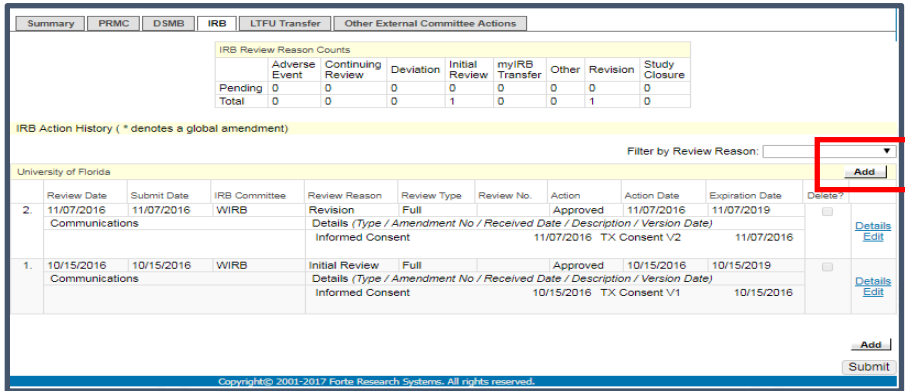


**Description:** If there are revisions to an informed consent form, the IRB may require that all active subjects be re-consented. This tip sheet explains how to use the OnCore “re-consent” functionality to record and track the re-consenting process.

## UPLOAD THE NEW VERSION OF THE CONSENT FORM

1. Navigate to **Menu > Protocols > PC Console > Reviews > IRB.**
2. Click the **[Add]** button.



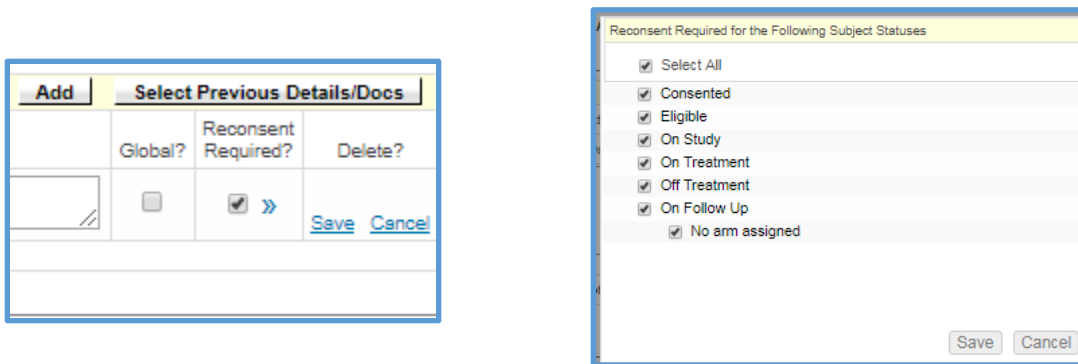
3. In the detail item row that appears, select the review item from the **Type** dropdown list.

**IMPORTANT:** In order to activate the OnCore re-consenting functionality correctly, the revised consent form you are adding must have the exact same document “**Type**” as the original version of the consent from the initial IRB review.

4. Enter the **Version Date** of the revised consent.
5. Enter the **Description** for the consent.

This description is very important for protocols with more than one consent. A good description will help the consenters find the correct consent (and the correct consent version) to use later in the subjects console when they are consenting subjects to this study.

6. The **Comments** field is a good place to provide additional details about the consent (e.g. changes made since the prior version).
7. Select the **[Re-consent Required]** checkbox.



8. Click [Save]. **NOTE:** You have created a detail line that only describes the consent. You still need to attach the actual consent document (see next steps).

- Under the consent detail line you just created, click the [File](#) hyperlink.
- Click **[Browse]** to locate and select the consent on your local computer or network hard drive.
- Click **[Open]**.
- Click **[Submit]** to save this document to this record.
- IMPORTANT! Select the [Release] checkbox.**
- Click [Submit and Close].

## THE “RE-CONSENT REQUIRED” (RR) FLAG

If the revised consent has been recorded and uploaded using the original document type and has the **[Re-consent Required]** checkbox checked, then subjects who consented on a previous version of this document have an **RR** superscript indicator in the **CRA Console > Accrual** tab.

The RR superscript indicates that this subject needs to review and accept a newer version of the consent form

Study Site	Patient MRN	Last Name	First Name	Seq No.	Arm	Level	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
West Clinic	SU1919616	Hoagland	Jacquelyn	CAR-7	2		ON FOLLOW UP	03/29/2015	3	D30	04/27/2015	<input type="checkbox"/>
South Clinic	AB16852Y <sup>RR</sup>	Johnson	Jody	CAR-6	1		ON FOLLOW UP	12/07/2015	3	D30	01/04/2016	<input type="checkbox"/>
South Clinic	VZ82196PM	Mallouk	Susan				NOT ELIGIBLE	08/11/2015	2			<input type="checkbox"/>
South Clinic	VG801418Y <sup>RR</sup>	Feraca	Roland				CONSENTED	02/02/2015	2			<input type="checkbox"/>
South Clinic	HK1961206	Sterritt	Donna				NOT ELIGIBLE	03/26/2015	2			<input type="checkbox"/>
South Clinic	PG86163C5 <sup>RR</sup>	Bailey	Wayne	CAR-11	1		ON TREATMENT	02/06/2015	3	D1	02/06/2015	<input type="checkbox"/>
North Clinic	ER71653DD	Garton	Ken	CAR-1	1		ON FOLLOW UP	07/26/2016	3	D1	02/07/2015	<input type="checkbox"/>
North Clinic	JI187051Q	Spitzer	Sophia	CAR-2	1		ON TREATMENT	06/04/2015	3	D1	06/04/2015	<input type="checkbox"/>
North Clinic	BS64707KS <sup>RR</sup>	Polyak	Paul	CAR-3			ON STUDY	04/22/2015	3			<input type="checkbox"/>
North Clinic	HH83191BM <sup>RR</sup>	Grobman	Lee				CONSENTED	05/05/2015	2			<input type="checkbox"/>

The **RR** indicator also appears on the consent document in the **Subject Console > Consent** tab until the subject accepts the newer version.

RR - Denotes a re-consent requirement currently exists.

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status
HIPAA Consent	Approved HIPAA Consent: V1	01/05/2015	01/05/2015	01/05/2016	05/15/2015	Accepted
Treatment Consent <sup>RR</sup>	English language Tx Consent: V1	01/05/2015	01/05/2015	01/05/2016	05/15/2015	Accepted

**Note:** The **RR** flag does not restrict your ability to add treatment information, but the **RR** does not go away until the re-consent is either recorded or marked as “not applicable”.

## RECORD A SUBJECT'S RE-CONSENT

1. Navigate to the **CRA Console**.
2. Click the **MRN** link for any subject with an <sup>RR</sup> superscript to open that subject record in the Subject Console.
3. Select the **Consents** vertical tab.
4. In the **Signed Date** field, enter the date that the subject re-consented.
5. Click **Select Consents**.
6. Indicate that the updated version of the consent was **Accepted**.
7. Click **Save**.

**NOTE:** The latest version of each consent type that was approved *on or prior to* the Signed Date appears in the pop-up consents window. To see earlier versions, click the + plus sign next to any of the consent types.

Indicate which version of each consent was presented to the subject, and whether she Accepted or Refused each one

After selections are made, clicking Save will add the selected consents and refresh the page.

Type	Description	Version Date	Approved Date	Expiration Date	Signed Date	Status	Include?
<input type="checkbox"/> HIPAA Consent	HIPAA V2	02/02/2015	02/02/2015	02/02/2016	12/05/2016	<input checked="" type="radio"/> Accepted <input type="radio"/> Refused	<input checked="" type="checkbox"/>
<input type="checkbox"/> Tissue Consent	Donor tissue consent v3	12/04/2016	12/04/2016	12/03/2017	12/05/2016	<input type="radio"/> Accepted <input checked="" type="radio"/> Refused	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> Treatment Consent	English Language Tx Consent v3	12/04/2016	12/04/2016	12/03/2017	12/05/2016	<input checked="" type="radio"/> Accepted <input type="radio"/> Refused	<input checked="" type="checkbox"/>
Treatment Consent	English Language Tx Consent V2	02/02/2015	02/02/2015	02/02/2016	12/05/2016	<input type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>
Treatment Consent	English Language Tx Consent V1	02/02/2014	02/02/2014	02/02/2015	12/05/2016	<input type="radio"/> Accepted <input type="radio"/> Refused	<input type="checkbox"/>

Click the + plus sign to see previous versions of any consent type

Save Cancel

## RECORD THAT THE RE-CONSENT IS NOT APPLICABLE

Alternatively, you can indicate that the re-consent is not applicable to the subject.

1. Navigate to the **Subject Console > Consent** tab.
2. Select the consent link that includes the <sup>RR</sup> superscript.
3. A box appears that allows you to indicate that the re-consent is not applicable.
4. If you make this choice, the **RR** superscript changes to **NA**.