

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 | 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). | 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). |
| 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. | 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). |

Curricula Vitae and Medical License

Submission Requirements
Document Requirements





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





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_DAIDS_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



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DAIDS Protocol Registration System (DPRS) – Gaining Access

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

Sign In

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?

- 1. 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).
- 2. 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

Internet Explorer - Login

https://daidses.niaid.nih.gov/ProtocolRegistration/login.aspx

 Protocol Registration
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Login

*User Name:

[Forgot User Name?](#)

*Password:

[Change Password / Forgot Password?](#)

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

DPRS – Home Screen

Home - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx

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Home

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

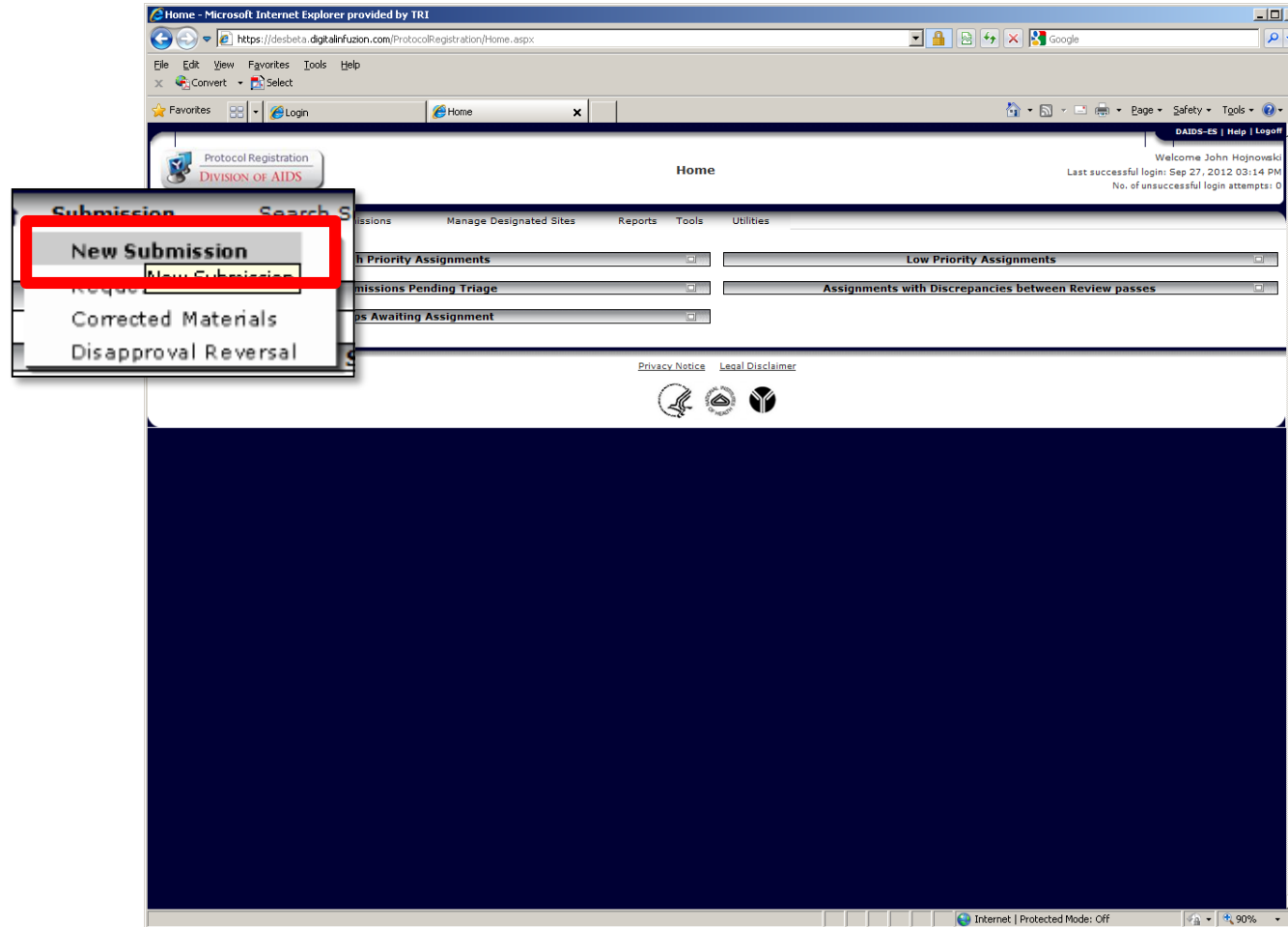


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DPRS – Creating an Initial Registration



DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAFU8c1ypCh6EFegf1Qr5HwA6KcSP1%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]

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=LxAF8c1ypCh6EFegf1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC...

New Submission x DAIDS Regulatory Support Cent...

Protocol Registration
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New Submission

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]

Select the Inves

*Se

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

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

DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6EFegf1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC...

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 Select Version A5292

To view LOA Versions, click the LOA button

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

☒ 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

Next Discard

Privacy Notice Legal Disclaimer

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

DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAFU8c1ypCh6EFegf1Qr5HwA6KcSP1%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

New Submission - Internet Explorer

https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6Eg8f1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC... Protocol Registration Summary New Submission

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 Go Reset

Enter email addresses for additional contacts

Additional Contacts:

Submissions
Select the applicable submission type

☐ Initial
☐ Amendment
☐ Continuing Review
☐ Deregistration

2368 record(s) found

| Select | IoR Person Name |
|-------------------------------------|------------------------------|
| <input type="checkbox"/> | Aditya Gaur [31882] |
| <input type="checkbox"/> | Adolf WallerKarchmer [30339] |
| <input type="checkbox"/> | Adrian Palfreman [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] |

2

LOA Registration
Additional ICF type
Additional ICF Language

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

Discard

Legal Disclaimer

DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6Efgf1Qr5HwA6KcSP1%2b0%2b32NWGwdF82Oeqxd%2f%2faC

Protocol Registration Summary New Submission

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

New Submission

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=LxAF8c1ypCh6Efgf1Qr5HwA6KcSP1%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

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

DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6Efgf1Qr5HwA6KcSP1%2b0%2b32NWGwdf82Oeqxd%2f%2faC

Protocol Registration Summary New Submission

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

New Submission

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

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

DPRS – Creating an Initial Registration

New Submission - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6Efgf1Qr5HwA6KcSP1%2b0%2b32NWGwdF82Oeqxd%2f%2faC

Protocol Registration Summary New Submission

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

New Submission

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

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

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=LxAF8c4ypCh6EfgB1Qr5HwA6KcSP1%2b0%2b32NWGwdF82Oeqxd%2f%2faC...

Protocol Registration Summary New Submission

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

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

***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 | 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 | | |

Upload Additional Files [x]

Uploaded Files list

P1081_1572.pdf

NA

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=1BF5Q3FpxoiV3A3b1%2fRZg%3d%3d&Nav=IQfHFnJDaIDcPdEizpWtytcxy1QCsr

Protocol Registration Summary Complete Submission Packet

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 | | |

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

[Save](#) [Person Information](#) [Submit](#) [Discard](#)

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

DPRS – Creating an Initial Registration

Person Information - Internet Explorer

https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx?SUB_ID=9%2bA36RUufmaxOK0TcmYFA%3D%3d&SSP_ID=IBFSIQ3FpxolV3A3bT%2RZg

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: aandrade@jhmi.edu1 Phone: 1-410-614-4036 Ext: | Select DAERS Role | <input type="radio"/> Yes <input type="radio"/> No |
| Charles W Flexner | CRS Leader | Email: flex@jhmi.edu1 Phone: 1-410-955-9712 Ext: | Reporter Access to All Protocols | <input type="radio"/> Yes <input type="radio"/> No |
| Denise Wright | Research Clinician | Email: dwright@jhmi.edu1 Phone: 1-410-614-4266 Ext: | Reporter Access to All Protocols | <input type="radio"/> Yes <input type="radio"/> No |
| Desiree Nock | Research Clinician | Email: Dnock1@jhmi.edu1 Phone: 1-410-955-4372 Ext: | Reporter Access to All Protocols | <input type="radio"/> Yes <input type="radio"/> No |
| Edward J. Fuchs | Research Associate | Email: efuchs@jhmi.edu1 Phone: 1-410-614-8762 Ext: | Reporter Access to All Protocols | <input type="radio"/> Yes <input type="radio"/> No |
| Ilene Wiggins | CRS Coordinator | Email: iwiggins1@jhmi.edu1 Phone: 1-410-614-2766 Ext: | 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=IBF5Q3FpxoiV3A3bT%2fRZg%3d%3d&Nav=IQfHFnJDaIDcPdEizpWtytcxy1QCsr

Protocol Registration Summary Complete Submission Packet

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 | | |

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

[Save](#) [Person Information](#) [Submit](#) [Discard](#)

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

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.:**  

[Back](#) [Submit](#) [Discard](#)

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

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:** 201 - Johns Hopkins University CRS

***Protocol No.:** A5292 **Select Version** ▼

[Back](#) [Submit](#) [Discard](#)

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

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:** 201 - Johns Hopkins University CRS

***Protocol No.:** A5292 Version 1.0

[Back](#) [Submit](#) [Discard](#)

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

DPRS – Creating an Initial Registration

The screenshot shows a web browser window with the URL https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=IBF5IQ3FpxoiV3A3bT%2fRZg%3d%3d&Nav=IQfHFnJDaIDcPdEizpWytcrx1QCsr. The page is titled "Notification" and features a "Protocol Registration DIVISION OF AIDS" logo. A navigation bar includes links for "Submission", "Search Submissions", and "Reports". The main content area displays a "Confirmation Of Submission: 2014-04-1560-01" and states that the registration material was submitted on Aug 27, 2014. It lists the submission types as "Initial" and the material received as "P1081 1572.pdf". The page concludes with contact information for the Protocol Registration Office and links to "Privacy Notice" and "Legal Disclaimer". Logos for the NIH, DAIDS, and RSC are visible at the bottom.

Notification - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SSP_ID=IBF5IQ3FpxoiV3A3bT%2fRZg%3d%3d&Nav=IQfHFnJDaIDcPdEizpWytcrx1QCsr

Protocol Registration Summary Notification

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

Notification

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](#)

NIH DAIDS RSC

DPRS – Copying a Submission

Search Submissions - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c1ypCh6EfgB1Qr5HwA6KcSP1%2b0%2b2JNWrqGy27oWfYvct6EIEG3z

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:

Select Date

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%2bA36RUufmaxOK0TcmYFA%3d%3d&SSP_ID=IBFSIQ3FpxoIV3A3bT%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

| | | | |
|--|--|--|--|
| <input type="checkbox"/> Initial | <input type="checkbox"/> Change of IoR on a Study | <input checked="" 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 | | |

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%2bA36RUufmaxOK0TcmYfA%3d%3d&SSP_ID=IBFSIQ3FpxoY3A3bT%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:** 201 - Johns Hopkins University CRS

***Protocol No.:** A5292 Version 1.0

[Back](#) [Submit](#) [Discard](#)

[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=nbW2Q4FU5DxpWwpt7e%2bw%3d%3d&Nav=Q3fHmJDaIdcPdElzpWtytcy1. The page header includes the "Protocol Registration DIVISION OF AIDS" logo and a "Notification" title. A user login bar at the top right says "Welcome Denise Wright", "Last successful login: Aug 27, 2014 06:09 AM", and "No. of unsuccessful login attempts: 0". A navigation bar contains links for "Submission", "Search Submissions", and "Reports".

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.

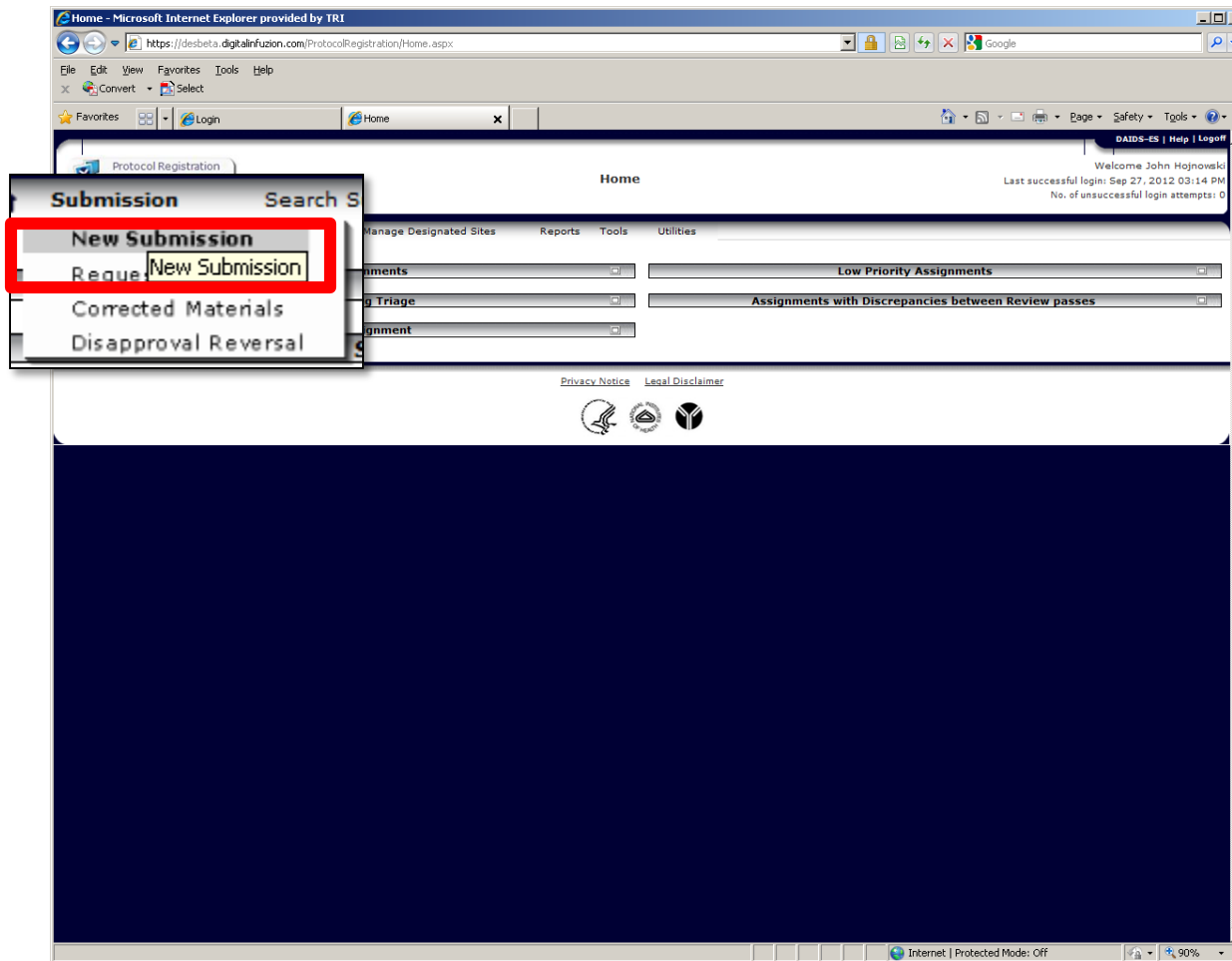
Should you have any questions or need additional information, please contact the Protocol Registration Office via phone 301-897-1707, fax 800-418-3544, or e-mail at protocol@tech-res.com.

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 Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases, and the Regulatory Support Center.

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=toVEu%2bJ29AmkoJWPMEn11M1vPcd7p3Kun/nM161CWmnoMhdcW908%2F

File Edit View Favorites Tools Help

Convert Select

Logon New Submission

Page Safety Tools

Protocol Registration
DIVISION OF AIDS

New Submission

Welcome John Hohnowski
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

| | | | |
|---|--|--|--|
| <input checked="" type="checkbox"/> Amendment | <input type="checkbox"/> Change of IoR on a Study | <input type="checkbox"/> LOA Registration | <input type="checkbox"/> Site Initiated Revised ICF |
| <input checked="" type="checkbox"/> Continuing Review | <input type="checkbox"/> Updated 1572 for existing IoR | <input type="checkbox"/> Additional ICF type | <input type="checkbox"/> Other Materials |
| <input type="checkbox"/> Deregistration | <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"/> Updated CV | | |

Next Discard

Privacy Notice

Done

Internet | Protected Mode: Off

DPRS – Creating a Multi-Purpose Submission

Sub Study LOV

Filter by: Sub Study Protocol Number Go Reset

Clear All

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 Hospital

*Protocol No: A5001

Select Sub-Studies: A5276s

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

*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: lihoinsuski@tech-res.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 | No |
|--|--|----|
| * 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 | | |
| Notes | <div> Upload Additional Files [x] </div> <div> Uploaded Files list Amendment and Annual Review submission.docx </div> | |

DPRS – Creating a Multi-Purpose Submission

Notification - Microsoft Internet Explorer provided by TRI

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SP_ID=EQvESvno7mWf7gkP14YhQ%3d%3d&Nav=7sRSNe6C%2bICD3MJKik%2fL7

File Edit View Favorites Tools Help

Convert Select

Favorites Home Notification x Doodle: DAIDS Protocol Regi...

DAIDS-ES | Help | Login

Associated Packets

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

Select a Packet

Select a Packet

A5276s - 101 - [2012-02-6667]

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, fax 800-418-3544, or e-mail at Protocol@tech-res.com.

Thank You,

The Protocol Registration Office

Privacy Notice Legal Disclaimer



Internet | Protected Mode: Off

DPRS – Creating a Multi-Purpose Submission

New Submission - Microsoft Internet Explorer provided by TRI

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?SP_ID=V8P19PlyfgdWUR2cAgdK4w%3d%3d&Nav=Fly71mOZ1YAzYDB6zgFFBQ7gis

File Edit View Favorites Tools Help

X 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

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](#)

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

DPRS – Requested/Corrected Material Submissions

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

Protocol Registration
 DIVISION OF AIDS

Home

Welcome Denise Wright
 Last successful login: Aug 27, 2014 12:25 PM
 No. of unsuccessful login attempts: 0

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=3b5MLG0HA%2b29DFHw7NDIQ%3d%3d&Nav=LxAPL8cXypChAEfEgBTQnSI

Corrected Materials

Protocol Registration
DIVISION OF AIDS

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

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

Protocol Registration Summary - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=zaSsgqYKG%2FgevOIR4VmfW%2btrMFawatXqTHdb%2bvdLQojvxBTocqEhswWsfieYRgf

desbeta.digitalinfuzion.com

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

Protocol Registration Summary

Submission Search Submissions Reports

Protocol Registration Summary
CRPMC Report
Regulatory Agency Information

Report For : ☒ All Versions ☐ Last Registered Version

From [Registration Status] Date :

To [Registration Status] Date :

Network :

Site :

Protocol :




Registration Status :
Acknowledged
Deregistered
Disapproved
In Progress
Paused
Registered

To run the default report, click **Run Report**. Click [customize](#) to modify the report display fields.

Select the report display type : ☐ HTML ☐ PDF ☒ Excel

Run Report

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

DPRS – Reports

Protocol Registration Summary - Internet Explorer

https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx?Nav=2a5sgqYK6%2fgev0R4VmfW%2btrMFawa0xqTHdb%2bvdL0ojv8T0cxqEhswW3fh

Protocol Registration
DIVISION OF AIDS

Protocol Registration Summary

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

Submission Search Submissions Reports

Protocol Registration Summary
CRPMC Report
Regulatory Agency Information

Select the desired check box(es) to display a field in your report. Clear the checkbox to remove the field from your report.




☐ 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 |

Select the report display type : ☒ HTML ☐ PDF ☐ Excel

[Previous](#) [Run Report](#) [Reset to Default](#)

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

DPRS – Reports

Regulatory Agency Information - Internet Explorer

https://desbeta.digitalinfuzion.com/ProtocolRegistration/Home.aspx?Nav=zaSsgqYK6%2fgevOIR4VmfW%2btrMFawaxqTHdb%2bvdCLoojvxBTocqEhswWshk

Regulatory Agency 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


Regulatory Agency Information


Submission Search Submissions Reports


Protocol Registration Summary
CRPMC Report
Regulatory Agency Information


*View Report For : ☐ All Regulatory ☒ Expired Regulatory

Please specify your criteria:

Organization Name: 

Network : 




Site : 

Protocol : 

To run the default report, click **Run Report**. Click [customize](#) to modify the report display fields.

Select the report display type : ☒ HTML ☐ PDF ☐ Excel

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



DPRS

Search



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

DPRS – Search Submissions

Search Submissions - Internet Explorer

https://desbeta.digitalinfusion.com/ProtocolRegistration/Home.aspx?Nav=LxAF8c4ypCh6EfgB1Qr5HwA6KcSP1%2b0%2b2JNwqGy27oWfNyvct6EIEG3z... DAIDS Regulatory Support Cent... Login Search Submissions

DAIDS-ES | Help | Logout

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:

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



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

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

The screenshot shows the DAIDS Regulatory Support Center website in an Internet Explorer browser window. The address bar displays <http://rsc.tech-res.com/>. The page features the NIH logo and the DAIDS RSC logo. A navigation bar includes links for Home, About the RSC, Frequently Asked Questions, Contact Information, Useful Links, and Web Site Update Log. A left sidebar lists various resources: Broadcast Memos, Tutorials and Tools, Regulatory Information, Protocol Development Information, Human Subjects Protection (HSP), Protocol Registration, Safety and Pharmacovigilance, Case Report Form (CRF) Management, and Clinical Study Information Office. The main content area has an orange banner with the text "Click here for important links for DAIDS Clinical Research Sites (CRSs) on the DAIDS RSC Website." Below this is a large image of laboratory equipment with the text "PROCEDURES LABORATORY" and "FDA Form 1572 Informed Consent IRB/EC Protocol Investigator of Record IND SAE". A paragraph describes the RSC's role in supporting clinical research activities. A right sidebar contains a "Document Title Search" box, "RSC Quick Contacts" with a dropdown menu, "Package Inserts", "Investigator Brochures", "Website Change Form", and "Latest News & Updates" with several news items.

DAIDS Regulatory Support Center - Internet Explorer

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

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

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 HPTN and IMPAACT Annual Meetings on June 17 - 19, 2014 Jun 13, 2014
- Updated IND and sec IND

Important Links

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

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

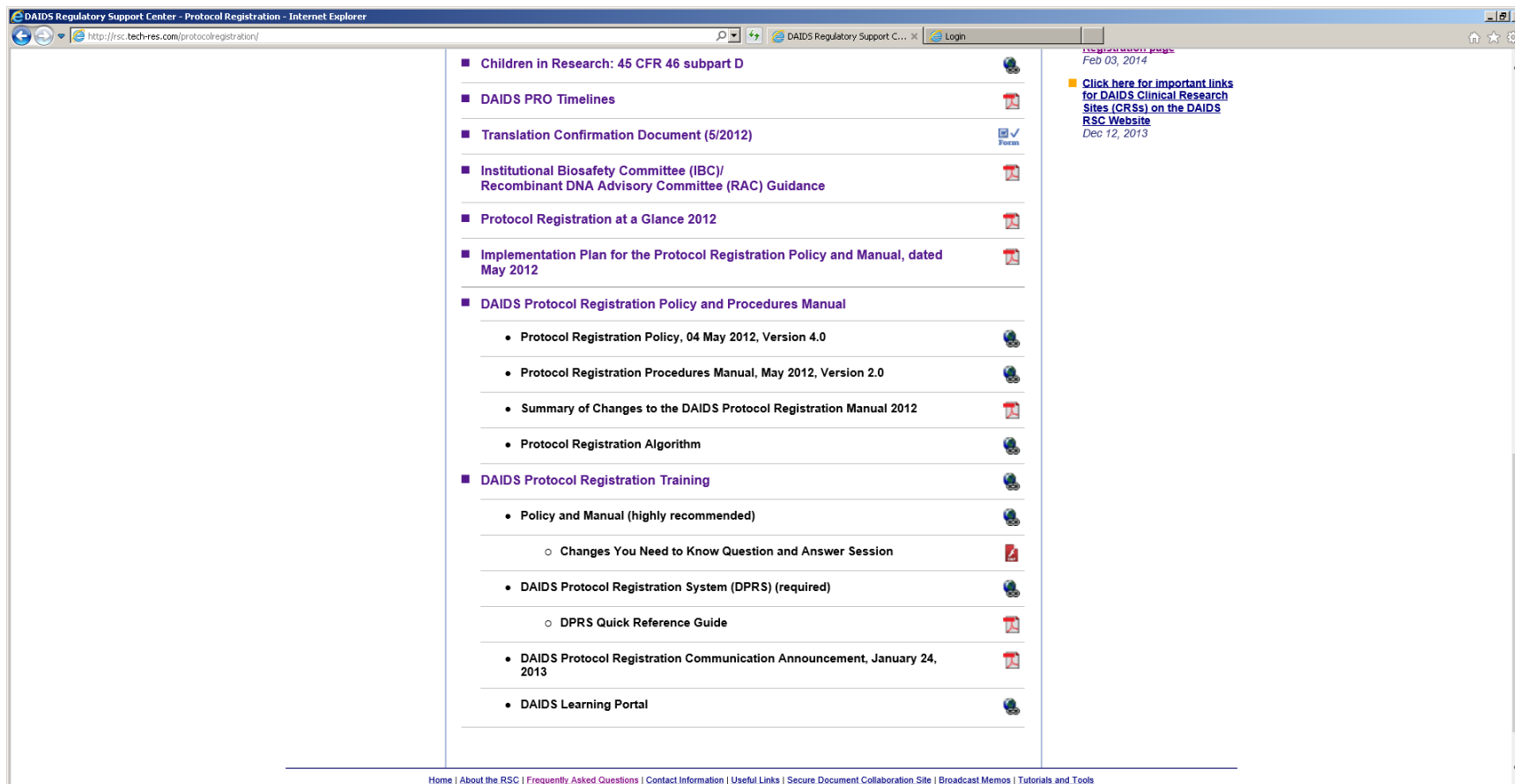
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Important Links



DAIDS Regulatory Support Center - Protocol Registration - Internet Explorer

http://rsc.tech-res.com/protocolregistration/

DAIDS Regulatory Support C... x Login

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

Click here for important links for DAIDS Clinical Research Sites (CRSS) on the DAIDS RSC Website
Feb 03, 2014
Dec 12, 2013

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