

DAIDS Protocol Registration Basic Training

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DAIDS Regulatory Support Center (RSC)
Protocol Registration Office



National Institute of
Allergy and
Infectious Diseases



Introduction

- The Division of AIDS (DAIDS) Office for Policy in Clinical Research Operations (OPCRO) has established a protocol registration process to ensure that all clinical research sites (CRSs) conducting NIAID (DAIDS)-supported and/or sponsored clinical research do so in accordance with [DAIDS Clinical Research Policies and Standard Procedures](#) in addition to all applicable regulations for human subjects protection and the use of investigational drugs, biologics and/or devices.
- Sites cannot begin the protocol registration process until the protocol has completed the DAIDS protocol development requirements.

Introduction

- **What is Protocol Registration?**
 - The DAIDS protocol registration process also verifies that site-specific informed consent forms contain the necessary information to comply with U.S. federal regulations. This includes the basic and additional informed consent form elements as required by U.S. federal regulations at 45 CFR §46.116, 21 CFR §50.25 and DAIDS Policy.

Introduction

■ What is the Protocol Registration Office?

- The DAIDS RSC Protocol Registration Office (PRO) receives and processes all protocol registration materials submitted by Clinical Research Sites (CRSs) participating in DAIDS-supported and/or sponsored clinical trials.
- The DAIDS RSC PRO ensures that all (CRSs) conducting NIAID (DAIDS)-supported and/or sponsored clinical research do so in accordance with DAIDS Clinical Research Policies and Standard Procedures in addition to all applicable regulations for human subjects protection and the use of investigational drugs, biologics and/or devices.

Objectives

■ Today's objectives

- Provide an understanding of the types of submissions the DAIDS RSC PRO receives and specific document requirements as specified in the DAIDS Protocol Registration Policy and Manual
- Describe how to submit materials to the DAIDS RSC Protocol Registration Office (PRO)
- Provide resources and methods to ask questions

Agenda

- **Types of submissions and document requirements**
- **Submitting materials using the DAIDS Protocol Registration System (DPRS)**
- **Resources**



DAIDS Protocol Registration

Submission Types and Document Requirements



Submission Types

- **Initial Registration**
 - Additional IC types/languages
- **Form FDA 1572/
DAIDS IoR Forms**
- **Curriculum Vitae
and Medical License**
- **IRB/EC/RE/IBC
approval documents**
 - IRB/EC
Termination/Suspension
- **Site Informed Consent
Forms (Site ICF)**
- **Amendments and
LoA submissions**
- **Other Submission Types**
 - Continuing Review
Submissions
 - Change of IoR submissions
 - Sub-studies
 - Deregistration

Initial Registration

Required Documents
Possible Outcomes



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Initial Registration Submission

- **A complete initial protocol registration submission must include:**
 - **Copy of the Form FDA 1572** signed and dated by the Investigator of Record (IoR) (for studies conducted under an IND) or Copy of the DAIDS IoR Form, signed and dated by the IoR (for non-IND studies)
 - **IoR Curriculum Vitae (CV)**, signed and dated
 - **IoR's Current Medical License/Equivalent**

Initial Registration Submission

- **Copy of all IRB/EC and other applicable Regulatory Entity (RE) approval letter(s)** and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS-approved version of a protocol
- **Documentation of Pediatric risk/benefit category** per 45 CFR 46 & 21 CFR 50
– *if applicable*

Initial Registration Submission

- **Institutional Biosafety Committee (IBC) approval**
– *if applicable*
- **Copy of all IRB/EC other applicable RE approved site-specific Informed Consent Forms (ICFs) in all languages including English translations**
– *if applicable*
- **Translation Confirmation Document**
– *if applicable*

Additional IC Language/ IC type Submissions

- **Additional IC Language**

If a CRS has previously received a DAIDS RSC PRO Registration Notification for one language (e.g., English) and later submits registration documents for a new language (e.g., Spanish), the new language is considered an Initial Registration as this is the first time the specific language has been submitted to the DAIDS RSC PRO for review.

- **Additional IC Type**

If a CRS has previously received a Registration Notification from the DAIDS RSC PRO for one informed consent type (e.g., main, pregnancy) and later submits registration documents for a new informed consent type (e.g., stored specimen, short form), the new informed consent type is considered an Initial Registration as this is the first time the informed consent form has been submitted to the DAIDS RSC PRO for review.

Registration Outcome

- **Registered** – All required materials were received and no changes are required.
- **Registered with Required Corrections** – Materials were received but some minor corrections or additional documentation is required. From the DAIDS RSC PRO standpoint the site may begin participation in the trial.
- **Materials Request** – All required materials were not submitted and additional documentation is required before the review can be completed.
- **Disapproval** – Notification from the DAIDS RSC PRO indicating that the site-specific informed consent forms (ICFs) do not include all the required basic and additional elements to comply with U.S. federal regulations and DAIDS policy.

Form FDA 1572/ DAIDS IoR Form

Submission Requirements
Document Requirements



Form FDA 1572 and DAIDS IoR Forms – Submission Requirements

- **Form FDA 1572** – Required for all Initial Registrations for studies being conducted under an IND application and when there is any major change to the information on the current Form FDA 1572.
- **DAIDS – IoR Form** – Should be submitted for Initial Registrations for studies not being conducted under an IND application and when there is any major change to the information on the current DAIDS IoR form.

Form FDA 1572 and DAIDS IoR Forms – – Document Requirements

- Affirmation that the Investigator will conduct the clinical trial according to the research protocol and all applicable US federal regulations. Investigators at non-U.S. sites affirm to DAIDS their commitment to comply with local laws and requirements throughout the course of the clinical trial by signing the Form FDA 1572.
- **A CRS must update and submit within 30 calendar days a revised copy of the Form FDA 1572/DAIDS IoR Form when there is *ANY major* change to the information on the current Form FDA1572/DAIDS IoR Form submitted to the DAIDS RSC PRO.**

Form FDA 1572 and DAIDS IoR Forms – – Document Requirements

- **Examples of major changes to the Form FDA 1572 or DAIDS IoR Form include:**
 - Change in IoR
 - Change in Sub-IoR
 - Addition of a new or additional DAIDS-approved location where the research will be conducted
 - Addition of a laboratory
 - Addition or change in an IRB/EC/RE that is responsible for review and approval of the clinical research protocol



Form FDA 1572 and DAIDS IoR Forms – Document Requirements

- **The complete legal name (first and last name)** should be listed for all study staff identified.
- **Non-U.S. CRSs should include the complete physical address,** including the country in all sections where an address is required.

Form FDA 1572 and DAIDS IoR Forms – Document Requirements

- In addition to U.S. FDA requirements, **DAIDS** requires that all sites participating in NIAID (DAIDS) -supported and/or sponsored clinical trials also list all regulatory entities/*approving entities* that must review and approve the clinical trial prior to implementation at a CRS in section 5.

Form FDA 1572 and DAIDS IoR Forms – Document Requirements (when more than 1 IoR)

If a CRS has more than one IoR sharing responsibilities for a clinical trial, the CRS has the following options:

- The CRS can submit a separate Form FDA 1572/DAIDS IoR Form for each IoR that is responsible for the study at that CRS(s) and other DAIDS-approved location(s). The CRS must provide documentation explaining that the investigators listed on the two Form FDA 1572s/DAIDS IoR Form are sharing responsibilities for the conduct of the study at the CRS and DAIDS-approved satellite location(s).

OR

Form FDA 1572 and DAIDS IoR Forms – Document Requirements (when more than 1 IoR)

- The CRS can submit one Form FDA 1572 /DAIDS IoR Form that lists both investigators in Section 1 of the Form FDA 1572 / DAIDS IoR Form. This indicates that both investigators are sharing equal responsibilities for the conduct of the study at the CRS(s) and other DAIDS-approved location(s).
 - Each investigator must sign and date Sections 10 and 11 of the Form FDA 1572/DAIDS IoR Form.
 - The CRS must provide documentation stating that the two investigators listed on the Form FDA 1572/DAIDS IoR Form are sharing responsibilities for the conduct of the study at the CRS(s) and other DAIDS approved location(s).

Form FDA 1572 and DAIDS IoR Forms – Document Requirements

	Form FDA 1572/DAIDS IoR Form Requirement	Additional Requirement
Option 1	<p>Separate Form FDA 1572/DAIDS IoR Form for each IoR that is responsible for the study at that CRS(s) and other DAIDS-approved location(s).</p>	<p>Documentation explaining that the investigators listed on the two Form FDA 1572s/ DAIDS IoR Forms are sharing responsibilities for the conduct of the study at the CRS and DAIDS-approved additional location(s).</p>
Option 2	<p>Single Form FDA 1572 /DAIDS IoR Form that lists both investigators in Section 1</p> <ul style="list-style-type: none"> Indicates that both investigators share equal responsibilities for the conduct of the study at the CRS(s) and other DAIDS-approved location(s). Each investigator must sign and date Sections 10 and 11 of the Form FDA 1572/DAIDS IoR Form. 	<p>Documentation explaining that the investigators listed on the two Form FDA 1572s/ DAIDS IoR Form are sharing responsibilities for the conduct of the study at the CRS and DAIDS-approved additional location(s).</p>

Curricula Vitae and Medical License

Submission Requirements
Document Requirements



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Curricula Vitae and Medical License – Submission Requirements

- **Required for all Initial Registrations and when there is any major change to the current CV on file with DAIDS.**
- **NOTE: Examples of major changes to the IoR CV include but are not limited to:**
 - Change in contact information
 - Change in education
 - Change in experience
 - New trainings
 - New publications

Curricula Vitae and Medical License – Document Requirements

- Provide a copy of the IoR current medical license documentation or equivalent with all CVs.

Document	Submission Requirement	Document Requirement
IoR CV	Updated CVs should be submitted for: <ul style="list-style-type: none">•ANY Major Changes•Every two years•Initial Registrations•Change of IoR submissions	<ul style="list-style-type: none">•Signed and dated•Contains all applicable experience supporting the investigator's qualification to function as the Investigator of Record
IoR Medical License	A current medical license or equivalent is required to be submitted whenever a CV is submitted.	Must be current.



IRB/EC/RE/IBC

Approval Documents

Submission Requirements
Document Requirements



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IRB/EC/RE/IBC Approval Documents – Submission Requirements

- **Required for all Initials, Amendments and LoA Registrations, Continuing Review Submissions, Site Initiated Revised ICFs, Administrative Registrations, and submission of Revised Site ICF(s) in response to a request for corrections.**

IRB/EC/RE/IBC Approval Documents – Submission Requirements

- **CRSs must submit a copy of ALL appropriate documentation to and from the IRB/EC/RE/Approving Entity along with a copy of all the final approval letter(s) to the DAIDS RSC PRO as part of the protocol registration submission.**
 - Submission letter from the site to the IRB/EC
 - Letter(s) from the IRB/EC documenting queries and changes required to the site-specific ICFs
 - Site response to the queries
 - Final approval letter(s)

IRB/EC/RE/IBC Approval Documents – Document Requirements

■ Required Identifiers

- **Complete Protocol Title for the current DAIDS-approved version of the protocol.** The DAIDS RSC PRO will accept a long or short title for those protocols which include both on the DAIDS sample informed consent forms.
- **DAIDS-ES and/or Network Protocol ID Number**
- **DAIDS Protocol Version Number from the final version of the protocol approved by DAIDS and/or the final version date of the protocol document approved by DAIDS.**

IRB/EC/RE/IBC Approval Documents – Document Requirements

- Per the DAIDS Policy for Enrolling Children (including Adolescents) in NIAID (DAIDS)-supported and/or sponsored Human Subject Clinical Research, for research studies including children or adolescents, DAIDS requires documentation of the IRB/EC designation of the pediatric risk/benefit category from the U.S. federal regulations and IRB/EC approval for involvement of children based on the determination specified by that category.
- http://www.niaid.nih.gov/LabsAndResources/resources/DAIDS_ClinRsrch/Documents/enrollingchildrenrequirements.pdf



IRB/EC/RE/IBC

Approval Documents

Termination/Suspension



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IRB/EC/RE/IBC Approval Documents – Submission/Document Requirements

- Notify DAIDS via the DPRS when an IRB/EC suspends or terminates a part of or all study activities

	Timeline	Protocol is Registered through DAIDS RSC PRO	Protocol is <u>not</u> Registered through DAIDS RSC PRO
IRB/EC suspends or terminates approval of research.	No later than 3 reporting days	Submit documentation to DAIDS via the DPRS	CRS must notify the appropriate DAIDS Program Officer (PO) or Contracting Officer's Representative (COR)

Informed Consent Form

Submission Requirements
Document Requirements





Informed Consent Requirements – Submission Requirements

- **Required for all Initial, Amendment and LOA Registrations if there was a change to a Site-specific ICFs, Continuing Review submissions if there was a change to the Site-Specific ICFs and submission of revised Site Specific ICFs in response to requested corrections.**

Informed Consent Requirements – Submission Requirements

- **Identifiers** - All site-specific ICF(s) must be able to be linked to the current DAIDS approved version of the protocol. The DAIDS-required identifying information is:
 - **Complete Protocol Title for the current DAIDS-approved version of the protocol.** The DAIDS PRO will accept a long or short title for those protocols which include both on the DAIDS-approved SIC forms.
 - **DAIDS-ES and/or Network Protocol ID Number**
 - **DAIDS Protocol Version Number from the final version of the protocol approved by DAIDS and/or the final version date of the protocol document approved by DAIDS.**

Informed Consent Requirements – Submission Requirements

IC Types Requirements

- **All site-specific ICF(s)** that will be used during the consent process at the site after review and approval by the IRB/EC and other applicable REs/Approving Entity(ies) must be submitted to the **DAIDS RSC PRO**.
- **If some SIC forms provided with the protocol will not be needed at a CRS, the CRS should document this either in the comments section of the ICF field of the DPRS or with a memo to the DAIDS RSC PRO with the registration submission.**

Informed Consent Requirements – Document Requirements

- **Site-specific ICF(s) must contain all information necessary to comply with U.S. federal regulations, local laws and regulations, and DAIDS policies.** This includes all the basic and additional elements, as appropriate, as outlined in U.S. federal regulations.
- **If a CRS deletes or makes any substantive change to basic and/or additional elements as presented in the DAIDS-approved SIC, the IoR or designee for the clinical trial must provide written documentation to explain the deletions/change(s) at the time of registration submission to the DAIDS RSC PRO.**

Informed Consent Requirements – Document Requirements

- **Top reasons changes are requested to Informed Consents**
 - **DAIDS Policy - Compensation**
 - **Basic Element 6 - Research related injury**
 - **Basic Element 1 - Purpose and Procedures /Introduction**
 - **Basic Element 5 - Confidentiality**
 - **Additional Element 3 - Costs to You**

Informed Consent Requirements – Document Requirements

■ DAIDS Policy - Compensation

- Compensation for Study Related Injury - The ICF must state that the U.S. National Institutes of Health (NIH) does not have a mechanism to provide direct compensation for research related injury. (If a mechanism to compensate for study related injury is available, this must be explained in the ICF.)

■ Basic Element 6 - Research related injury

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. (45 CFR §46.116)

Informed Consent Requirements – Document Requirements

- **Basic Element 1 - Purpose and Procedures/Introduction**
 - A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental (45 CFR §46.116)

Informed Consent Requirements – Document Requirements

■ Basic Element 5 - Confidentiality

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (45 CFR §46.116)

■ Additional Element 3 - Costs to You

- Any additional costs to the subject that may result from participation in the research (45 CFR §46.116)

Amendment and LoA Registrations

Submission Requirements



Amendment and LOAs – Submission Requirements

- **A complete Amendment or LoA registration submission must include:**
 - **Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation** from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS-approved version of the LoA
 - **Documentation of the date the Amendment or LoA** and any revised site-specific ICF(s) were submitted to the local IRB/EC

Amendment and LOAs – Submission Requirements

- **Institutional Biosafety Committee (IBC) approval**
– *if applicable*
- **Copy of all IRB/EC other applicable RE approved revised site-specific ICFs** - all languages including English translations
– *if applicable*
- **Translation Confirmation Document**
– *if applicable*

Amendment and LOAs – Submission Requirements

- **Additional Amendment and LOA implementation requirements:**
 - **Amendments and LOAs should be implemented immediately** upon CRS receipt of all required IRB/EC and Regulatory Entity (RE) approvals unless the LoA or Amendment specifies otherwise.
 - **The CRS may delay implementing an Amendment/LOA if IRB/EC/RE approved Amendment or LoA states protocol changes will be implemented once specific operational issues are addressed.** The IRB/EC/RE documentation must be kept in the site's regulatory files for verification by monitors.
 - Pages 40-45 of the PR Manual



Amendment and LOAs – Submission Requirements

- **Updated Amendment and LOA implementation requirements:**
 - **A CRS must submit Amendment/LOA registration documents to the DAIDS PRO within 14 calendar days of the CRS's receipt of all the required final written IRB/EC/RE approval documentation for the LOA.**

Other Submission Types

Change of IoR
Continuing Review
Sub-studies
Deregistration



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Change of IoR Submissions

- **Memo requesting the change of IoR**
(IRB/EC Letter is acceptable)
- **Copy of the new Form FDA 1572, signed and dated by the new IoR** (for studies conducted under an IND) or **Copy of the new DAIDS IoR Form, signed and dated by the new IoR** (for non-IND studies)
- **New IoR CV, signed and dated and current Medical License/Equivalent**

Continuing Review Submission

- The DHHS regulations require that all DHHS supported research undergo continuing IRB/EC review at intervals appropriate to the degree of risk, but **NOT LESS** than once per year.
- Continuing review should be performed prior to the expiration date specified on the IRB/EC approval letter(s) and/or site-specific ICFs. The frequency of ongoing reviews should be documented in IRB/EC policies and procedures and may be protocol/study specific.
- CRSs can visit the OHRP website for additional guidance related to continuing review.

Sub-Study Registration Requirements

An Embedded Sub-Study

A sub-study that is part of a main protocol that may or may not have a separate ICF. Embedded sub-studies have the same protocol version number as the main study and a separate protocol number and/or DAIDS protocol ID number.

If the main study amends, when protocol registering to the amendment, sites are required to protocol register to all embedded sub-studies. A CRS will receive a registration notification for each embedded sub-study that is submitted for protocol registration.

Sub-Study Registration Requirements

A Stand Alone Sub-Study

This is a sub-study that is not part of the main protocol but requires participants to be enrolled in the main study or have previously participated in the main study. A stand-alone sub-study is an independent protocol that may or may not have the same protocol version number/date as the main study and will always have a separate protocol number and/or DAIDS protocol ID number.

A CRS should submit all required documents (i.e. IRB/EC approval letter(s), site-specific informed consent form(s)), Form FDA 1572 and/or DAIDS IoR Form, and IoR CV) when registering to a stand-alone sub-study. A CRS will receive a registration notification for each stand-alone sub-study that is submitted for protocol registration.

Sub-Study Registration Requirements

Type of Sub-Study	Form Requirement	Registration Requirement	Registration Requirement
Embedded Sub-Study	The Form FDA 1572 or DAIDS IoR form submitted for the main study is acceptable for the sub-study.	The sub-study registration submission must be created along with the main study submissions.	Registrations to sub-studies are part of the main registration however are processed independently for tracking purposes.
Stand Alone Sub-Study	The Form FDA 1572 or DAIDS IoR form must list the correct sub-study title.	The sub-study registration submission must be created independently from the main study submission.	Registrations are considered independent registrations.

Sub-Study Submissions

- **Registration for embedded sub-studies is required for all versions of the main study** unless the site informs the DAIDS RSC PRO that they are no longer participating in the embedded sub-study and request deregistration.
- **Registration for stand alone sub-studies is required for all versions of the sub-study independent of the main study.**

Deregistration

Deregistration can occur when:

- The CRS no longer has participants on study (all follow-up has been completed) and does not plan to enroll additional subjects
- If no participants were ever enrolled at the CRS and the study has closed to accrual.

A complete deregistration submission must include:

- A Memo requesting deregistration as the CRS no longer intends to participate in the protocol(s)

AND/OR

- A Copy of the IRB/EC closure/termination letter for the protocol(s)

Submitting Materials to the DAIDS RSC Protocol Registration Office

Using the DAIDS
Protocol Registration System (DPRS)



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Submitting Materials to the DAIDS RSC Protocol Registration Office

Agenda

- **Requirements**
 - Gaining Access
- **The DPRS**
 - Logging in/Home Screen
 - Reports
 - Search
 - Creating Submissions



DPRS

Requirements and Gaining Access



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Submitting Materials to the Protocol Registration Office – Requirements

- Sites participating in NIAID (DAIDS)-supported and/or sponsored clinical research that requires protocol registration, are required to submit protocol registration materials to the DAIDS RSC PRO through the DAIDS Protocol Registration System (DPRS).
- Information on the DPRS and how to access the system is available in the DAIDS RSC website and at the below link.

https://www.daidscrs.com/partners/Page_Training/Page_D AIDS_CRS_Training_Calendar/Protocol_Registration_DPRS_Training.htm

Submitting Materials to the Protocol Registration Office

- If a CRS encounters problems when submitting protocol registration materials through the DPRS, a CRS can submit protocol registration materials via e-mail to the DAIDS Electronic Protocol Registration (EPR) mailbox. If a CRS submits materials through the EPR mailbox, the email message must outline the details of what is being submitted, and the kind of registration that is being submitted.
- epr@tech-res.com



DPRS

Logging In and Home Screen



DAIDS Protocol Registration System (DPRS) – Gaining Access

https://www.daidsrsc.com/Training/PRT/Pages/Protocol_Registration_Welcome_Page.aspx - Internet Explorer

Sign In

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Protocol Registration Training

Protocol Registration Home | Policy and Manual Training | DPRS Training | Resources

Protocol Registration

Protocol Registration (PR) is the process by which DAIDS confirms and tracks Clinical Research Site (CRS) compliance with NIAID (DAIDS) policies, Institutional Review Board (IRB) requirements, and U.S. federal regulations for investigational research involving human subjects. PR enables DAIDS to collect regulatory documents associated with investigator qualifications and responsibilities, and confirm that site-specific informed consent forms comply with U.S. regulations and appropriate guidelines.

What Training is Available?

- PR Policy and Manual Training**
 - Includes training on the DAIDS PR Policy and Manual.
 - New!** An e-learning module (web-based training) is available in the DAIDS Learning Management System (DAIDS LMS).
- DAIDS Protocol Registration System (DPRS) Training**
 - Includes training on the web-based system (DPRS) used to submit PR documents.
 - Currently available as an e-learning module in the DAIDS LMS.

Who Should Attend Training?

- NIAID (DAIDS) supported and/or sponsored clinical research site staff:
 - Responsible for preparing and/or submitting documents for PR
 - Involved with reviewing and/or tracking PR documents
- DAIDS and network operations staff assisting sites with implementation of the PR Policy.

DPRS – Logging In

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Login

*User Name: [Forgot User Name?](#)

*Password: [Change Password / Forgot Password?](#)

Please e-mail questions or comments about User Name or Login to DAIDS-ESSupport@niaid.nih.gov or call or fax your request to:

Phone: 1 (866) 337-1605 (USA toll-free) or 1 (240) 499-2239 (Outside USA)

Fax: 1 (866) 337-1606 (USA toll-free) or 1 (301) 948-2242 (Outside USA)

Live assistance is available 8:30 A.M. to 5:30 P.M., U.S. Eastern Time, Monday through Friday (excluding U.S. Holidays).

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DPRS – Home Screen

Home - Internet Explorer
 https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx

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Home

DAIDS-ES | Help | Logoff

Welcome Denise Wright
 Last successful login: Aug 27, 2014 06:09 AM
 No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Submissions

Any

Receipt Number	Type	Site	Protocol No.	Submission Status	Days Remain	View Submitter
2014-04-1363-01	Continuing Review	201	A5318 - 1.0	Review in Progress	-32	
2014-04-1358-01	Site Initiated Revised ICF	201	HPTN 069/A5305 - 3.0	Review in Progress	-32	
2014-04-1494-01	Continuing Review	201	HPTN 066 - 2.0	Review in Progress	-25	
New! 2014-04-1561-01	Continuing Review	201	A5292 - 1.0	Review in Progress	15	
New! 2014-04-1560-01	Initial	201	A5292 - 1.0	Review in Progress	10	
2014-04-0197-01	Initial	201	A5327 - 1.0	Registered with Required Corrections	-	
2014-04-0092-00	Continuing Review	201	A5306	Pending Submission	-	

Alerts

Select

Type	Message	Start Date	Delete
Alert	Corrected Materials are required for 2014-04-0197 , Initial, CRS 201 - Johns Hopkins University CRS, Protocol A5327 AND version 1.0	8/11/2014 1:00:10 AM	X
Alert	Response for materials requested pending.2014-04-0197 , Initial, CRS 201 - Johns Hopkins University CRS, Protocol A5327 , version 1.0	6/13/2014 1:00:50 AM	X

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DPRS

Creating Submissions



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Creating Submissions

Initial

Copying a Submission

Multi-Purpose Submissions

Requested/Corrected Materials

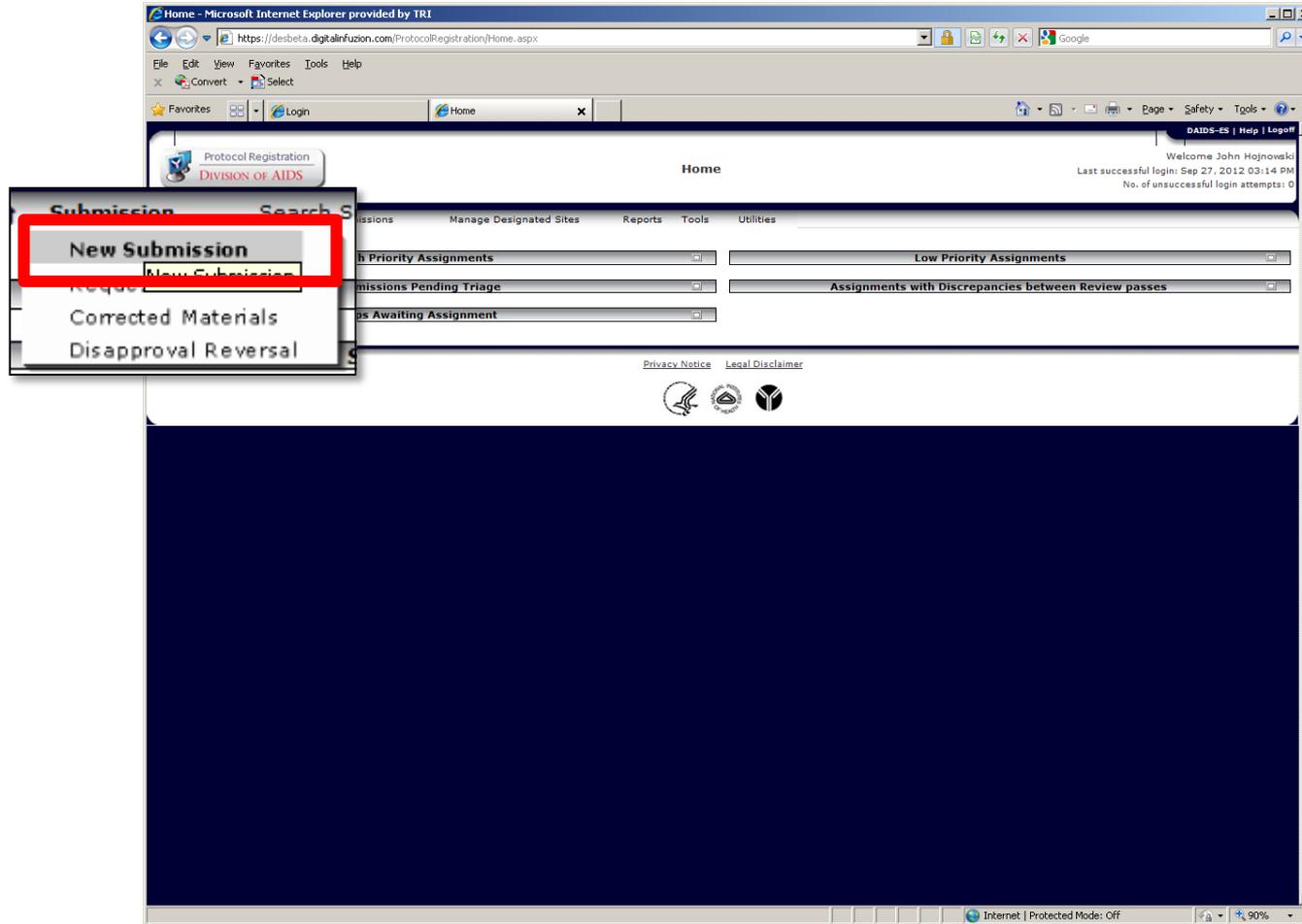


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DPRS – Creating an Initial Registration



DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCh6EFegf1Qr5HW6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

Protocol Registration
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New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: [] Select Version [v]
To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: []
Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: []

Submissions
Select the applicable submission types

<input checked="" type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

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DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCh6EFegB1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

New Submission | DAIDS Regulatory Support Cent...

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:29 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details

To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No.: [] Select Version [v]

Select the Invest...
*Se

Filter by: Protocol No. [v] a5250 [] Go [] Reset []

Add more search criteria

Clear All []

1 record(s) found

Select	Protocol No.	Current Study Status	Full Title	Network	Comments
<input type="radio"/>	A5250	Closed to Accrual	Durability of Adherence in Self-Management of HIV (DASH)	ACTG	Restricted study, Cannot participate

Enter email add

Additional C

Submissions

Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration

Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV

LOA Registration
 Additional ICF type
 Additional ICF Language

Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Next [] Discard []

Privacy Notice | Legal Disclaimer



DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1jrpCh6EFegB1Qr5HWa6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292
Select Version
To view LOA Versions, click the LOA button

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: [Empty field]

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: [Empty field]

Submissions
Select the applicable submission types

<input checked="" type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

Privacy Notice Legal Disclaimer

DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCh6EFegB1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292

Select Version
Version 1.0

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR:

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts:

Submissions
Select the applicable submission types

<input type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

Privacy Notice Legal Disclaimer

DPRS – Creating an Initial Registration

Protocol Registration
DIVISION OF AIDS

New Submission

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]

IoR LOV

Filter by: IoR Person Name

2368 record(s) found

Select	IoR Person Name
<input type="checkbox"/>	Aditya Gaur [31882]
<input type="checkbox"/>	Adolf WallerKarchmer [30339]
<input type="checkbox"/>	Adrian Palfreeman [31366]
<input checked="" type="checkbox"/>	Adriana Andrade [31609]
<input type="checkbox"/>	Adriana Weinberg [31557]
<input type="checkbox"/>	Adriano Lazzarin [32024]
<input type="checkbox"/>	Adrien May [31161]
<input type="checkbox"/>	Adrienne Rogers [30538]
<input type="checkbox"/>	Agnes Moses [32275]
<input type="checkbox"/>	Aida Asmelash [32150]

Additional Contacts: [Clear All]

Submissions: Initial, Amendment, Continuing Review, Deregistration

LOA Registration, Site Initiated Revised ICF, Additional ICF type, Other Materials, Additional ICF Language, IRB/EC Suspension/Termination

Legal Disclaimer

DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCH6Efgf1Qr5HwA6KcSP11%2b0%2b32NWGwdf82Oeqxd%2f%2faIC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0
To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]
Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

*Add New IoR: First Name Middle Name Last Name Email Address Add

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts:

Submissions
Select the applicable submission types

<input type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

[Privacy Notice](#) [Legal Disclaimer](#)

DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=Lx AFL8c1ypCh6EgB1Qr5HwA6KcSP1%2b0%2b32NWGwdF82Oeqxd%2f%2faC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0
To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]
Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, click here to add the IoR name.

*Add New IoR: Protocol Registration Officeocol@tech-res.com Add

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
Select the applicable submission types

<input checked="" type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

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DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCh6EgB1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0
To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]
Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

*Add New IoR: First Name Middle Name Last Name Email Address Add
X Protocol Registration Office

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
Select the applicable submission types

<input checked="" type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

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DPRS – Creating an Initial Registration

New Submission - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypChEgEgB1Qr5HwA6KcSP11%2b0%2b32NWGwdF82Oeqxd%2f%2faIC

Protocol Registration
DIVISION OF AIDS

New Submission

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0
To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]
Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

*Add New IoR: First Name Middle Name Last Name Email Address Add

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
Select the applicable submission types

<input checked="" type="checkbox"/> Initial	<input type="checkbox"/> Change of IoR on a Study	<input type="checkbox"/> LOA Registration	<input type="checkbox"/> Site Initiated Revised ICF
<input type="checkbox"/> Amendment	<input type="checkbox"/> Updated 1572 for existing IoR	<input type="checkbox"/> Additional ICF type	<input type="checkbox"/> Other Materials
<input type="checkbox"/> Continuing Review	<input type="checkbox"/> Updated IoR Form for existing IoR	<input type="checkbox"/> Additional ICF Language	<input type="checkbox"/> IRB/EC Suspension/Termination
<input type="checkbox"/> Deregistration	<input type="checkbox"/> Updated CV		

Next Discard

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DPRS – Creating an Initial Registration

Save Successful

Packet Number: 2014-04-1560

Site & Protocol details
 To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

*Add New IoR: First Name Middle Name Last Name Email Address Add

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
 Select the applicable submission types

Initial Change of IoR on a Study LOA Registration Site Initiated Revised ICF

Amendment Updated 1572 for existing IoR Additional ICF type Other Materials

Continuing Review Updated IoR Form for existing IoR Additional ICF Language IRB/EC Suspension/Termination

Deregistration Updated CV

Upload Documents
 Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
 Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More		
* FDA 1572 More		
* Updated IoR Form for existing IoR More		
* IoR CV More		
* Informed Consent Forms More		

DPRS – Creating an Initial Registration

New Submission - Internet Explorer
 https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF18c1ypCh6EFegB1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faIC

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

***Add New IoR:** First Name Middle Name Last Name Email Address Add

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
 Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration
 Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV
 LOA Registration
 Additional ICF type
 Additional ICF Language
 Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Upload Documents
 Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
 Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More	✗ P1081_1572.pdf - Uploaded on 27-Aug-2014 - Not Yet Submitted	
* FDA 1572 More		
* Updated IoR Form for existing IoR More		
* IoR CV More		
* Informed Consent Forms More		
Other More		NA

Upload Additional Files [x]

Uploaded Files list
 P1081_1572.pdf

Notes

Submission History

Aug 27 2014 6:47AM Denise Wright : Pending Submission

DPRS – Creating an Initial Registration

Complete Submission Packet - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=1BF5IQ2FpxoiV3A30T1%2FRZg%3D%3d&Nav=IQHfFnJDaIDcPdEzpwYtcsy1QCsr

Protocol Registration Summary Complete Submission Packet

Submissions
Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration

Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV

LOA Registration
 Additional ICF type
 Additional ICF Language

Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Upload Documents
Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More	P1081_1572.pdf - Uploaded on 27-Aug-2014 - Not Yet Submitted	
* FDA 1572 More		na
* Updated IoR Form for existing IoR More		na
* IoR CV More		na
* Informed Consent Forms More		na
Other More		NA

Notes

Submission History

Aug 27 2014 6:51AM Denise Wright : Pending Submission

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[Legal Disclaimer](#)

DPRS – Creating an Initial Registration

Person Information - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SUB_ID=9%26A36RUufmaxOK0TcmYFA%3d%3d8SSP_ID=IBFSIQ3PpxoiV3A1B1%2FRZg

Protocol Registration Summary Person Information

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Protocol Registration
DIVISION OF AIDS

Person Information

Submission Search Submissions Reports

In the grid below:

- List all persons who are named in the attached 1572/IoRA Form for this protocol
- List any persons not named in the attached 1572/IoRA Form, who need access to DAERS (i.e., Reporter role) for this protocol

For each person listed:

- In the "DAERS role" column, select the applicable role or select none
- In the "Listed on 1572/IoRA Form?" column, select "Yes" or "No"

Notes:

- Changes are processed when the current submission is approved.
- Once approved, this information will not be available for further modifications unless an updated submission packet is created (applies to Change Of IoR, Updated 1572 and Updated IoR form submission types)
- Your CRS Coordinator may use Site Enrollment Module in DAERS to provide updated site staff information.

View FDA 1572

* Person Name	* Association Role	* Contact Information	* DAERS Role ?	* Listed on 1572/IoRA Form?
Adriana Andrade	Investigator	Email: <input type="text" value="aandrade@jhmi.edu1"/> Phone: <input type="text" value="1-410-614-4036"/> Ext: <input type="text"/>	Select DAERS Role	<input type="radio"/> Yes <input type="radio"/> No
Charles W Flexner	CRS Leader	Email: <input type="text" value="flex@jhmi.edu1"/> Phone: <input type="text" value="1-410-955-9712"/> Ext: <input type="text"/>	Reporter Access to All Protocols	<input type="radio"/> Yes <input type="radio"/> No
Denise Wright	Research Clinician	Email: <input type="text" value="dwright@jhmi.edu1"/> Phone: <input type="text" value="1-410-614-4266"/> Ext: <input type="text"/>	Reporter Access to All Protocols	<input type="radio"/> Yes <input type="radio"/> No
Desiree Nock	Research Clinician	Email: <input type="text" value="Dnock1@jhmi.edu1"/> Phone: <input type="text" value="1-410-955-4372"/> Ext: <input type="text"/>	Reporter Access to All Protocols	<input type="radio"/> Yes <input type="radio"/> No
Edward J. Fuchs	Research Associate	Email: <input type="text" value="efuchs@jhmi.edu1"/> Phone: <input type="text" value="1-410-614-8762"/> Ext: <input type="text"/>	Reporter Access to All Protocols	<input type="radio"/> Yes <input type="radio"/> No
Ilene Wiggins	CRS Coordinator	Email: <input type="text" value="iwiggin1@jhmi.edu1"/> Phone: <input type="text" value="1-410-614-2766"/> Ext: <input type="text"/>	Reporter Access to All Protocols	<input type="radio"/> Yes <input type="radio"/> No

Add another person

Save Restore Back To Submission

DPRS – Creating an Initial Registration

Complete Submission Packet - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=1BF5IQ2FpxoiV3A30T1%2FRZg%3D%3d&Nav=IQHfFnJDaIDcPdEzpwYtcrx1QCsr

Protocol Registration Summary Complete Submission Packet

Submissions
Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration

Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV

LOA Registration
 Additional ICF type
 Additional ICF Language

Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Upload Documents
Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More	P1081_1572.pdf - Uploaded on 27-Aug-2014 - Not Yet Submitted	
* FDA 1572 More		na
* Updated IoR Form for existing IoR More		na
* IoR CV More		na
* Informed Consent Forms More		na
Other More		NA

Notes

Submission History

Aug 27 2014 6:51AM Denise Wright : Pending Submission

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DPRS – Creating an Initial Registration

-- Webpage Dialog

https://desbeta.digitalinfuzion.com/ProtocolRegistration/UI/UserControls/SiteSubmissions/ConfirmSubmissionContainer.aspx?SSP_ID=956748&Mode=C&EMAIL=0

Packet Number: 2014-04-1560

Site & Protocol details

To confirm a submission, select the same site and protocol for the submission.

***Site:** 

***Protocol No.:**  

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DPRS – Creating an Initial Registration

Webpage Dialog

https://desbeta.digitalinfuzion.com/ProtocolRegistration/UI/UserControls/SiteSubmissions/ConfirmSubmissionContainer.aspx?SSP_ID=956748&Mode=C&EMAIL=0

Packet Number: 2014-04-1560

Site & Protocol details

To confirm a submission, select the same site and protocol for the submission.

***Site:** 

***Protocol No.:**  

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DPRS – Creating an Initial Registration

-- Webpage Dialog

https://desbeta.digitalinfuzion.com/ProtocolRegistration/UI/UserControls/SiteSubmissions/ConfirmSubmissionContainer.aspx?SSP_ID=956748&Mode=C&EMAIL=0

Packet Number: 2014-04-1560

Site & Protocol details

To confirm a submission, select the same site and protocol for the submission.

***Site:** 

***Protocol No.:**  

[Privacy Notice](#) [Legal Disclaimer](#)

DPRS – Creating an Initial Registration

Notification - Internet Explorer
https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=1BF5IQ3FpxoiV3A30T%2FRZg%3D%3d&Nav=IQfHFn3Da1DcPdE1zpwYtcrx1QCsr... Protocol Registration Summary Notification

Protocol Registration
DIVISION OF AIDS

Notification

DAIDS-ES | Help | Logoff
Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Submission Search Submissions Reports

Notification

Confirmation Of Submission: 2014-04-1560-01

Your registration material(s) was submitted on Aug 27, 2014

The following submission types have been submitted for Site 201 - Johns Hopkins University CRS and Study A5292 1.0

- Initial

The following material(s) has been received

- P1081 1572.pdf

The above data is based on the information that was entered during your submission. If you find this data to be in error, please provide any necessary corrections so that your submission can be processed more efficiently.

This message is an acknowledgement of receipt of materials. At this time, your materials are under review. This message is NOT a notification that materials received are complete and accurate or that your protocol registration has been approved. A separate e-mail message will be sent notifying you of the completeness of materials or approval decision.

The status of the submission can be viewed in the DAIDS-ES Protocol Registration System.

Should you have any questions or need additional information, please contact the Protocol Registration Office via phone 301-897-1707, fax 800-418-3544, or e-mail at protocol@tech-res.com.

Thank You,
The Protocol Registration Office

[Privacy Notice](#) [Legal Disclaimer](#)

DPRS – Copying a Submission

Search Submissions - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=Lx AFL8c1ypCh6EgB1Qr5HwA6KcSP1%2b0%2b32NWrqGy27oWNYvct6EIEG3z

Search Submissions

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Protocol Registration
DIVISION OF AIDS

Search Submissions

Submission Search Submissions Reports

Packet Number:

Submission Type: From To

Site:

Protocol No.:

IoR Name:

Show only Registration Submissions

Submission Status:

Submissions

Submission Date	Packet Number	Submission Type	Site	Site Id	Protocol No	Status	Status Date	Edit	Create Copy	Submission History	Notifications	View Submitter
27-Aug-2014	2014-04-1561	Continuing Review	Johns Hopkins University CRS	201	A5292 1.0	Review in Progress	27-Aug-2014					
27-Aug-2014	2014-04-1560	Initial	Johns Hopkins University CRS	201	A5292 1.0	Review in Progress	27-Aug-2014					
1-Jul-2014	2014-04-1494	Continuing Review	Johns Hopkins University CRS	201	HPTN 066 2.0	Review in Progress	1-Jul-2014					
20-Jun-2014	2014-04-1360	Site Initiated Revised ICF	Johns Hopkins University CRS	201	A5327 1.0 LOA 1	Completed	30-Jun-2014					
20-Jun-2014	2014-04-1360	LOA Registration	Johns Hopkins University CRS	201	A5327 1.0 LOA 1	Registered	25-Jun-2014					
20-Jun-2014	2014-04-1358	LOA Registration	Johns Hopkins University CRS	201	HPTN 069/A5305 3.0 LOA 3	Registered	25-Jun-2014					
20-Jun-2014	2014-04-1363	Continuing Review	Johns Hopkins University CRS	201	A5318 1.0	Review in Progress	20-Jun-2014					
20-Jun-2014	2014-04-1358	Site Initiated Revised ICF	Johns Hopkins University CRS	201	HPTN 069/A5305 3.0 LOA 3	Review in Progress	20-Jun-2014					
10-Jun-2014	2014-04-1017	Updated IoR Form for existing IoR	Johns Hopkins University CRS	201	A5320 1.0	Completed	18-Jun-2014					
5-Jun-2014	2014-04-0936	Corrected Materials	Johns Hopkins University CRS	201	A5320 1.0	Registered	16-Jun-2014					
30-May-2014	2014-04-0846	Site Initiated Revised ICF	Johns Hopkins University CRS	201	A5303 1.0 LOA 4	Completed	11-Jun-2014					
30-May-2014	2014-04-0846	LOA Registration	Johns Hopkins University CRS	201	A5303 1.0 LOA 4	Registered	6-Jun-2014					
15-May-2014	2014-04-0574	Updated 1572 for existing IoR	Johns Hopkins University CRS	201	HPTN 069/A5305 3.0	Completed	30-May-2014					
15-May-2014	2014-04-0574	Continuing Review	Johns Hopkins University CRS	201	HPTN 069/A5305 3.0	Completed	29-May-2014					

DPRS – Copying a Submission

Create Copy - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SUB_ID=9%26A36RUufmaxOK0TcmYFA%3D%3d&SSP_ID=IBFSIQ3PxxoIY3A3B1%2FRZg

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
 To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0 Select LOA Version

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
 Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration

Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV

LOA Registration
 Additional ICF type
 Additional ICF Language

Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Upload Documents
 Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
 Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More	P1081_1572.pdf - Uploaded on 27-Aug-2014 - Submitted on 27-Aug-2014	
* Informed Consent Forms More		
Other More		

Notes

DPRS – Copying a Submission

Create Copy - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SUB_ID=9%26A36RUufmaxOK0TcmYFA%3D%3d&SSP_ID=IBFSIQ3PpxoIY3A1B1%2FRZg

Packet Number: Packet Number will be generated upon saving this submission

Site & Protocol details
 To initiate a submission, select a site and protocol

*Site: 201 - Johns Hopkins University CRS

*Protocol No: A5292 Version 1.0 Select LOA Version

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Adriana Andrade [31609]

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Submissions
 Select the applicable submission types

Initial
 Amendment
 Continuing Review
 Deregistration
 Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV
 LOA Registration
 Additional ICF type
 Additional ICF Language
 Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Upload Documents
 Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
 Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	Notes
* IRB/EC/RA Documentation More	P1081_1572.pdf - Uploaded on 27-Aug-2014 - Submitted on 27-Aug-2014	
* Informed Consent Forms More		
Other More		

Upload Additional Files [x]

Uploaded Files list

P1081_1572.pdf

Notes

DPRS – Copying a Submission

-- Webpage Dialog

https://desbeta.digitalinfuzion.com/ProtocolRegistration/UI/UserControls/SiteSubmissions/ConfirmSubmissionContainer.aspx?SSP_ID=95675&Mode=A&EMAIL=0

Packet Number: 2014-04-1561

Site & Protocol details

To confirm a submission, select the same site and protocol for the submission.

***Site:** 

***Protocol No.:**  

[Privacy Notice](#) [Legal Disclaimer](#)

DPRS – Copying a Submission

The screenshot shows a web browser window with the URL https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=nbW2Q4FU5DxpWwbt7e%2bw%3d%3d3dNav=IQfHmJDaIDcPdeIzpWtytocy1. The page title is "Notification" and it is part of the "Protocol Registration DIVISION OF AIDS" system. The user is identified as Denise Wright, with a last successful login on Aug 27, 2014 at 06:09 AM and zero unsuccessful login attempts.

The main content area is titled "Notification" and contains the following text:

Confirmation Of Submission: 2014-04-1561-01

Your registration material(s) was submitted on Aug 27, 2014

The following submission types have been submitted for Site 201 - Johns Hopkins University CRS and Study A5292 1.0

- Continuing Review

The following material(s) has been received

- P1081 1572.pdf

The above data is based on the information that was entered during your submission. If you find this data to be in error, please provide any necessary corrections so that your submission can be processed more efficiently.

This message is an acknowledgement of receipt of materials. At this time, your materials are under review. This message is NOT a notification that materials received are complete and accurate or that your protocol registration has been approved. A separate e-mail message will be sent notifying you of the completeness of materials or approval decision.

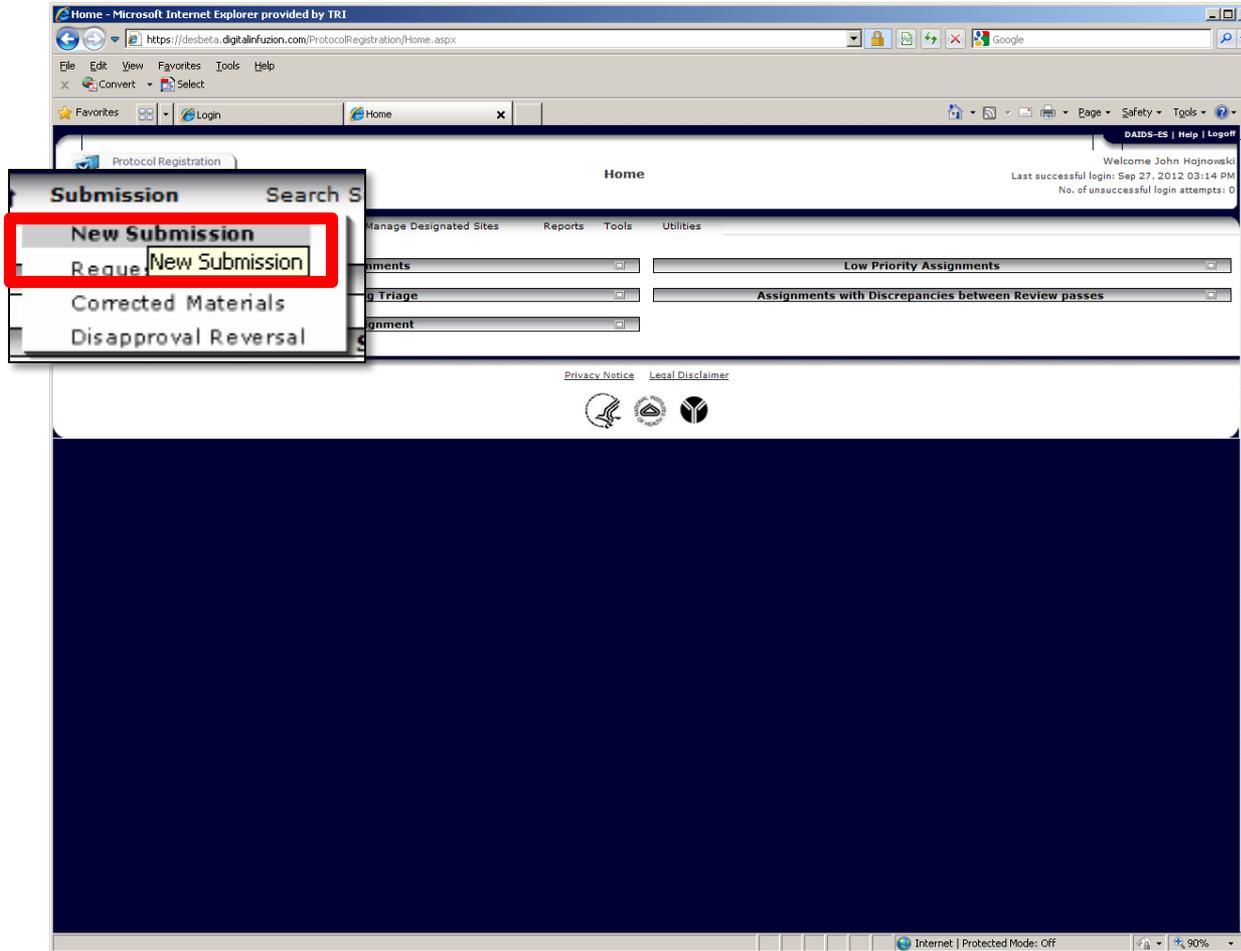
The status of the submission can be viewed in the DAIDS-ES Protocol Registration System.

Should you have any questions or need additional information, please contact the Protocol Registration Office via phone 301-897-1707, fax 800-418-3544, or e-mail at protocol@tech-res.com.

Thank You,
The Protocol Registration Office

At the bottom of the page, there are links for [Privacy Notice](#) and [Legal Disclaimer](#), and three logos: the NIH logo, the DAIDS logo, and the RSC logo.

DPRS – Creating a Multi-Purpose Submission



DPRS – Creating a Multi-Purpose Submission

New Submission - Microsoft Internet Explorer provided by TRI

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=tdVEu%2bJ29AmkoJWPMEn11M1vPcl7p3Kun/nM161CWmnoMhlcW908%2F

Protocol Registration
DIVISION OF AIDS

New Submission

Welcome John Hojnowski
Last successful login: Sep 27, 2012 03:14 PM
No. of unsuccessful login attempts: 0

Submission Search Submissions Manage Designated Sites Reports Tools Utilities

Packet Number: Packet Number will be generated upon saving this submission

Version 4.0

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Gregory K. Robbins [31008]

IND: N/A

Submissions
Select the applicable submission types

Amendment
 Continuing Review
 Deregistration

Change of IoR on a Study
 Updated 1572 for existing IoR
 Updated IoR Form for existing IoR
 Updated CV

LOA Registration
 Additional ICF type
 Additional ICF Language

Site Initiated Revised ICF
 Other Materials
 IRB/EC Suspension/Termination

Next Discard

Done

DPRS – Creating a Multi-Purpose Submission

Sub Study LOV

Filter by: Sub Study Protocol Number

1 record(s) found

Select	Sub Study Protocol Number
<input checked="" type="checkbox"/>	A5276s

Protocol Registration
DIVISION OF AIDS

Submission Search Submissions

Site & Protocol details
To initiate a submission, select a site and protocol

*Site: 101 - Massachusetts General Hos

*Protocol No: A5001

Select Sub-Studies: A5276s

Select the Investigator of Record (IoR) below for the above protocol a

*Select IoR: Gregory K. Robbins [31008]

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications:

Additional Contacts: lihojnowski@techres.com

Upload Documents

Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files
Required: Either upload a document or enter notes for a document type.

Document Type	File-Date Uploaded	
* IRB/EC/RA Documentation More	Amendment and Annual Review submission.docx - Uploaded on 15-Oct-2012 - Not Yet Submitted	
* Informed Consent Forms More		
Other More		

[Upload Additional Files](#) [x]

Uploaded Files list

[Amendment and Annual Review submission.docx](#)

Notes

DPRS – Creating a Multi-Purpose Submission



Associated Packets

Select the packet number to view any other associated packets created for the Main Study/ Embedded Sub-Study(ies):

Notification

Confirmation Of Submission: 2012-02-6666-01

Your registration material(s) was submitted on Oct 15, 2012

The following submission types have been submitted for Site 101 - Massachusetts General Hospital ACTG CRS and Study A5001.4.0

- Amendment
- Continuing Review

The following material(s) has been received

- Amendment and Annual Review submission.docx
- Amendment and Annual Review submission.docx

The above data is based on the information that was entered during your submission. If you find this data to be in error, please provide any necessary corrections so that your submission can be processed more efficiently.

This message is an acknowledgement of receipt of materials. At this time, your materials are under review. This message is NOT a notification that materials received are complete and accurate or that your protocol registration has been approved. A separate e-mail message will be sent notifying you of the completeness of materials or approval decision.

The status of the submission can be viewed in the DAIDS-ES Protocol Registration System.

Should you have any questions or need additional information, please contact the Protocol Registration Office via phone [801-897-1707](tel:801-897-1707), fax: [800-418-3544](tel:800-418-3544), or e-mail at Protocol@tech-rs.com.

Thank You,

The Protocol Registration Office

[Privacy Notice](#) [Legal Disclaimer](#)



DPRS – Creating a Multi-Purpose Submission

New Submission - Microsoft Internet Explorer provided by TRI

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SP_ID=V8P19PlyfgdWUR2cAqdk4w%3d%3d8Nav=Fly71mOZ1YAzYDB6zgfFBQ7gjs

File Edit View Favorites Tools Help

Convert Select

Favorites Home New Submission Doodle: DAIDS Protocol Regi... Packet number: 2012-02-0557

Site & Protocol details

To initiate a submission, select a site and protocol

*Site: 101 - Massachusetts General Hospital ACTG CRS

*Protocol No: A5276s Version 4.0

To view LOA Versions, click the LOA Registration checkbox below

IND: N/A

Select the Investigator of Record (IoR) below for the above protocol and site.

*Select IoR: Martin S. Hirsch [15044]
Gregory K. Robbins [31008]

Note: Before adding a new IoR, verify IoR name doesn't exist.

Cannot find IoR, [click here](#) to add the IoR name.

Enter email addresses for additional contacts who need to receive notifications.

Additional Contacts: jhojnowski@tech-res.com

Receipt Date:

Submissions

Upload Documents

Upload the submission documents against the applicable document types listed below. An uploaded file can be linked to multiple document types by selecting from a list of already uploaded files

Required: Either upload a document or enter notes for a document type.

To copy documents from the main packet, [click here](#)

Document Type	File-Date Uploaded	No
* IRB/EC/RA Documentation More	✗ Amendment and Annual Review submission.docx - Uploaded on 15-Oct-2012 - Not Yet Submitted	
* Informed Consent Forms More	✗ Amendment and Annual Review submission.docx - Uploaded on 15-Oct-2012 - Not Yet Submitted	
Other More		

[Upload Additional Files](#) [x]

Uploaded Files list

[Amendment and Annual Review submission.docx](#)

Notes

Turn-Off Notification

Turn-off Notification

Internet | Protected Mode: Off

90%

DPRS – Creating a Multi-Purpose Submission

Webpage Dialog

https://desbeta.digitalinfuzion.com/ProtocolRegistration/UI/UserControls/SiteSubmissions/ConfirmSubmissionContainer

Packet Number: 2012-02-6667

Site & Protocol details

To confirm a submission, select the same site and protocol for the submission.

*Site: 101 - Massachusetts General Hospital ACTG CRS

*Protocol No.: A5276s

Version 4.0

Back Submit Discard

[Privacy Notice](#) [Legal Disclaimer](#)

NIH National Institute of Health

https://desbeta.digitalinfuzion.com/ProtocolRegistrat Internet | Protected Mode: Off

DPRS – Requested/Corrected Material Submissions

Home - Internet Explorer
 https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx
 Home
 DAIDS Regulatory Support Cent...
 DAIDS-ES | Help | Logoff
 Welcome Denise Wright
 Last successful login: Aug 27, 2014 12:25 PM
 No. of unsuccessful login attempts: 0

Protocol Registration
 DIVISION OF AIDS

Submission Search Submissions Reports

New Submission
 Requested Materials
 Corrected Materials
 Disapproval Reversal

Submissions

Any

Receipt Number	Type	Site	Protocol No.	Submission Status	Days Remain	View Submitter
2014-04-1363-01	Continuing Review	201	A5318 - 1.0	Review in Progress	-32	
2014-04-1358-01	Site Initiated Revised ICF	201	HPTN 069/A5305 - 3.0	Review in Progress	-32	
2014-04-1494-01	Continuing Review	201	HPTN 066 - 2.0	Review in Progress	-25	
New! 2014-04-1561-01	Continuing Review	201	A5292 - 1.0	Review in Progress	15	
New! 2014-04-1560-01	Initial	201	A5292 - 1.0	Review in Progress	10	
2014-04-0197-01	Initial	201	A5327 - 1.0	Registered with Required Corrections	-	
2014-04-0092-00	Continuing Review	201	A5306	Pending Submission	-	

Alerts

Select

Type	Message	Start Date	Delete
Alert	Corrected Materials are required for 2014-04-0197 , Initial, CRS 201 - Johns Hopkins University CRS, Protocol A5327 AND version 1.0	8/11/2014 1:00:10 AM	X
Alert	Response for materials requested pending.2014-04-0197 , Initial, CRS 201 - Johns Hopkins University CRS, Protocol A5327 , version 1.0	6/13/2014 1:00:50 AM	X

Privacy Notice Legal Disclaimer



DPRS – Requested/Corrected Material Submissions

Corrected Materials - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SUB_TYPE=3&SMLG0HA%2Bh29DFHw7NJKQ%3d%3d&Nav=LXAPL8cXypChAEfEgF1QnSI

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Aug 27, 2014 06:09 AM
No. of unsuccessful login attempts: 0

Protocol Registration
DIVISION OF AIDS

Corrected Materials

Submission Search Submissions Reports

List of Submissions

List Submission for Latest Registered Protocol Version List Submission for All Protocol Version

Go

Select	Site	Study Version	Submission Type	Completed Date	Submission Status
<input type="checkbox"/>	201	A5327 v 1.0	2014-04-0197-Initial	5/13/2014 1:22:16 PM	Registered with Required Corrections

Create Packet

[Privacy Notice](#) [Legal Disclaimer](#)



DPRS

Reports



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

DPRS – Reports

The screenshot shows a web browser window displaying the "Protocol Registration Summary" page. The page header includes the "Protocol Registration" logo and the "DIVISION OF AIDS" text. The main title is "Protocol Registration Summary". In the top right corner, there is a user greeting: "Welcome Denise Wright", "Last successful login: Aug 27, 2014 06:09 AM", and "No. of unsuccessful login attempts: 0".

The navigation menu includes "Submission", "Search Submissions", and "Reports". A left sidebar contains a dropdown menu for "Protocol Registration Summary" with sub-items: "CRPMC Report" and "Regulatory Agency Information".

The main content area features a "Report For" section with radio buttons for "All Versions" (selected) and "Last Registered Version". Below this are two date fields: "From [Registration Status] Date:" and "To [Registration Status] Date:". There are three text input fields for "Network:", "Site:", and "Protocol:". A "Registration Status" dropdown menu is open, showing options: "Acknowledged", "Deregistered", "Disapproved", "In Progress", "Paused", and "Registered".

At the bottom of the form area, there is a note: "To run the default report, click **Run Report**. Click [customize](#) to modify the report display fields." Below this is a label "Select the report display type:" with radio buttons for "HTML", "PDF", and "Excel" (selected). A "Run Report" button is positioned below the radio buttons.

The footer contains links for "Privacy Notice" and "Legal Disclaimer", and three logos: the NIH logo, the DAIDS RSC logo, and the Regulatory Support Center logo.

DPRS – Reports

The screenshot shows a web browser window displaying the "Protocol Registration Summary" page. The browser's address bar shows the URL: <https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx?Nav=za5sgqYKG%2FgevOR4VnfW%2btrMFawatXqTHdb%2bvdLCojvx8T0cxqEhswW3h>. The page header includes the "Protocol Registration" logo for the "DIVISION OF AIDS" and the title "Protocol Registration Summary". A user greeting in the top right corner reads: "Welcome Denise Wright", "Last successful login: Aug 27, 2014 06:09 AM", and "No. of unsuccessful login attempts: 0".

The main content area features a navigation menu on the left with options: "Submission", "Search Submissions", and "Reports". The "Reports" section is active, displaying a list of report categories: "Protocol Registration Summary", "CRPMC Report", and "Regulatory Agency Information".

The central area is titled "Select the desired check box(es) to display a field in your report. Clear the checkbox to remove the field from your report." It contains a grid of checkboxes for various report fields:

Select All		Unselect All	
<input type="checkbox"/> Study Network	<input checked="" type="checkbox"/> Registration Type	<input checked="" type="checkbox"/> IRB Meeting Date	<input type="checkbox"/> Date Version Distributed
<input type="checkbox"/> Site Network	<input checked="" type="checkbox"/> Receipt Date	<input checked="" type="checkbox"/> IRB Letter Date	<input type="checkbox"/> Days Elapsed Since Version Distributed Till Receipt Date
<input checked="" type="checkbox"/> Protocol number	<input checked="" type="checkbox"/> Registration Status	<input type="checkbox"/> IRB Approval Expiration Date	<input type="checkbox"/> Deregistered Date
<input checked="" type="checkbox"/> Site Number	<input checked="" type="checkbox"/> Registration Status Date	<input type="checkbox"/> Initial Registration Version	<input type="checkbox"/> Date Amendment Sent To Local IRB
<input checked="" type="checkbox"/> Site Name	<input checked="" type="checkbox"/> Investigator Of Record (IOR Number)	<input type="checkbox"/> Initial Registration Date	<input type="checkbox"/> Date Amendment Implemented At Site
<input type="checkbox"/> Site Status	<input checked="" type="checkbox"/> IRB Name	<input type="checkbox"/> Protocol Status	<input type="checkbox"/> Administrative Registration
<input checked="" type="checkbox"/> Study Version	<input checked="" type="checkbox"/> IRB Review Type	<input type="checkbox"/> Accrual/On-Study	<input type="checkbox"/> Country
<input checked="" type="checkbox"/> Packet Number	<input checked="" type="checkbox"/> IRB Approval Date	<input type="checkbox"/> Latest Version Distributed To Sites	<input checked="" type="checkbox"/> IND Status

Below the checkboxes, there is a "Select the report display type" section with radio buttons for "HTML" (selected), "PDF", and "Excel". At the bottom of this section are three buttons: "Previous", "Run Report", and "Reset to Default".

At the bottom of the page, there are links for "Privacy Notice" and "Legal Disclaimer", and three logos: the Department of Health and Human Services, the National Institutes of Health, and the National Institute of Allergy and Infectious Diseases.

DPRS – Reports

The screenshot shows a web browser window titled "Regulatory Agency Information - Internet Explorer". The address bar contains a URL from "desbeta.digitalinfuzion.com". The page header includes the "Protocol Registration DIVISION OF AIDS" logo on the left, the title "Regulatory Agency Information" in the center, and user information on the right: "Welcome Denise Wright", "Last successful login: Aug 27, 2014 06:09 AM", and "No. of unsuccessful login attempts: 0".

The main content area features a navigation menu on the left with options: "Submission", "Search Submissions", and "Reports". The "Reports" section is active, showing a sidebar with "Protocol Registration Summary", "CRPMC Report", and "Regulatory Agency Information" (selected).

The central form area is titled "*View Report For:" and includes a dropdown menu with options: "All Regulatory", "Expired", and "Regulatory". Below this, it says "Please specify your criteria:" and "Please Select an Option". A dropdown menu is open, listing: "Expired", "Expiring in 30 days", "Expiring in 60 days", "Expiring in 90 days", and "Expiring in 120 days".

Below the dropdown are four input fields, each with a small icon to its right:

- Organization Name:
- Network:
- Site:
- Protocol:

At the bottom of the form area, there is a "Run Report" button. Below the button, text reads: "To run the default report, click **Run Report**. Click [customize](#) to modify the report display fields. Select the report display type : HTML PDF Excel".

The footer contains links for "Privacy Notice" and "Legal Disclaimer", and three logos: the NIH logo, the DAIDS RSC logo, and the Regulatory Support Center logo.



DPRS

Search



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

DPRS – Search Submissions

Search Submissions - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=Lx AFL8c1ypCh6EgB1Qr5HWa6KcSP1%2b0%2b32NWrqGy27oWNYvct6EIEG3z

DAIDS Regulatory Support Cent... Login Search Submissions

DAIDS-ES | Help | Logoff

Welcome Denise Wright
Last successful login: Sep 02, 2014 02:10 PM
No. of unsuccessful login attempts: 0

Protocol Registration
DIVISION OF AIDS

Search Submissions

Submission Search Submissions Reports

Packet Number:

Submission Type: From To

Site:

Protocol No.:

IoR Name:

Show only Registration Submissions

Submission Status:

Submissions

Submission Date	Packet Number	Submission Type	Site	Site Id	Protocol No	Status	Status Date	Edit	Create Copy	Submission History	Notifications	View Submitter
Pending	2014-04-1565	Updated CV	Johns Hopkins University CRS	201	A5276s 4.0	Pending Submission	2-Sep-2014					
Pending	2014-04-1565	Continuing Review	Johns Hopkins University CRS	201	A5276s 4.0	Pending Submission	2-Sep-2014					
Pending	2014-04-1565	Amendment	Johns Hopkins University CRS	201	A5276s 4.0	Pending Submission	2-Sep-2014					
2-Sep-2014	2014-04-1564	Amendment	Johns Hopkins University CRS	201	A5001 4.0	Review in Progress	2-Sep-2014					
2-Sep-2014	2014-04-1564	Continuing Review	Johns Hopkins University CRS	201	A5001 4.0	Review in Progress	2-Sep-2014					
2-Sep-2014	2014-04-1564	Updated CV	Johns Hopkins University CRS	201	A5001 4.0	Review in Progress	2-Sep-2014					
2-Sep-2014	2014-04-1563	Initial	Johns Hopkins University CRS	201	A5292 1.0	Review in Progress	2-Sep-2014					
27-Aug-2014	2014-04-1560	Initial	Johns Hopkins University CRS	201	A5292 1.0	Canceled	2-Sep-2014					
27-Aug-2014	2014-04-1561	Continuing Review	Johns Hopkins University CRS	201	A5292 1.0	Review in Progress	27-Aug-2014					
1-Jul-2014	2014-04-1494	Continuing Review	Johns Hopkins University CRS	201	HPTN 066 2.0	Review in Progress	1-Jul-2014					
20-Jun-2014	2014-04-1360	Site Initiated Revised ICF	Johns Hopkins University CRS	201	A5327 1.0 LOA 1	Completed	30-Jun-2014					
20-Jun-2014	2014-04-1360	LOA Registration	Johns Hopkins University CRS	201	A5327 1.0 LOA 1	Registered	25-Jun-2014					
20-Jun-2014	2014-04-1358	LOA Registration	Johns Hopkins University CRS	201	HPTN 069/A5305 3.0 LOA 3	Registered	25-Jun-2014					
20-Jun-2014	2014-04-1363	Continuing Review	Johns Hopkins University CRS	201	A5318 1.0	Review In Progress	20-Jun-2014					



Resources

Contacts and Important Links



Resources - Contacts

The Protocol Registration Office

- PRO correspondence E-mail: protocol@tech-res.com
- Phone: 1-301-897-1707



DAIDS-ES Support

- E-mail: DAIDS-ESSupport@niaid.nih.gov
- Phone: 1 (866) 337-1605 (USA toll-free) or 1 (240) 499-2239 (Outside USA)

Important Links

Protocol Registration Manual and Policy

- **Link to the 2012 DAIDS Protocol Registration Manual**
 - <http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/prmanual.pdf>
- **Link to the 2012 DAIDS Protocol Registration Policy**
 - <http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/protocolregpolicy.pdf>

DAIDS RSC Website

- <http://rsc.tech-res.com>

Important Links

DAIDS Regulatory Support Center - Internet Explorer
http://rsc.tech-res.com/

NIH National Institute of Allergy and Infectious Diseases | DAIDS Regulatory Support Center

Secure Document Collaboration Site * For DAIDS Only | Customer Feedback

Home | About the RSC | Frequently Asked Questions | Contact Information | Useful Links | Web Site Update Log

Broadcast Memos
Tutorials and Tools
Regulatory Information
Protocol Development Information
Human Subjects Protection (HSP)
Protocol Registration
Safety and Pharmacovigilance
Case Report Form (CRF) Management
Clinical Study Information Office

Click here for important links for DAIDS Clinical Research Sites (CRSS) on the DAIDS RSC Website.

PROCEDURES LABORATORY
FDA Form 1572
Informed Consent
IRB/EC Protocol
Investigator of Record
IND SAE

The Regulatory Support Center (RSC) plays a key role in supporting a wide range of clinical research activities and programs administered by the Office for Policy in Clinical Research Operations (OPCRO), of the Division of AIDS (DAIDS). DAIDS is a major component of the National Institute of Allergy and Infectious Diseases (NIAID). The majority of the National Institutes of Health (NIH) research effort related to HIV infection and AIDS is managed by the NIAID.

For more information about the [DAIDS RSC](#) click [here](#).

Document Title Search
Search Help

RSC Quick Contacts
- Select One -

Package Inserts
Investigator Brochures
Website Change Form

Latest News & Updates

- The DAIDS Network Financial Disclosure Forms have been posted to the Protocol Registration page**
Aug 7, 2014
- The DAIDS Financial Disclosure Guidance has been posted to the Protocol Registration page**
Jun 19, 2014
- Get Answers to Your Questions at the DAIDS RSC Information Booth at the ACTG Network Meetings on June 24 - 25, 2014**
Jun 19, 2014
- Get Answers to Your Questions at the DAIDS RSC Information Booth at the HPFN and IMPACT Annual Meetings on June 17 - 19, 2014**
Jun 13, 2014
- Updated IND and sec IND**

Important Links

The screenshot shows the DAIDS Regulatory Support Center website in Internet Explorer. The browser address bar shows the URL <http://rsc.tech-res.com/protocolregistration/>. The page features the NIH logo and the DAIDS RSC logo. A navigation menu includes links for Home, About the RSC, Frequently Asked Questions, Contact Information, Useful Links, and Web Site Update Log. The main content area is titled "Protocol Registration" and includes a link to "Click here for Protocol Registration FAQs". Below this, the text explains the role of the DAIDS Protocol Registration Office (PRO) and the registration process. A list of important links is provided, including "Guidance Regarding DAIDS Deregistration Process", "Protocol Registration Checklist", "Form FDA 1572 for Investigator Registration", and "Financial Disclosure Form". A sidebar on the right contains a "Document Title Search" box, "RSC Quick Contacts" dropdown, "Package Inserts", "Investigator Brochures", "Website Change Form", and "Latest News & Updates" section with several news items dated in 2014.

DAIDS Regulatory Support Center - Protocol Registration - Internet Explorer
<http://rsc.tech-res.com/protocolregistration/>

NIH National Institute of Allergy and Infectious Diseases DAIDS RSC Regulatory Support Center

Secure Document Collaboration Site * For DAIDS Only Customer Feedback

Home | [About the RSC](#) | [Frequently Asked Questions](#) | [Contact Information](#) | [Useful Links](#) | [Web Site Update Log](#)

Broadcast Memos
Tutorials and Tools
Regulatory Information
Protocol Development Information
Human Subjects Protection (HSP)
Protocol Registration
Safety and Pharmacovigilance
Case Report Form (CRF) Management
Clinical Study Information Office

Protocol Registration

[Click here for Protocol Registration FAQs](#)

What does DAIDS/RSC Protocol Registration Office do?

The DAIDS Protocol Registration Office (PRO) at the RSC receives and processes all protocol registration materials submitted by sites participating in DAIDS-supported and/or sponsored clinical trials. They work closely with the DAIDS Protocol Registration Team (PRT) to establish internal procedures and processes.

The DAIDS protocol registration process verifies that sites have received the necessary Institutional Review Board (IRB)/ Ethics Committee (EC) and other applicable Regulatory Entity (RE)/Approving Entity approvals and have provided to DAIDS all documentation pertaining to investigator qualifications and responsibilities that are required by the U.S. federal regulations and the National Institutes of Health (NIH). The DAIDS protocol registration process also verifies that site-specific informed consent forms contain the necessary information to comply with U.S. federal regulations.

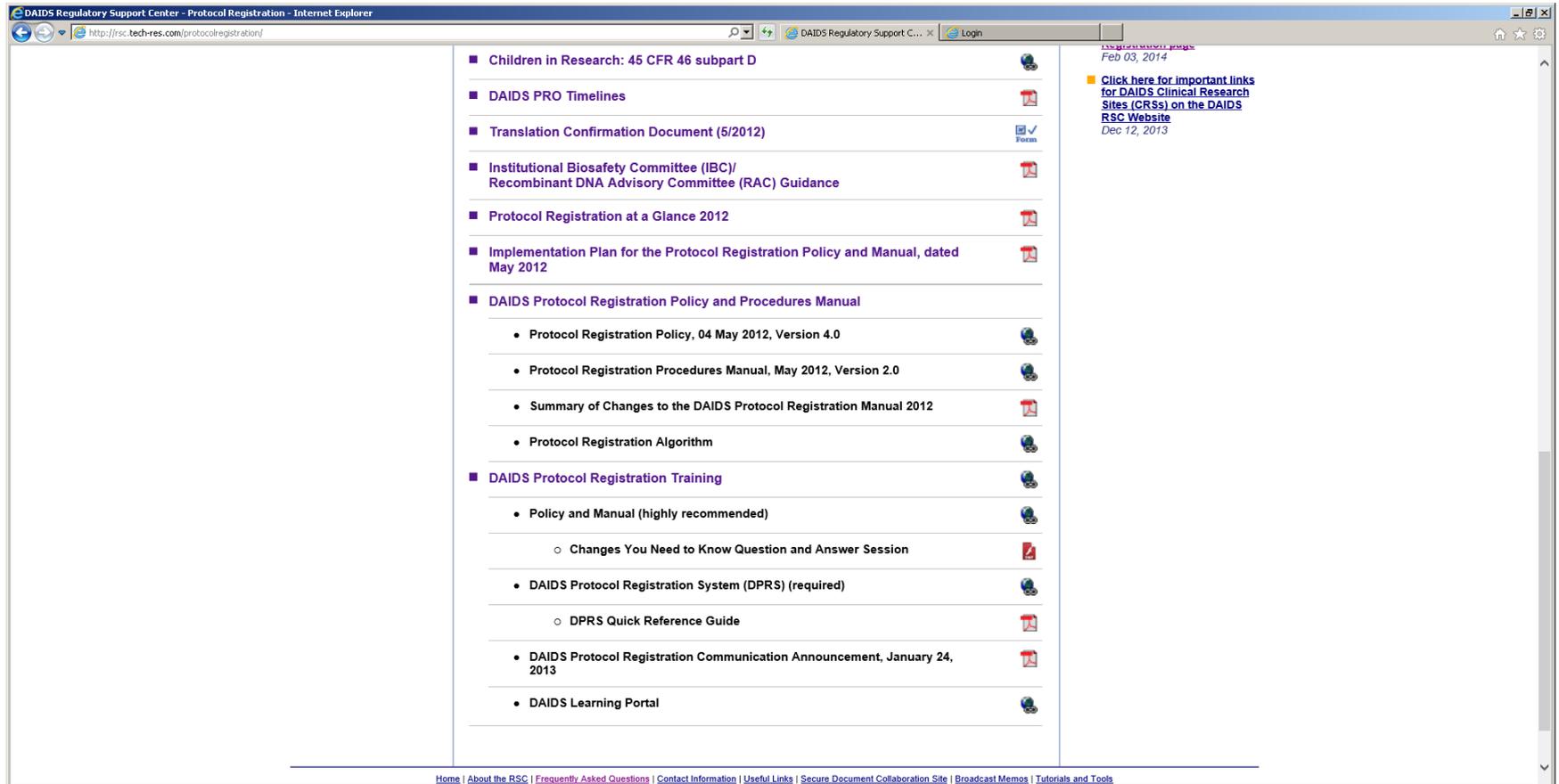
- Guidance Regarding DAIDS Deregistration Process**
- Protocol Registration Checklist**
This document must be submitted with each submission made through the electronic protocol registration (EPR) mailbox to the DAIDS PRO.
 - Protocol Registration Checklist - April 2010**
- Form FDA 1572 for Investigator Registration**
A protocol specific Form FDA 1572 must be submitted with each initial protocol registration submission for protocols conducted under an IND.
- Financial Disclosure Form**
Process for collection of Financial Disclosure Forms for all investigators and sub-investigators listed on Form FDA 1572.
 - DAIDS Financial Disclosure Guidance**

Document Title Search
Search Help
RSC Quick Contacts
- Select One -
Package Inserts
Investigator Brochures
Website Change Form

Latest News & Updates

- The DAIDS Network Financial Disclosure Forms have been posted to the Protocol Registration page**
Aug 7, 2014
- The DAIDS Financial Disclosure Guidance has been posted to the Protocol Registration page**
Jun 19, 2014
- Get Answers to Your Questions at the DAIDS RSC Information Booth at the ACTG Network Meetings on June 24 - 25, 2014**
Jun 19, 2014
- Get Answers to Your Questions at the DAIDS RSC Information Booth at the HPTN and IMPAACT Annual Meetings on June 17 - 19, 2014**
Jun 13, 2014
- Updated IND and sub-IND

Important Links



The screenshot shows a web browser window titled "DAIDS Regulatory Support Center - Protocol Registration - Internet Explorer". The address bar displays "http://rsc.tech-res.com/protocolregistration/". The main content area is a list of links, each with a small icon to its right. The links are organized into several sections:

- Children in Research: 45 CFR 46 subpart D** (Globe icon)
- DAIDS PRO Timelines** (Calendar icon)
- Translation Confirmation Document (5/2012)** (Checkmark icon)
- Institutional Biosafety Committee (IBC)/ Recombinant DNA Advisory Committee (RAC) Guidance** (Calendar icon)
- Protocol Registration at a Glance 2012** (Calendar icon)
- Implementation Plan for the Protocol Registration Policy and Manual, dated May 2012** (Calendar icon)
- DAIDS Protocol Registration Policy and Procedures Manual**
 - Protocol Registration Policy, 04 May 2012, Version 4.0** (Globe icon)
 - Protocol Registration Procedures Manual, May 2012, Version 2.0** (Globe icon)
 - Summary of Changes to the DAIDS Protocol Registration Manual 2012** (Calendar icon)
 - Protocol Registration Algorithm** (Globe icon)
- DAIDS Protocol Registration Training** (Globe icon)
 - Policy and Manual (highly recommended)** (Globe icon)
 - Changes You Need to Know Question and Answer Session** (Calendar icon)
 - DAIDS Protocol Registration System (DPRS) (required)** (Globe icon)
 - DPRS Quick Reference Guide** (Calendar icon)
 - DAIDS Protocol Registration Communication Announcement, January 24, 2013** (Calendar icon)
 - DAIDS Learning Portal** (Globe icon)

On the right side of the page, there is a sidebar with a link: **Click here for important links for DAIDS Clinical Research Sites (CRSS) on the DAIDS RSC Website** (Dec 12, 2013). Above this link is a date: Feb 03, 2014.

At the bottom of the page, there is a navigation bar with the following links: [Home](#) | [About the RSC](#) | [Frequently Asked Questions](#) | [Contact Information](#) | [Useful Links](#) | [Secure Document Collaboration Site](#) | [Broadcast Memos](#) | [Tutorials and Tools](#)



Conclusion

- **THANK YOU**

The DAIDS Protocol Registration Team