requisition PHI fields will become editable and information may be corrected.
3. After completing corrections, scroll to the bottom of the requisition and attest “Yes, my edits are complete, and data is ready for review”. The status state will change from “Sign Out Rescinded with PHI” to “PHI Data Updated, Ready for Sign Out Review”.
4. An email notification with subject line “A Clinical Report Was Rescinded by a Requisitioner. PHI has been updated. Sign Out User Must Review Requested Changes, Edit and Approve/Reject Revised Clinical Report” will be sent to the Sign Out User to review the requested correction. Status state and comments will be viewable to all users within the requisition case history.
5. The Geneticist (Sign Out user) will now review the changes to the requisition. If they accept the requested changes, no further action is required. An email will be sent alerting the requisitioner that the case is signed out, and the requisition status will change to “Report Accepted, Sign Out Complete”.

7.8.2. Non-PHI Correction

Changes to Non-PHI fields require review by Accessioners, Laboratory, and Sign Out users. Non-PHI changes may impact OICR's LIMS system and/or clinical report details. Accessioners must approve the change(s) to non-PHI fields, laboratory users must review the draft genomic report, and replace the existing draft report if non-PHI fields are impacted, and the sign out user must review and revise the existing clinical report.

1. Complete steps in section 9.8, steps 1 and 2, selecting "non-PHI only".
2. Revise affected non-PHI fields within the requisition, attest "Yes, my edits are complete and data is ready for review", and submit.
3. The status state of the requisition will change from "Report Accepted, Sign Out Complete" to "Reopened" (prior to edits of non-PHI) and finally to status "Submitted". An email will be sent to Accessioners, Requisitioners, Laboratory and Sign Out users with subject header "A Clinical Report Has Been Rescinded by a Requisitioner. Non-PHI information fields are updated. Accessioners, Laboratory and Sign Out Users Must Review Changes".
4. If desired, you can download the requisition. Select the study requisition and from the "Actions" column and select "Download Requisition". This PDF will contain PHI. Prior requisition form versions are available in the requisition case history.

Note: existing sample submission workflows and approvals will be reactivated. Accessioners will approve the revised submission. An email will be sent advising to ship samples, this may be ignored. Laboratory users will update the draft clinical report, and a revised clinical report will be issued.

7.8.3 Both Non-PHI and PHI Correction

Changes to both Non-PHI and PHI fields require review by Accessioners, Laboratory, and Sign Out users. Non-PHI changes may impact OICR's LIMS system and/or clinical report details. Accessioners must approve the change to non-PHI fields, Laboratory users must review the draft genomic report, and replace the existing draft report if non-PHI fields are impacted, and the Sign Out user must review and revise the existing clinical report. Changes to PHI fields may only be reviewed by the Sign Out User and will impact the final clinical report.

1. Complete steps [9.8 Rescinding \(Correcting\) a Signed Out Clinical Report \(Requisitioner\)](#), 1 and 2, selecting "PHI and non-PHI".
2. Revise affected PHI and non-PHI fields within the requisition, attest, and submit.
3. The status state of the requisition will change from "Report Accepted, Sign Out Complete" to "Reopened" (prior to edits of non-PHI and PHI) and finally to status "Submitted". An email will be sent to Accessioners, Requisitioners, Laboratory and Sign Out users with subject header "A clinical report has been rescinded by a requisitioner. Non-PHI and PHI information fields are updated. Accessioners, Laboratory and Sign Out users must review changes".

4. If desired, you can download the requisition. Select the study requisition and from the “Actions” column, select “Download Requisition” for your records. This PDF will contain PHI. Prior requisition form versions are available in the requisition case history.
5. Note, existing sample submission workflows and approvals will occur. Accessioners will approve the revised submission. Note, an email will be sent advising to ship samples, this may be ignored. Laboratory users will update the draft clinical report, and a revised clinical report will be issued.

7.9 Reverting Edits to PHI on a Rescinded Clinical Report After Sign Out User Rejection (Requisitioner)

If the Sign Out user rejects the Requisitioner’s change request(s) to PHI, an email will be received “Requisitioner edits to PHI fields were rejected by the Sign Out user. Edit submission, revert prior edits and resubmit. The status of the requisition will revert to “Sign out rescinded with PHI” from “PHI updated, ready for review”.

1. In the case history, or from within the requisition, review the Sign Out user’s justification for rejecting the PHI change request. Select “Edit Submission” and revert prior changes to PHI. Attest changes (reversions) are complete and select “Submit”, as seen below.
2. The status of the requisition will change to “PHI updated, ready for review”. The Sign Out user will receive an email notification to review the requested changes (reversions) and release the clinical report. When the Sign Out user approves the clinical report the Requisitioner will receive an email “A clinical report has been signed out. Case report complete. Requisitioner, download clinical report.” The requisition status will change to “Report Accepted, Sign Out Complete”.

8 Accessioner Processes

After a Requisitioner submits a new requisition, or after they have edited a requisition, the requisition must be approved by an OICR Accessioner. An OICR Accessioner may be responsible for approving requisitions from several study specific requisitions and requisition user accounts. OICR Accessioners are assigned to each study specific requisition and multiple Accessioners may be responsible for one or more studies. If you are designated an Accessioner, you will receive an email notification of a new requisition with ID and instructions indicating next actions that are required upon logging into the OICR Genomics Requisition System. Please note, samples should not ship prior to acceptance of a requisition.

8.1 Approving a Submission (Accessioner)

1. When a Requisitioner submits a new requisition, the OICR Accessioner will receive a notification email with the subject header “A Requisition Has Been Submitted; Accessioner Approval Required”. This email will identify the requisition ID and user

account submitting the requisition. The Accessioner may click on the login link embedded within the email or login directly to the OICR Genomics Requisition Portal to approve the submission.

2. Upon login to the [OICR Genomics Requisition Portal](#) your user Dashboard will display recent activity. Navigate to the Submissions tab and select the study specific requisition. From the study dashboard, select the requisition that is pending approval by clicking on the requisition ID and review the submission for accuracy; ensure study IDs match the study specific requisition.
 - a. The requisition may be approved directly from the Study Submission page by selecting “Approve” in the actions column.
 - b. Alternatively, the requisition may be approved directly from the requisition form after review by selecting “Approve” from the drop-down menu in the right-hand margin of the requisition.
3. After selecting “Approve” for a requisition, the Approval dialogue box will appear. The Accessioner may add a comment if desired; do not include PHI. This comment will be visible to all users in the requisition case history. Select “Approve”.
4. After Accessioner approval, the Requisitioner will receive an email with the subject header “Your Requisition Was Approved. Ship Materials to OICR.”
5. The Accessioner will receive an email notification with the subject header “Anticipate Sample Shipment to Tissue Portal. Samples may arrive within 24-48 hours.

8.2 Approving a Requisitioner Edited Submission (Accessioner)

A Requisitioner may edit a requisition at any time, even after sign out (rescinded clinical report). When these events occur, Accessioners, Laboratory, Sign Out and Administrator roles are notified by email. If the Requisitioner edits the requisition prior to Accessioner approval and material shipment, the requisition record will reflect the most recent version; all requisition versions may be reviewed in the requisition case history. If materials have been received at OICR, the following procedure must be followed.

1. If a requisition is edited prior to sign out, the Accessioner will receive an email. Instructions are provided within the body of the emails.
2. Login to the [OICR Genomics Requisition Portal](#). Navigate to the Submissions tab and select the study specific requisition ID for review. The status of an edited requisition reverts from “Submission Approved” or “Draft report ready for review” to “Submitted” status.

3. Within the requisition, select the case history as seen below.

Tools ▾

☐ ID

V2PILOT-74
SUBMITTED
MARCH 12, 2021, 15:09
[View](#)

V2PILOT-75
SUBMISSION REOPENED
MARCH 12, 2021, 15:03
[View](#)

V2PILOT-71
SAMPLE WITHDRAWN
MARCH 11, 2021, 17:40
☐

ID: V2PILOT-74

Submitted March 12, 2021, 15:09
Submitted By: Dax Torti (dtorti26@gmail.com)

[Submission](#) **Case History**

#	Action	Updated By	Updated At	Comment	Submission
5	Submitted	Dax Torti (dtorti26@gmail.com)	March 12, 2021, 15:09		View Submission
4	Submission Reopened	Dax Torti (dtorti26@gmail.com)	March 12, 2021, 15:08		View Submission

4. Review changes to the requisition by comparing non-PHI requisition fields between the original submission and the revised submission and/or case history comment fields. Both the original and the revised requisition are available in the case history. Note date stamps and successive change logs.
5. Verify requisition date and time stamps to ensure you are reviewing the edited requisition as seen below.

Tools ▾

☐ ID

V2PILOT-74
SUBMITTED
MARCH 12, 2021, 15:09
[View](#)

V2PILOT-71
SAMPLE WITHDRAWN
MARCH 11, 2021, 17:40
☐

Viewing Revision History ID: V2PILOT-74

Submitted March 11, 2021, 17:55
Submitted By: Dax Torti (dtorti26@gmail.com)

6. If non-PHI field changes are acceptable, approve the requisition as documented in [Approving a Submission \(Accessioner\)](#). Note, changes may have occurred within PHI fields that are not visible to the Accessioner (your) role. Review the case history comments. If this occurs, only a Sign Out user may review the change in PHI, however the requisition may be approved. The Sign Out user will review PHI related changes at a later stage.
7. Upon Accessioner approval, the Requisitioner will receive an email with the subject header "Your Requisition Was Approved. Ship Materials to OICR.". The Accessioner will receive an email notification with the subject header "Anticipate Sample Shipment to Tissue Portal. Samples may arrive within 24-48 hours. These notifications may be disregarded by both parties.
8. If materials were previously received at OICR and accessioned into MISO LIMS but have not yet been transferred outside of OICR Tissue Portal, make required changes to LIMS identities, and/or tissue types may be made to LIMS and/or material labels.
9. If materials (nucleic acid aliquots) have been transferred to the Translational Genomics Laboratory, and changes are required to LIMS identities, notify the Administrator. Laboratory staff (MLTs) will update LIMS entries and/or update material labels.

8.3 Denying a Submission (Accessioner)

An Accessioner may be required to deny (reject) a requisition prior to approval or after a Requisitioner edit, due to inaccurate data entry or an observed discrepancy in data entry.

1. From the user dashboard, navigate to the “Submissions” tab and select the study specific requisition.
2. From the study submissions dashboard, select “Deny” from the “Actions” column. Alternatively, the requisition may be denied directly from the drop-down menu at the top of the requisition.
3. Upon selection of “Deny”, a dialog box will appear. Within this dialog box, provide a justification for denial of the requisition by selecting “Add Comment”. Do not include PHI. Click “Deny”. This information will appear in the case history of the requisition; see section [Requisition Case History Review \(All Users\)](#). The case status will appear as “SUBMISSION DENIED”.
4. The Accessioner will receive a confirmatory email “An OICR Accessioner Denied a Submitted Requisition.”
5. The Requisitioner will receive an email notification with the subject header “A Requisition Has Been Denied. Reopen, Edit Submission, Resubmit.”

8.4 Withdrawing a Study Specific Requisition (Mistaken Submission) (Accessioner)

A Requisitioner may accidentally submit a requisition in error. Should a Requisitioner catch this error, they may withdraw the sample before receipt at OICR. This situation could occur after shipment and/or receipt at OICR. If this situation occurs, the Accessioner will receive an email notification with subject “A Requisition Has Been Cancelled (Mistaken Submission)”.

8.5 Consent Withdrawal (Accessioner)

Consent withdrawal is initiated by the Requisitioner role, however the Accessioner role must immediately flag the associated MISO identity within OICR’s LIMS system.

1. A notification email with subject “Patient consent has been withdrawn; stop processing samples and/or data” will be received by all roles including Requisitioner, Accessioner, Laboratory, Sign Out and Administrator. Consent withdrawal will appear within the requisition case history and may be quickly identified on study dashboards under “Consent Withdrawn”. The requisition status will display “Consent Withdrawn”.
2. Within MISO LIMS, search for the respective requisition ID. Edit the identity under Identity>Consent>, mark record as “Revoked”.
3. Laboratory technicians (Accessioners) must retrieve all samples and derivatives from all associated workgroups and move materials to respective “consent withdrawn” locations in -20°C or -80°C located within Tissue Portal. Samples and derivatives may require destruction and/or return to external site. Seek direction from the Administrator.

8.6 Downloading Requisition Non-PHI Field Tables for MISO LIMS Entry

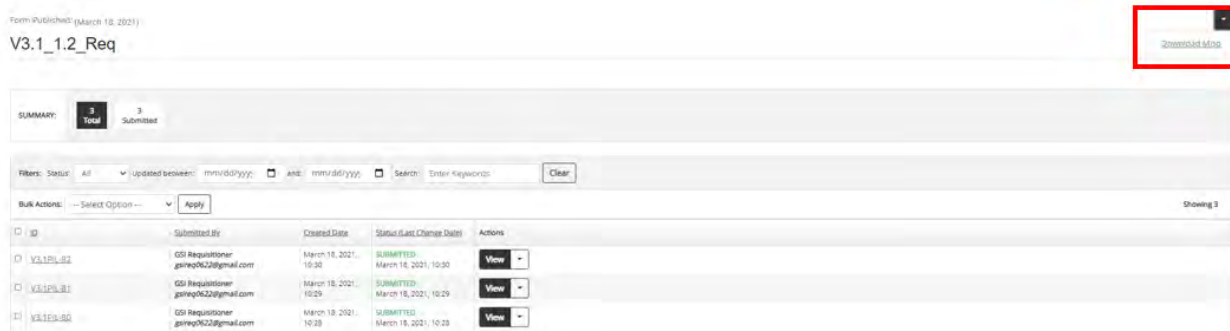
Non-PHI fields may be downloaded as a table for quick entry into OICR Genomics' MISO LIMS. This process may be completed for a single requisition, or in bulk for the complete study.

8.6.1 Single Requisition MISO LIMS Download Feature

1. To access LIMS-ready excel tables for an individual requisition, navigate to a specific requisition on a study dashboard and select "Download Miso". The "Download Miso" feature may also be accessed directly from within a requisition.
2. A excel file will be downloaded to your respective "downloads" folder by your browser. This information may be used for data entry.

8.6.2 Bulk Requisition MISO LIMS Download Feature

1. Navigate to a study specific dashboard. In the upper right corner, select "Download Miso".



2. A dialogue box will appear. Select "Generate Report". A excel file will be downloaded to your respective "downloads" folder by your browser. This information may be used for LIMS data entry.

9 Laboratory Processes

The Cancer Genomics Interpreter (CGI) team prepares draft clinical and QC reports and uploads PDF documents for review by Sign Out users. This team aggregates pipeline outputs to create a draft genomic report. This protocol is limited to uploading the draft clinical and QC report to a respective requisition via the OICR Genomics Requisition Portal for review by licensed Geneticists only.

9.1 Uploading a Draft Clinical Report (Laboratory)

1. From your account dashboard, navigate to the submissions tab and select the study.
2. Select the requisition ID by marking the record, and under the "Actions" column, select "Edit Submission".

3. Scroll to the requisition header “Data Report”. Upload the draft clinical report PDF (no PHI) under Data report>Genomic report (PDF). Upload the QC Report under Data report>QC report (PDF). Select “Data is ready for review” and click submit. The draft report can no longer be edited by a Laboratory user until Geneticist (Sign Out user) review.
4. A notification email with subject header “A draft clinical report is ready for review” will be sent to the Sign Out user, prompting review of the clinical report. The requisition status will display “Draft Report Ready for Review”.

9.2 Re-Opening (Revising) a Rejected Draft Clinical Report (Laboratory)

A Geneticist (Sign Out user) may reject a draft clinical report. The CGI team is responsible for addressing and seeking a resolution under direction from the Geneticist.

1. A notification email with subject “A Draft Report Was Not Accepted. Amend Draft Report.” Will be received.
2. From the study requisition dashboard, select the case with status “Draft Report Not Accepted”.
3. From the requisition case history, review the Geneticist’s comments and seek resolution, see below. If further discussion is required, contact the responsible Geneticist. Revise the draft genomic report.
4. From the case history tab, select edit, or from the study requisition dashboard, select the requisition and under “Actions” select “Edit Submission”.
5. Scroll to the bottom of the requisition and select “Reopen submission”. A text box will appear. Provide a justification for reopening and editing the draft genomic report as seen below. Click “Submit”.
6. The requisition status will change from “Draft Report Not Accepted” to “Submission Approved”. A notification email will be sent to the Sign Out user “Rejected Draft Clinical Report has been Reopened by CGI,” alerting Geneticists that a revised clinical report is anticipated. The data report PDF fields will now permit upload of a new genomic report and/or QC report.
7. To remove the existing erroneous draft genome report or QC report, click “Remove”.
8. Upload the corrected and versioned draft genomic report and/or QC PDF report, select “Data is ready for review” and click “submit”. The draft report can no longer be edited by a Laboratory user. Note, prior draft reports may be reviewed in the requisition case history.
9. A notification email with subject header “A draft genomic report is ready for review” will be sent to the Sign Out user, prompting review of the clinical report. The requisition status will display “Draft Report Ready for Review”.

9.3 Reviewing a Requisitioner-Edited Submission to “Non-PHI” or “PHI & Non-PHI” (Laboratory)

A Requisitioner may edit a requisition at any time, including after case sign out. When these events occur, Accessioners, Laboratory, Sign Out and Administrator roles are notified by email. The dashboard status of requisitions will revert to “Submitted”. The Accessioner is responsible for reviewing and approving non-PHI related changes. The requisition case history documents all versions of a requisition, including change request comments. Updates to LIMS, Revised QC and/or genomic reports may be required.

If materials have been received at OICR, and transferred to the Translational Genomics Laboratory, the following steps must be followed by Laboratory roles (MLTs and CGI).

9.3.1 Prior to Sign Out (Laboratory-MLTs)

- 1) Login to the [OICR Genomics Requisition Portal](#). Navigate to the Submissions tab and select the study specific requisition ID that was edited by the Requisitioner as noted in the notification email.
- 2) If the requisition status is “Submitted”, the Accessioner has not reviewed the changes to the requisition and updates to MISO LIMS records have not occurred. Do not proceed until status changes to “Submission Approved”.
- 3) If the requisition status is “Submission approved”, MLTs must review the changes to materials associated with the requisition ID within MISO LIMS for associated sample aliquots, libraries, or library aliquot change logs; update any affected material labels.

9.3.2 Reviewing a Requisitioner-Edited Submission (Laboratory-CGI)

- 1) Login to the [OICR Genomics Requisition Portal](#). Navigate to the Submissions tab and select the study specific requisition ID that was edited by the Requisitioner as noted in the notification email
- 2) If the requisition status is “Submitted”, the Accessioner has not approved the changes to the requisition and updates to MISO LIMS records have not occurred; wait until status is “Submission approved” before proceeding.
- 3) If the requisition status is “Submission approved”, CGI must review the changes to the requisition for non-PHI field changes that are not captured within MISO LIMS that may alter the draft genomic report and/or QC report. Verify requisition date and time stamps to ensure you are reviewing the updated requisition.
- 4) If necessary, revise the draft genomic and QC report with changed information following procedures as outlined in [Uploading a Draft Clinical Report \(Laboratory\)](#).

9.4 Consent Withdrawal (Laboratory)

1. Consent withdrawal will appear within the requisition case history and may be quickly identified on study dashboards under “Consent withdrawn”. The requisition status will display “Withdraw Consent”.
2. If data is processing, the process/workflow may complete. The record must be marked in MISO as “Consent Withdrawn” and no further processing/analysis is permitted.

10 Sign Out Processes

Licensed Geneticists (CCMG/ACMG) must review and approve draft genomic reports prior to inclusion of PHI and release of the clinical report to requisitioners for inclusion in patient medical records.

10.1 Reviewing and Accepting/Rejecting a Draft Clinical Report (Sign Out)

A notification email with subject “A draft clinical report is ready for review” will be received.

1. From your account dashboard, navigate to the submissions tab and select the study specific requisition dashboard.
2. All study requisitions requiring review will have status “Draft Report Ready for Review” Select “Edit Submission” for the respective requisition from the “Actions” column.
3. Within the requisition, scroll down to the section header “Data Report”. Click on the “Genomic report (PDF)” and “QC Report (PDF)” to download and review both reports.
4. Select either “Accept” or “Reject” the draft clinical report.

If rejected, a note must be entered within the text field that will appear below the reject radio button. Do not include any PHI in your explanation for rejecting the report. The requisition status will display “Draft report not accepted”, and the requisition is locked pending review. Consult with the CGI team to discuss the case and seek resolution. CGI will reopen the requisition and provide a response, which will be visible in the case history. If a resolution is found, repeat steps 1-4.

If accepted, update the draft report to include PHI. Upload the PHI containing clinical report PDF and select “Submit”. The clinical report is now viewable to the Requisitioner. The requisition status will display “Report Accepted, Sign Out Complete”.

10.2 Reviewing Change Requests to Submitted Requisition Prior to Clinical Report Sign Out or Rescinded Reports with Changes to PHI and Non-PHI (Sign Out)

Requisitioners may edit a requisition at any stage of submission, including after a report is signed out by a Geneticist. If a change request occurs after sign out and affects PHI fields only, refer to section [12.3](#) below. If a change request occurs after sign out and affects non-PHI fields only, refer to section [12.4](#) below.

This section should be followed if the case has never been signed out, or if a clinical report was rescinded due to changes in both PHI and non-PHI requisition fields. The status of a requisition will revert to “Submitted. In both scenarios, after Accessioner and Laboratory review and revision, an email notification will be sent to the Sign Out user with the subject “A draft clinical report is ready for review” and status “Draft Report Ready for Review”. A revised (if necessary)

draft genomic and QC report will be available for review. Note, previous draft genomic and QC reports are available for review in the requisition case history.

If Requisitioner submitted changes affect both non-PHI and PHI, only the Sign Out user may review PHI changes. Review the requisition case history comments. The following steps must be followed.

- 1) For requisitions with no prior signed out clinical report, an email will be received with the subject “A requisition was edited by a Requisitioner; confirm and/or update affected records.” If a clinical report was rescinded due to changes in PHI and non-PHI fields, an email will be received with the subject “A clinical report was rescinded by a requisitioner. Non-PHI and PHI information fields are updated. Accessioners, Laboratory and Sign Out users must review changes.” Role based instructions are provided within the body of the emails. Accessioners will approve non-PHI changes and update MISO LIMS entries. CGI will update the draft genomic and QC reports and status will change to “Draft Report Ready for Review”.
- 2) Navigate to the requisition as specified in the notification email. Review the case history comments and requisition versions to determine changes to non-PHI and/or PHI fields as seen below. Both the original and the revised requisition(s) are available in the case history.

ID: V3PIL-78

PHI Data Updated, Ready for Sign Out Review March 15, 2021, 18:04
Submitted By: GSI Requisitioner (gsireq0622@gmail.com)

Submission Case History

#	Action	Updated By	Updated At	Comment	Submission
7	PHI Data Updated, Ready For Sign Out Review	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 18:04		View Submission
6	Sign Out Rescinded With PHI	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 17:54		View Submission
5	Report Accepted, Sign Out Complete	GSI Signout (gsisign0622@gmail.com)	March 15, 2021, 16:39		View Submission
4	Draft Report Ready For Review	GSI Laboratory (gsilab0622@gmail.com)	March 15, 2021, 15:18		View Submission
3	Submission Approved	GSI Accessioner (gsiacc0622@gmail.com)	March 15, 2021, 15:03		
2	Submitted	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 15:00		
1	Submitted	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 15:00		View Submission

- 3) Follow steps as detailed in 12.1 [Reviewing and Accepting/Rejecting a Draft Clinical Report \(Sign Out\)](#).

10.3 Reviewing Change Requests to Rescinded Clinical Reports (PHI Correction Only) (Sign Out)

If a Requisitioner notices errors in both non-PHI and PHI fields, follow the procedure as outlined in section [12.2](#). If a Requisitioner notices an error on a signed out clinical report that impacts PHI only, follow these steps. The requisitioner must trigger re-opening of the requisition and clinical report. If a signed out clinical report is rescinded, the Geneticist will receive a notification email “A clinical report was rescinded by a requisitioner. PHI has been updated. Sign Out user must review requested changes, edit and approve/reject revised clinical report”. The status of the signed-out requisition will revert from “Report Accepted, Sign Out Complete” to “Reopened” to “Sign Out Rescinded with PHI” and finally “PHI Data Updated, Ready for Sign Out Review”.

1. From within the requisition, scroll to the Sign Out Rescind- [Non-PHI] section header at the bottom of the requisition and review the Requisitioner’s comment field as seen below:

2. Navigate to the case history and review corrected requisition PHI information (in the example above, treating physician field).
3. From the case history (shown) or from the main dashboard, select “Edit Submission”.

#	Action	Updated By	Updated At	Comment	Submission
7	PHI Data Updated, Ready for Sign Out Review	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 18:04		View Submission
6	Sign Out Rescinded With PHI	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 17:54		View Submission
5	Report Accepted, Sign Out Complete	GSI Signout (gsisign0622@gmail.com)	March 15, 2021, 16:39		View Submission
4	Draft Report Ready For Review	GSI Laboratory (gsila0622@gmail.com)	March 15, 2021, 15:18		View Submission
3	Submission Approved	GSI Accessioner (gsiac0622@gmail.com)	March 15, 2021, 15:03		
2	Submitted	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 15:00		
1	Submitted	GSI Requisitioner (gsireq0622@gmail.com)	March 15, 2021, 15:00		View Submission

10.3.1 Accepting a PHI Related Change Request (Requisitioner initiated)

4. Scroll to the section “Approve Draft Report” and select “Accept” (the draft report does not contain PHI and is not impacted by a change in PHI). Next, remove the existing clinical report (containing PHI), and replace it with the clinical report with the corrected PHI. Scroll to the bottom of the requisition and select “Submit.” The state of the requisition will change from “PHI Data Updated, Ready for Sign Out Review” to “Report Accepted, Sign Out Complete.” The administrator, laboratory, requisitioner and sign out user will receive a notification “A clinical report has been signed out. Case report

complete.”

APPROVE DRAFT REPORT [NON-PHI]

Do you accept the draft report in its current form with no further changes?

☐ Accept

☐ Reject

Do not add PHI to the clinical report at this stage. A PHI containing clinical report is uploaded at a subsequent stage.

SIGN OUT REPORT [PHI]

If you accept the draft report, integrate required patient PHI and upload final report. *

20_10_20_OCT-01-132B-CAP-OCT20.pdf

Recover

20_10_20_OCT-01-132B-CAP-OCT20.pdf (0.198 MB)

Uploaded by: GSI Signed on: Mar 2021, 4:39 PM

Attached documents: pdf

10.3.2 Rejecting a PHI Related Change Request (Requisitioner initiated)

5. If you disagree with the Requisitioner's requested PHI related changes, do not update the PHI containing clinical report. Scroll to the section "Approve Draft Report" and select "Reject" (the draft report does not contain PHI and is not impacted by a change in PHI). In the comments box, include your justification for not updating the PHI on the clinical requisition; a comment is required. Do not include PHI. Scroll to the bottom of the form and select submit.

V3Pilot

Tools

APPROVE DRAFT REPORT [NON-PHI]

Do you accept the draft report in its current form with no further changes?

☐ Accept ☒ Reject

Do not add PHI to the clinical report at this stage. A PHI containing clinical report is uploaded at a subsequent stage.

If you do not accept the draft report, please indicate reasons why. Do not include PHI in your response, as this field will be visible in case history and is visible to all roles. *

If you do not accept the draft report, please indicate reasons why. Do not include PHI in your response, as this field will be visible in case history and is visible to all roles.

6. The Requisitioner, Sign Out User and Administrator will receive an email "Requisitioner edits to PHI fields were rejected by the Sign Out User. Edit submission, revert prior edits and resubmit." The state of the requisition will remain at "PHI Data Updated, Ready for Sign Out Review".
7. Note, the Requisitioner will revert their prior edits to the requisition PHI and resubmit for review by the Sign Out user. The Sign Out user will receive another email, "A Clinical Report Was Rescinded by a Requisitioner. PHI has been updated. Sign Out User Must Review Requested Changes, Edit and Approve/Reject Revised Clinical Report". Follow section 12.3 and 12.3.3 steps 1-4 when this email is received to approve and sign out (release) the clinical report with no changes to PHI.

10.4 Reviewing Change Requests to Rescinded Clinical Reports (Non-PHI Correction Only)

A Requisitioner may notice an error in non-PHI on a clinical report after review of a signed out clinical report. The requisitioner must trigger re-opening of the requisition and clinical report. If a signed out clinical report is rescinded, the Geneticist will receive a notification email "A clinical report was rescinded by a requisitioner. Non-PHI information fields are updated. Accessioners, Laboratory and Sign Out users must review changes". The status of the signed-out requisition will revert from "Report Accepted, Sign Out Complete" to "Reopened" and finally "Submitted". Normal requisition workflows and notifications are active. Follow

instructions in section [12.1, Reviewing and Accepting/Rejecting a Draft Clinical Report \(Sign Out\)](#). Prior requisition versions may be reviewed in requisition case history.

10.5 Consent Withdrawal (Sign Out)

Withdrawal of patient consent is initiated by the study Clinical Coordinator (Requisitioner).

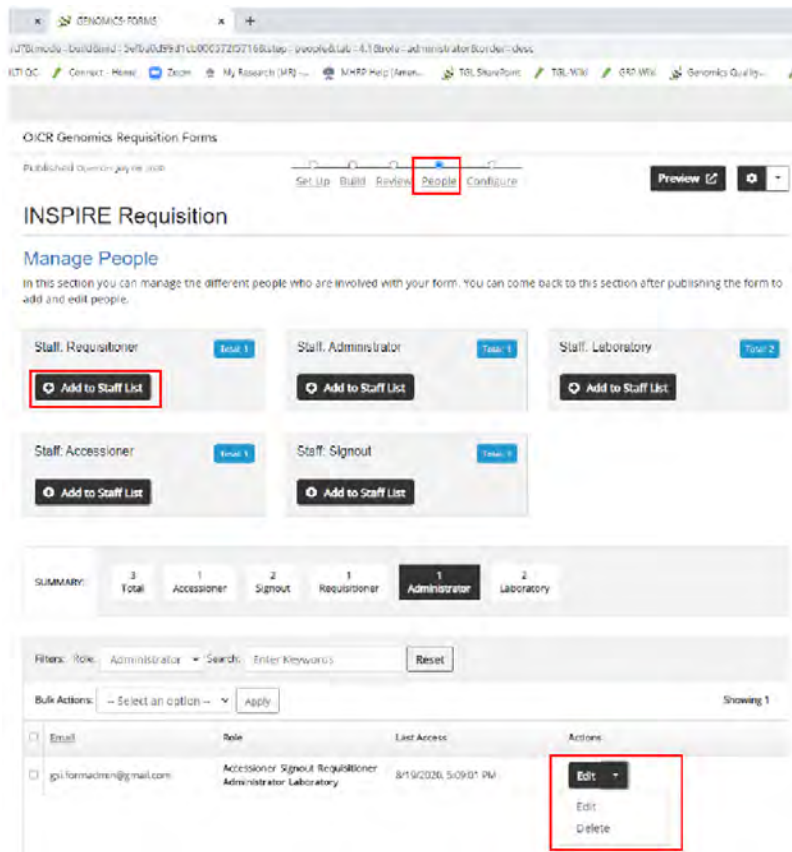
1. A notification email with subject “Patient consent has been withdrawn; stop processing samples and/or data” will be received by all roles including Requisitioner, Accessioner, Laboratory, Sign Out and Administrator. Consent withdrawal will appear within the requisition case history and may be quickly identified on study dashboards under “Consent withdrawn”. The requisition status will display “Withdraw Consent”.
2. If the clinical report has not been signed out, stop review. If Sign Out is complete, no further action is required.

11 Administrator Processes

The study specific administrator has no access to PHI but can build requisition forms, configure study-specific roles, audit submission logs, and edit email templates.

11.1 Configuring Study Specific User Roles

Users for each study requisition form must be defined and access granted or revoked by the Administrator; refer to “request a user account/access change request” section.



11.1.1 Adding a User

1. Navigate to the “Manage Forms” tab and select the study specific requisition form.
2. Click on the subheader “People.”
3. For each available role, assign an institutional email address by clicking “Add to Staff List” as seen above. A popup box will appear. Multiple email addresses may be added at once to a specific role.
4. User roles may also be edited under the “Actions>edit” menu. A popup window will appear and enable assignment of multiple roles to a single user, or to change their individual role assignments within a study specific requisition. Alter the user’s roles by marking or unchecking the roles that apply.

11.1.2 Removing a User

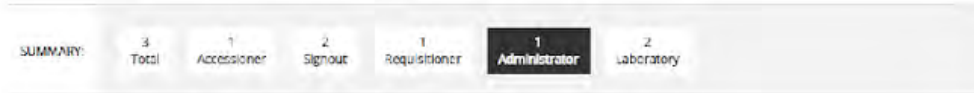
To remove a user from a study specific requisition, click the drop-down in “Actions>Edit” and select “Delete”.

11.1.3 Bulk User Role Removal

Multiple users may also be deleted at once (bulk) by selecting the users in the table. From the Bulk Actions menu, select “Delete”, and “Apply”.

11.1.4 Reviewing Master Role Records for Study Specific Requisitions

For each study requisition, assigned user roles (Accessioner, Sign Out, Requisitioner, Administrator, Laboratory) may be reviewed and/or edited by navigating and clicking on the respective role within the summary banner as seen below. Role specific bulk user role Addition/Removal may be completed with this feature and/or editing of a single role.



11.2 Building/Modifying Requisition Forms

11.2.1 Configure Requisition Form Title, Description, Requisition ID (Study Code)

1. From the cloned form gear box, select "Form Settings" or select "Set Up".
2. Enter the "Form Title" of the new requisition form following the template "Study_Name Requisition Form"; see figure below for subsequent text fields requiring configuration.
3. Enter a custom study specific description in "Description" text field if preferred.
4. Specify a study specific "Form Key", ie for the OCTANE study, "OCT"; this letter string will appear on all requisition IDs and may include a site specific code for master studies with multiple sites.
5. Specify a "Submission Title Format", or how the requisition ID will appear on Forms. For example, "OCT-[numberid]", would appear as OCT-0001.
6. Click "Save".

Dashboard My Account Manage Forms Submissions

Published (new) On July 19, 2019

Set Up Build Review People Configure Submissions Preview

OCTANE Requisition

Set Up Form

In this section you will set up the basic information and preferences for your form.

Basic Information

Title and Language:

English

Form Title: * OCTANE Requisition

Description: This requisition form contains Personal Health Information (PHI); PHI is visible to

Add Language

Confirmation Message

Your answers have been successfully saved.

This will be the message when user submit forms.

Form Key:

OCT

This will be used as a key to identify the form.

Submission Title Format:

OCT-{numberid}

This will be used as template for displaying title in submission tab.

Related Website URL:

https://forms.oicr.on.ca

The website where the form will be embedded or related to.

Show Custom Settings

Preferences

Form Type *

WebForm Content Moderation Form

Will your form be public on forms.oicr.on.ca? *

Yes No

Making the form public will make it available on the forms.oicr.on.ca home page.

Form icon/logo (optional):

No file chosen Upload

Max file size: 100MB Allowed extensions: png, gif, jpg, jpeg, svg

Added to the forms homepage box that promotes this form.

Form description (optional):

A user account and study authorization is required, contact dax.tor@oicr.on.ca.

Added to the forms homepage box that promotes this form, helps to describe what the form

11.2.2 Add/Configure Form Section Headers (Titles)

Section Form Headers segregate related questions with a section specific title as seen below. To create or configure a section header, follow these instructions:

Requisitioner's Information [PHI]

firstname *
FORM


lastname *
ADMIN

email *
gsi.formadmen@gmail.com

1. From the Study specific requisition form navigate to the “Build Form”.
2. From the right-hand margin, under “Sections”, select “Sections”. A popup will appear. Specify the section header title. A section description may be added and will appear below the title on the requisition form. Click “Save”

11.2.3 Define Role Based Access to PHI or Processes Specific to a Forms Section

Certain sections of a form may contain PHI that must be restricted to authorized roles (see Role Based PHI Access). To define a section as PHI:

1. When creating a new section or when editing an existing section (select the edit icon (pencil ), a popup will appear as seen below. Select the “Permissions” tab.
2. Mark the state (ie the process that the section relates to): init, submit, delete, reopen, withdraw sample, approve, deny, withdraw sample, approve, deny, withdraw consent, draft report ready for review, report accepted-signout complete, withdraw consent, draft report not accepted.
3. Under “Permission”, specify each user role that may view and/or edit a section by selecting: “No Access”, “Read” only or “Write”, see below; this must be specified for each process stage.

English Permissions

Section (Permissions)

States	Permission
<input checked="" type="checkbox"/> Init	Accessioner No Access Administrator No Access Invitee No Access Laboratory No Access Requisitioner No Access Signout No Access Submitter No Access

Save Cancel

11.2.4 Adding/ Configuring a Requisition Form New Text Field

The “Build” page allows extensive customization of any form.

1. To add a new text field, select “Text” under “Form Field Types”.
2. Add text to the “Label/Question” field as it is intended to appear on the form. A “Note” may be added (optional) and will appear as a text bubble to the right of the text field. See below.
3. Text Field inputs may be restricted by specifying a “Text Input”. Character entry may be restricted to text, numeric, email address, email addresses, or URLs. For numeric entries, input ranges may be specified and units.

11.2.5 Obligate Text Field Configuration


If a text field must be populated with information by the user, a condition may be set requiring data entry. This forces the user to enter data to enable the “Save” feature.


1. To force user data entry, select the “Settings” tab
2. If data entry is required, mark the option “Make this a required question” and click “Save”.

11.2.5.1 Altering the Order of Text Fields

1. Navigate to the study specific requisition form via “Manage Forms”>Study specific Requisition>”Build”
2. Drag the field text box to the desired order and click “Save”.

11.2.5.2 Editing General Text Field Options on Cloned Requisition Forms

All study specific requisition fields may be customized by clicking on the edit icon (pencil ). These activities may be conducted from the “Build” page.

1. To edit the text of a given text box as it appears on the requisition form, click the edit icon  . Edit the text field “Label/Question”. A “Note” may be added and will appear as a text bubble when a user hovers their cursor over the respective text field. See figure in “[Adding/ Configuring a Requisition Form New Text Field](#)”. If required, specify/alter if text entry is required by marking/unmarking the option “Make this a required question” and click “Save” as seen in [15.2.5.1 Obligate Text Field Configuration](#).

11.2.6 Adding or Configuring a Form’s Multiple-Choice Selection Field

Forms may contain options for users to select materials for submission. To create or configure a multiple-choice dialog box, follow these steps.

1. Under Form Field Types, select “Multiple Choice”. Set the text box “Label/Question”. Under “Multiple Choice Field” select “Choose multiple (checkbox)”.
 - a. Within the “Options” text field, each option must be entered using the following text markup, where “1” is the unique identifier of the option, and “|” demarks the checkbox from the text field
 - 1|250µl of buffy coat
 - 2|1 x 10ml whole blood (STRECK or EDTA)
 - 3|3 x 10ml whole blood (STRECK)
 - **If you are migrating this form from a previous version, do not split up the unique identifier and the text field.** The unique identifier is used by the requisition system to record which option was selected.
2. If this is a required response, under the “Settings” tab, select “Make this a required question”.

11.2.7 Add a Downloadable File (PDF) to a Study Requisition

If a guidance document for a particular text field is requested by a user, a downloadable PDF may be associated with a text field, by uploading a PDF to the form template using the “upload” option, as seen below:

English Settings

Inputs (English)

Basic Info

Label/Question: *

Patient study ID

☐ Hide the label/question within the form display

Note (optional):

Note image (optional):

Max file size: 100MB Allowed extensions: png, gif, jpg, jpeg, svg

Upload

Max file size: 100MB Allowed extensions: png gif jpg jpeg svg

11.2.8 Add Ability to Upload a File (PDF) to a Study Requisition

A user role may require the ability to upload a file/document to a specific requisition. Note, if access to the file is restricted to specific user role or contains PHI, configure the section header user role permissions as specified in section “Define Role Based Access to PHI or Processes Specific to a Forms Section”. To configure this option:

1. Navigate to Build>Form Field Types>File Upload.
2. Enter text into the “Label/Question” dialogue box. Add a note if a description of the field is required.

3. Specify the maximum file size, permitted file types (png, jpg, pdf).
4. From the “Settings” tab, mark “Make this a required question” if the uploaded document is a required field. Click “Save”.

11.2.9 Add a Calendar Field

Certain dates may be considered PHI (procedure date). To configure role-based visibility of a date, configure the section header user role permissions as specified in section “Define Role Based Access to PHI or Processes Specific to a Forms Section”.

1. Navigate to Build>Form Field Types>Date
2. Enter text into the “Label/Question” dialogue box. Add a note if a description of the field is required.

11.2.10 Publish a Study Specific Requisition Form to Users

A cloned study specific requisition is only viewable to the Administrator during draft phases. Upon completion of a Requisition Draft, the Form must be published. To publish a form:

1. Navigate to “Manage Forms>Study Specific Requisition”.
2. Select “Preview” to view the final format of the requisition as it will appear to users. Edit as necessary to finalize the draft.
3. Select “Publish” from the navigation menu.

11.2.11 Unpublish a Study Specific Requisition Form

1. Navigate to “Manage Forms>Study Specific Requisition”. Select the gear icon (right upper margin) and select “Unpublish”.

11.3 Audit Study and Patient Specific Requisition Form User Actions (Log)

1. Navigate to Manage Forms>Study Specific Requisition.
2. From the gear icon in the upper right margin, select “Download Submissions Logs”. An excel sheet is generated which specifies date and time of action, user who performed action, associated email account, requisition form, requisition ID, and action performed.

11.4 Configuring Role Based Email Notifications

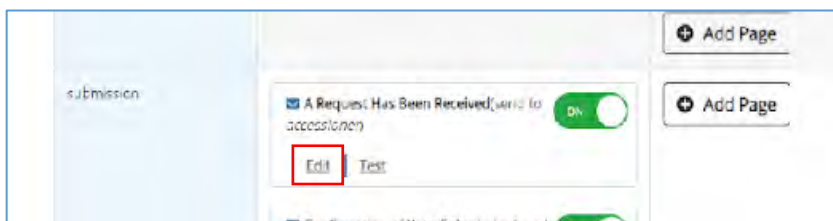
As action items arise from initiation of a requisition submission through to approval of a clinical report by a Geneticist, responsible user roles receive notification emails that either confirm a completed activity or notify of a required action.

For each study requisition, role-based email notifications may be configured. Default/standard email notifications are preconfigured via the template clinical study requisition form. When a requisition form is cloned, it may then be further configured to notify additional users and/or provide study specific email notifications. Customization of email text and/or subject headers may be requested via the Administrator.

Each related series of email notifications are grouped thematically by process or action (form stage) including submission, withdraw submit (mistaken Requisitioner submission), approval (role-based action), withdraw approve (patient consent withdrawal), data ready for review, Sign Out complete, Sign Out not accepted (amendment alert). These notifications occur upon completion of critical role-based workflow stages.

To configure emails:

1. Navigate to the “Manage forms” tab and select the study specific requisition form.
2. Click on the subheader “configure”.
3. Under the “emails” column, click “edit” on a particular “Form Stage-Emails” as seen below.



4. Various fields may be edited from the edit window, see below. Various settings are preconfigured upon cloning of a study requisition template.
 - a. Change the sender “email from” address, i.e. the email address from which all notification emails are sent
 - b. Configure/alter email recipients for a given email notification. If additional roles require notification at a particular forms stage, or users request to be notified of other user role actions, these users may receive notifications by marking the user role(s) specified via “Email Recipient (s)”. Assigning requisition user accounts to specific roles is detailed in Configuring Study Specific User Roles.
 - c. Email subject header may be modified by editing the text under “Email Title/Subject”
 - d. Email content (text and html format) may be edited.

Edit Email Notification

Form Stage: Submission

Associated state: *

submit

Email From

requeston.genomics@oicr.on.ca

Email Recipient(s): *

☐ Submitter
 ☐ Invited
 ☐ Requisitioner
 ☐ Administrator
 ☒ Accessioner
 ☐ Laboratory
 ☐ Signout

Other:

E.g. recipient1@email.com, recipient2@email.com

Delay:

0 second(s)

Email Title/Subject: *

A Requisition Has Been Submitted; Accessioner Approval Required.

Email Body: *

[Add Variable](#)

```

1 <!DOCTYPE html>
2 <html lang="en">
3
4 <head>
5   <title><CONTACTS-FORMS/ti-1>
6   <meta charset="utf-8" />
7   <meta content="width=device-width" name="viewport" />
8   <style>
9     @font-face {
10      font-family: Avenir;
  
```

5. Copy html markup within the "Email Body" field. Paste text to Visual Studio Code (Microsoft). Save text with file extension .html. HTML markup will become color coded. See below.
 - a. All text that appears "white" is visualized on the email as text and may be altered.

- b. Email html markup may also be configured, including text boxes and fields. This may include the format of “submitted on”, “submitted by”, Email header fields, “Next Steps”, login button text, email signatures etc.
- c. When editing markup in Visual Studio Code, the draft changes may be reviewed by right clicking on the text field and selecting “open with live server”. This will open a browser window and display the email as it would appear if sent from the Requisition portal. Changes to the text (html markup) may be saved to a local directory for future reference.
 - i. After completing and reviewing edits in Visual Studio Code, copy the html markup to the “Email Body” field.
 - ii. Select “save” at the bottom of the “Edit Email Notification” configuration window.

12 Global User Roles

There are three global user roles: Form Administrators, global Administrators, and no role set. Every user has no role until they are granted one by a global Administrator.

Current list of global Administrators

- Morgan Taschuk
- Ryan Falkenberg
- Miki Wong

Current list of Form Administrators

- Morgan Taschuk
- Carolyn Ptak

13 Form Administrator Processes

The Form Administrator is a global role that can perform the same tasks as study specific Administrators (Section 11), but can see all requisition study forms. The Form Administrator can additionally clone new forms, archive and delete forms, and back up and restore forms from Github.

13.1. Creating (cloning) a new requisition form

1. Navigate to the “Manage Forms” tab and select the form to be cloned.
2. Click on the gear box in the right-hand margin and select “Clone Form”.
3. Select the clone draft form. Note the cloned form will be titled “OICR Genomics Requisition Form Template” with the exact time the form was cloned.

13.2. Permanently Delete a Draft Study Specific Requisition Form

1. Navigate to “Manage Forms>Study Specific Requisition”.
2. From the gear icon in the upper right margin, select “Delete Form”.
3. To permanently delete a form, select the checkbox.
4. A second confirmatory dialog box will appear. The form administrator password is required to delete the form. Select Yes, Delete. This form may only be recovered from system archives stored off site

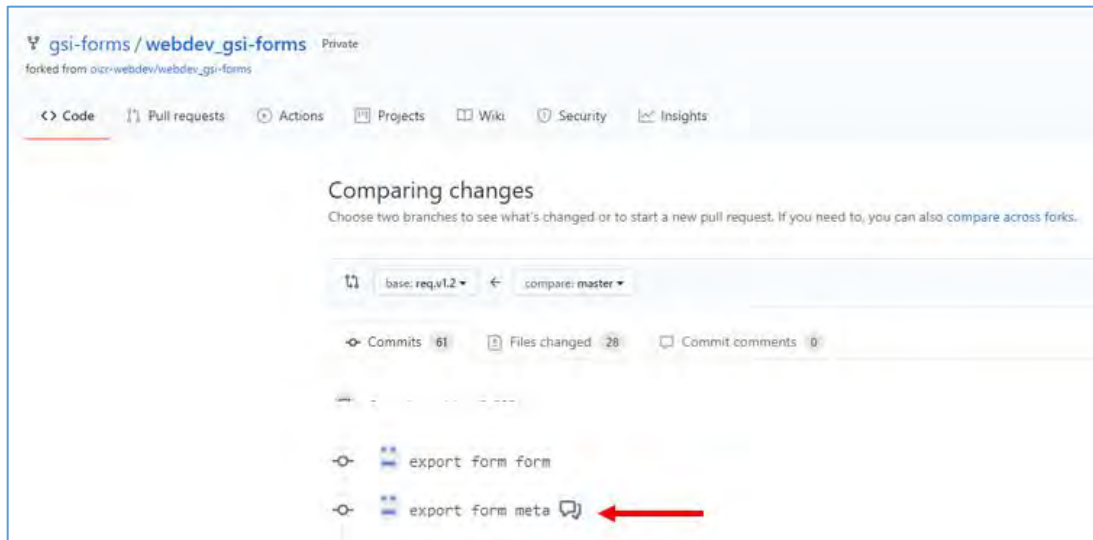
13.3 Archive a Study Specific Requisition Form

1. Navigate to “Manage Forms>Study Specific Requisition”.
2. From the gear icon in the upper right margin, select “Delete Form” and select “No, don’t delete, archive only” as seen below.
3. To view archived forms, navigate to “Manage Forms” from the Dashboard, and select “show archived”.
4. The archived form may be cloned, imported, exported or undeleted from the requisition gear icon. When an archived form is “undeleted”, the form will reappear on the forms dashboard.
5. The Excel-based report may be configured for specific information.

13.4 Committing (Exporting) Individual Form Metadata to Github

All changes to a specific form’s metadata may be committed to the private OICR Github repository (webdev_gsi-forms). Exporting a form will “copy” a form’s existing meta data which includes form structure, question definitions, workflows, and emails. Submissions will not be impacted, nor are they exported to Github. Staff assigned to the form will not be impacted, nor will assigned staff be exported to Github. Should the need arise in future, the import function of the requisition system may recall the form metadata to an active form from Github.

1. From a requisition form menu, navigate to the gear icon and select “Export Form” as seen below.
2. A dialogue box will appear to confirm the export of the form template to Github.
3. Review the export in Github (https://github.com/gsi-forms/webdev_gsi-forms) by navigating to the “<> code” icon and selecting “Compare” as seen below.
4. Scroll downward to the appropriate commit which will appear as “export from meta”.



5. Click on “export form meta” as seen above, record the commit ID. This ID will help confirm the correct form is imported if the need arises in future.
6. At the bottom of the page, include a comment regarding the form committed and changes made to the form.
7. Comments may be reviewed from the “compare” Github page.

13.5 Importing Individual Form Metadata from Github to the Requisition System

Forms committed (exported) to Github may be imported to the OICR Genomics Requisition System. Note, importing a form will replace an individual form’s existing meta data which includes form structure, question definitions, workflows, and emails. Existing submissions will not be impacted. Staff assigned to the form will not be impacted.

1. Navigate to the Requisition portal. From the gear icon, select “IMPORT”.
2. A dialogue box will appear, select “Import”. The form’s metadata will be imported and replace existing form metadata.
3. A dialog box will appear in the upper right corner confirming “The form has been successfully imported”.

13.6 Saving a Copy of the Requisition System Software to a Local Drive

Major software revisions must be registered using QW-029 Software Update Form before updating the software version tag in Github. The OICR Genomics Requisition System software version token will be updated on all webpages and emails when the Github software tag is updated; this process occurs through a cron job and is executed in approximately 10 minutes. This includes all forms, emails, and webpages. https://github.com/gsi-forms/webdev_gsi-forms/releases/tag/req.v1.3

1. To download a copy of the OICR Genomics Requisition Portal software, navigate to https://github.com/gsi-forms/webdev_gsi-forms/tags
2. Download the appropriate software version.

13.7 Merging Published Requisition Forms (New Software Release)

Legacy requisition forms may be merged into a new unified study form if required by the Forms Administrator. This scenario may occur if form fields change, such as with the addition of a new assay to a clinical study, or if software versions result in large scale changes to requisition system workflows. All existing requisitions will be ported into the new study form and will be permanently removed from the legacy study form. To execute a merger, proceed with the following steps.

1. Prior to moving existing (legacy) study specific requisitions to a new form, navigate to the gear icon and select “MISO download”.

2. Save a copy of the excel report as seen below. Note the requisition “Submission ID” field will be the same between the original study form present in version 1 of the (legacy) form, and in version 2 of the new form after importing the requisition. The requisition ID “ID” however, will be updated. The number will remain the same, but the form key will change to the new requisition form “form key”, in the example below the new form key is “V3PIL-XX”. If the forms key is not changed between version 1 (legacy) and version 2 of the form, the requisition ID will remain exactly the same.

ID	Submission ID	Patient stu	Sample stu	Select sub	FFPE block	Site of biog	Tumour ty	% Tumour	% Necrosis	Sample stu	Select sub	1 x 10 whole blood *
id	submissionid	patientPati	tumourSan	specimenT	specimenF	tumourSite	tumourTyp	tumourPen	tumourNec	bloodSamp	specimenB	specimenWholeBloodOpt
V3PIL-77	604fae9d7ddad4010f7dcf28	asdf	asdf	10 x 10 uM	No Answer	asdf	Primary	56	56	styw	250µl of bi	No Answer
V3PIL-78	604faed47ddad4010f7dcf49	sdfg-revise	sdfgs	5 x 10 uM	No Answer	sdfg	Primary	78	78	vgndfg	250µl of bi	No Answer
V3PIL-79	604faf0d7ddad4010f7dcf63	sfdg	sdfgs	10 x 10 uM	No Answer	sfdg	Primary	78	78	sfdgs	250µl of bi	No Answer

3. Unpublish the legacy form to prevent new submissions from occurring from the legacy form.
4. Select “Move Submissions” from either the gear icon on the “Manage Forms” tab, or directly from the form specific configuration pages as seen below.
5. A warning dialog will appear. Follow instructions listed and select “Yes, Move”.

- Note, the case history for each imported requisition will contain all prior status stage changes executed from the legacy form. Any existing versioned draft genomic, QC or signed out clinical report will be viewable to authorized study roles. PDF files will retain the legacy study requisition ID and will not be updated.
- From the new form, repeat steps 1& 2. Use the “Submission ID” to map old requisitions to the new requisition “ID”. Provide this mapping key to the study requisitioners if the forms key has changed. They may need to update their records to ensure continuity.
- Update MISO LIMS records to record the updated requisition ID, only if forms keys have changed.
- Inform the requisitioner, that the legacy form will no longer be visible, nor will the legacy form be populated with requisitions.

14 Global Administrator Processes

The global Administrator is a role that permits full access to the Requisition system, except for PHI and submissions.

The screenshot shows the OICR Genomics Requisition Forms Admin Menu. The top navigation bar includes a 'View Forms' button and a user profile for 'morgan.taschuk@oicr.on.ca'. The main menu has tabs for 'Users', 'Site Configuration', 'Manage Content', 'Manage Forms', and 'Submissions'. The 'Users' tab is active, displaying a 'User List' table. The table has columns for Username, Display Name, Status, Roles, Last Access, and Actions. Two users are visible: 'webdev.oicr@gmail.com' (Ollie Operator, Blocked, 4/20/2022, 10:30:01 PM) and 'kaman.wu@oicr.on.ca' (Kaman1 Wu, Blocked, 3/9/2021, 4:20:36 PM). A 'Bulk Actions' dropdown is set to 'Select an option --' and an 'Apply' button is present. A 'Reset' button is also visible in the filters section.

Username	Display Name	Status	Roles	Last Access	Actions
webdev.oicr@gmail.com	Ollie Operator	Blocked		4/20/2022, 10:30:01 PM	Edit
kaman.wu@oicr.on.ca	Kaman1 Wu	Blocked		3/9/2021, 4:20:36 PM	Edit

14.1 Navigating the Admin Menu

- Click the logged-in user’s name at the top left and select “Admin Menu”.
- A new view on the Dashboard will be visible with 5 tabs: Users, Site Configuration, Manage Content, Manage Forms, and Submissions. Manage Forms and Submissions operate the same way as for other users.
 - Users: listing all users of the Requisition Portal. The table shows the user’s email and display name, status of the account, any global user roles, the last access time of the user, and an Actions dropdown.

- b. Site Configuration: Top level configuration for the Requisition Portal as a whole, including setting who can register accounts, what happens when a user's account is cancelled, etc.
- c. Manage Content: view and change the base pages and emails for the whole site.
- d. Manage Forms: same as for other users (see section 5)
- e. Submissions: same as for other users (see section 5). Note that the global Administrator cannot see submissions or PHI.

14.2 Promoting a user to Form Administrator or global Administrator

All Form Administrators and global Administrators need access both to the administrative functions as well as access to the Github repositories that back the Requisition system.

First, grant the role within the Requisition Portal.

1. Go to the Admin Menu and select the Users tab.
2. Locate the user in the table and click 'Edit' in the Actions dropdown.
3. In the User Settings section, select "administrator" for global administrator or "form administrator" to give the user the appropriate role.
4. Click "Save Changes".

Next, grant permissions on Github to [webdev_gsi-forms](https://github.com/gsi-forms/webdev_gsi-forms) and [nodejs-apps](https://github.com/gsi-forms/nodejs-apps).

1. Contact the user to get their Github username
2. Go to https://github.com/gsi-forms/webdev_gsi-forms
3. Click on the Settings tab
4. Under Access, click on Collaborators and teams
5. Under Manage access, click the 'Add people' button.
6. Enter the Github username for the new admin. Select 'Admin' for the role, and click 'Add to this repository'.
7. The new admin should get an email inviting them to the repository, or they can navigate to the repository to accept the invitation.
8. Repeat steps 1-7 for <https://github.com/gsi-forms/nodejs-apps>.

14.3 Modify a system email

"System email" refers to an email such as the new user email or the forgotten password email, that is not an email notification from a particular study. See section 11.4 for study-specific emails.

1. Go to the Admin Menu and select the Manage Contents > ALL CONTENTS tab
2. In the content type summary section, select "emailtpl" to filter by emails.

3. Locate the email in question in the table. See the screenshot below. Click on the Title to open the email in the Github repository https://github.com/gsi-forms/webdev_gsi-forms.
 - a. Note that the Edit button in the Action drop down does not work correctly and will not save. You can use this to edit the HTML in a WYSIWYG editor, however, and then copy the HTML to Github.
4. Edit the html for the email as desired.
5. Add a commit message to the box at the bottom explaining what was changed. Select 'Commit directly to master branch' and 'Commit changes'.
6. Within about 15 minutes, the table on 'Manage Contents' page should show a new last modified time and the email will be ready to send.

The screenshot shows the 'Manage Contents' page. At the top, there is a 'CONTENT TYPE SUMMARY' section with a grid of buttons representing different content types and their counts: 31 Total, 4 banner, 9 emailtpl (highlighted), 1 files, 1 images, 5 modules, 7 pages, 1 privateFiles, and 1 videos. Below this is a '2 weblinks' button.

Below the summary is a filters section with 'Filters: Status: All', 'Update between: yyyy-mm-dd' and 'and: yyyy-mm-dd', and a 'Search: Enter Keywords' field with a 'CLEAR' button.

Below the filters is a 'Build Actions' section with a dropdown menu set to '-- Select Option --' and an 'Apply' button. To the right of this section, it says 'Showing 9'.

The main part of the screenshot is a table with the following columns: Title, Author, Created, Status (Last Change Date), Public, Kind, and Actions. The table contains three rows of email templates, all with a status of 'UNPUBLISHED' and a last change date of 'April 20, 2022'. Each row has an 'Edit' button in the Actions column.

	Title	Author	Created	Status (Last Change Date)	Public	Kind	Actions
<input type="checkbox"/>	[siteName] - User Update Email ↗ _emailtpl/ums_user_update_email_verify_email.md		October 11, 2018	UNPUBLISHED April 20, 2022	Private	emailtpl	Edit ▼
<input type="checkbox"/>	[siteName] - User Change Password ↗ _emailtpl/ums_user_change_password_email.md		October 11, 2018	UNPUBLISHED April 20, 2022	Private	emailtpl	Edit ▼
<input type="checkbox"/>	[siteName] - Account Unfrozen ↗ emailtol/ums user account unfrozen em		March 15,	UNPUBLISHED	Private	emailtol	Edit ▼