What is Summary Accrual?

For OnCore studies that do not require individual subject registration, the **Summary Accrual** functionality provides a simplified way to report study accrual data.

What OnCore Studies Can Use Summary Accrual?

- The study does not have clinical services occurring in a UF Health location (e.g. blood draws, labs, EKG's).
- The study will not use an OnCore calendar.
- Sponsor invoicing is not dependent on participant visit data.
- The Office of Clinical Research (OCR) must verify that the study qualifies. Once verified, OCR will set the Summary Accrual field to YES on the PC Console > Main screen.

Examples of studies that can use Summary Accrual include:

- Studies using only questionnaires or surveys, including anonymous surveys
- Studies collecting retrospective data
- Studies collecting or using de-identified data or samples
- Internally-funded studies where all activities are performed in research space

General Considerations

- Before entering any Summary Accrual Data, the protocol status must be Open to Accrual. For details, see Open <u>a Protocol to Accrual</u>.
- Study team member(s) who are responsible for entering accrual must be listed as protocol staff for the protocol in OnCore. For details, see <u>Assign Study Staff</u>.



If no one on your study team has OnCore access, please contact the Office of Clinical Research Quality Assurance (OCR QA) team via <u>OCR-QA@ahc.ufl.edu</u> to get your protocol open to accrual.

- Summary Accrual data should be entered at least once a month.
- The Office of Clinical Research Quality Assurance (OCR QA) team will follow up with any Summary Accrual studies that do not have current accrual data.
- Study teams with OnCore access may enter accrual data in one of two ways:
 - 1) Manual entry using the PC Console > Accrual screen

OR

2) Spreadsheet upload using the Summary Accrual Import Tool



If no one on your study team has OnCore access, you will need to enter your accrual data into a <u>special excel spreadsheet</u> and send to the OCR QA team via <u>OCR-QA@ahc.ufl.edu</u> for upload.

ENTER SIMPLE ACCRUAL DATA MANUALLY

If the only accrual information you need to enter is the number of subjects enrolled within a certain time period, manually entering this data into OnCore is quick and easy. If you want to also track optional demographic information on your accruals, we recommend you use **Summary Accrual Import Tool** to enter your accrual data (see next section).

- 1. Log in to OnCore.
- 2. Navigate to Menu > Protocols > PC Console > Accrual.
- 3. In the Select Protocol field, type in the OnCore protocol number OCR##### (or other study identifier).
- 4. Click on [Update].

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- 5. Enter the following required fields:
 - From Date Beginning of the accrual time period you are reporting on
 - Thru Date Last day of the accrual period you are reporting on
 - Accrual Number of subjects enrolled.
 - Internal Accrual Reporting Group Always select Research Center

Note: For institutional reporting purposes, each summary accrual record should not span beyond a given month. For example, all accruals for January can be recorded with a single entry with a **From Date** of "01/01/2021" and a **Thru Date** of "01/31/2021". Multiple records may be used for a given month when additional reporting fields are added (e.g. Race, Ethnicity, Age, etc.).

Enter any other additional fields as desired and/or appropriate (e.g. Race, Ethnicity, Age, etc.).
 Note: If your team wants to track any of the optional demographic information on your accruals, or for larger datasets, we recommend that you use the Summary Accrual Import Tool (see next section).

★ PC Console																?
Protocol No.: OCR39604 Library: Academic Hea						h Center PI:					Sponsor					
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Eligibility		02/21/2020	03/21/2020		Research Cen	nter								14	Edit	<u>Copy</u>
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7. Click [Add] and [Close].

UPLOAD ACCRUAL DATA USING THE SUMMARY ACCRUAL IMPORT TOOL

The summary accrual import tool allows users to upload an excel spreadsheet of enrollment data and subsequently import those enrollments into OnCore as summary accruals. This method is recommended if you have a lot of accrual data to enter.

What Protocols Can Use the Import Tool?

- The OnCore protocol has been configured for Summary Accrual.
- The protocol has/had a time period where the OnCore study status is/was **Open to Accrual**.
- The study team member who will be using the import tool has OnCore access and is listed on the protocol's <u>Staff</u> tab in OnCore.

Prepare Import Data Spreadsheet for Summary Accrual Tool

- 1. Open, download, and save a copy of the import template.
 - This template is available on the landing page of the <u>Summary Accrual Import Tool</u>.
 - Each time the data sheet is opened, you will need to select "Enable Macros" for the tool to work appropriately.



• When copying data into the spreadsheet, you should only paste the **content of the cells**. We recommend using "Paste Special" and **Values** or **Text**, depending on your version of Excel.

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Validation Operation None Add Subtract	All merging conditional formats <u>Multiply</u> Divide	Result
Skip blanks Paste Link	Transpos <u>e</u> OK Cancel	Inserts the contents of the Clipboard as text without any formatting.

• For more information about pasting options in Excel, see Microsoft Support tips.

- 2. Complete spreadsheet columns A-N as applicable:
 - Name, Descriptions, Notes
 - Label column No study data should be entered in this column.
 - **On Study Date** Note: This is the only **REQUIRED** field.
 - Date of enrollment in MM/DD/YYYY format
 - Must fall within the study's Open to Accrual period for the institution
 - For de-identified subjects (e.g. anonymous survey, collection of de-identified sample), use the date that the data or sample became available to the study team.
 - For many studies, this will be the only field used for recording Summary Accrual.
 - Institution
 - Must match institutions listed in PC Console > Institution.
 - Defaults to University of Florida if left blank.
 - Gender
 - Should match OnCore values
 - Male
 - Female
 - Unknown
 - Alternately, you can use the Gender tab of the worksheet to provide a mapping scheme.
 - **Date of Birth** **Delete this column from the spreadsheet if using the Age at Enrollment column**
 - Participant's date of birth in MM/DD/YYYY format
 - Age at Enrollment **Delete the Date of Birth column if using this Age at Enrollment column**
 - Participant's age in years at time of enrollment
 - Use this column instead of the Date of Birth column if you are tracking age and date of birth is not available for all subjects
 - Ethnicity
 - Should match OnCore values:
 - Hispanic or Latino
 - Non-Hispanic
 - Subject Refused
 - Unknown
 - Alternately, use the Ethnicity tab of the worksheet to provide a mapping scheme.
 - Race
- Should match OnCore values:
 - White
 - Black or African American
 - Unknown

- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Subject Refused
- Unknown
- Alternately, use the Race tab of the worksheet to provide a mapping scheme.
- Disease Site
 - For Oncology only.
 - Should match the Data Table 3 Disease Sites as listed in OnCore.
 - Alternately, use the Disease Site tab of the worksheet to provide a mapping scheme.
- Diagnosis
 - Not currently available leave blank
- First Name (of recruiter)
 - First name of person who recruited the participant (must match first name in OnCore)
- Last Name (of recruiter)
 - Last name of person who recruited the participant (must match last name in OnCore)
- Email Address (of recruiter)
 - Email address of person who recruited the participant (must match email address in OnCore)
- Zip Code
 - Participant's Zip Code at time of enrollment
- 3. Go to the Date worksheet (2nd tab), complete columns A-B:
 - First Day of Study Enrollment
 - Last Day of Study Enrollment

This step is optional but will assist in data validation.

4. Save your spreadsheet.



Each time the data sheet is uploaded, the tool will write over all existing entries. Your data spreadsheet must include all historical accrual data as well as any new entries. We recommend keeping a single running copy of the import spreadsheet to keep all cumulative accrual data.

Import Your Completed Spreadsheet

1. Go to the Summary Data Import Tool <u>https://ocr-apps.ahc.ufl.edu/accrual/</u>

UF FL	ORIDA
 The summary accrual import tool allows users to upload a file with protocol enrollments and subsequently import those enrollments in OnCore as summary accruals. This summary accrual import process only applies to protocol Eligibility below). Protocol Eligibility • The protocol is configured for summary accrual • The protocol does not have clinical services occurring in a UF Health location (e.g. blood draws, labs, EKG's). • The protocol will not use an OnCore calendar. • Import tool users must be listed as protocol staff for the protocol in OnCore. Note: the login credentials are the same as OnCore login credentials 	Login Inter OnCore Protocol No (e.g. OCR12345) Inter OnCore Username Inter OnCore Password Proceed

- 2. In the login fields, enter the study's OnCore protocol number and your OnCore username and password.
- 3. Click [Proceed].

Summary Accrual Tool Home	
	Hello, ezettler! To proceed, upload the accrual data in excel file format Protocol no: OCR27182 Title: Pancreatic Volume in Preclinical Type 1 Diabetes Upload excel file: Choose File No file chosen
	Ignore OnCore Mapping Tabs: Upload

- 4. Click on [Choose File] select your saved import spreadsheet.
- 5. Leave the Ignore OnCore Mapping Tabs checkbox unchecked.

Note: If your source data has different names for fields that capture the same information as fields in OnCore (e.g. your data has "Yes" for Hispanic and "No" for Non-Hispanic), you can set up a mapping tabs in your input data sheet so that OnCore recognizes and maps these values. Contact <u>OnCore-Support@ahc.ufl.edu</u> for details.

6. Click [Upload].

Version 06/01/2023

Summary Accrual Tool Home Review	Data
	OCR11565: None
	Please review the data before proceeding
	We received 94 accrual records. The data from your import file have been processed and a summary is provided below. Please review the transformed data and click the "Proceed" button to import the accruals to your protocol. **IMPORTANT* All existing enrollment records for your protocol in OnCore will be deleted and replaced with this new dataset. Please make sure that your dataset includes ALL enrolled participants. Excluded rows: 3 rows either have missing On study date or invalid data format. These
	rows will be excluded from the accrual import. Modified rows: 0 rows have values without a corresponding value on one of the data
	mapping tabs. These rows will still be imported, however the values marked "No mapping found" will be left blank/null. Other rows: 91 rows were successfully transformed using a corresponding value on one of
	the data mapping tabs. These rows will be imported as shown below. Re-import Data Proceed

- 7. You will get a screen that provides a summary of the data the tool is getting ready to import.
- 8. You are also reminded that the import tool will write over all existing enrollment data for this protocol. Your spreadsheet should always include ALL enrolled participants.
- 9. The processed data rows are described as follows:
 - Excluded rows You either have a missing **On Study** date or an invalid data format. These rows will not be uploaded. If you want these values to be uploaded, check and correct your import sheet and click [Re-import Data].
 - Modified rows These rows that have missing mapping tabs. The row will be uploaded but you may be
 missing data. Be sure to scroll down in the summary screen and review any rows that says "No mapping
 found". These will be left blank. If you want these values to be uploaded, check and correct your import
 sheet and click [Re-import Data].
 - Other rows These rows had at least one value that corresponded to a mapping tab. This should match the total number of participant enrollment records listed on the import template.



ZIP CODE ISSUE: If you notice that ".0" has been appended to the end of zip codes (e.g. 32653.0), you are using an outdated copy of the excel upload template. Download an <u>updated copy of the template</u>, insert all of your cumulative accrual data into the updated template, and re-import the data. Discard old template.

- 10. Once your data is clean, click [Proceed].
- 11. You will see a confirmation and summary of the record import.

Summa	ary Accru	ual Tool Ho	me Review Data								
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			B	Failed to ir Successful	nport in C ly importe	InCore d into OnCor	e	als imported i			
From Date	To Date	Institution	Internal Accrual Reporting Group	Gender	Age Group	Ethnicity	Race	DiseaseSite	Recruited By	Zip Code	A