CHECK IN SUBJECT VISITS

Description: Checking in a study visit involves submitting visit information, which consequently updates the status of the visit. A visit will have one of four statuses: **Planned**, **Occurred**, **Missed**, or **N/A**. This tip sheet describes how to:

- Check in **Planned** visits as **Occurred**, **Missed**, or **N/A**
- Add unplanned/unexpected procedures to a visit
- Add unplanned/unexpected visits
- Change a procedure **Billing Designation** from the planned designation

Audience: Study team members who are responsible for recording study visits in OnCore.

CHECK IN AN OCCURRED VISIT

1. **Find your subject.**

2. On the subject record in the Subject Console, click the **Calendar** vertical tab.

3. In the header section of the calendar, click on the **blue hyperlink** for the visit you are checking in.

> ⚠️ *Reminder: Visit hyperlinks within a given calendar segment will only become active and available for check-in once the "trigger date" or **Start Date** associated with that segment has been entered into OnCore for this subject.*

4. The **Subject Visit Update** page opens.

5. The first field on this page is the **Visit Date**. The date in this field defaults to the **Planned Date** shown on the calendar. Change this date as necessary.

> ⚠ *If there are tolerances set for this visit and your new date falls out of the tolerance, you will get a warning message. You can still check in this visit.*
>
> *The visit will be recorded in the subject's **Subject Console > Deviations tab.***

6. Next to the **Visit Date** field is the **Visit Status** box. Notice that by default, the **Planned** radio button is selected.

7. Click the **Occurred** radio button.

8. Review the **Procedures** table at the bottom of the screen. The table lists the labs, panels, and procedures that have been scheduled within the visit. Unless they are marked as **Missed** or **N/A**, it is assumed that the visit has occurred as planned and that the procedures have been performed on the **Visit Date**, unless otherwise indicated by editing the **Procedure Date**.

| Procedures	**9a**				**9b**	**9c**	**9d**	
Procedure	Procedure Date	SOC	SOC Modifier		Missed	Missed Count	N/A	Location
Fever Prevention Index Procedure		☐			☐		☐	
Hourly Core Body Temperature		☑	○ Q0 ◉ Q1 ○ U		☐		☐	
Daily White Blood Cell Count		☐			☐		☐	
Shiver monitoring and control protocol	03/19/2018	☐			☐		☐	

9. If needed, enter **Visit Procedure Variations.** If a **Procedure** was:

   a. Performed on a **different date** than the **Visit Date**, enter the date in the **Procedure Date** field. Note: Blank means the procedure **was** performed on the default **Visit Date** – There is no need to type that date here again.

   b. Missed, click the **Missed** checkbox. Enter the reason in the pop-up box.

   c. Supposed to happen multiple times in the visit, but one or more of the repeats were missed, click the **Missed** checkbox **and** indicate how many were missed in the **Missed Count** field. Enter the reason in the pop-up box.

   d. Not applicable for this subject, click the **N/A** checkbox. Enter the reason in the pop-up box.

10. Click **[Submit And Close]** to return to the Subject Calendar.

11. On the Subject Calendar, your visit now shows up as **Occurred** and the **Visit Date** is now displayed.

| Procedure Toggle Full Screen	Forms	Treatment
		Baseline 1@1 Days
		1
		Screening
Planned Date		10/01/2016
Visit Status		Occurred
Visit Date		10/01/2016
Adverse Events		X

ENTER ADDITIONAL PROCEDURES TO AN OCCURRED VISIT

Sometimes you will also need to document unplanned **Additional Procedures** that happened within an occurred visit.

1. First, follow all the steps for Check in an Occurred Visit, including clicking **[Submit]** or **[Submit And Close].**

2. If needed, re-open the occurred visit to which you want to add the unplanned procedures.

3. Notice that after an occurred visit has been submitted, it will have some extra buttons at the bottom of the screen. Click the **[Additional Procedures]** button.
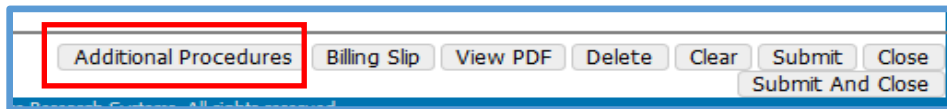
4. A pop-up window opens with three horizontal tabs:

   a. **Charge Master** - Not applicable at UF yet.

   b. **Protocol Procedures** - This tab lists the labs, panels, and procedures that have already been set up for this protocol. If any of the unexpected procedures are on this list, click the **Select?** checkbox for each of them, and click **[Submit].** Enter the reason(s) for adding in the pop-up box.
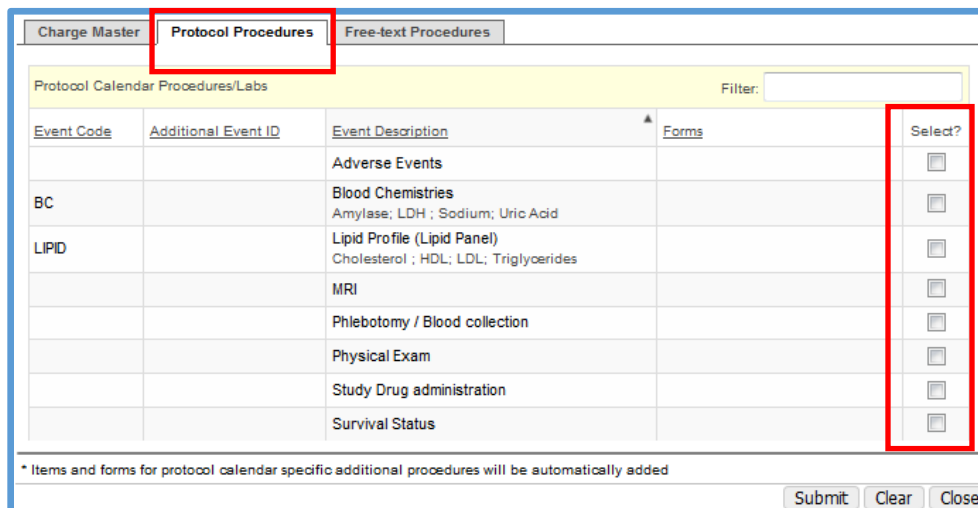
   c. **Free-text Procedures** - If any unexpected procedure is not already in the protocol list, you can add it by typing the new procedure name into the **Clinical Procedure** box, clicking the small blue Add hyperlink. Repeat for each procedure as needed, then Click **[Submit].** Enter the reason(s) for adding in the pop-up box.
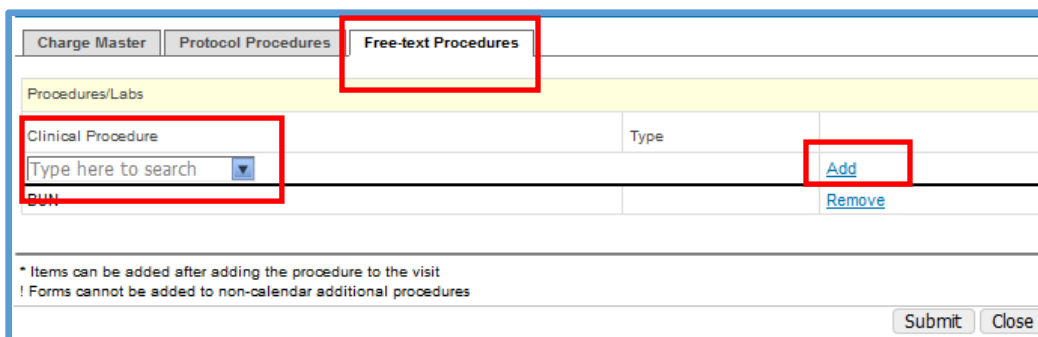
5. Once you have added all unexpected procedures, click **[Submit And Close]** to return to the Subject Calendar.

CHECK IN A MISSED VISIT

1. **Find your subject.**

2. On the subject record in the Subject Console, click the **Calendar** vertical tab.

3. In the header section of the calendar, click on the **blue hyperlink** that describes the missed visit.

4. Click the **Missed** radio button.

5. Click **[Submit And Close]** to return to the Subject Calendar.

6. On the Subject Calendar, the **Visit Status** now shows up as **Missed** and the original planned **Visit Date** displays in **red.**

Procedure Toggle Full Screen	Forms	Treatment Baseline 1@1Days 1 Screening
Planned Date		06/05/2017
Visit Status		Missed
Visit Date		06/05/2017
Adverse Events		X

CHECK IN A RESCHEDULED MISSED VISIT

If you have recorded a planned visit as **Missed**, but the subject subsequently was able to reschedule or "make it up", you can delete the **Missed** visit and re-check it in as **Occurred**.

1. **Find your subject.**

2. On the subject record in the Subject Console, click the **Calendar** vertical tab.

3. In the header section of the calendar, click on the **blue hyperlink** for the **Missed** visit you are now checking in.

4. Click the **[Delete]** button at the bottom of the screen and then click **[OK].** Note that this has undone (or removed) the visit information, allowing you to go back and mark the visit as **Occurred**.

5. Click on the **blue hyperlink** of the visit again.

6. Change the **Visit Date** to the rescheduled date.

> ⚠️ *If there are tolerances set for this visit and your new date falls out of the tolerance, you will get a warning message. You can still check in this visit.*
>
> *The visit will be recorded in the subject's **Subject Console > Deviations tab.***

7. In the **Visit Status** box at the top middle of the screen, click the **Occurred** radio button.

8. If this rescheduled visit requires that subsequent visits be "shifted" to conform to the protocol, click the drop-down menu next to **Reset Calendar** and select **All Visits** or **Current Segment,** as applicable.

9. Click **[Submit And Close]** to return to the Subject Calendar.

10. On the Subject Calendar, your visit now shows up as **Occurred** and the new **Visit Date** is displayed.

11. If you reset the calendar, subsequent planned dates have been adjusted.

CHECK IN A N/A VISIT

A **N/A** visit status indicates that the visit does not apply to this subject. Marking a visit N/A will create a visit variation in the Financials Console.

1. **Find your subject.**

2. On the subject record in the Subject Console, click the **Calendar** vertical tab.

3. In the header section of the calendar, click on the **blue hyperlink** that describes the N/A visit.

4. In the **Visit Status** box at the top middle of the screen, click the **N/A** radio button.

5. Click **[Submit And Close]** to return to the Subject Calendar.

6. On the Subject Calendar, the **Visit Status** now shows up as **N/A** and the original planned **Visit Date** displays in **red.**

ENTER ADDITIONAL AND/OR UNEXPECTED SUBJECT VISITS

At times, subjects will be seen for additional or unexpected visits that are not on the calendar. These visits should be recorded on the subject's **Additional Visits** vertical tab.

1. **Find your subject.**

2. On the subject record in the Subject Console, click the **Additional Visits** vertical tab.

3. Click the **[New]** button on the far right. The **Subject Visit Update** screen appears.

4. Complete the following fields:

   - Visit Date

   - Visit Description

5. Click **[Submit];** the [**Additional Procedures**] button will appear at the bottom of the screen.

6. Click **[Additional Procedures].**

7. Add all of the procedures in this unplanned visit using the Additional Procedures functionality.

   NOTE: Additional Visits do NOT appear on the subject calendar.

CHANGE A BILLING DESIGNATION FROM THE PLANNED DESIGNATION

Billing Designations indicate how the costs will be covered for the procedures within each visit. These are determined prior to study start-up by the study Financial Coordinator using UF and Medicare Coverage Analysis rules and the final budget. The planned designations for each procedure are entered into OnCore by the OCR office.

If the planned **Billing Designation** for a specific visit/procedure needs to be added/updated/corrected for **all subjects going forward**, the study team must submit an amended billing grid/budget to the OCR office so that the OnCore billing plan, budget, and calendar are updated appropriately.

In <u>rare circumstances</u>, the **Billing Designation** for a specific procedure **for a specific subject** needs to be updated (e.g. a procedure designated as a Routine Cost "SOC" procedure will be paid for by the study **for this subject**).

> ⚠️ *WARNING! Changing a default planned Billing Designation will result in a visit variation in the Financials Console.*
>
> *It may also have an impact on the budget, calendar, and sponsor invoicing functionalities in OnCore, and subsequently increase the patient care billing compliance risk for this study.*
>
> *It is highly recommended that you check with your Group Supervisor, Financial Coordinator and/or Epic Charge Reviewer before changing a Billing Designation in OnCore.*

Change from Study Paid to SOC

1. In the **Procedures** list, locate the procedure that needs a change in designation.

Procedures								
Procedure	Procedure Date	SOC	SOC Modifier		Missed	Missed Count	N/A	Location
Fever Prevention Index Procedure	03/18/2018	☐			☐		☐	
Hourly Core Body Temperature	03/18/2018	☑	○ Q0 ● Q1 ○ U		☐		☐	
Daily White Blood Cell Count	03/18/2018	☐			☐		☐	

2. In the **SOC** column, check the SOC checkbox.

3. Enter the **Reason for Change** in the resulting pop-up box and click **[OK]**.

4. Update the radio button in the **SOC Modifier** column to indicate the correct billing modifier:

   - Use **Q0** to designate the **item under investigation** in the qualifying trial/study
   - Use **Q1** to identify a **qualifying "Routine Cost"** provided in a qualifying trial/study
   - Use **U** if modifier is **unknown**

5. Click **[Submit]**. The changed procedure now shows as a blue hyperlink; when clicked, OnCore displays the pop-up box that indicates the **Reason for Change**.

Procedures								
Procedure	Procedure Date	SOC	SOC Modifier		Missed	Missed Count	N/A	Location
Fever Prevention Index Procedure	03/18/2018	☐			☐		☐	
Hourly Core Body Temperature	03/18/2018	☑	○ Q0 ● Q1 ○ U		☐		☐	
Daily White Blood Cell Count	03/18/2018	☑	○ Q0 ● Q1 ○ U		☐		☐	

Change from SOC to Study Paid

1. In the **Procedures** list, locate the procedure that needs a change in designation.

2. In the **SOC** column, uncheck the SOC checkbox.

3. Enter the **Reason for Change** in the resulting pop-up box and click **[OK]**.

4. The **SOC** and **SOC Modifier** columns are now blank.

5. Click **[Submit]**. The changed procedure now shows as a blue hyperlink; when clicked, OnCore displays the pop-up box that indicates the **Reason for Change**.