Study Chairs, Co-chairs and Vice Chairs User Guide to Access Investigator's Brochures through NIAID Clinical Research Management System (NIAID CRMS)



This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No.75N93021D00038, entitled, Comprehensive and Rapid Response to NIAID Research Programs, and Task Order 75N93024F00001, entitled Task Area F: Regulatory and Quality Assurance Services: NIAID/Division of AIDS: Regulatory Support Center.

Page 1 Version 1.0 September 2024

A. Locating the Investigator's Brochure (IB) on the IB interface

After receiving an email notification regarding an IB distribution, please follow the steps below to access the IB:

- Click on https://ncrms.niaid.nih.gov to access the NIAID CRMS.
- Log into the NIAID Clinical Research Management System (NIAID CRMS) using your login and password.
- If you do not have access to DAERS please contact NCRMS at (240) 778-2517 or CRMSSupport@niaid.nih.gov.

llergy and Infectious Diseases Management System (NIAID CRMS)	
*User Name: *Password: Login	Forgot User Name? Change Password / Forgot Password?

• Click on the Investigator's Brochure link on the tool bar.





B. Acknowledging Receipt of the IB

Under the IB Notification section, view the IB notification(s).

					NIAID CRMS Help Logou
Adverse Experience Reporting DIVISION OF AIDS		Welcome Kimberly Scars Login Time: 19-SEP-2024 11:26 AN No. of unsuccessful login attempts: (
Investigator's Brochure RSC					
The table below lists IB notifications dis	tributed by DAIDS Regula	tory Support Center. Notifications have to be acknow	vledged prior to accessing the IB documents. Please click on the "Acknowledge	/Decline" button in order to provide your final decision. Your o	ecision cannot be changed.
	-	_			
Enter product/brand/other name	O Pending Notific	ations (n=1) 💿 All Notifications		<u></u>	
Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)	
Acknowledge or Decline_	19-Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine	

Click the Acknowledge or Decline button.

Adverse Experience Reporting Division of AIDS		Investigator's Brochure		NIAID CRHS Help Logout Welcome Kimberly Scarsi Login Time: 19-5EP-2024 11:26 AM No. of unsuccessful login attempts: 0
Investigator's Brochure RSC	en Contra Natification have to be a	knowledged prior to accessing the IB documents. Please click on the "Acknowledg	(Decline" hotels is a decks and the constitution from the states. Margin	desister encode a
		knowledged phor to accessing the 1b documents. Please click on the Acknowleds	e/Decline button in order to provide your final decision. Your	ecision cannot be changed.
Enter product/brand/other nami	itions (n=1) 💿 All Notifications		X	
Action and agreement Status Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)	
Acknowledge or Decline_ 1 -Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine	

Read the IB Receipt Confirmation and Confidentiality Agreement that appears in the pop-up window.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

Please review the receipt confirmation and confidentiality agreement. Once reviewed, please select one of the options below (Acknowledge or Decline) and submit your final decision. Your decision cannot be changed.

• <u></u>]+	investigator s prochare receipt commu	ation and comits	dentianty rigi coment			
Distributed to:	[Study Chair/Co-Chair/Vice Chair]					
Distributed By:	DAIDS RSC Safety Information Center (RIC)	Distributed on	a: DD-MMM-YYYY			
RIC Email:	RIC@tech-res.com	RIC Telephon	ne: 1-301-897-1708			
RE:	[Notification title created by RSC]	[Notification title created by RSC] RIC Fax: 1-301-897-1710				
Investigat	Investigator's Brochure (IB) Included in this Notification/Distribution Study Product associated with the IB					
[Display Name of II	3 Documents (s)]		[Study Product Selected for Distribution]			

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement

As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to Study Chairs, Co-chairs and Vice Chairs participating in DAIDS-sponsored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-chairs and Vice Chairs are responsible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced <u>only</u> for the purpose of conducting DAIDSfunded studies.

All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents.



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Page 3 Version 1.0 September 2024

- Please make the appropriate selection regarding your participation in the study.
- Select whether you are participating by Confirming that you will be participating in the study or not
 participating in the study by Confirming that you will NOT be participating in the study then submit to save
 your selection.

 I hereby confirm that I will be participating in the study(ies) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby agree to keep confidential per the terms stated above, to which I am legally bound. I hereby confirm that I will NOT be participating in the study(ies) that use the drugs listed above and I DECLINE to access the IBs and IB documents included in this distribution.
Submit Cancel

• The image below provides a view of the IB Receipt Confirmation Agreement selection saved successfully.

Investigator's Brochure Receipt Confirmation and Confidentiality Agreement				
Investigator's Brochure Receipt Confirmation and Confidentiality Agreement				
Investigator's Brochure Receipt Confirmation Saved Successfully.				
Close				

- * Please note that your selection is final and cannot be changed.
- * Please note that the submit button may take a few seconds to update and only needs to be clicked once.
- * If you incorrectly decline access, you will need to email the RIC (RIC@tech-res.com) to request access, which will cause a delay in your IB access.
- * Saving and Printing options will be available after the confirmation window is closed.



C. Saving and Printing the IB Receipt Confirmation

• You will be able to access the signed confirmation under the Acknowledgement Status by clicking on either "Acknowledged" or "Decline" on the left side under the IB Notification section. This confirmation can then be saved or printed for your records.

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Investigator's Brochure RS	с				
he table below lists IB notifications of	distributed by DAIDS Regula	tory Support Center. Notifications have to be acknow	wledged prior to accessing the IB documents. Please click on the "Acknowledge	/Decline" button in order to provide your final decision. Your o	lecision cannot be changed.
inter product/brand/other name	O Pending Notific	ations (n=0) 🖲 All Notifications		X	
Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)	
Acknowledged (19-Sep-2024)	-Sep-2024	Test IB Document	Modification Document (<u>01-Sep-2018</u>]	Zidovudine	

• The image below provides a view of the IB Receipt Confirmation Agreement selection once opened to print or save.

Distributed By: DAIDS RSC Safety Information Center (RIC) Distributed on: 15-Aug-2024 RIC RIC@tech-res.com RIC Telephone: 1-301-897-1708 RI: Test IB - OSM PQ RIC Fex: 1-301-897-1708 RI: Test IB - OSM PQ RIC Fex: 1-301-897-1710 Investigator's Brochure (IB) Included in this Notification/Distribution Study Product associated with the IB 1-301-897-1710 As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to Study Chairs, Co-Chairs and Vice Chairs participating in DAIDS-sponsored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-Chairs and Vice Chairs proposible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced gnly for the purpose of conducting DAIDS-funded studies. All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-Chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents. I hereby confirm that I will be participating in the study(les) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby a	Distailanted But	Study Chair, A5403			
RE: Test IB - 0SM PQ RIC Pax: 1-301-897-1710 Investigator's Brochure (IB) Included in this Notification/Distribution Study Product associated with the IB IB_Zidovudine_Test document (06-Aug-2024) Zidovudine As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to Study Chairs, Co-Chairs and Vice Chairs participating in DAIDS-spansored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-Chairs and Vice Chairs are responsible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced gnly for the purpose of conducting DAIDS-funded studies. All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-Chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents. I hereby confirm that I will be participating in the study(les) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby agree to keep confidential per the terms stated above, to which I am legally bound.	Distributed By:	DAIDS RSC Safety Info	rmation Center (RIC)	Distributed on:	15-Aug-2024
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IB_Zidovudine_Test document (06-Aug-2024) Zidovudine As the Investigational New Drug Application (IND) sponsor, DAIDS provides Investigator's Brochures (IBs) to Study Chairs, Co-Chairs and Vice Chairs participating in DAIDS-sponsored protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-Chairs and Vice Chairs performance of the second protocols. Because the IB contains proprietary and confidential information, the IB must be kept confidential and accounted for. Therefore, Study Chairs, Co-Chairs and Vice Chairs are sponsible for acknowledging receipt of IBs sent to them. IBs contain third-party, proprietary and confidential information and may be disclosed or reproduced <u>only</u> for the purpose of conducting DAIDS-funded studies. All copies of IBs must be retained as essential documents in accordance with the ICH Guidance E6, federal regulations and the DAIDS Policy on Record Retention. DAIDS strongly urges Study Chairs, Co-Chairs and Vice Chairs to establish and maintain a system for the use and secure storage of the documents. I hereby confirm that I will be participating in the study(ies) that use the drugs listed above and I acknowledge receipt of this Notification/Distribution from DAIDS. I understand that selecting this option will allow me to access the IBs included in this Notification/Distribution, which I hereby agree to keep confidential per the terms stated above, to which I am legally bound.	Inv	estigator's Brochure (18) Included in this	Study Product	associated with the
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Name: Jordan Lake Date: 15-Aug-2024	acknowledge re will allow me to	eceipt of this Notification o access the IBs includes	/Distribution from DA	IDS. I understand that distribution, which I her	selecting this option
	Name:	Jordan Lake	Date:	15-Aug-2024	



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Page 5 Version 1.0 September 2024 • You will be able to print or save your Declined confirmation by clicking on "Declined" to open the document.

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Declined (31-Aug-2018)	30-Aug-2018	IB QA Test 1	Maraviroc - IB Test (01-Aug-2018)	Maraviroc
(31-Aug-2018)			Maraviroc - IB SOC - Test (01-Aug-2018)	

D. Saving and Printing the IB

 You will be able to access the IB document(s) by clicking on the PDF icon or IB date hyperlink under IB Notification section.

Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)
Acknowledged (31-Aug-2018)	31-Aug-2018	Updated Investigator's Brochure for Maraviroc	Maraviroc dated October 2017 (<u>01-Oct-2017</u> 🔁	Maraviroc
			Maraviroc Summary of Changes dated October 2017 (01-Oct-2017	

• You will not be able to click or access the IB(s) if you choose <u>not to</u> participate in the study. You will also not be able to save or print the IB for your records. The IB(s) can only be saved or printed for your records after you choose to participate in the study.

E. Where to Get Help

• If you have additional questions regarding IBs please contact RIC at <u>RIC@tech-res.com</u> or by selecting RSC on the navigation menu.

The table below lists IB notifications dis	The Lable below lists Ib Instantiations distributed by DAIDS Regulatory Support Center. Notifications have to be acknowledged prior to accessing the IB documents. Please click on the "Acknowledge/Decline" button in order to provide your final decision. Your decision cannot be changed.							
Enter product/brand/other nami 🦻 🖉 Pending Notifications (n=1) 🖲 All Notifications 🕼								
Acknowledgement Status	Distributed by RSC on	IB Notification Email	IB Document (Version Date)	Product(s)				
Acknowledge or Decline	19-Sep-2024	Test IB Document	Modification Document (01-Sep-2018)	Zidovudine				



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