Protocol Consents in EpiSoft

EpiSoft now supports up to 3 different types of Consent linked to a Protocol

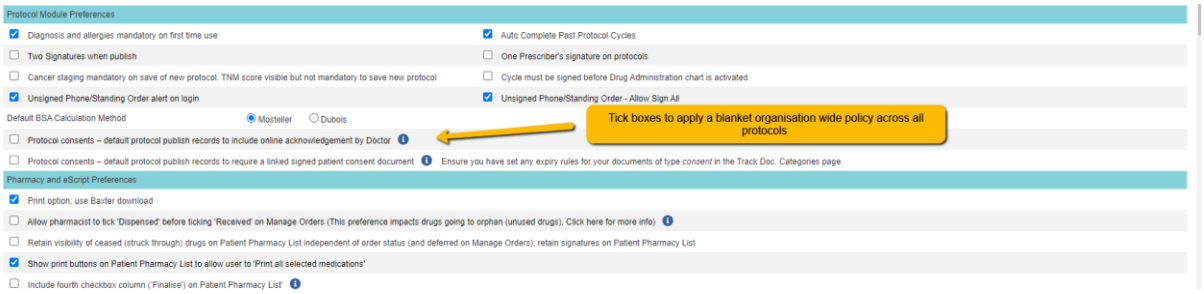
These are:

1. A simple acknowledgement by the doctor that the patient has consented to the treatment
2. A signed patient consent to treatment as you typically get signed by the Dr and the patient and upload to the Patient Documents - this can now be linked to protocol cycles for better compliance / tracking to specific treatments
3. A third party approval with an expiry such as from BloodSTAR

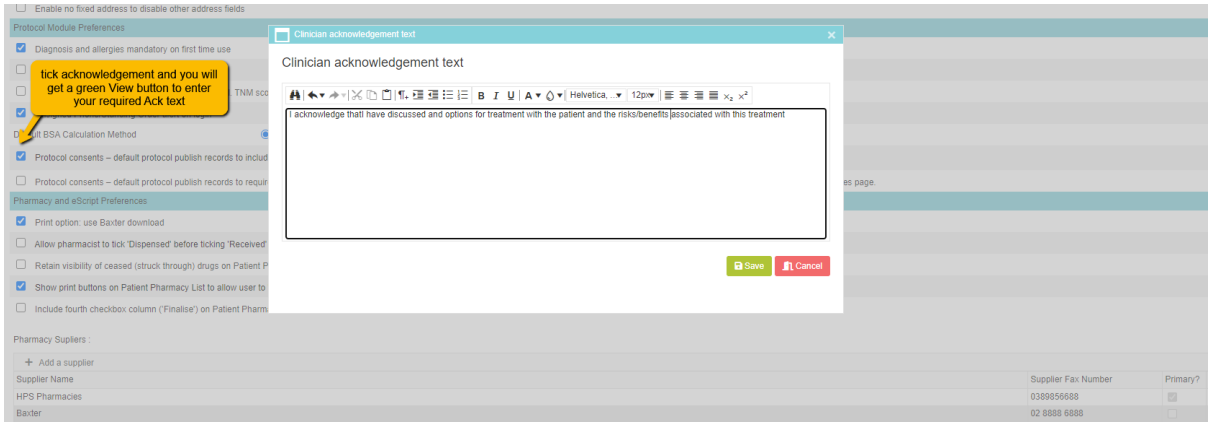
Initial Setup

Based on your organisation policy, you need to determine if all protocols should have a simple Acknowledgement statement signed by the cliknician (and only some protocols require a Consent signed by the patient) OR all protocols require a Consent signed by the patient.

This rule then needs to be set in the Organisation Preference. You can change this rule if your policy changes at some stage but as a general rule, these flags on Org Prefs page will be set once and not be changed.



Before finalising your organisation setup, if Acknowledgement is one of these preferences, you must create the Acknowledgement statement in the associated popup:

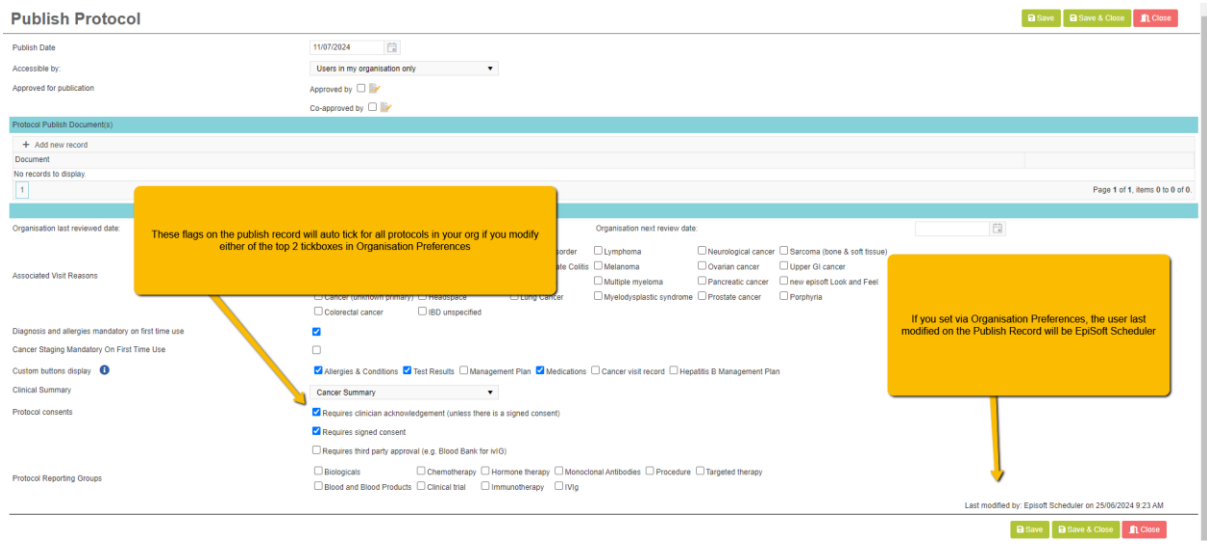


Background Process runs to update your records

Once organisation preferences is saved with changes to one or both of these two tick boxes, will then trigger a background process which might take a few minutes to run that will:

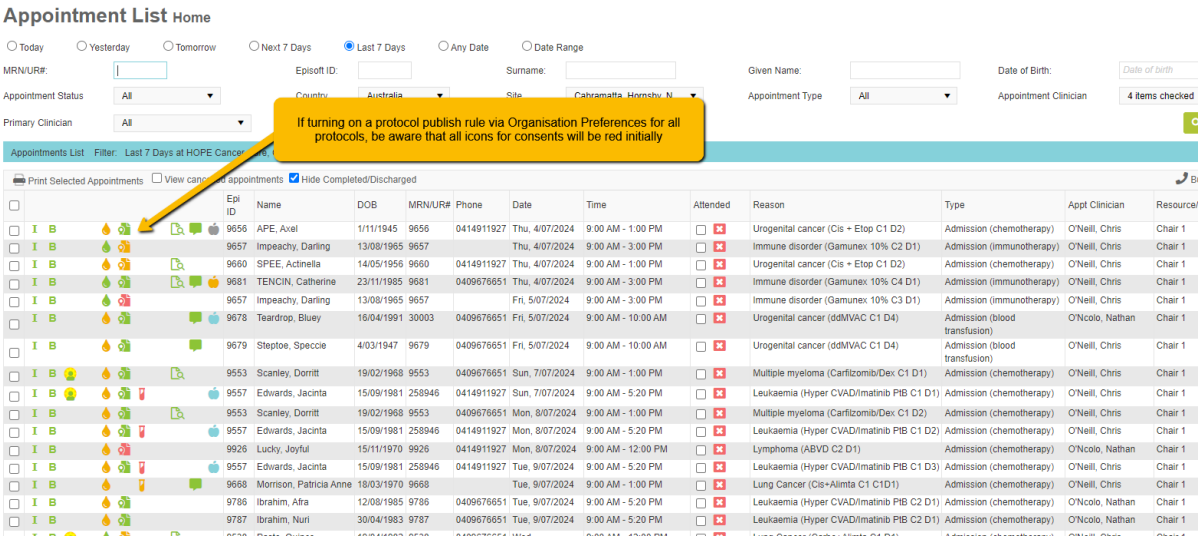
1. Update all your Protocol Publish records to match what you have ticked on the Organisation

Preferences



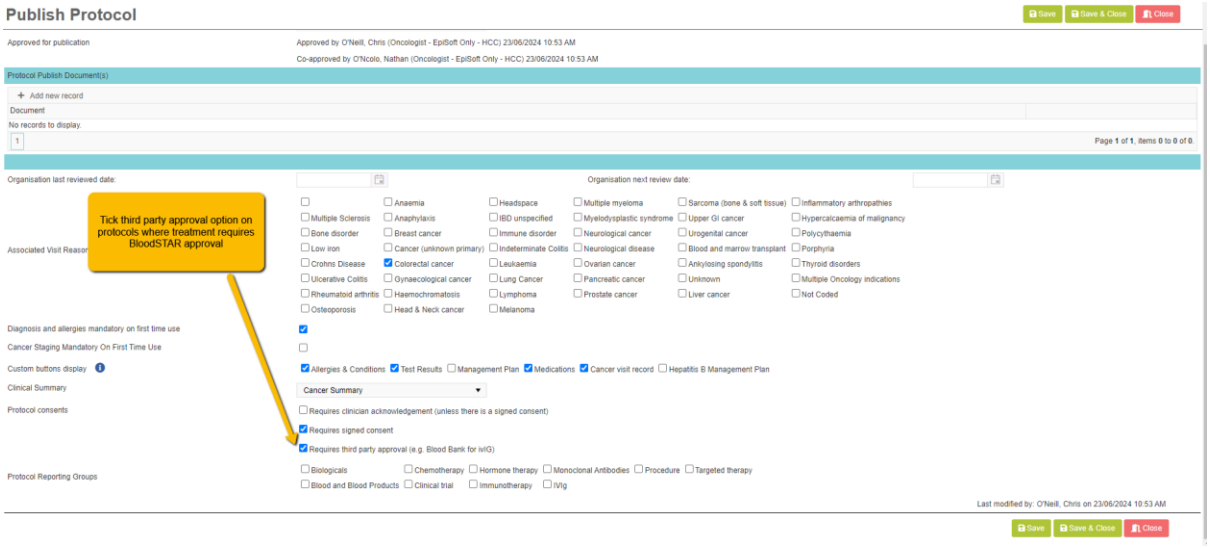
2. Update all patient protocol cycles with a cycle start date of today or in the future to require the consent type you have set

3. You will start to see red icons on the appointment worklist and red buttons at the top of edit protocol and on the drug chart as patients may have signed consents in their documents but none of them have yet been linked



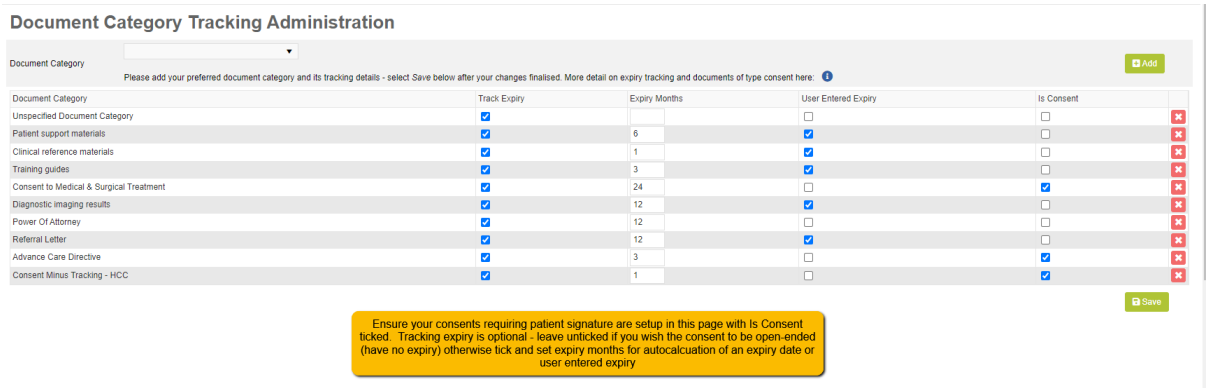
4. Any new protocols you create and publish will be ticked by default to match your organisation policy.

If you want to set protocol specific rules in addition to your organisation preference, you can set these flags in the protocol publish records. For example, for your IvIG protocols, you will likely want to check the third party approval checkbox to track your BloodSTAR approvals. If you use the Acknowledgement functon as a rule, you may tick some high risk treatments as requriing a signed patient consent.



When you make a change to a publish record to the consent ticks, part 2 (and 3) of the background process will run to reset the consent rules for all the patient protocols that match that publish records. It will never remove existing linked consents or data but will set the rules for new ones.

Consent document tracking setup - the final setup is to check if any patient signed consent document categories are setup as you require them in the Document Category Tracking Administration page (called Track Doc Categories in the System Administraiton menu). Here you can set the rules for which document categories you have access to should be tracked to have a System Calculated Expiry or a User Entered Expiry. If Is Consent is ticked, this document will be able to be linked to a patient protocol as a consent to treatment. If you require additional categories for your consents other than the ones already available please contact help@episoft.com.au



This is also where you can set up expiry date tracking for patient signed consents. For example, you may want to set no expiry if the consent will be valid for as long as the treatment or else you may require a new consent to be signed every twelve months.

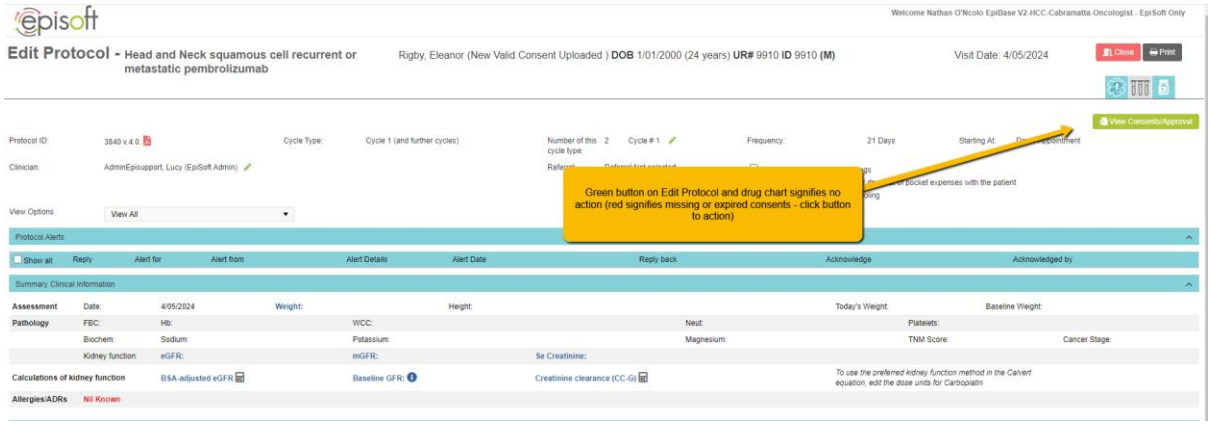
You do not need to track BloodSTAR document expiries through this module as third party approvals are tracked a different way so this module is for tracking treatment consents (signed by the patient and the doctor).

This completes the setup for your Protocol Consents module.

Buttons on Edit Protocol and Drug Chart

Once set up you will also start to see red buttons in the top right of Edit Protocol and Drug Chart signifying that a consent is required but is not complete/linked. This button is not visible when in New Protocol mode (only when protocol page is in Edit mode). This button can be used to enter the consent data or link an existing consent to a protocol.

A green buton on these pages signifies the consent data for that cycle is valid / complete.

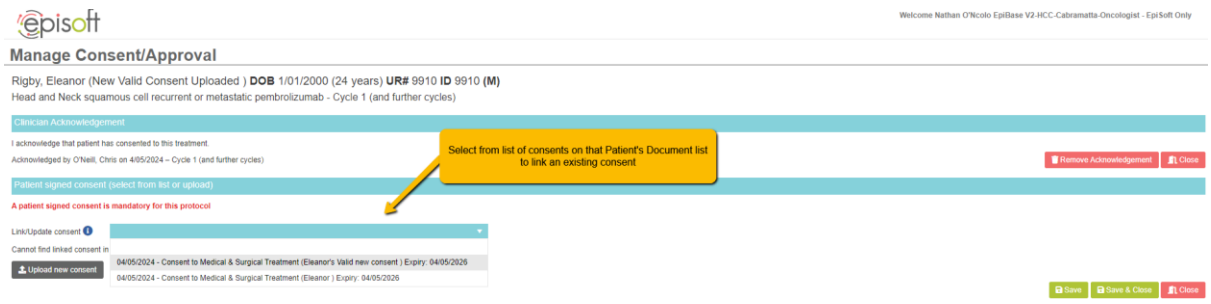


Linking Consents to Patient Protocols

Consent documents
You can link a Consent to a protocol if the protocol publish record has been ticked as requiring a consent OR ticked as requiring an acknowledgement (on the basis that if you have a signed consent, an acknowledgement is not required). To do this, click the Manage Consents/Approvals button on the top of Edit Protocol.

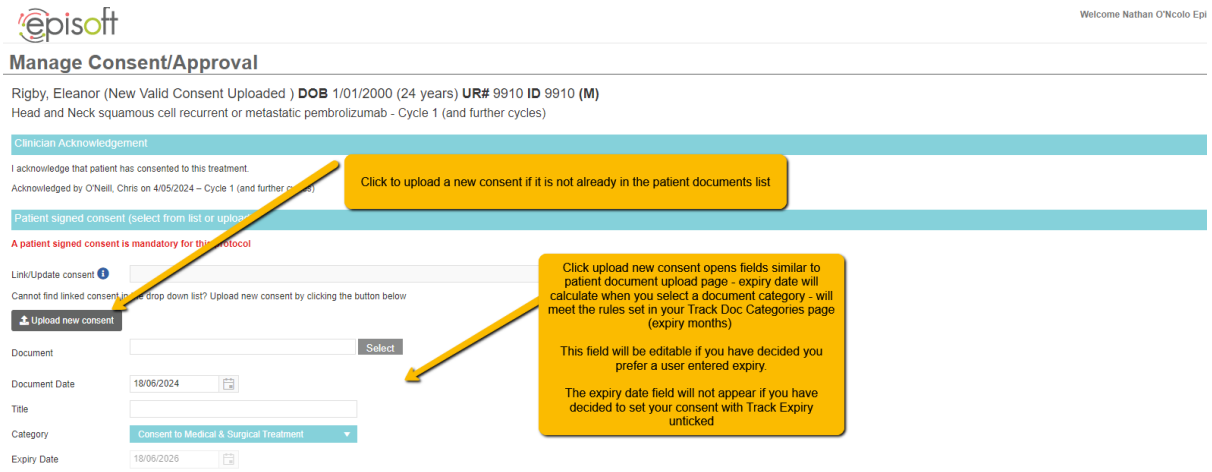
There will be a dropdown list with all the non expired consents that you have uploaded to Patient Documents. Documents will only appear in this list if the expiry date is later than the cycle start date date and the document category has been set to tracking in Track Doc Categories page.

The expiry date matching rules have been designed on the basis that if the patient consent is valid at the start of the cycle, the consent will remain valid to end of that same cycle (but will not be valid for future cycles).

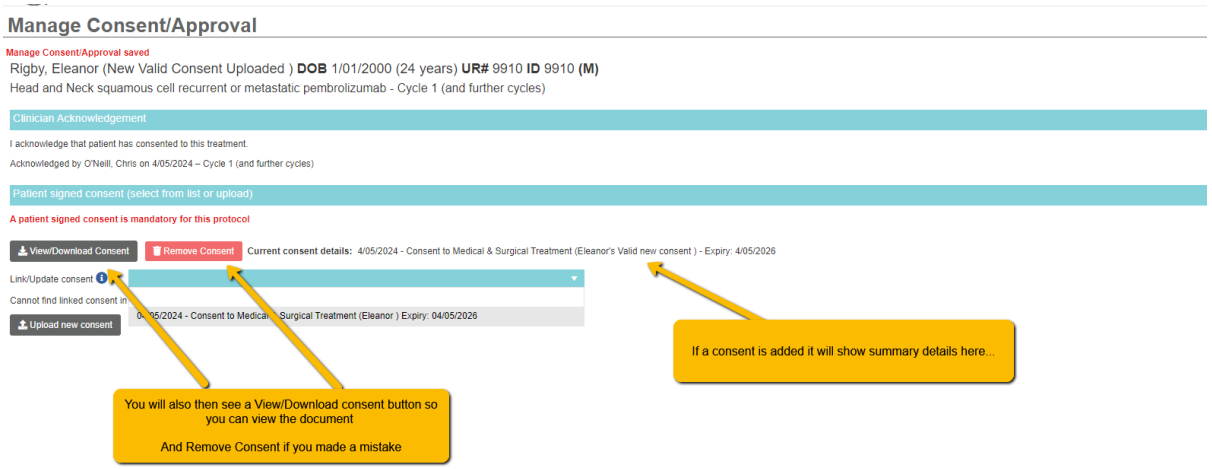


If the consent document has not previously been uploaded to the Patient Documents page, then

you can choose to upload a new consent document at this time via the Manage Consents/Approvals page. See below.



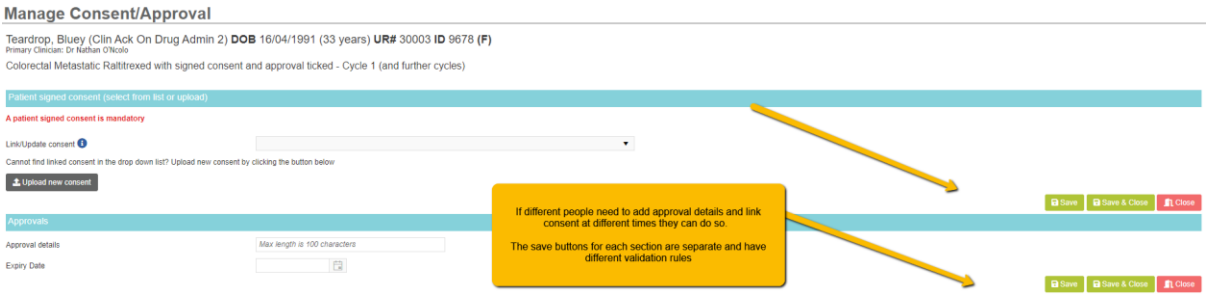
Once uploaded as new or linked from existing patient documents list, the page will display the consent metadata. You can view / download the consent document or if you have made a mistake, you can remove the consent.



Third party approvals

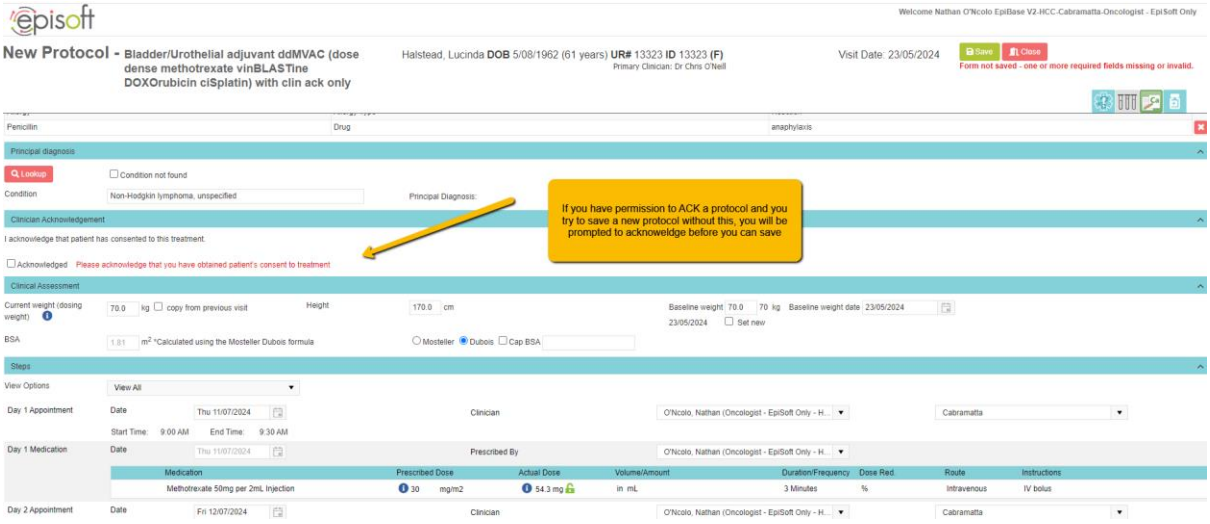
Adding third party approval details to a Protocol - if the protocol publish record has been ticked as requiring a third party approval, when you open the Manage Consents/Approvals from the top of the Edit Protocol page, you will see the approval section to which you can add a short description and an expiry date.

It would be more common for the protocol to require not just a third party approval but a consent as well in which case the Manage Consent/Approval page will appear as below.

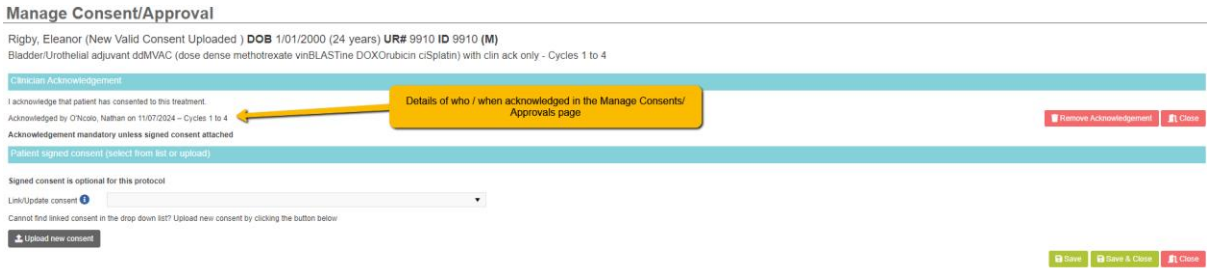


Clinician acknowledgements

Adding Acknowledgements to Patient Protocols - if the protocol publish record has been ticked as requiring an acknowledgement, when you add a new protocol to a patient, the acknowledgement text will be on the page and it will be mandatory to check if you have the permission to acknowledge. If you are adding protocol on behalf of a clinician who must later acknowledge, you will not be prompted for this and after saving the protocol, the Manage Consents/Approvals from the top of the Edit Protocol page, you will see the approval section to which you can add a short description and an expiry date.

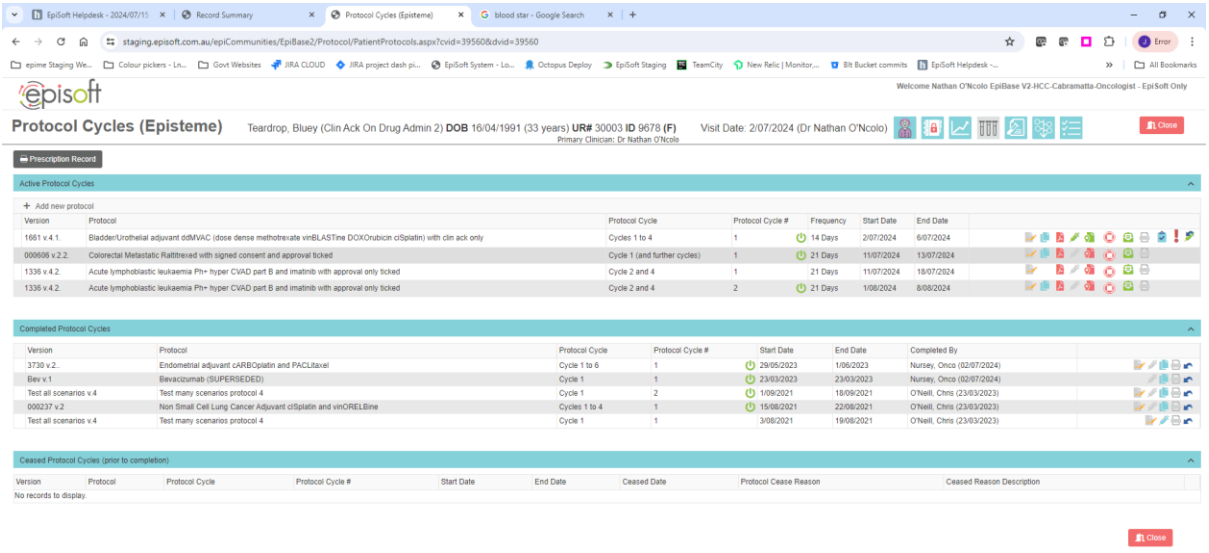


After acknowledging you and other staff can see the details in the Manage Consents/Approvals page



Flags / Icons to track status

The appointment status and protocol cycles list both show the Consent Icon that displays as green (consent section complete), orange (consent section complete but due for review or update expiring consent within 22 days of the cycle start date), red - consent is expired or missing. The tooltip shows the details.



If the patient is on mutliple treatments in one day as an inpatient, this as you know groups the appointments on the appointment list. In this case, the icon colour will show the least compliant consent (red trumps orange for example) and the tooltip will show the details of all protocols for that day.

Previous function - Document icon and tracking / expiry - this is still available on the Appointment list but should no longer be required for protocol treatments as there is now a hard link to the protocol and a dedicated icon. If you prefer to continue to use this function instead of the linked consents function, do not go through the setup steps and this icon will continue to work as it did previously.

Copy forward rules

An acknowledgement, consent or approval will copy forward for all future cycles of this protocol including when the cycle type changes. It will not copy if:

1. The future cycle start date is later than the expiry date on the consent (and third party approval will cease copying for the same reason)
2. It is the same protocol but with a different system ID or version number
3. If the protocol publish record rule has changed for example that particular protocol no longer requires a consent

Acknowledgements have no expiry date so will continue to copy forward for future cycles of that protocol for that patient regardless of the cycle start date.

Moving protocol date from past to future

If you modify a protocol pubish record consent tick box (or organisation preference consent preference), the abovementioned Background Process runs. However it only runs on cycles that have start dates now or in the future. You may have active cycles for a particular patient that are in the past because, for example, their treatment is on hold for some reason. If this happens and you need to move a past protocol to the future, as you move it forward, it will pick up the rule from the protocol publish record and apply it to that protocol.