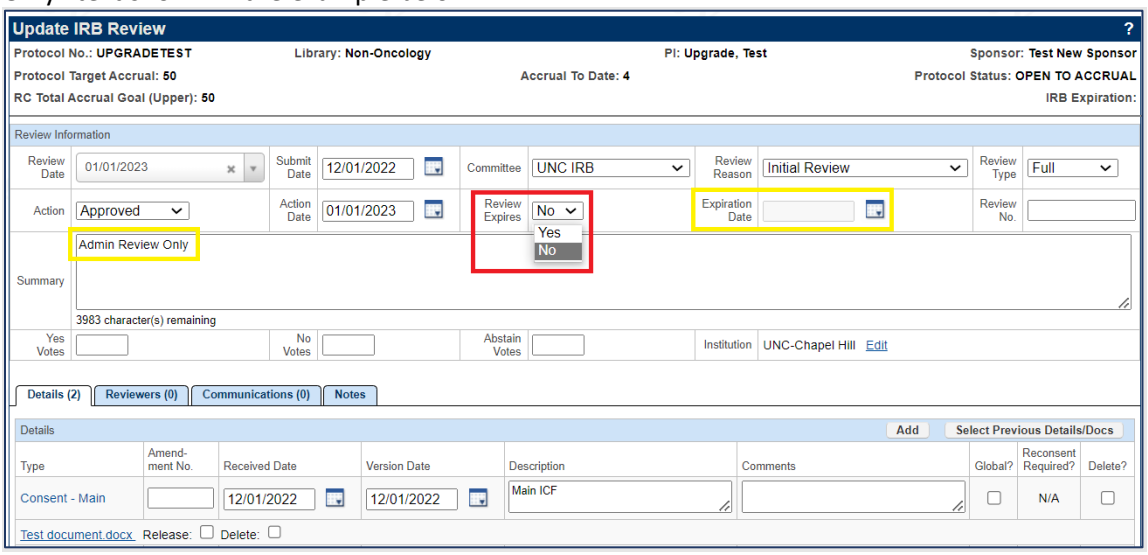
Protocol Management

IRB Reviews that do not expire

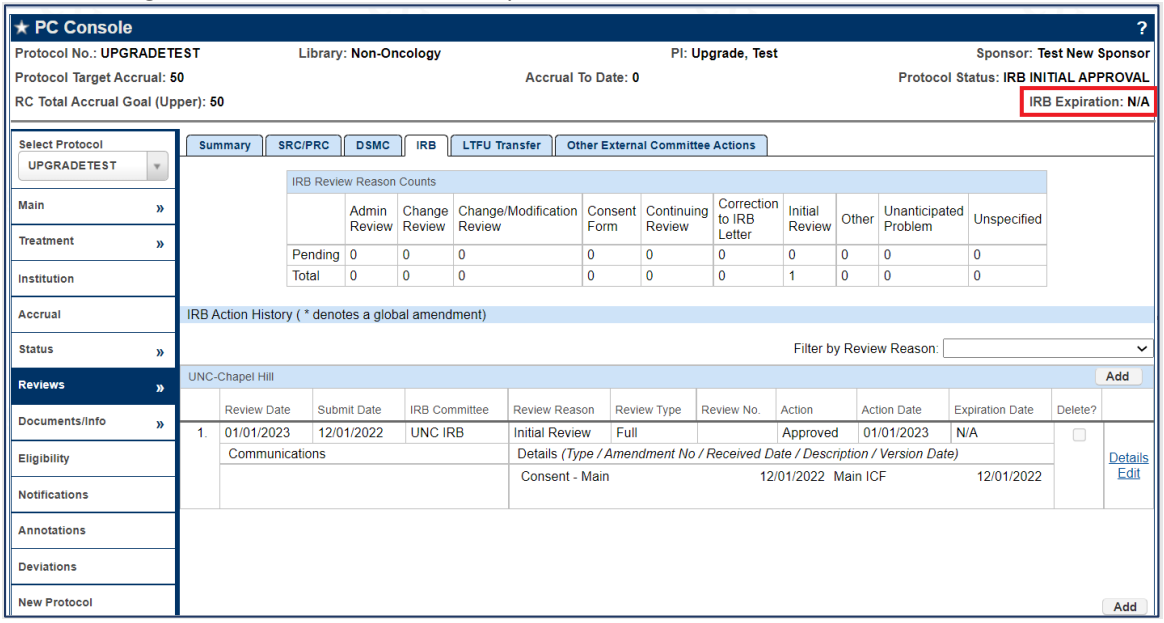
For studies under Administrative Review only, users can now indicate that a review will not expire. To do this, please use the workflow below:

When creating an IRB review (**PC Console** > **Reviews** > **IRB** tab > **Add**) or updating a previously entered review, the user will notice the addition of a new **Review Expires** field that will allow them to designate if a review will expire or not. If the "No" option is chosen, the **Expiration Date** field will no longer be active, and no information can be entered.

If this option is utilized, the user should also indicate the reasoning in the **Summary** field, such as the "Admin Review Only" text shown in the example below.



After clicking **Submit** and **Close**, the IRB Expiration date will show as N/A in the PC Console Header.

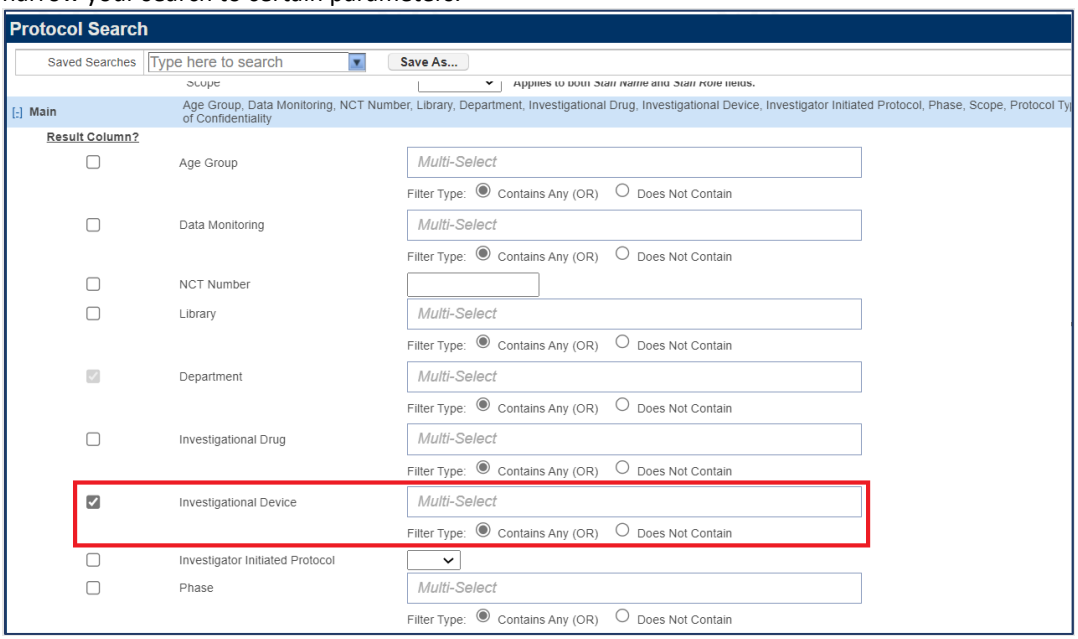


Protocol Search

When utilizing the Protocol Search function (Menu > Protocols > Protocol Search), users will notice the addition of the following fields and the ability to search based on their criteria:

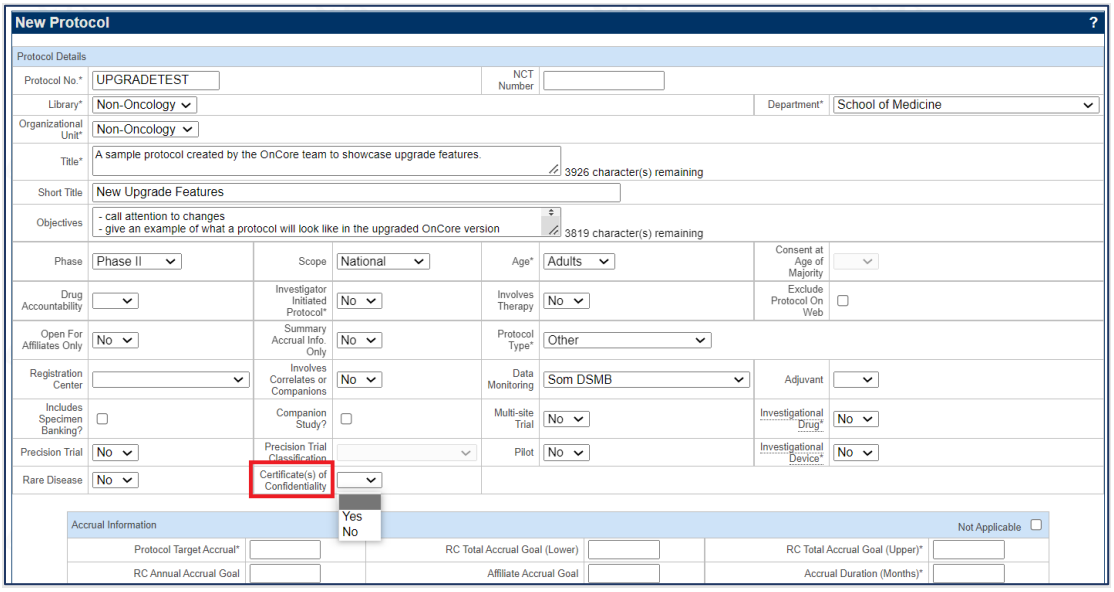
Protocol Search > Main > **Investigational Device**

You can select the checkbox to include this information as a column in your report results or enter one or more items in the field to narrow your search to certain parameters.



Certificates of Confidentiality

When creating a new protocol (PC Console > New Protocol), there is an additional field in the Protocol Details section that allows the user to select if a particular study has a **Certificate of Confidentiality**. The options in this field are Yes, No, and blank.



For studies already in OnCore, this field will be blank after the upgrade. To change the information in this field, navigate to the **PC Console** of your intended protocol and click **Update**. Use the drop-down menu to select the option appropriate for your protocol, then click **Submit**.

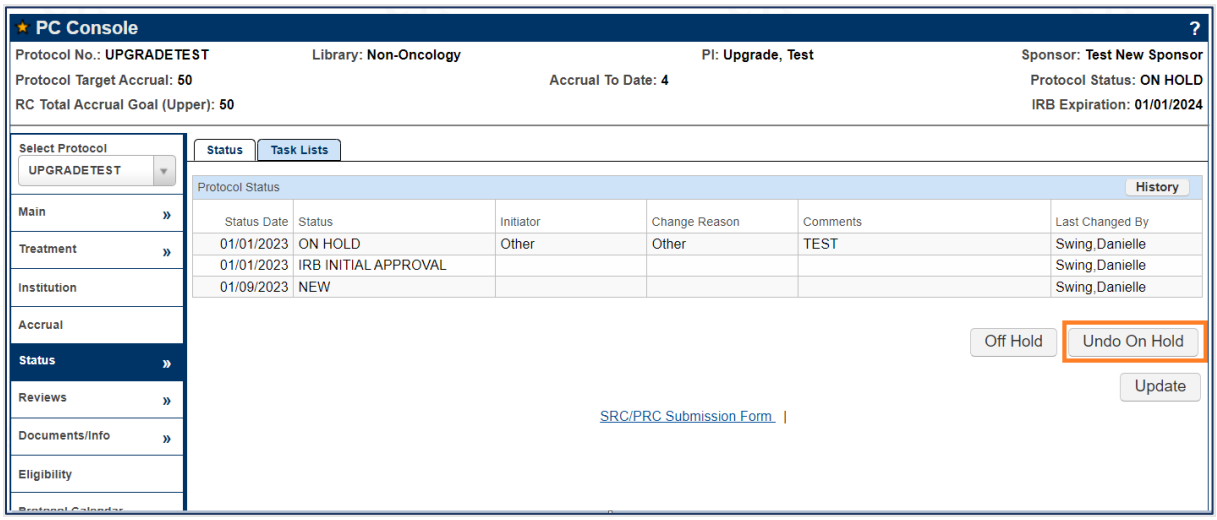
For more information about CoCs, the NIH has more information on their website.

For department/division managers only:

Undo On and Off Hold Statuses

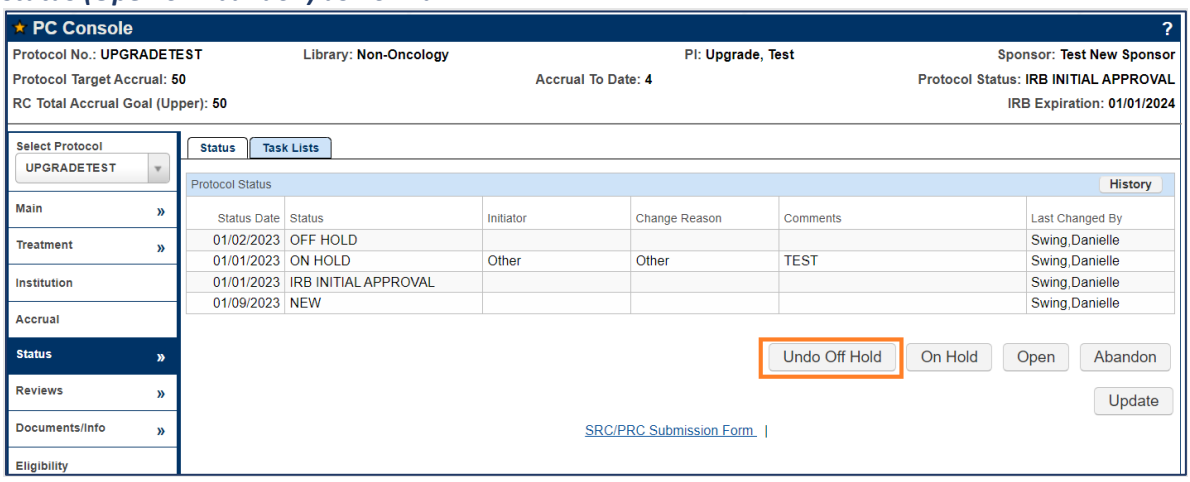
After updating a protocol's status to **On Hold** (**PC Console** > **Status**), users will now see the additional option of **Undo On Hold** for their next status update.

This option should only be utilized if the study was placed On Hold in error. Otherwise, users should use the Off Hold status as normal.



Similarly, after updating a protocol's status to **Off Hold** (**PC Console** > **Status**), users will now see the additional option of **Undo Off Hold** for their next status update.

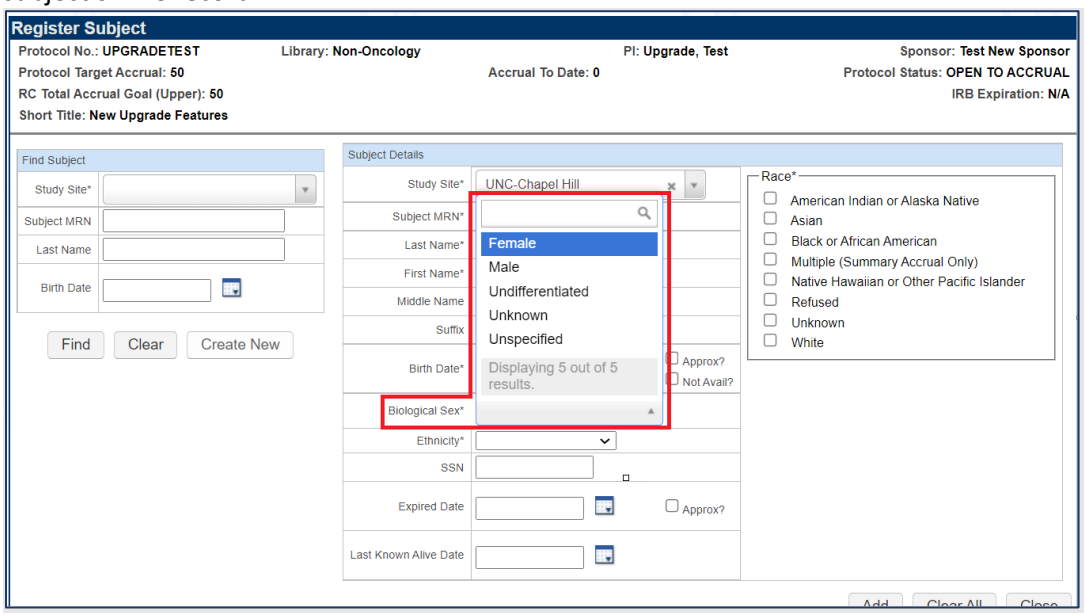
This option should only be utilized if the study was taken Off Hold in error. Otherwise, users should choose the next status (Open or Abandon) as normal.



Subject Management

Register Subject/Update Demographics – Biological Sex

When registering a new subject (**CRA Console** > **Register Subject** > **Create New**), the user will notice the Gender field has been replaced with a field titled **Biological Sex**. The dropdown menu contains the three previous Gender options and an additional two selections. This information should correspond with the information from the Sex at Birth field in the subject's EPIC record.

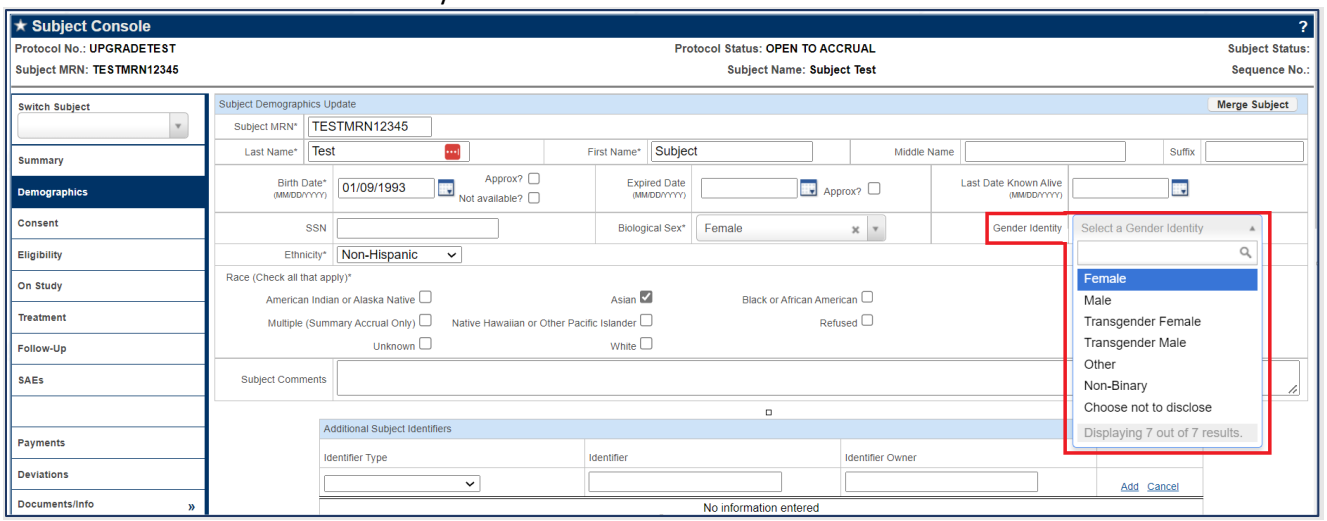


Subjects previously registered in OnCore will have the **Biological Sex** field populated by the selection previously chosen for Gender.

Other places in OnCore where Gender has been updated to Biological Sex:
Subject Console > **Summary**
PC Console > **Accrual** (only when protocol is set to **Summary Accrual Only**)

Register Subject/Upgrade Demographics - Gender Identity

When registering a new subject or updating an existing subject's demographic information (**Subject Console** > **Demographics**), users will notice a difference in the Subject Demographics Update section of the page. Instead of one field labeled Gender, there are now two distinct fields labeled **Biological Sex** and **Gender Identity**. **Biological Sex** will contain the designation given to the subject at registration, or the selection from the previous version's Gender field. The **Gender Identity** field is a dropdown menu with seven choices. This information should correspond with the information from the Gender Identity field in EPIC

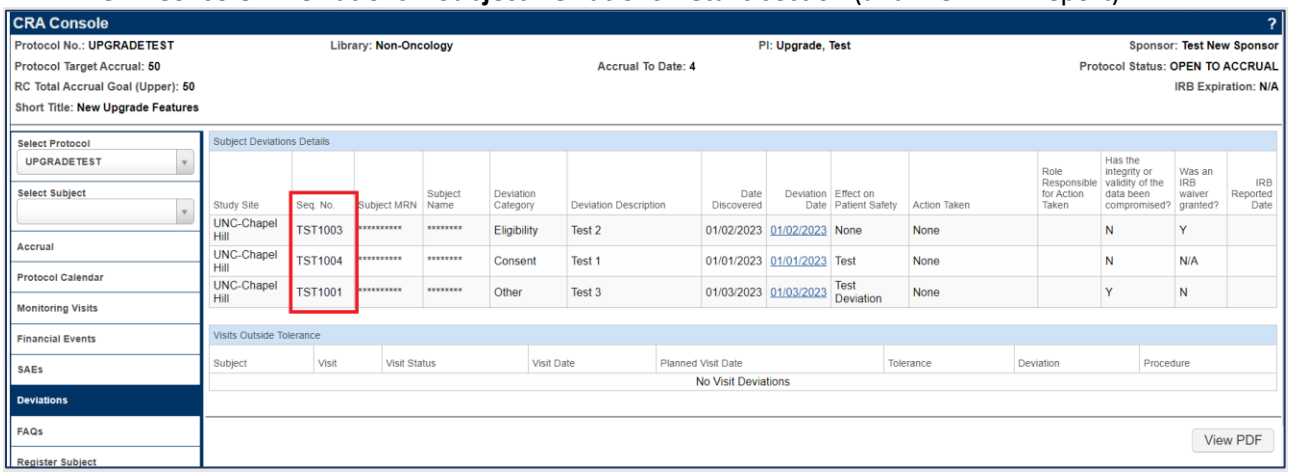


Sequence No. in Subject Deviations

When monitoring subject deviations, users will notice the addition of a **Seq. No. Column** to assist in identifying subjects, even when the user does not have permissions to view subject PHI or Show PHI selected in the user menu.

The changes can be seen in the following locations:

- **PC Console** > [protocol] > **Deviations** > **Subject Deviations** page (and **View PDF** report)
- **Team Console** > **Deviations** > **Subject Deviations** page
- **CRA Console** > **Deviations** > **Subject Deviations Details** section (and **View PDF** report)



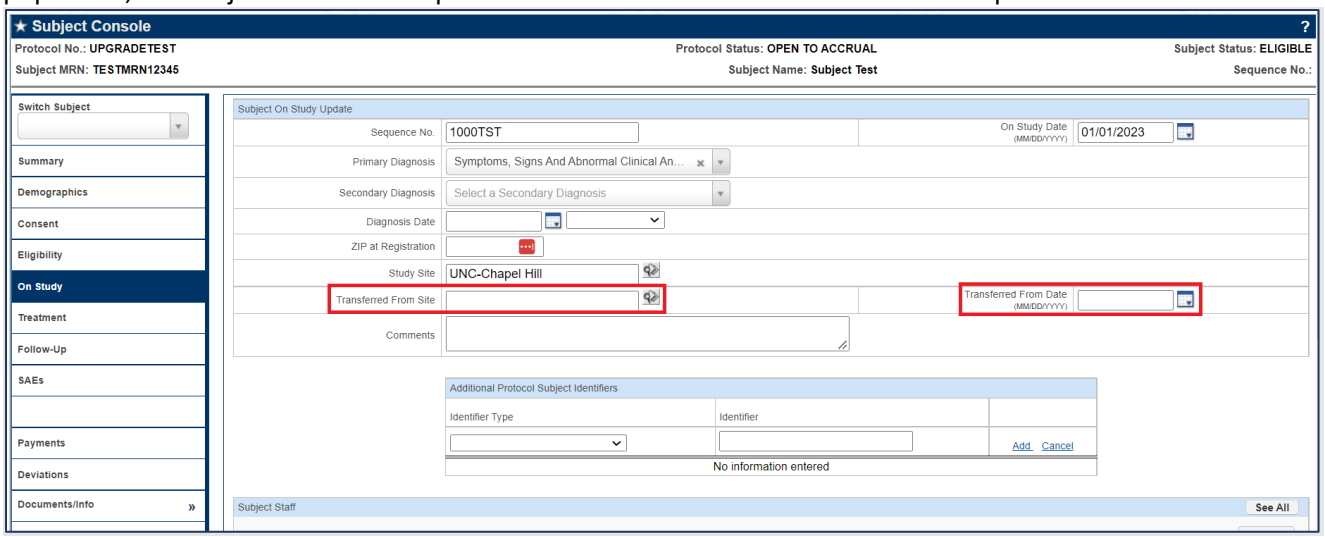
*Please note: information in this column will not be populated unless a sequence number has been entered for the subject (**Subject Console** > **On Study** > **Sequence No.**)*

On Study – Study Site Transfer

When placing a subject on study (Subject Console > On Study), users will notice a difference in the **Subject On Study Update**. Instead of one field reading Transferred Date, there are now two distinct fields:

Transferred From Site: The Transferred From Site field allows you to record the study site where the subject was previously enrolled on the protocol before transferring to the current study site. Click the browse box to select a study site; the drop-down list includes all organizations with the study site trait, active or inactive, and regardless of the logged-in user's organization access.

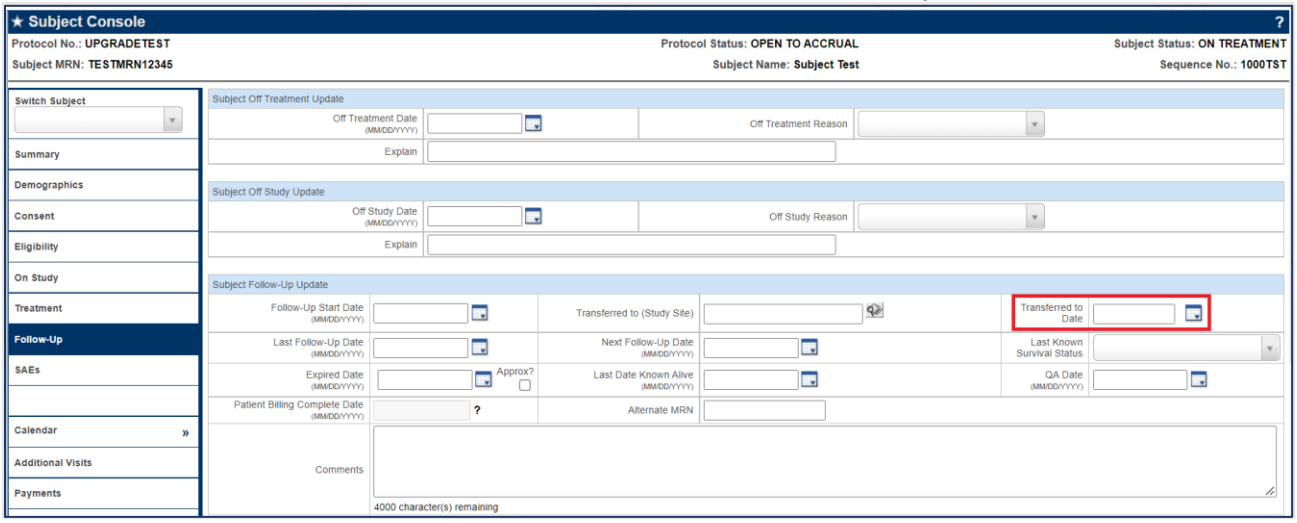
Transferred From Date: The Transferred From Date field allows you to indicate the date a subject (who was enrolled on the protocol at another study site) transferred from that study site to the current study site. When this field is populated, the subject will not be reported on the Data Table 3 and Data Table 4 reports or the CTRP Accrual Report.



Follow-Up – Transferred to Date

When updating a subject's Follow-Up status (**Subject Console** > **Follow-Up**), users will notice the addition of a new field in the Subject Follow-Up Update section:

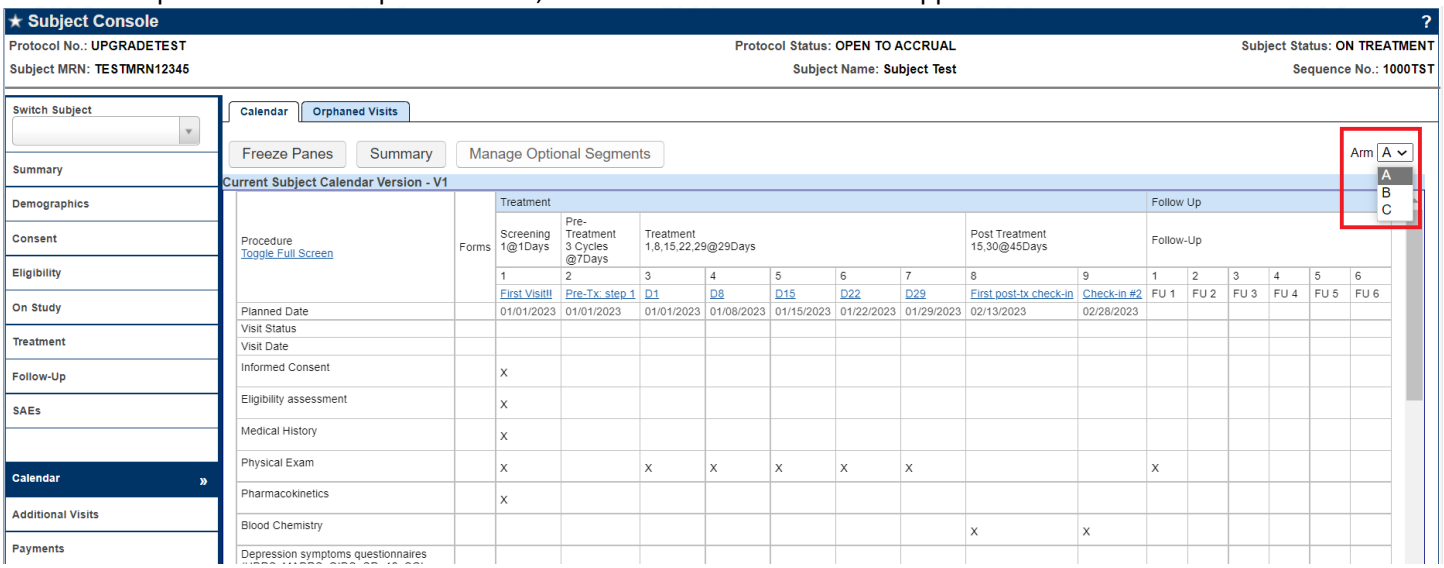
Transferred To Date: The date a subject transferred for follow-up to a study site other than the one where treatment was administered. Use this field in combination with the Transferred to (Study Site) field.



(The **Alternate MRN** field is still available but has now been moved to the fourth line of this section, above the Comments box)

On Treatment – Subject on Multiple Arms

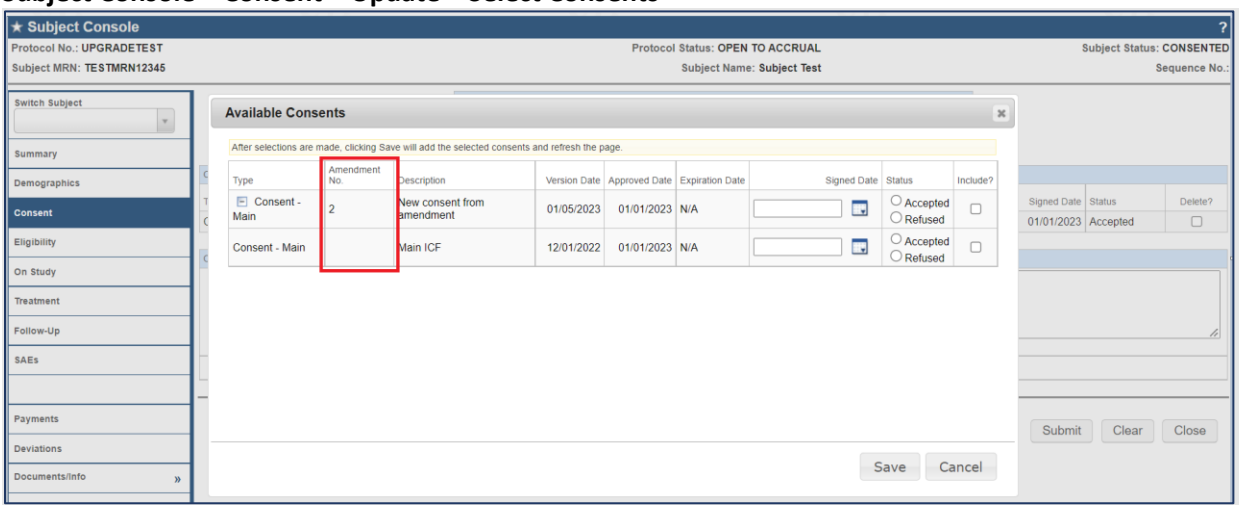
When a subject is assigned to multiple arms on a protocol **(Subject Console** > **Treatment** > **Add**), users will now be able to select a specific arm more easily on the subject's calendar. When viewing the subject calendar (**Subject Console** > **Calendar**), an **Arm** dropdown menu will appear if the subject has been placed on more than one arm. When the user chooses an option from the dropdown menu, the calendar for that arm will appear.



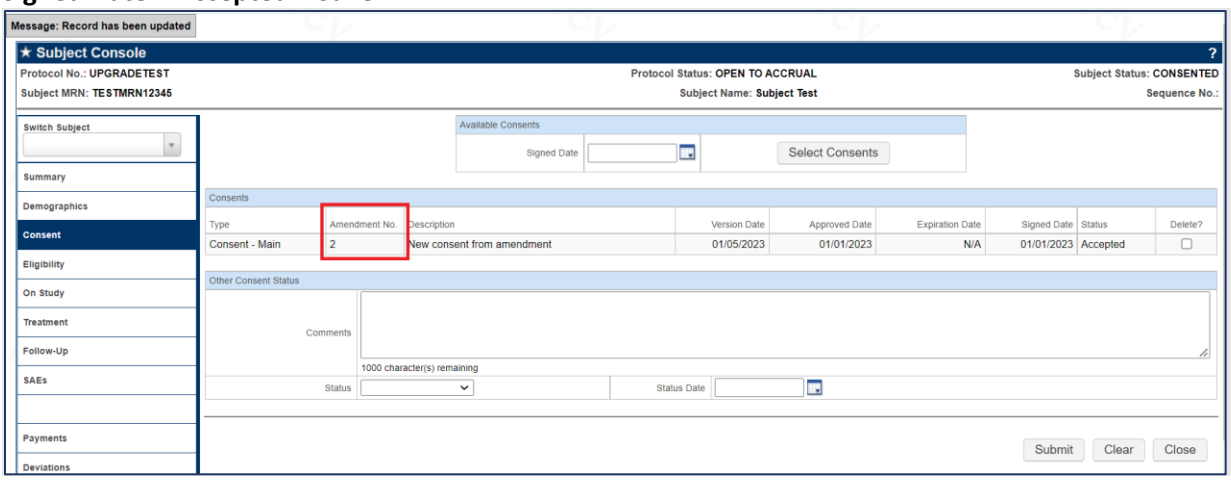
Consents – Amendment No.

When adding consent information to a subject's record (**Subject Console** > **Consent**), users will notice an additional column in the **Available Consents** table that displays the **Amendment No**. This information is populated based on the Amendment No. field in the details section of the IRB Review. Once a consent is chosen, the amendment information will also appear in the Consents table.

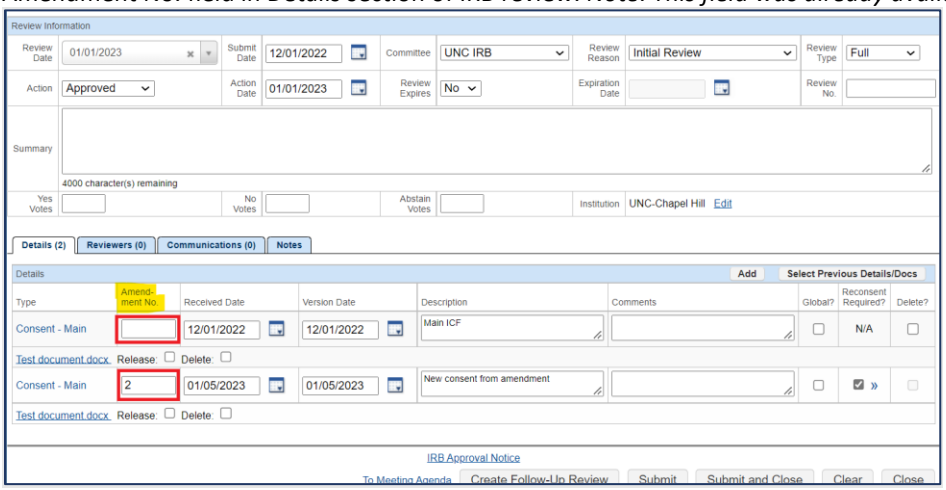
Subject Console > **Consent** > **Update** > **Select Consents**



Signed Date > **Accepted** > **Save**

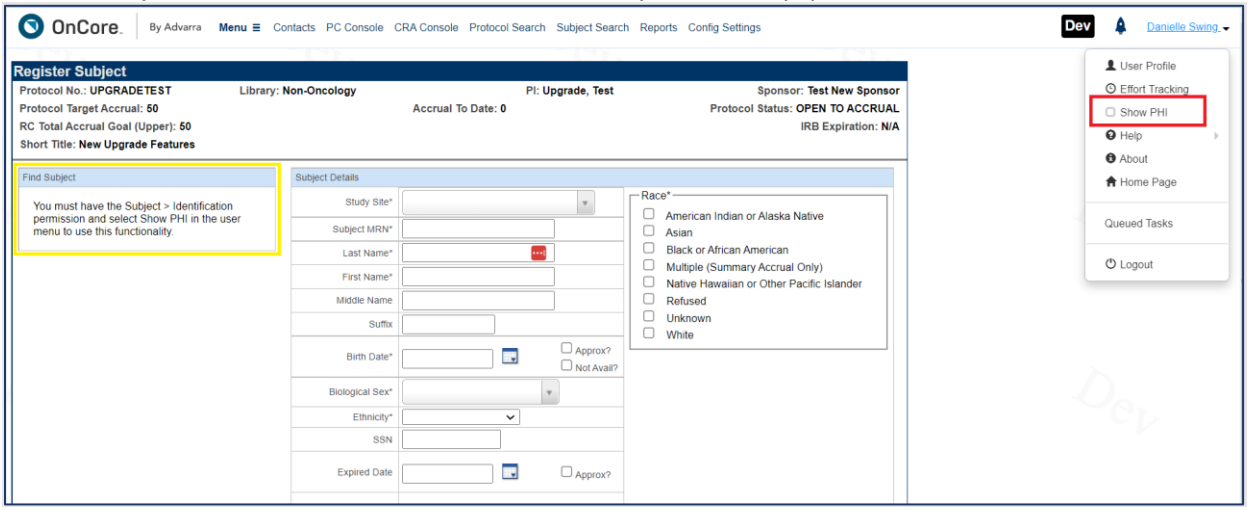


Amendment No. field in Details section of IRB review. *Note: This field was already available in the most recent OnCore version.*

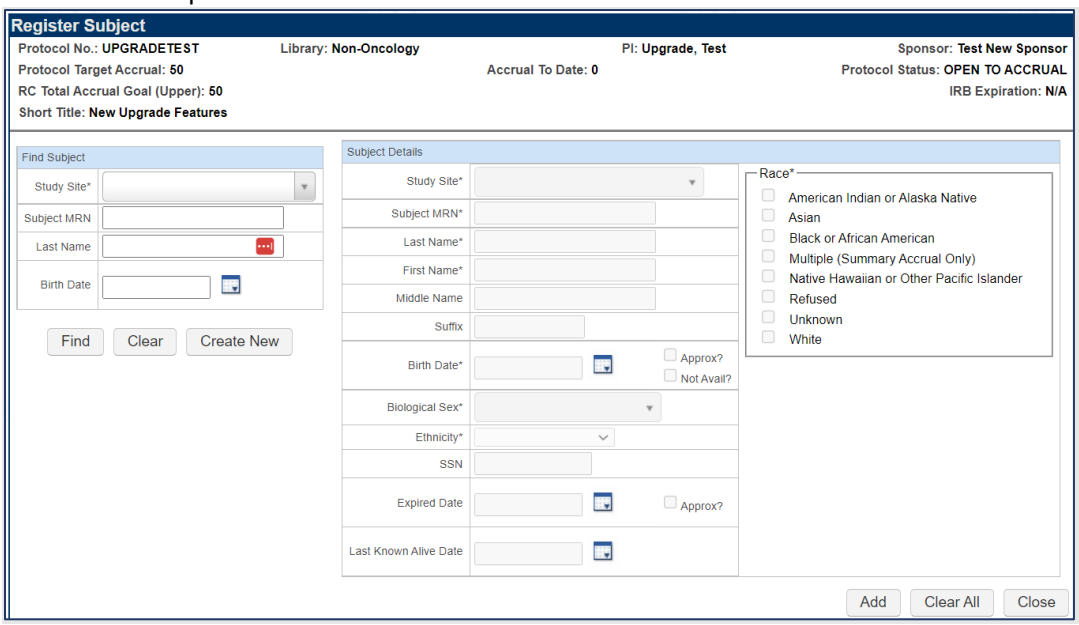


Register Subject - Find Subject

When registering a new patient to a study (**CRA Console** > **Register Subject**), the user might not see the fields in the **Find Subject** box. Instead, they will see a message alerting them as to why it is unavailable. If you have confirmed the **Show PHI** checkbox has been selected in the user menu but still see this message, you do not have permission for this functionality. Please reach out to the OnCore team if you have any questions.

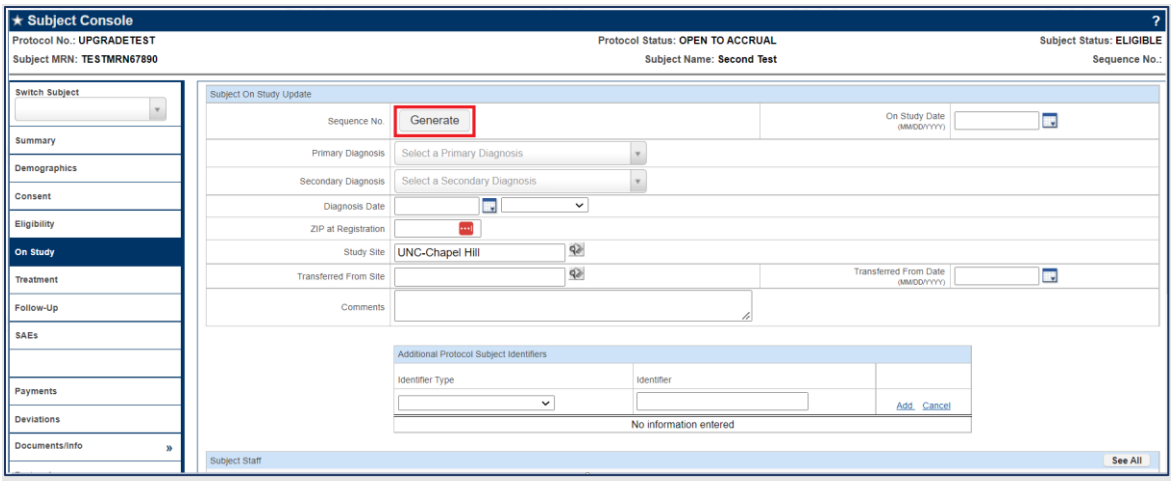


This is what the **Register Subject** page will look like if the user has selected the **Show PHI** checkbox in the user menu and has the correct permissions in OnCore.

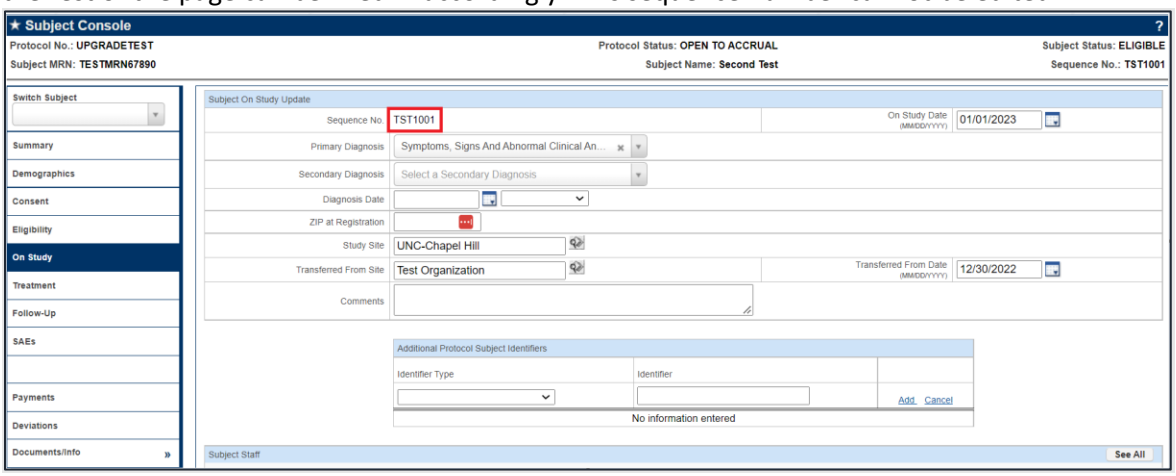


On Study – Generate Sequence No.

When placing a subject on study (**Subject Console** > **On Study**) on a protocol utilizing Automated Sequence Numbers users will notice an additional "Generate" button. Previously, the **Sequence No.** field was inactive, and a sequence number was assigned to a subject after the **On Study Date** was entered and the user clicked **Submit**.
Now, users will see a **Generate** button in the **Sequence Number** field.



Clicking **Generate** will populate a sequence number in this field (based on the preferences set up in the PC Console), and the rest of the page can be filled in accordingly. This sequence number cannot be edited.

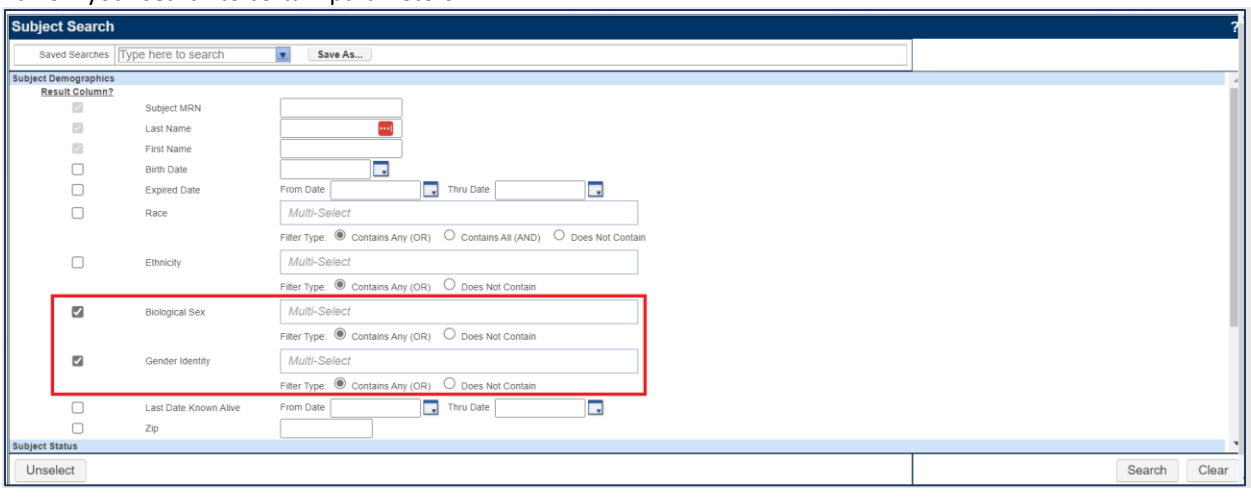


Subject Search

When utilizing the Subject Search function (Menu > Subjects > Subject Search), users will notice the addition or update of the following fields and ability to search based on their criteria:

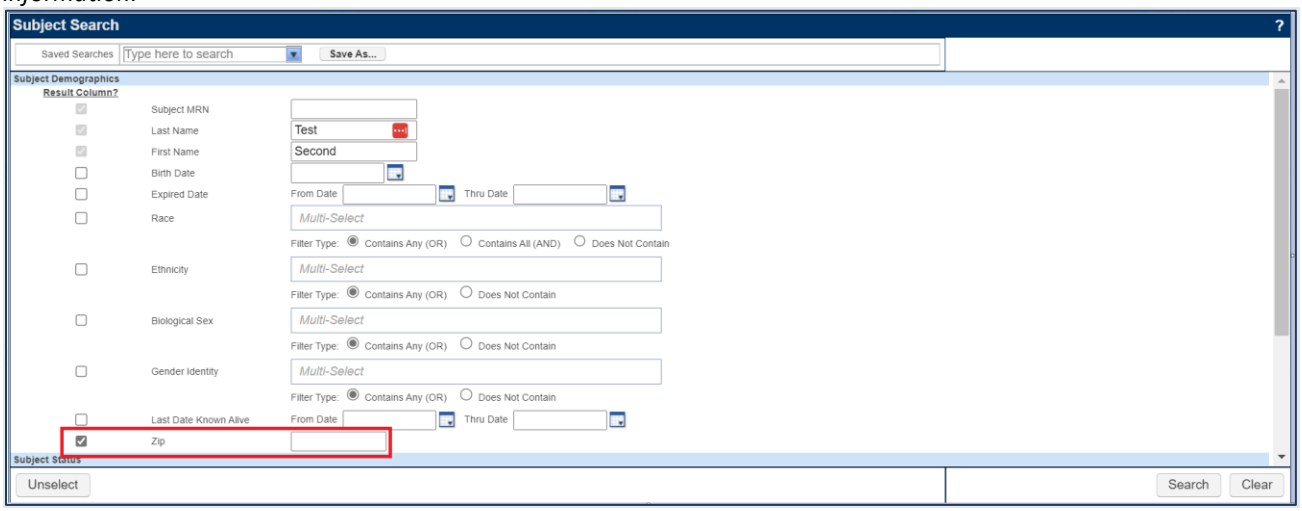
Subject Search > Subject Demographics > **Biological Sex** and **Gender Identity**

You can select the checkbox to include this information as a column in your report results or enter one or more items in the field to narrow your search to certain parameters.



Subject Search > Subject Demographics > **Zip**

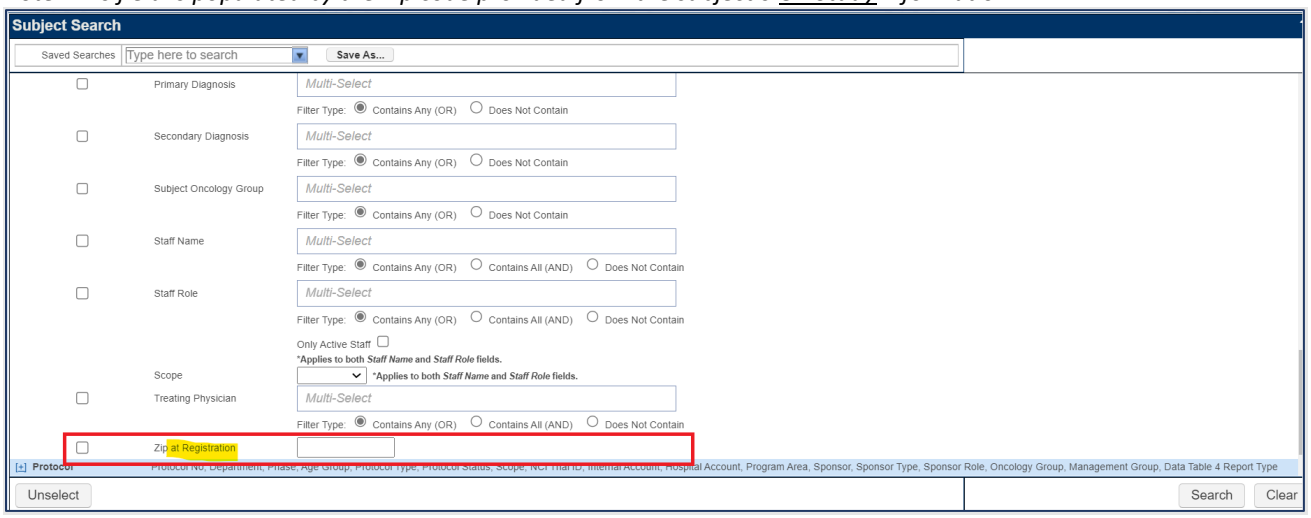
You can select the checkbox to include this information as a column in your report results or type a zip code into the field to narrow your search to certain parameters. *Note: This field is populated by the Zip code provided from the subject's Demographics information.*



Subject Search > On Study > **Zip <u>at Registration</u>**

You can select the checkbox to include this information as a column in your report results or type a zip code into the field to narrow your search to certain parameters.

Note: This field is populated by the Zip code provided from the subject's On Study information.

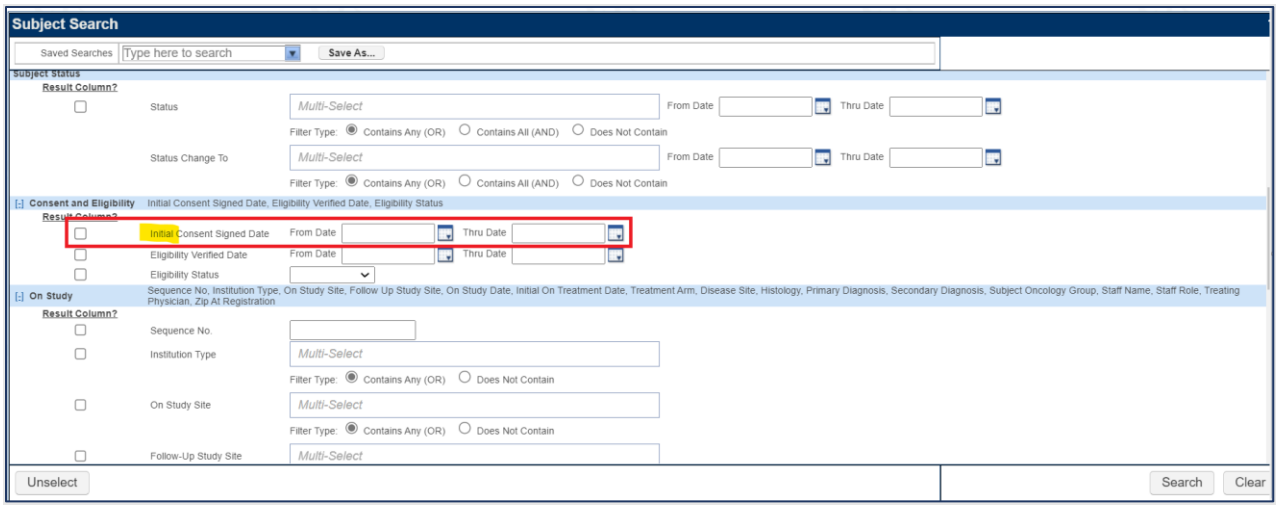


Subject Search > Consent and Eligibility > **Initial Consent Signed Date**

This field has been updated from Consent Signed Date. You can select the checkbox to include this information as a column in your report results or add dates to narrow your search.

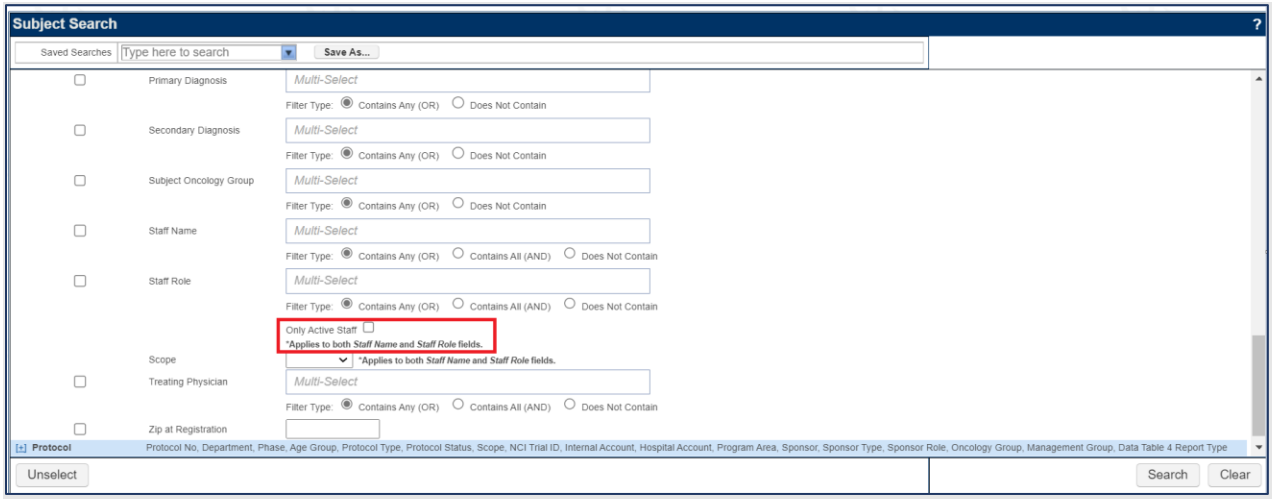
Initial Consent Signed Date

Matches subjects with a Subject Console > Consent tab > Signed Date in the date range entered. The subject's *first* consent signed date is used for the search. The From Date and Thru Date fields can be used together or independently. When From Date or Thru Date is blank, the search assumes there is no lower or upper bound to the date, respectively.



Subject Search > On Study > **Staff Name** and/or **Staff Role**

When this checkbox is selected, the results include only active staff that also match the Staff Name and Staff Role selections. The results will be listed in the Active Staff Name/Role column. If this checkbox is left unselected, both active and inactive staff results will be returned.



Calendars

Financials

Other