



SCHARP

Statistical Center for HIV/AIDS
Research and Prevention

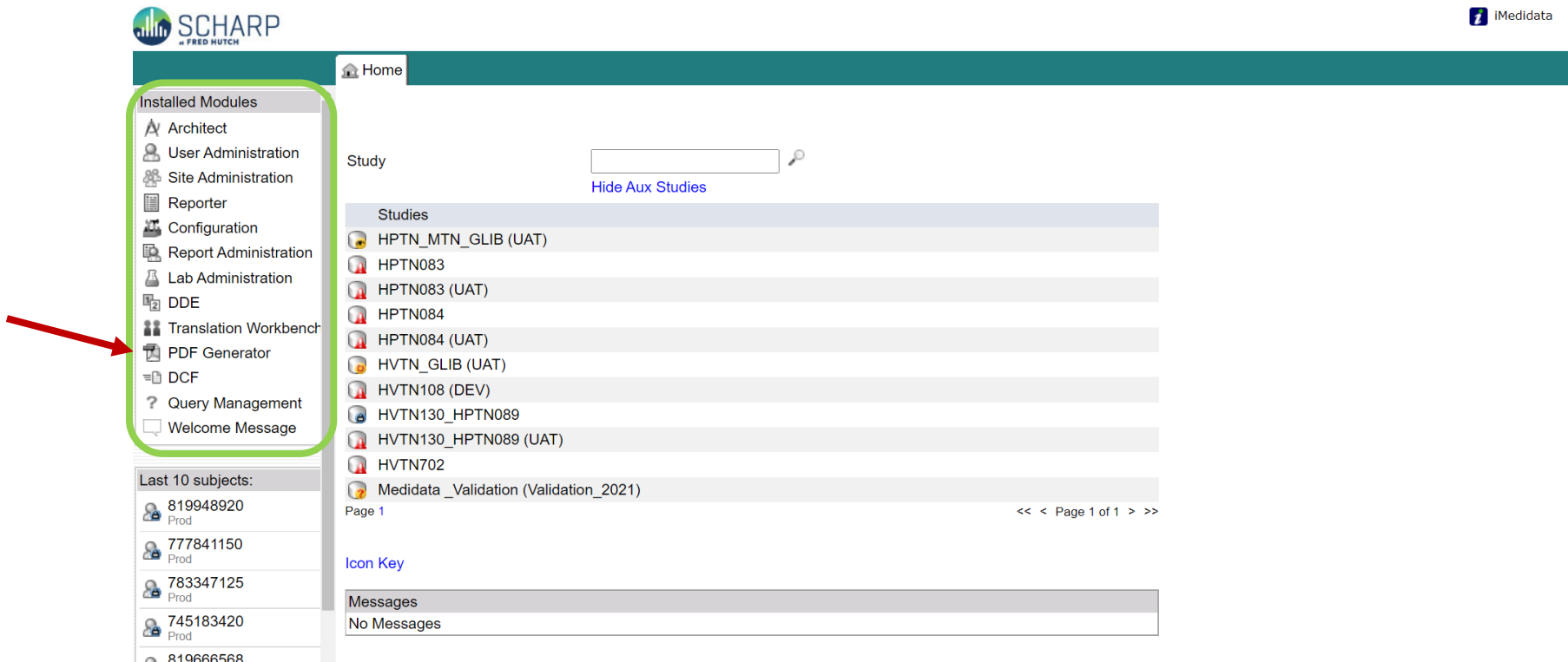
How-To Guide for Creating Participant Casebooks (Data PDFs)

October 2021

How-To Guide for Creating Participant Casebooks (Data PDFs)

Generating the PDF Request

- 1) Sign into Medidata Rave and navigate to the page displaying the list of studies to which you have access. On the left-hand side of the screen the list of “Installed Modules” to which you have access will be displayed. Select PDF Generator.



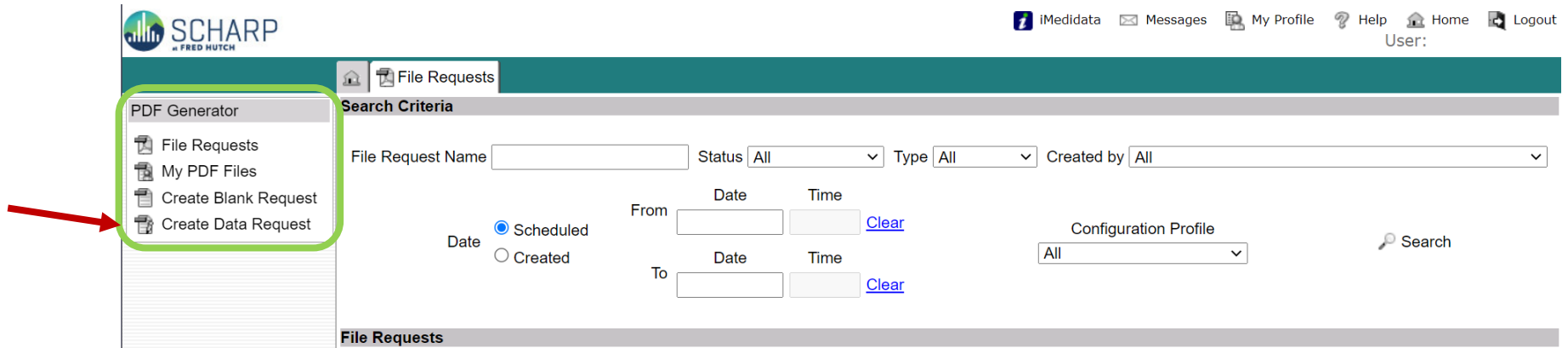
The screenshot shows the Medidata Rave interface. At the top left is the SCHARP logo. A navigation bar contains a 'Home' button. On the left, a sidebar titled 'Installed Modules' is highlighted with a green border, and a red arrow points to the 'PDF Generator' option. The main content area features a search bar for 'Study' with a magnifying glass icon and a link to 'Hide Aux Studies'. Below this is a table of studies:

Study
HPTN_MTN_GLIB (UAT)
HPTN083
HPTN083 (UAT)
HPTN084
HPTN084 (UAT)
HVTN_GLIB (UAT)
HVTN108 (DEV)
HVTN130_HPTN089
HVTN130_HPTN089 (UAT)
HVTN702
Medidata _Validation (Validation_2021)

At the bottom of the sidebar, there is a section for 'Last 10 subjects:' listing IDs like 819948920, 777841150, 783347125, 745183420, and 819666568. The main content area also includes a 'Messages' section showing 'No Messages' and a 'Page 1' indicator with navigation arrows.

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2) This is the initial view of PDF Generator. Select Create Data Request.



The screenshot shows the SCHARP PDF Generator interface. At the top left is the SCHARP logo with 'at FRED HUTCH' below it. To the right of the logo are navigation links: iMedidata, Messages, My Profile, Help, Home, and Logout. Below these links is a 'User:' field. The main header is a dark teal bar with a 'File Requests' tab. Below the header is a 'Search Criteria' section with the following elements:

- File Request Name:
- Status:
- Type:
- Created by:
- Date: Scheduled (selected), Created
- From: Date Time [Clear](#)
- To: Date Time [Clear](#)
- Configuration Profile:
- [Search](#)

On the left side, a sidebar menu is visible, containing the following items:

- PDF Generator
- File Requests
- My PDF Files
- Create Blank Request
- Create Data Request (highlighted with a green box and a red arrow pointing to it)

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3) On the initial screen for the Data PDF are the following items which will need to be completed. Here is a description for those items:

Item 1 – The Name of the File: Create a recognizable file name for the request.

Item 2 – Configuration Profile: For Data PDFs use No Annotations.

Item 3 – Study, Role & Locale: Select the study, your assigned Role within Medidata (e.g. Investigator) & select **English** for Locale

Item 4 – Site Groups and Sites: Select your site

Item 5 – Folder Exclusions: Select Folders to exclude from the PDF, if any

Item 6 – Scheduled Execution: Select the date and time

Item 7 – Subjects: Select the Participants for whom you are creating Casebooks

Item 8 – Form Exclusions: Select Forms to exclude from the PDF, if any

The screenshot shows the SCHARP PDF Generator interface. At the top, there is a navigation bar with the SCHARP logo and user options: iMedidata, Messages, My Profile, Help, Home, and Logout. Below this is a breadcrumb trail: File Requests > Data PDF. The main content area is titled 'PDF File Request' and contains several input fields and dropdown menus. Eight green circles with numbers 1 through 8 are overlaid on the form to indicate key items to be completed:

- 1: Name and Description input fields.
- 2: Configuration Profile dropdown menu (set to 'Profile 1 - No Annotations').
- 3: Study, Role, and Locale dropdown menus (Locale is set to 'English').
- 4: Site Groups and Sites dropdown menu.
- 5: Folder Exclusions dropdown menu.
- 6: Scheduled Execution Date and Time input fields, with a 'Clear' button.
- 7: Subjects dropdown menu.
- 8: Form Exclusions dropdown menu.

At the top of the form area, there are 'Save' and 'Cancel' buttons. On the left side, there is a 'PDF Generator' sidebar with options: File Requests, My PDF Files, Create Blank Request, and Create Data Request.

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Here is an example where the following are completed:

- The Name of the File (Item 1)
- Configuration Profile (Item 2)
- Study, Role and Locale (Item 3)

The screenshot shows the SCHARP PDF Generator interface. The top navigation bar includes the SCHARP logo, user navigation links (iMedidata, Messages, My Profile, Help, Home, Logout), and a 'User:' field. The main content area is titled 'PDF File Request' and contains the following form elements:

- Item 1:** A text input field for 'Name' containing 'HPTNXX Casebooks-Site'.
- Item 2:** A dropdown menu for 'Configuration Profile' set to 'Profile 1 - No Annotations'.
- Item 3:** A dropdown menu for 'Study' set to 'HPTN083 (Prod)', a dropdown for 'Role' set to 'Investigator', and a dropdown for 'Locale' set to 'English'.

Additional form elements include a 'Description' field, 'Scheduled Execution' fields for 'Date' and 'Time' with a 'Clear' link, and expandable sections for 'Display multiple log lines per page', 'Site Groups and Sites', 'Folder Exclusions', 'Subjects', and 'Form Exclusions'. A 'Save' button is visible at the top of the form area.

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4) Use the '+' symbol or triangle arrows (identified below) to expand the selection.

The screenshot shows the SCHARP web application interface. At the top left is the SCHARP logo with 'at FRED HUTCH' below it. To the right of the logo are navigation links: iMedidata, Messages, My Profile, Help, Home, and Logout. Below these links is a 'User:' field. A dark green navigation bar contains tabs for 'File Requests' and 'Data PDF'. Below the 'Data PDF' tab, there are two main sections: 'Site Groups and Sites' and 'Subjects'. The 'Site Groups and Sites' section has a '+' icon circled in red. The 'Subjects' section has a downward-pointing triangle icon circled in red. Below these sections are two more expandable menus: 'Folder Exclusions' and 'Form Exclusions', both with downward-pointing triangle icons circled in red. The 'Folder Exclusions' menu lists: Interim Visit, Interim Visit - OLE, Ongoing Logs, Participant Unblinding, Product Choice - OLE, and Seroconvector Schedule. The 'Form Exclusions' menu lists: Adverse Event, Adverse Event Y/N, ART Medication, ART Medication Y/N, CD4/Viral Load Results, and Concomitant Medications. On the left side of the interface, there is a 'PDF Generator' sidebar with options: File Requests, My PDF Files, Create Blank Request, and Create Data Request.

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5) Use the checkboxes to indicate selections for Participants (Subjects), Folder or Form Exclusions.

For Participants, select the checkbox at the top to select all participants for that page of the list. To add additional participants to the request, click on subsequent pages and select either the checkbox at the top for all participants on each page or individual participants.

The screenshot displays the SCHARP interface for creating Data PDFs. At the top, there are navigation tabs for 'File Requests' and 'Data PDF'. Below this, there are several configuration options:

- Name** and **Description** input fields.
- Configuration Profile**: Profile 1 - No Annotations (dropdown)
- Scheduled Execution**: Date and Time input fields, with a [Clear](#) link.
- Study**: HPTN083 (Prod) (dropdown)
- Role**: Investigator (dropdown)
- Locale**: English (dropdown)
- Display multiple log lines per page**: (checkbox)
- Site Groups and Sites**: World (dropdown)

Below the configuration options, there are two 'Subjects' panels. The left panel shows a list of subjects with checkboxes, all of which are checked. The right panel shows a paginated view of the same list, with the first checkbox unchecked and the last checkbox checked. Red arrows indicate the flow from the first panel to the second.

Subject ID	Selected
<input checked="" type="checkbox"/>	
<input checked="" type="checkbox"/> 858100596	
<input checked="" type="checkbox"/> 858104187	
<input checked="" type="checkbox"/> 858109232	
<input checked="" type="checkbox"/> 858113640	
<input checked="" type="checkbox"/> 858114511	
<input checked="" type="checkbox"/> 858116584	
<input checked="" type="checkbox"/> 858120720	
<input checked="" type="checkbox"/> 858124172	
<input checked="" type="checkbox"/> 858128976	
<input checked="" type="checkbox"/> 858132888	
12345678910>>>	

Subject ID	Selected
<input type="checkbox"/>	
<input checked="" type="checkbox"/> 858179311	
<input type="checkbox"/> 858182316	
<input type="checkbox"/> 858183358	
<input type="checkbox"/> 858183971	
<input checked="" type="checkbox"/> 858187858	
<input type="checkbox"/> 858189216	
<input checked="" type="checkbox"/> 858192339	
<input type="checkbox"/> 858192915	
<input type="checkbox"/> 858193538	
<input type="checkbox"/> 858195675	
<a href"=""><<<12345678910>>>	

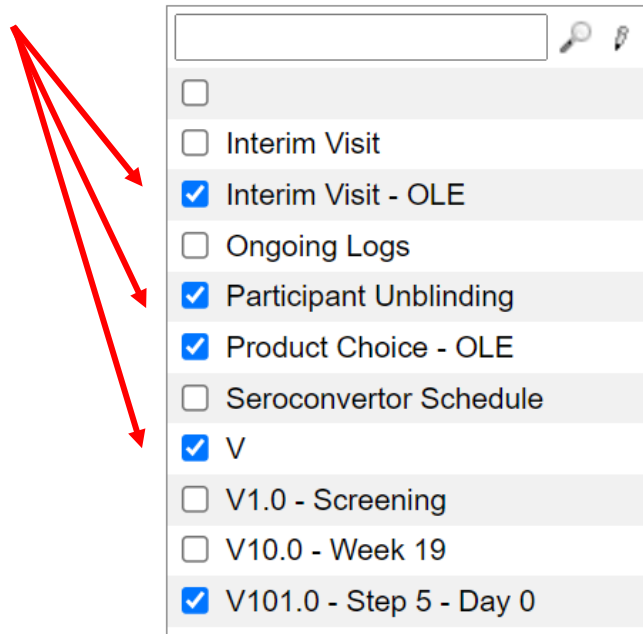
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For Folder or Form Exclusions, select the checkboxes for folders or forms to exclude from the PDF.

Note: There can be just folders to exclude; just forms to exclude; both folders and forms; or no folders or forms.

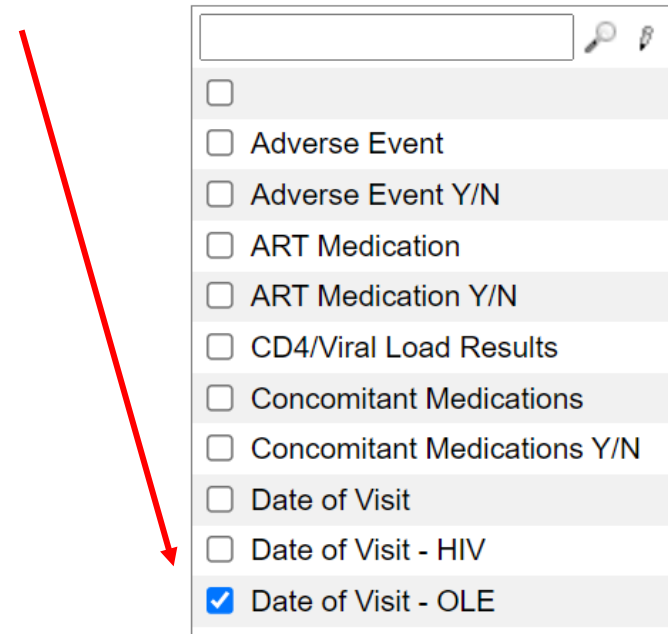
Although selecting the checkbox at the top to exclude all folders or all forms is possible, it is not recommended to select all for creation of Participant Casebooks.

Folder Exclusions



<input type="checkbox"/>
<input type="checkbox"/> Interim Visit
<input checked="" type="checkbox"/> Interim Visit - OLE
<input type="checkbox"/> Ongoing Logs
<input checked="" type="checkbox"/> Participant Unblinding
<input checked="" type="checkbox"/> Product Choice - OLE
<input type="checkbox"/> Seroconvertor Schedule
<input checked="" type="checkbox"/> V
<input type="checkbox"/> V1.0 - Screening
<input type="checkbox"/> V10.0 - Week 19
<input checked="" type="checkbox"/> V101.0 - Step 5 - Day 0

Form Exclusions



<input type="checkbox"/>
<input type="checkbox"/> Adverse Event
<input type="checkbox"/> Adverse Event Y/N
<input type="checkbox"/> ART Medication
<input type="checkbox"/> ART Medication Y/N
<input type="checkbox"/> CD4/Viral Load Results
<input type="checkbox"/> Concomitant Medications
<input type="checkbox"/> Concomitant Medications Y/N
<input type="checkbox"/> Date of Visit
<input type="checkbox"/> Date of Visit - HIV
<input checked="" type="checkbox"/> Date of Visit - OLE

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6) Select the date for the PDFs to be created by clicking in the date box and using the calendar.

The screenshot shows the SCHARP PDF Generator interface. The top navigation bar includes the SCHARP logo and user options: iMedidata, Messages, My Profile, Help, Home, and Logout. The main content area is titled 'PDF File Request' and contains several form fields:

- Name: HPTNXX Casebooks-Site
- Description: (empty)
- Configuration Profile: Profile 1 - No Annotations
- Study: HPTN083 (Prod)
- Role: Investigator
- Locale: English
- Scheduled Execution: Date (with a calendar pop-up) and Time

The calendar pop-up shows the month of September 2021. The date 10 is highlighted in red, indicating it is the selected date. The text 'Today is 10 Sep 2021' is displayed at the bottom of the calendar.

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7) Input the time for the PDFs request to start.

Note: Use 24-hour format.

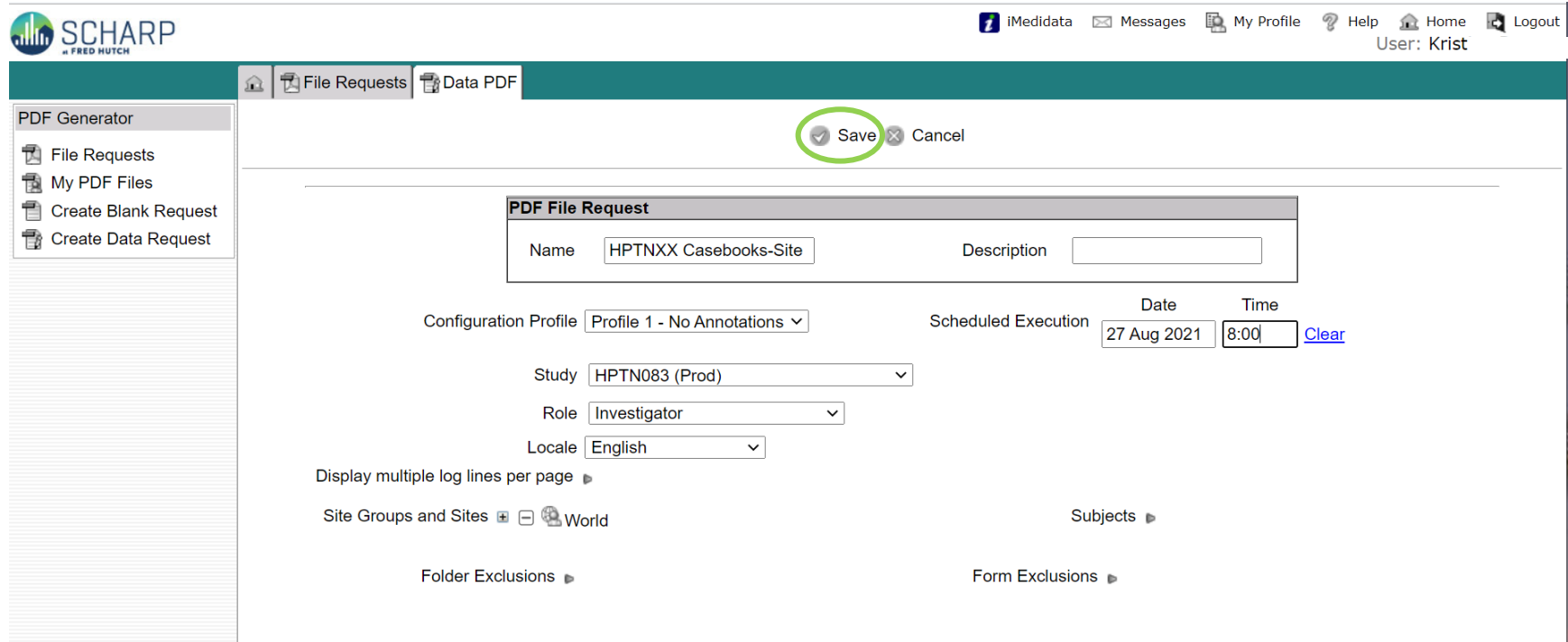
The screenshot shows the SCHARP PDF Generator interface. The main form is titled "PDF File Request" and contains the following fields:

- Name: HPTNXX Casebooks-Site
- Description: (empty)
- Configuration Profile: Profile 1 - No Annotations
- Scheduled Execution: Date: 27 Aug 2021, Time: 8:00 (highlighted with a green circle)
- Study: HPTN083 (Prod)
- Role: Investigator
- Locale: English

Additional options include "Display multiple log lines per page", "Site Groups and Sites" (World), "Folder Exclusions", "Subjects", and "Form Exclusions". The interface also includes a "Save" button and a "Cancel" button.

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8) Select Save. Request will begin on designated date and time.

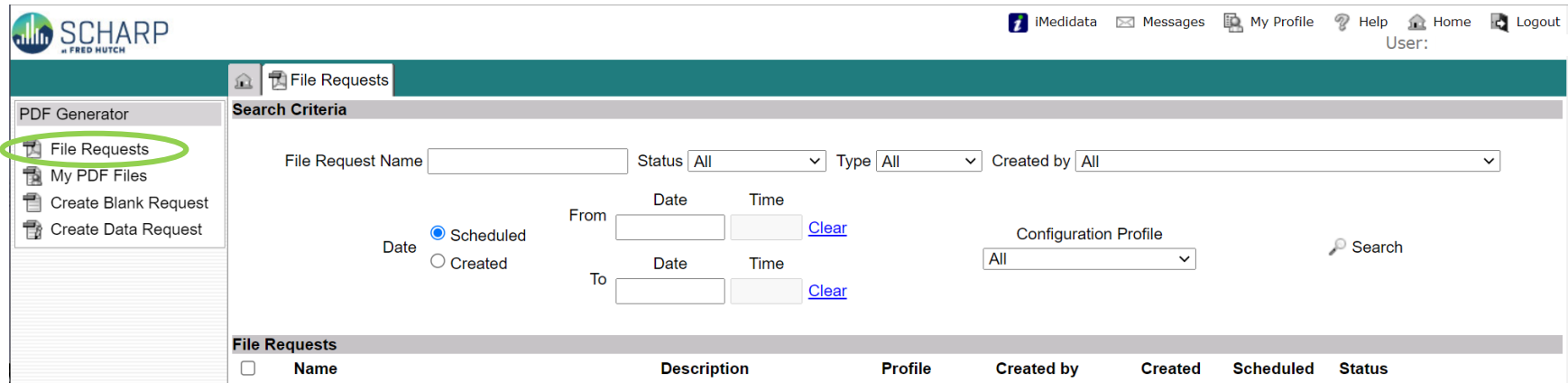


The screenshot shows the SCHARP PDF Generator interface. At the top, there is a navigation bar with the SCHARP logo and user information (User: Krist). Below the navigation bar, there is a sidebar menu with options: File Requests, My PDF Files, Create Blank Request, and Create Data Request. The main content area displays a 'PDF File Request' form. The form includes a 'Save' button circled in green, and a 'Cancel' button. The form fields are: Name (HPTNXX Casebooks-Site), Description (empty), Configuration Profile (Profile 1 - No Annotations), Scheduled Execution (Date: 27 Aug 2021, Time: 8:00, Clear button), Study (HPTN083 (Prod)), Role (Investigator), and Locale (English). There are also expandable sections for 'Display multiple log lines per page', 'Site Groups and Sites', 'Subjects', 'Folder Exclusions', and 'Form Exclusions'.

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Check the status of a PDF Request

1) Select File Requests



The screenshot shows the SCHARP web application interface for managing file requests. At the top right, there are navigation links for iMedidata, Messages, My Profile, Help, Home, and Logout. The main header includes the SCHARP logo and the text 'Statistical Center for HIV/AIDS Research and Prevention'. Below the header, there is a 'File Requests' tab. On the left side, a sidebar menu under 'PDF Generator' contains options: 'File Requests' (highlighted with a green circle), 'My PDF Files', 'Create Blank Request', and 'Create Data Request'. The main content area is titled 'Search Criteria' and includes a search form with the following fields: 'File Request Name' (text input), 'Status' (dropdown menu set to 'All'), 'Type' (dropdown menu set to 'All'), and 'Created by' (dropdown menu set to 'All'). There are also date and time filters for 'From' and 'To', each with 'Date' and 'Time' sub-inputs and a 'Clear' link. A 'Date' section has radio buttons for 'Scheduled' (selected) and 'Created'. A 'Configuration Profile' dropdown menu is set to 'All', and a 'Search' button is located to its right. Below the search criteria, there is a table header for 'File Requests' with columns: Name, Description, Profile, Created by, Created, Scheduled, and Status. A checkbox is visible next to the 'Name' column header.

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- 2) Complete any of the fields to narrow down the list. Select Search.
Click the Live Status Update checkbox to monitor progress in real-time. *(Not mandatory.)*
Status column shows current status. Status can be one of the following:
 - Scheduled – Request has been scheduled and date or time is in the future
 - Unscheduled – Request created, but no date has been entered
 - In Progress – Request is being generated
 - Completed – Request has been completed
 - Execution Error – Request did not process. A tooltip shows the text of the exception.

The screenshot shows the 'File Requests' interface. At the top, there is a 'Search Criteria' section with several filters: 'File Request Name' (HPTN 083), 'Status' (All), 'Type' (Data PDF), and 'Created by' (All). Below these are date and time filters for 'From' and 'To', a 'Configuration Profile' dropdown (All), and a 'Search' button. A table below lists the requests. The first row is highlighted and shows a request named 'HPTN 083 - Casebooks Example' with a status of 'In Progress'. A red arrow points to the 'Status' column header, and a green circle highlights the 'Live Status Update' checkbox, which is checked. At the bottom, there are two buttons: 'Create Blank Request' and 'Create Data Request'.

Name	Description	Profile	Created by	Created	Scheduled	Status
HPTN 083 - Casebooks Example		Profile 1 - No Annotations		10 Sep 2021 7:30:24	10 Sep 2021 00:00:00	In Progress

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3) Status will show Completed when finished.

File Requests

Search Criteria

File Request Name: Status: Type: Created by:

Date: Scheduled Created

From: Date Time [Clear](#)

To: Date Time [Clear](#)

Configuration Profile: [Search](#)

File Requests

<input type="checkbox"/>	Name	Description	Profile	Created by	Created	Scheduled	Status	
<input type="checkbox"/>	HPTN 083 - Casebooks Example		Profile 1 - No Annotations		10 Sep 2021 7:30:24	10 Sep 2021 00:00:00	Completed	

1

Live Status Update

[Create Blank Request](#) [Create Data Request](#)



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Retrieving the PDF Request

1) Within PDF Generator, select “My PDF Files” and select “PDF Files With Data”.

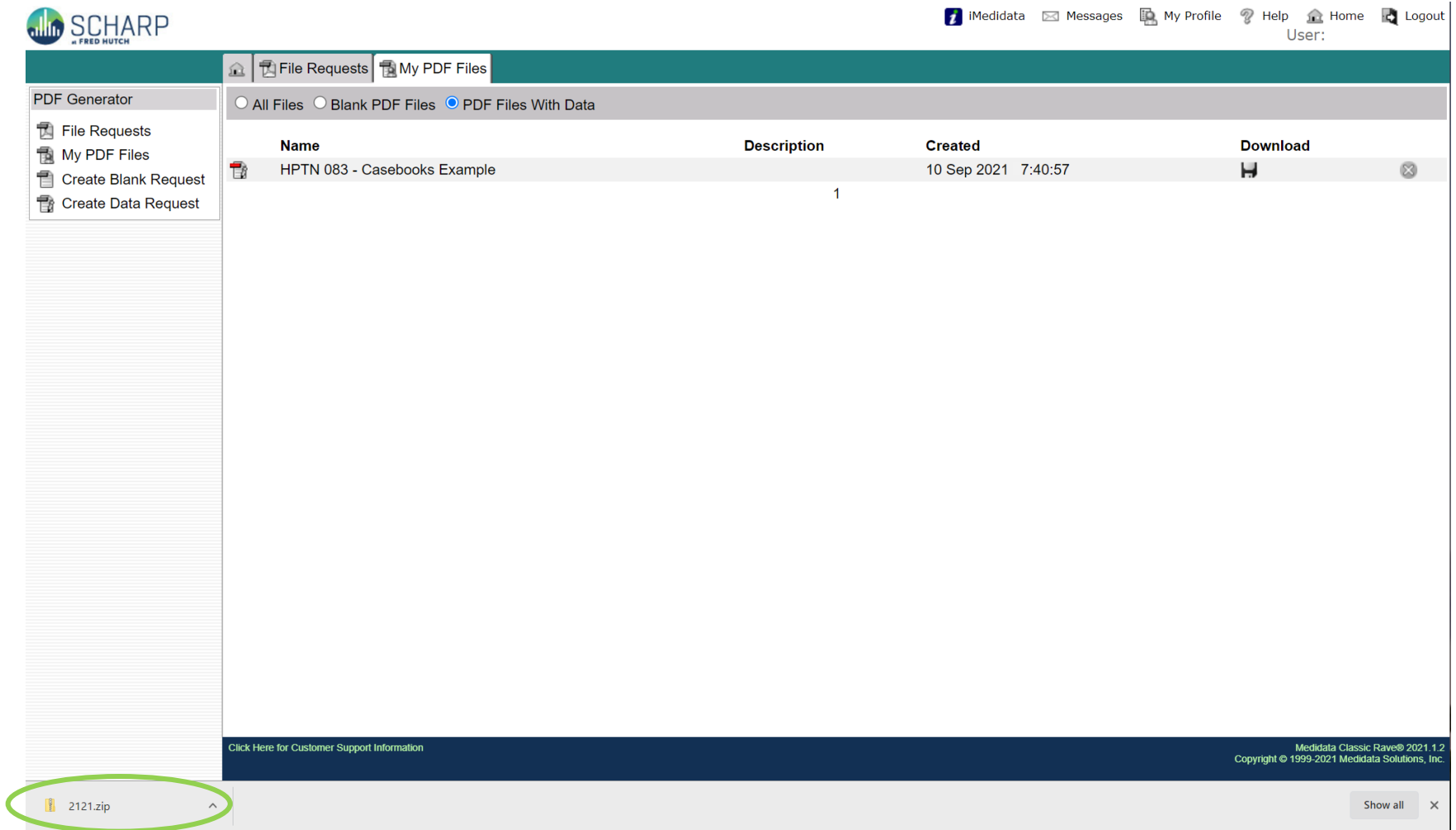
Select Download.

A screenshot of a web application interface. At the top, there are three tabs: 'File Requests', 'My PDF Files', and 'My PDF Files'. The 'My PDF Files' tab is active. Below the tabs, there are three radio buttons: 'All Files', 'Blank PDF Files', and 'PDF Files With Data'. The 'PDF Files With Data' radio button is selected and circled in green. Below this is a table with the following columns: 'Name', 'Description', 'Created', and 'Download'. The table contains one row with the following data: 'Name: HPTN 083 - Casebooks Example', 'Description: 1', 'Created: 10 Sep 2021 7:40:57', and 'Download: [Download icon]'. The 'Download' button and the 'PDF Files With Data' radio button are circled in green.


Name	Description	Created	Download
HPTN 083 - Casebooks Example	1	10 Sep 2021 7:40:57	[Download icon]

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2) The PDF will download into a .zip folder.



The screenshot shows the SCHARP PDF Generator interface. On the left is a sidebar with a 'PDF Generator' section containing links for 'File Requests', 'My PDF Files', 'Create Blank Request', and 'Create Data Request'. The main area has a breadcrumb trail 'File Requests > My PDF Files' and radio buttons for 'All Files', 'Blank PDF Files', and 'PDF Files With Data' (which is selected). Below this is a table with the following data:

Name	Description	Created	Download
HPTN 083 - Casebooks Example	1	10 Sep 2021 7:40:57	

At the bottom of the interface, a dark blue footer contains the text 'Click Here for Customer Support Information' and 'Medidata Classic Rave® 2021.1.2 Copyright © 1999-2021 Medidata Solutions, Inc.'. A white download bar at the very bottom shows a file named '2121.zip' with a download icon and a 'Show all' button.

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3) Open the .zip folder.






Open the folder with the Study Number and then open the folder with the Site Name.

Name	Type	Compressed size
HPTN083 Prod	File folder	

Name	Type
31958-Adolescent and Young Adult Research at the CORE Center (AYAR at CORE)	File folder

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4) Each Participant’s Casebook will be listed as separate files. Save the files to a secure location.

Name	Type	Compressed size
 844101968.pdf	Adobe Acrobat Document	6,735 KB
 844114387.pdf	Adobe Acrobat Document	1,392 KB
 844117441.pdf	Adobe Acrobat Document	431 KB
 844134100.pdf	Adobe Acrobat Document	5,019 KB
 844142456.pdf	Adobe Acrobat Document	433 KB

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More Information & Tips:

- Casebooks are large files and take time to be generated.
 - Schedule the PDF Requests to generate outside of 'normal' business hours (M-F, 8am-5pm).
 - Weekends or late night/early morning hours work best.
- If internet bandwidth is problematic, select a smaller number of participants to generate at a time.
- Do not schedule requests so they overlap as it will cause an execution error.
 - For example, do not schedule a request containing 5 ppts at 08:00am and then the next request for 5 ppts at 08:15am. The first request will not be completed when the second begins, which will cause an execution error for the first request.
- You **must** use the Role you are assigned within Medidata (e.g. Investigator) in order to download the PDFs when they are completed. If you use another Role, you will not be able to view nor download the completed PDFs.
- For more information here is the Medidata Knowledge Space Link for the PDF Generator:
<https://learn.mdsol.com/rave/pdf-gen/en/rave-pdf-generator-69850545.html>