**Dear OpenClinica Customer,**

With the release of **OpenClinica 4 Stack 20**, we've introduced greater flexibility in managing form access. You can now configure not only *whether* a user has access to a form, but also *what level* of access they have directly within the **Users and Roles** interface.

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# What's New

## Granular Control Over Form Access Levels

Previously, form access worked as a simple **on/off** model:

- Access to a form was controlled by **Manual Permission Tags** (applied in *Study Designer*).

- The **level** of access (Read-only, Review, or Edit) was always determined by the user's **role default**.

  - For example, Clinical Research Coordinators (CRCs) had **Edit** access to all forms they could open.

Now, with **Stack 20**, you can manage **form-specific access levels** for each role with permission tag configurations.

You can still use Manual Permission Tags to grant or revoke access, but you can now also set the **exact access level**—Read-only, Review, Edit, or No Access—per role, per form.

This means you can:

- Change a CRC's access to a single form from *Edit* to *Read-only* or *Review* without changing their role.

- Give Data Managers or Monitors access to view contact forms.

- Give Monitors access to edit a form that tracks their review activities.

This eliminates the need to create redundant custom roles solely to handle special-case form permissions.

## Unified Permission Model Applies to Contact Forms

Manual permission tags now override the default access rules for contact forms across Study Runner, providing finer control over participant contact data.

**Examples:**

- **Revoking contact form access:** By default, site-level CRCs and Investigators have *Edit* access to contact forms. You can now apply a manual permission tag and set it to **No Access** for the CRC or Investigator role to remove their ability to open or edit those forms.

- **Granting contact form access:** Any role—including those that are not CRC or Investigator—can now be granted **Read-only**, **Review**, or **Edit** access to contact forms when business needs require it.

Manual permission tags always take precedence over contact form defaults. This ensures consistent, predictable control of access rights and stronger protection of personally identifiable information (PII).

ℹ️ **Note:** Keep this change in mind when configuring roles and form permissions for any studies created before the Stack 20 deployment.

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# What's Unchanged

The enhanced form permission model applies **only to form access and data interaction**. It does **not** change how other system actions are governed by roles, such as:

- Closing queries

- Remove / restore

- Participant management, SDV, sign-off functions, etc.

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# Next Steps

Once **Stack 20** is deployed, existing studies will retain their current default access levels. You can begin applying the new permission model to both existing and new studies at any time by updating form settings or role configurations.

The **one exception** is that if a study has a manual permission tag applied to a contact form, you may need to review form access permissions for the above studies and confirm whether they should be updated once Stack 20 is released. Impacts and options are described by scenario.

# Non-CRC / Investigator has Access to Manual Permission Tag

## End-user impact

While users will have greater ability to view forms with contact data, their access remains limited to those forms; no additional methods for retrieving contact data are being introduced.

- **Form access via PDP:** Users will now have access to view forms containing contact data items.
- **Participant XML / JSON Casebooks / Extracts / Clinical Data API Results:** Affected forms will now be included in the dataset. However, contact data will remain masked for all users.
- **Participant Audit Log:** Affected forms will now be included in the audit log, with values unmasked. However, contact data will remain visible in the Participant audit section for CRCs and Investigators only.

## Options

1. Leave as is

End users will experience the impacts described above.

2. Update Manual Permission Tag to Read Only, Review or Edit

The impacts will be as follows:

- **General form data access**: User will have the level of access assigned to the manual permission tag. Meaning, the CRC will now have read only access to the contact form.
- **Queries Page:** To act on queries in the Queries page, the user needs at least Review-level access.
- **Participant PDF Casebooks**: Form data will now be available in Participant PDF Casebooks.
- **Signature** (PI Only): Form will be included in signature

3. Update Manual Permission Tag to No Access

End users will not have access to contact forms on any screen.

# CRC / Investigator has No Access to Manual Permission Tag

## End user impact

Users will no longer have access to the affected contact forms. This change does not impact their ability to view contact data in the Participant Audit Log or the General Information section on the PDP.

- **Queries Page**: Queried items on these forms no longer appear on Queries Page
- **Participant PDF Casebooks**: Form is not included in Participant PDF Casebook
- **Signature** (PI Only): Form is not included in signature attestation

## Options

1. Leave as is

End-users will experience the impacts described above.

2. Update Manual Permission Tag to Read Only, Review or Edit

The impacts will be as follows:

- **General form data access**: User will have the level of access assigned to the manual permission tag. Meaning, the CRC will now have only the selected level of access to the contact form.
- **Queries Page:** To act on queries in the Queries page, the user needs at least Review-level access.
- **Participant PDF Casebooks**: Form data will now be available in Participant PDF Casebooks.
- **Signature** (PI Only): Form will be included in signature attestation

For detailed guidance on how roles and form access permissions work in Stack 20, refer to **Managing Form Access and Permissions**.

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**Thank you** for using OpenClinica.

We're excited to bring you a more flexible, transparent, and secure way to manage form permissions in **Stack 20**.

If you have questions or need help configuring permissions in your studies, please contact your CSM.

**The OpenClinica Team**