DAIDS Protocol Registration Basic Training

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Protocol Registration Office

National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No. HHSN272201000013C, entitled NIAID DAIDS Regulatory Support Center (RSC).

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

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	Single Form FDA 1572 /DAIDS IoR Form that lists both investigators in Section 1 • 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: •**ANY** Major Changes •Every two years •Initial Registrations •Change of IoR submissions	•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/DAIDSClinRsrch/Documents/enrollingchildrenrequirements.pdf

IRB/EC/RE/IBC Approval Documents

Termination/Suspension

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 not 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

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)

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

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_Calen dar/Protocol_Registration_DPRS_Training.htm.

Submitting Materials to the Protocol Registration Office

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

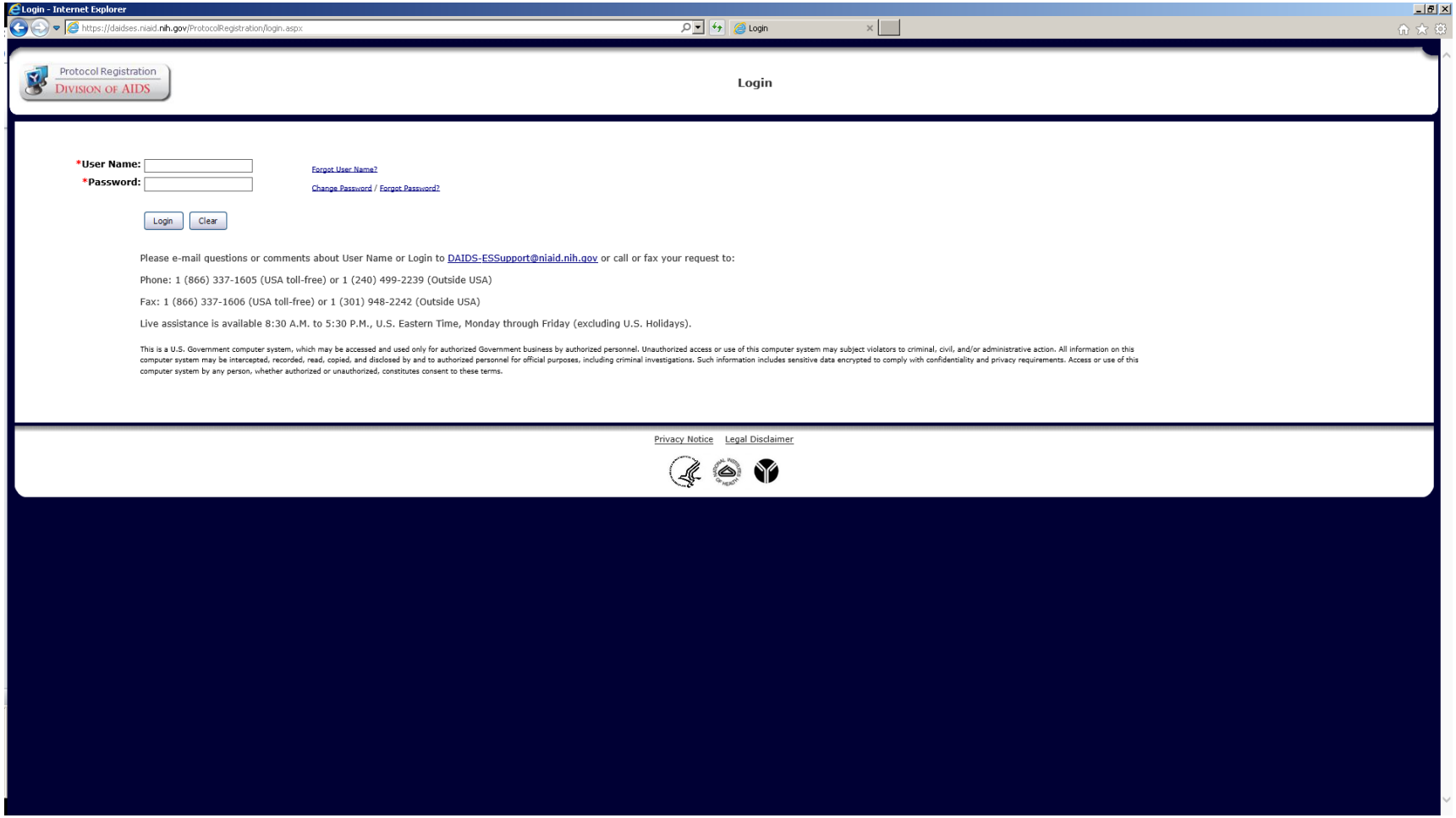
- epr@tech-res.com

DPRS

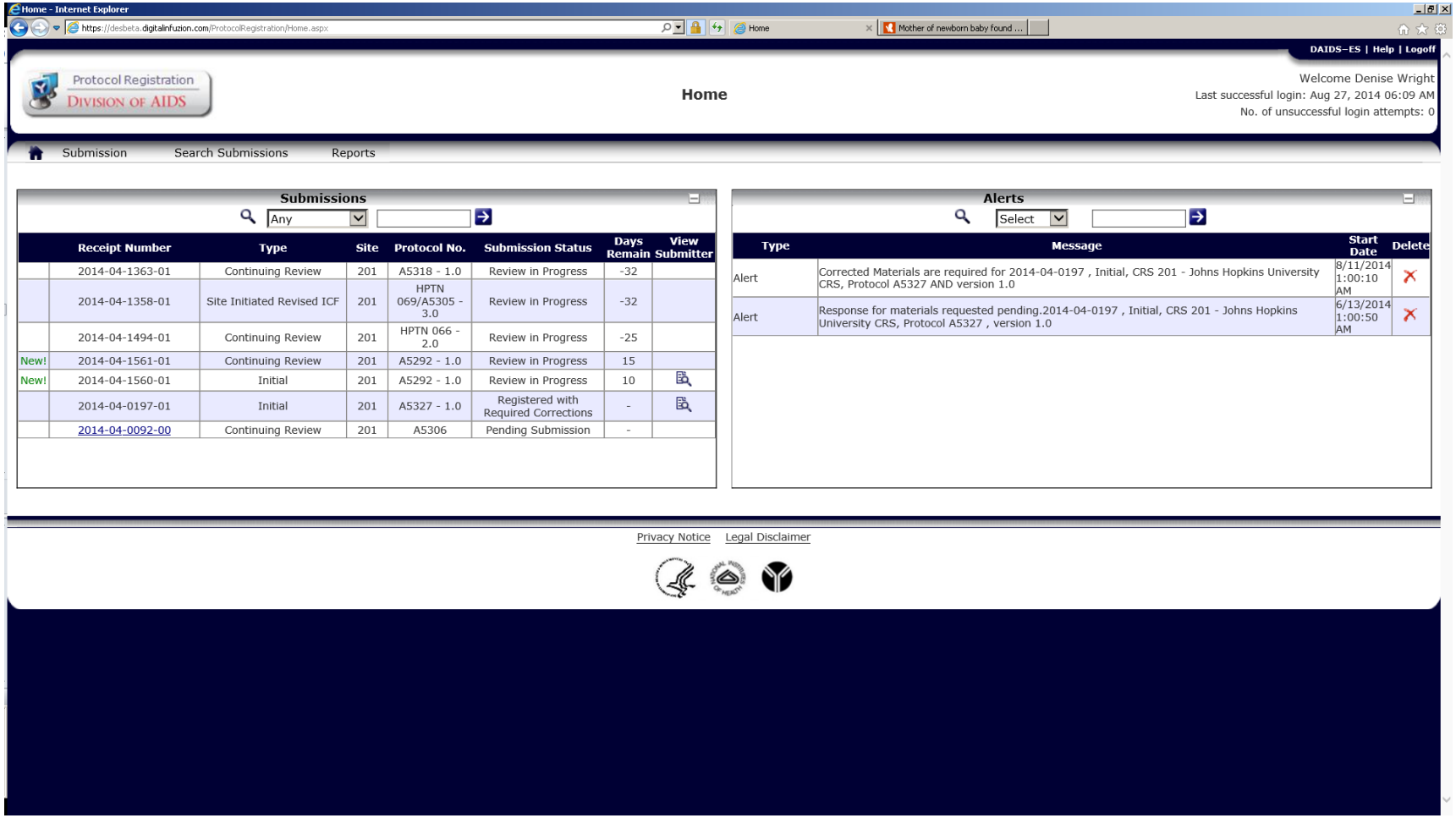
Logging In and Home Screen

DAIDS Protocol Registration System (DPRS) – Gaining Access

DPRS – Logging In



DPRS – Home Screen



DPRS

Creating Submissions

National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

Creating Submissions

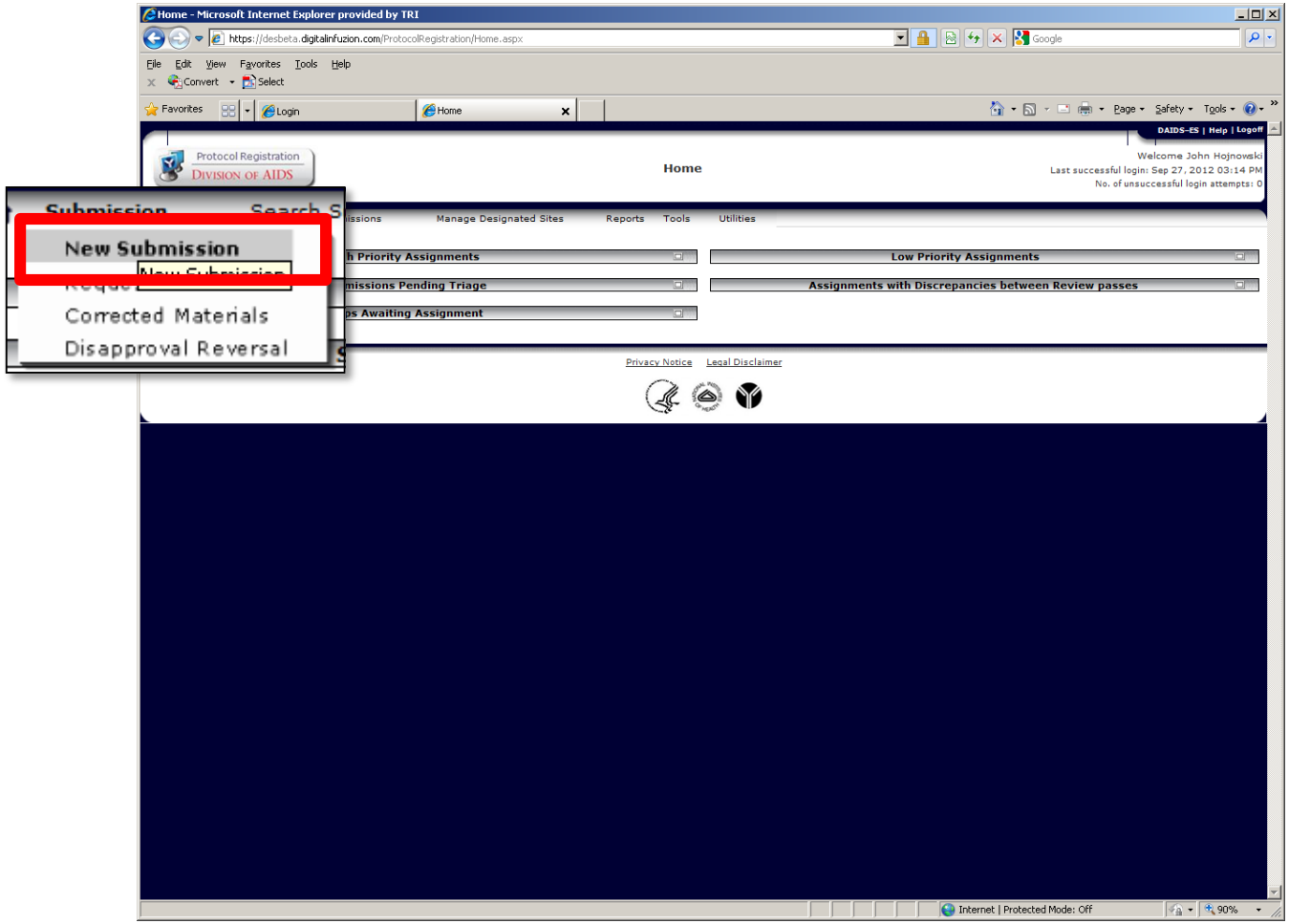
Initial

Copying a Submission

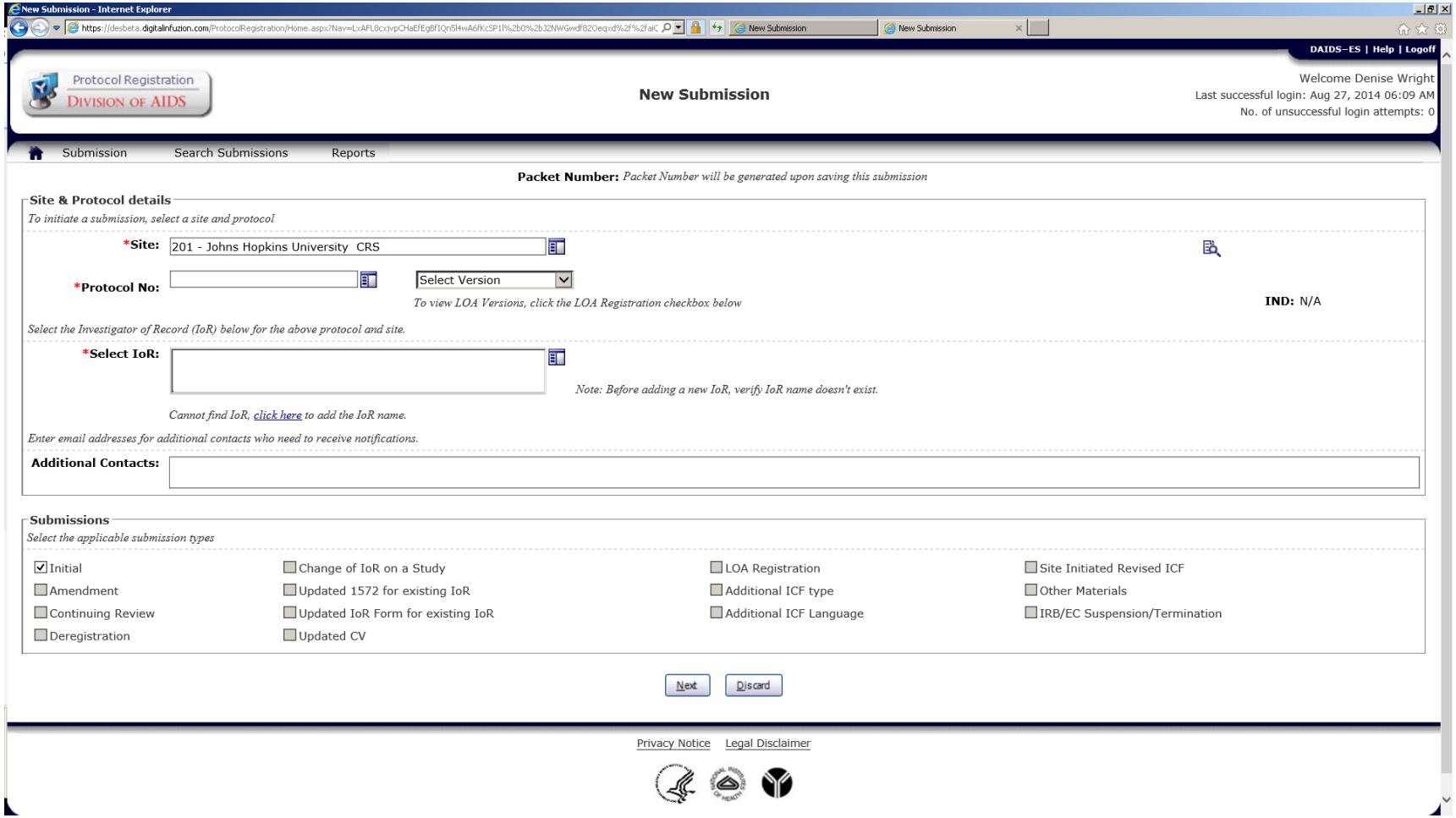
Multi-Purpose Submissions

Requested/Corrected Materials

DPRS – Creating an Initial Registration



DPRS – Creating an Initial Registration



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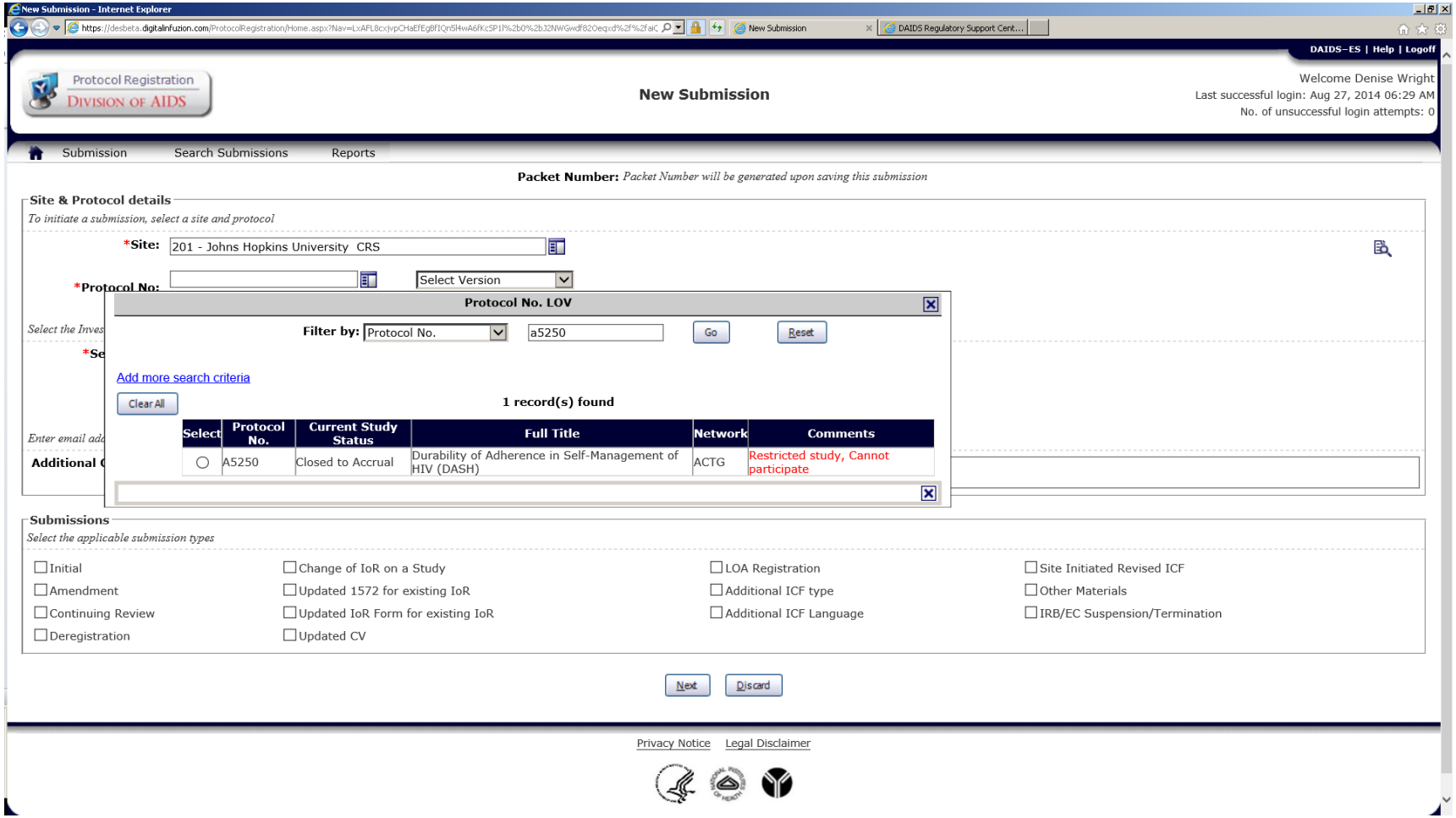
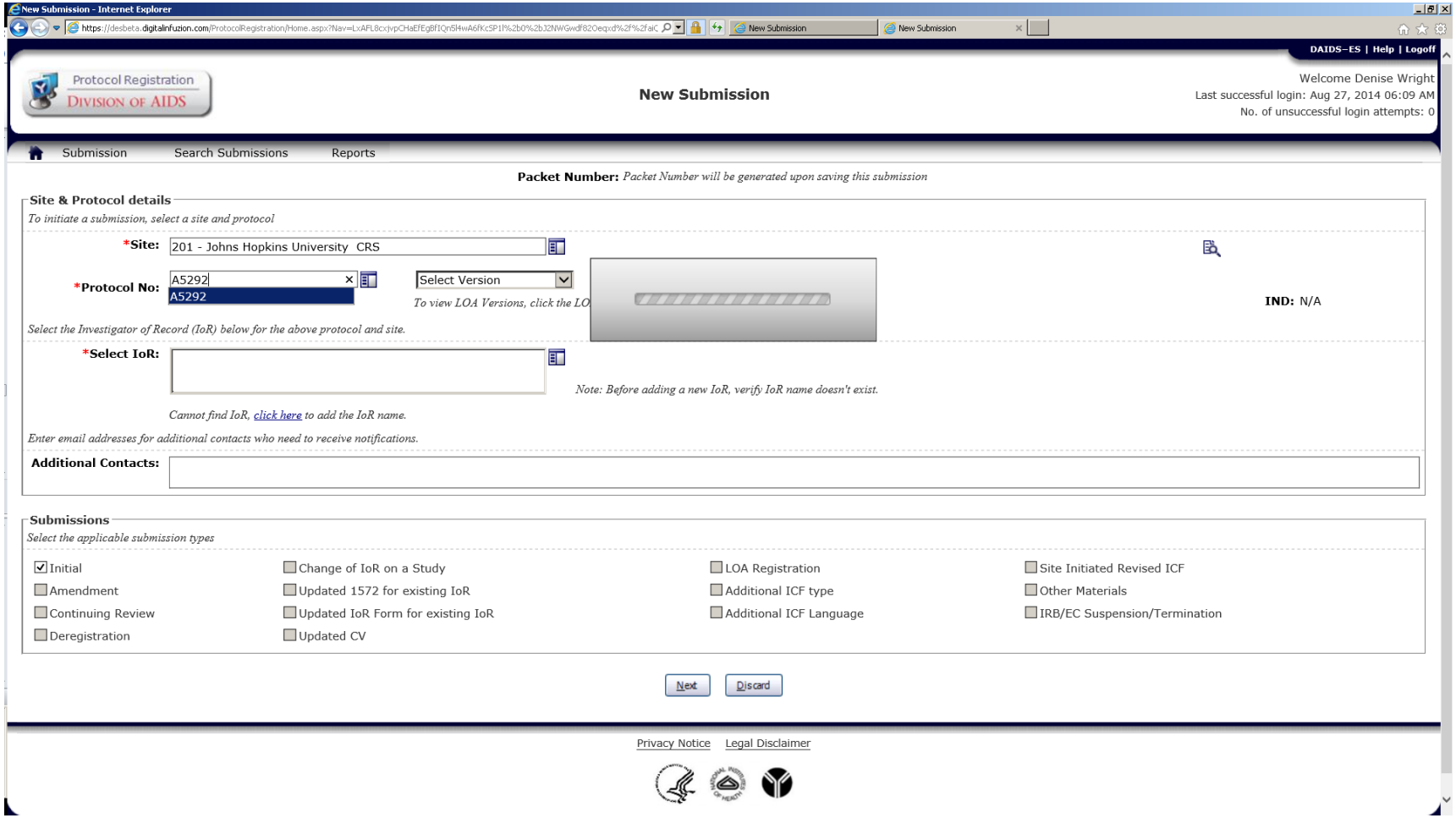
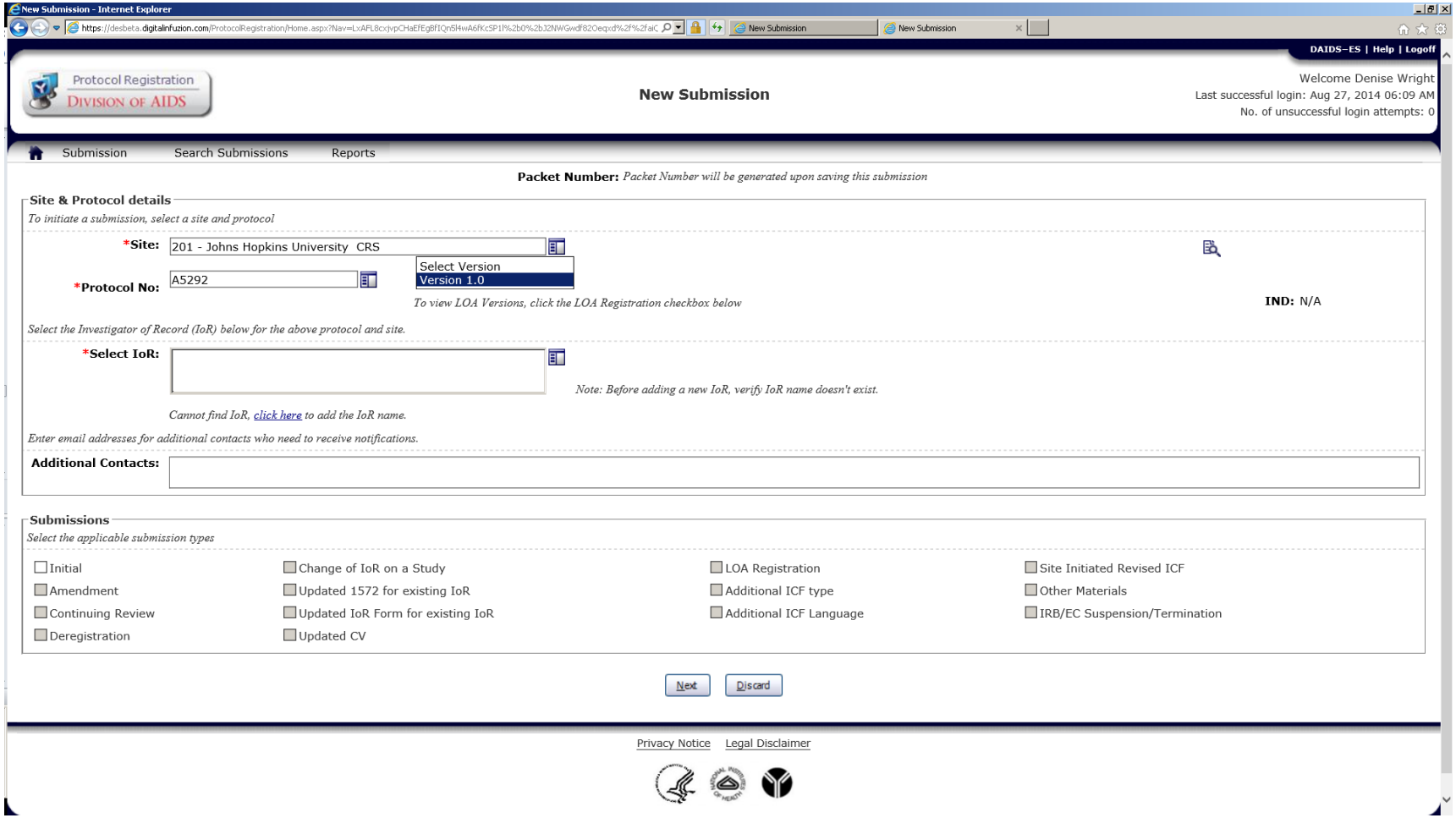


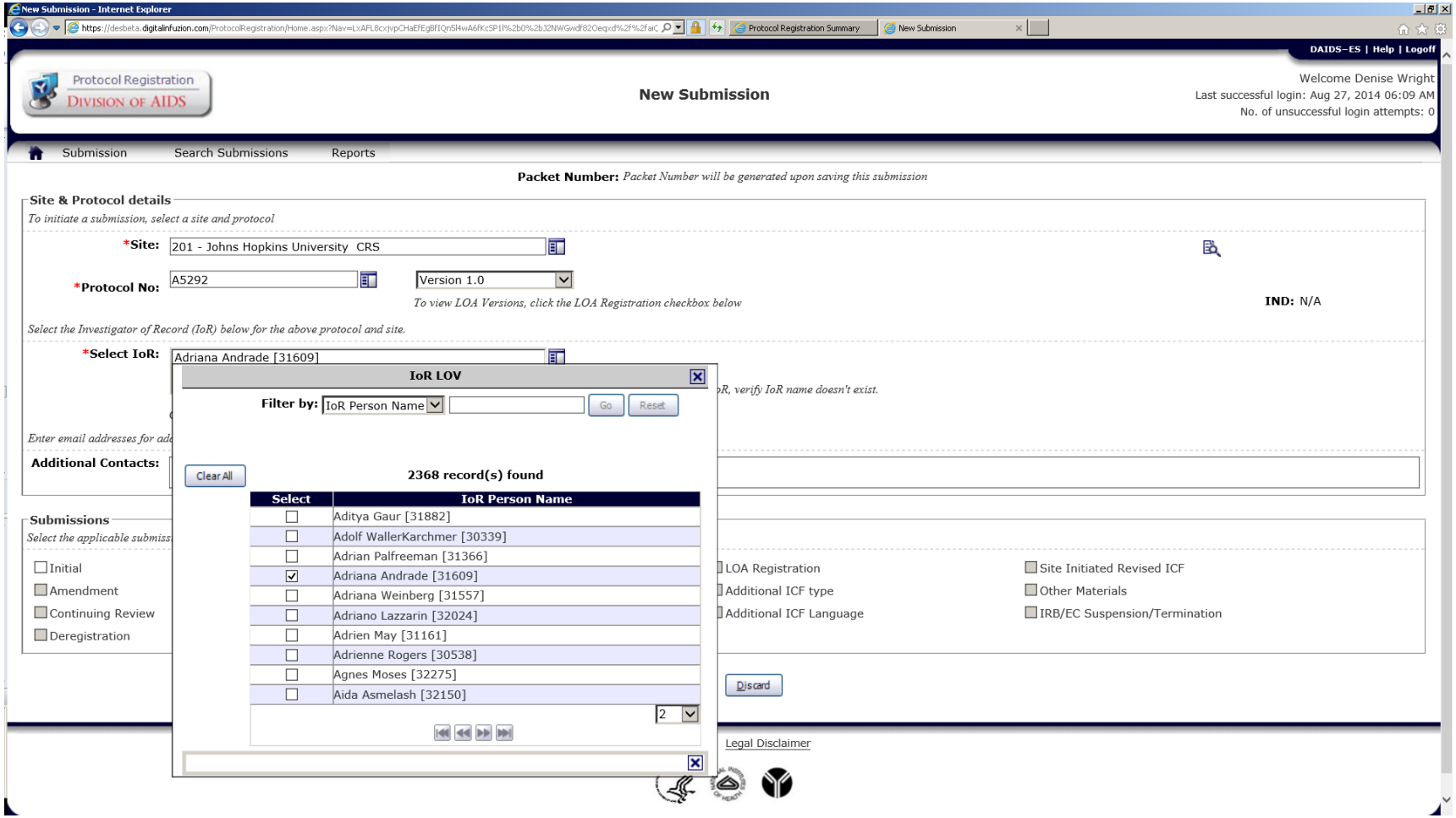
DPRS – Creating an Initial Registration



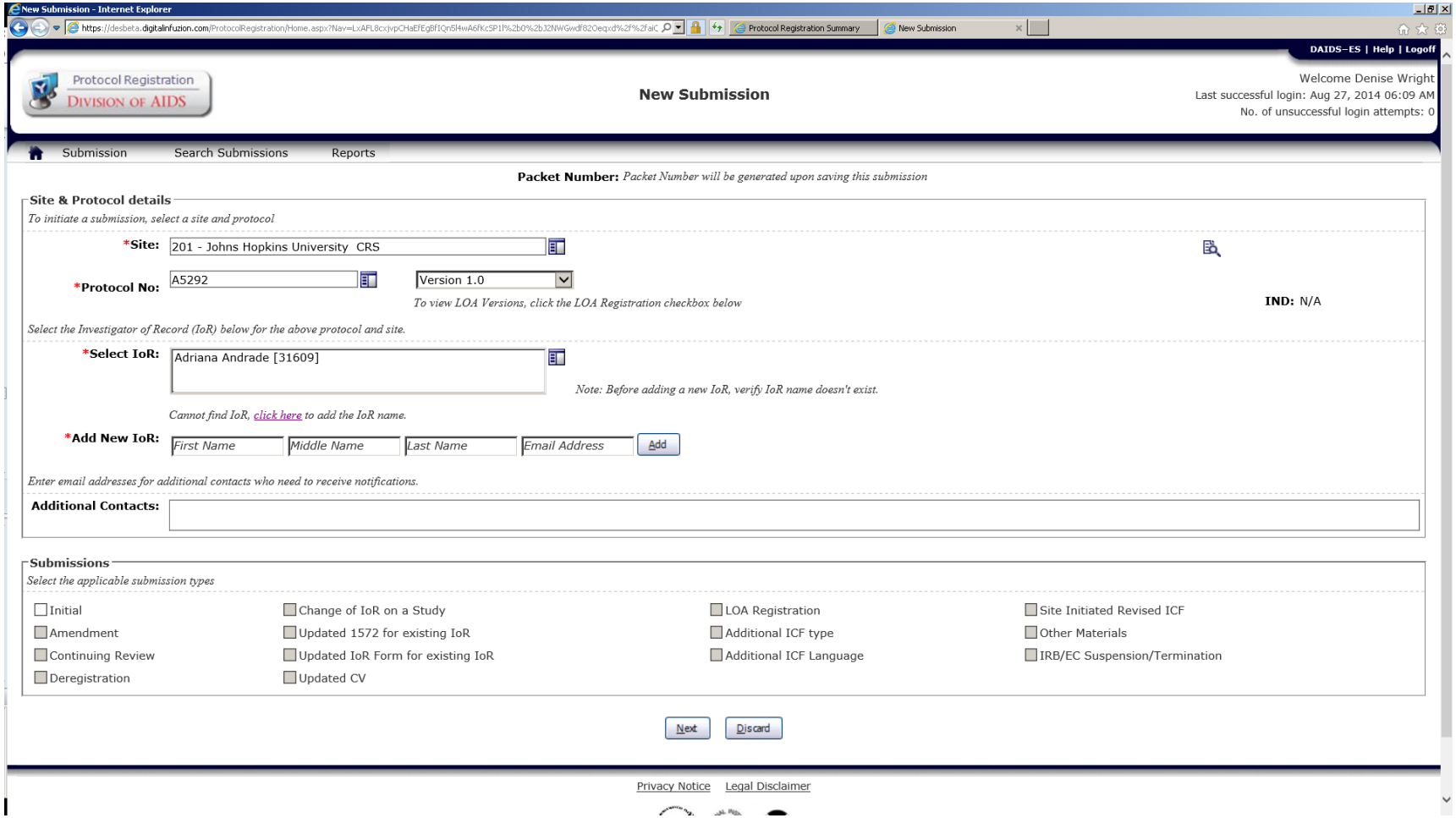
DPRS – Creating an Initial Registration



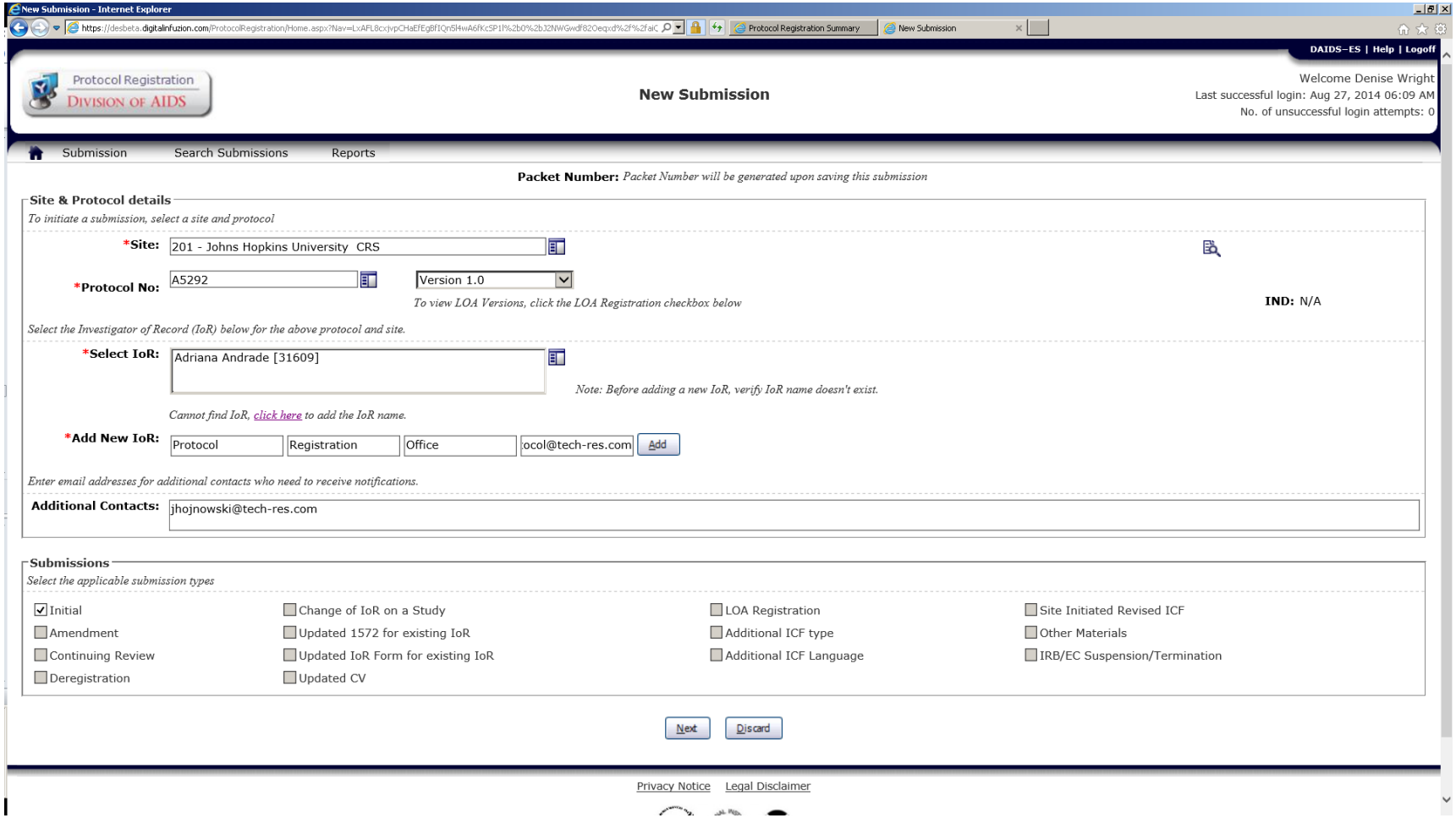
DPRS – Creating an Initial Registration



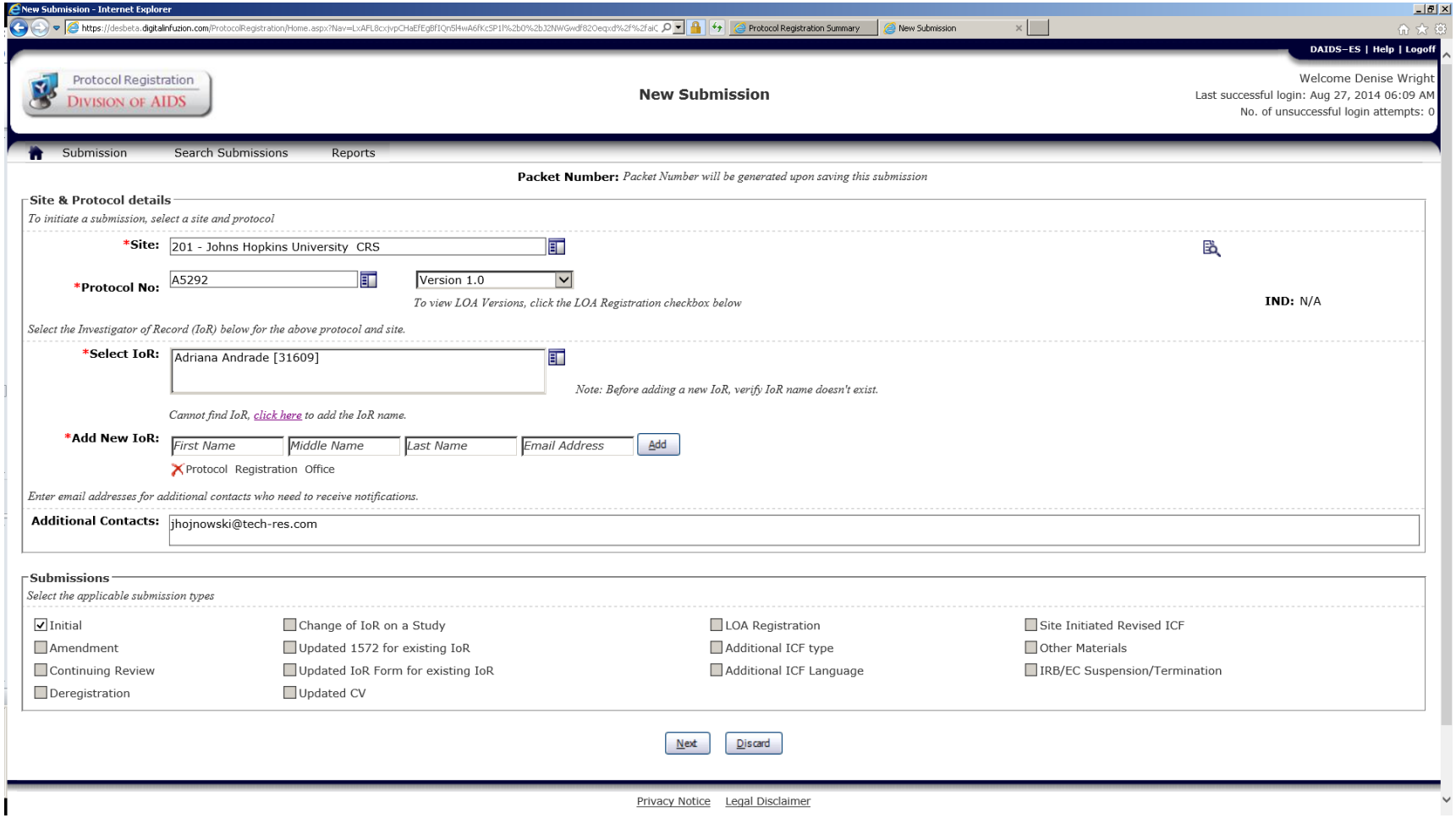
DPRS – Creating an Initial Registration



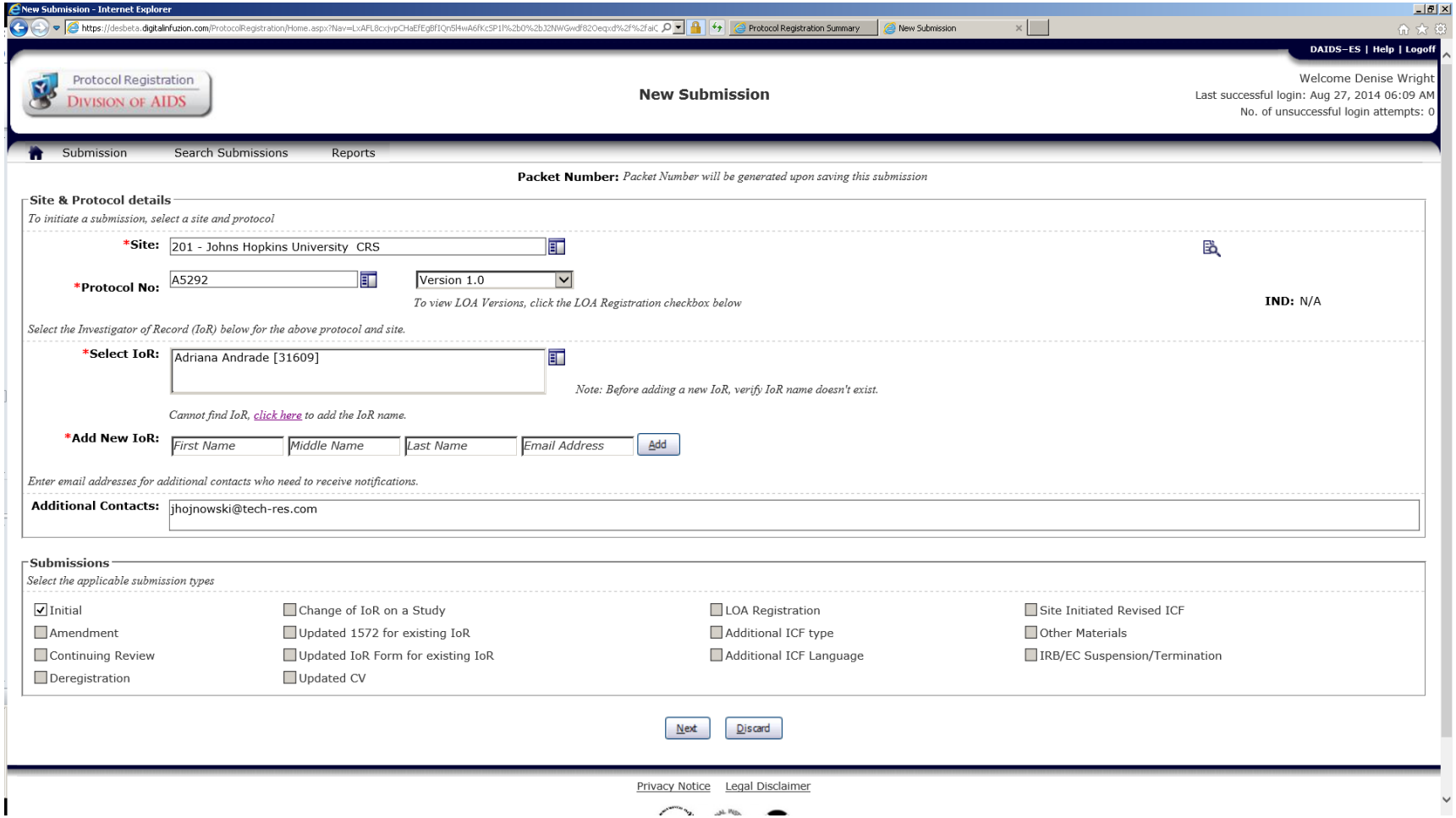
DPRS – Creating an Initial Registration



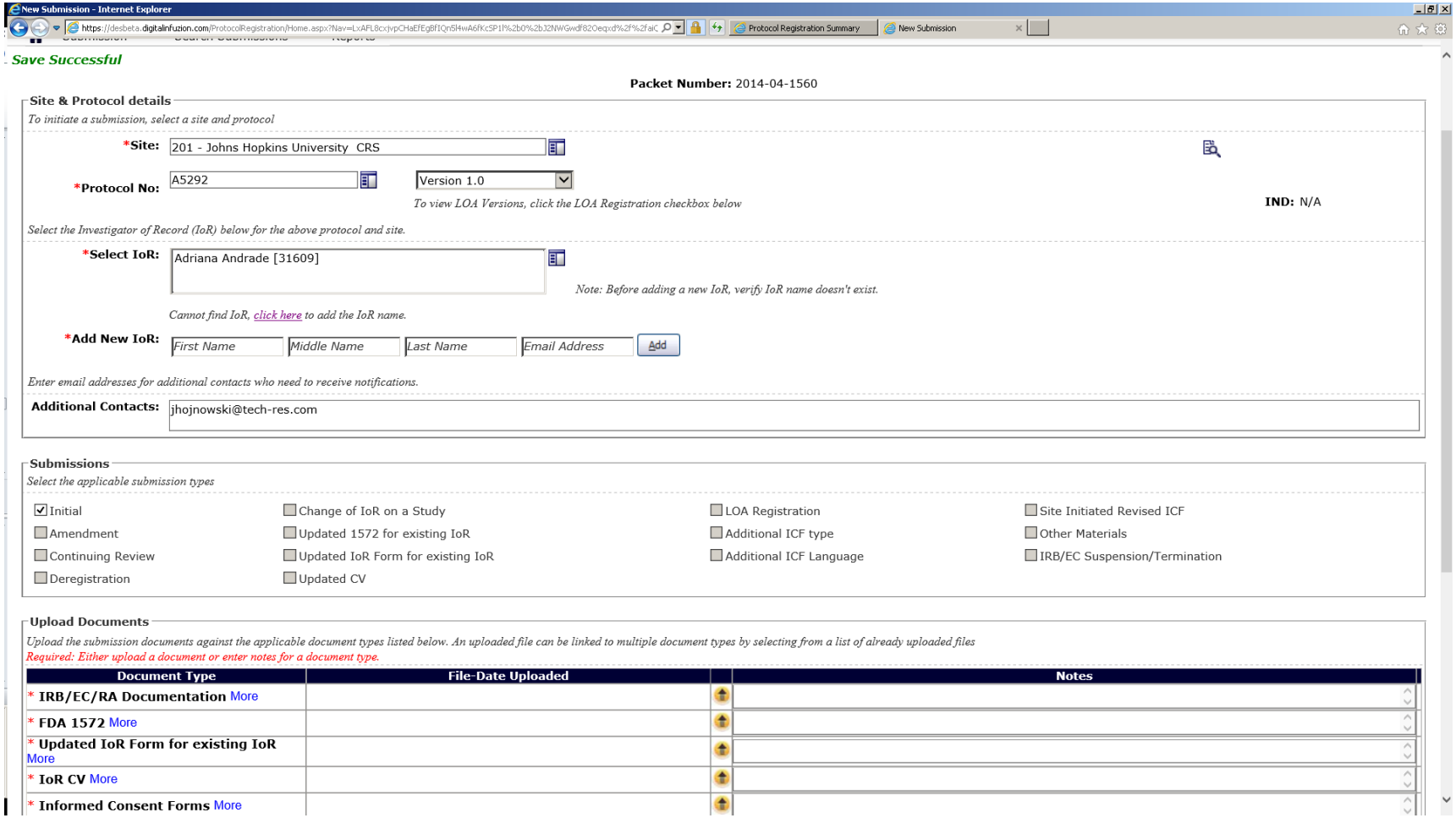
DPRS – Creating an Initial Registration



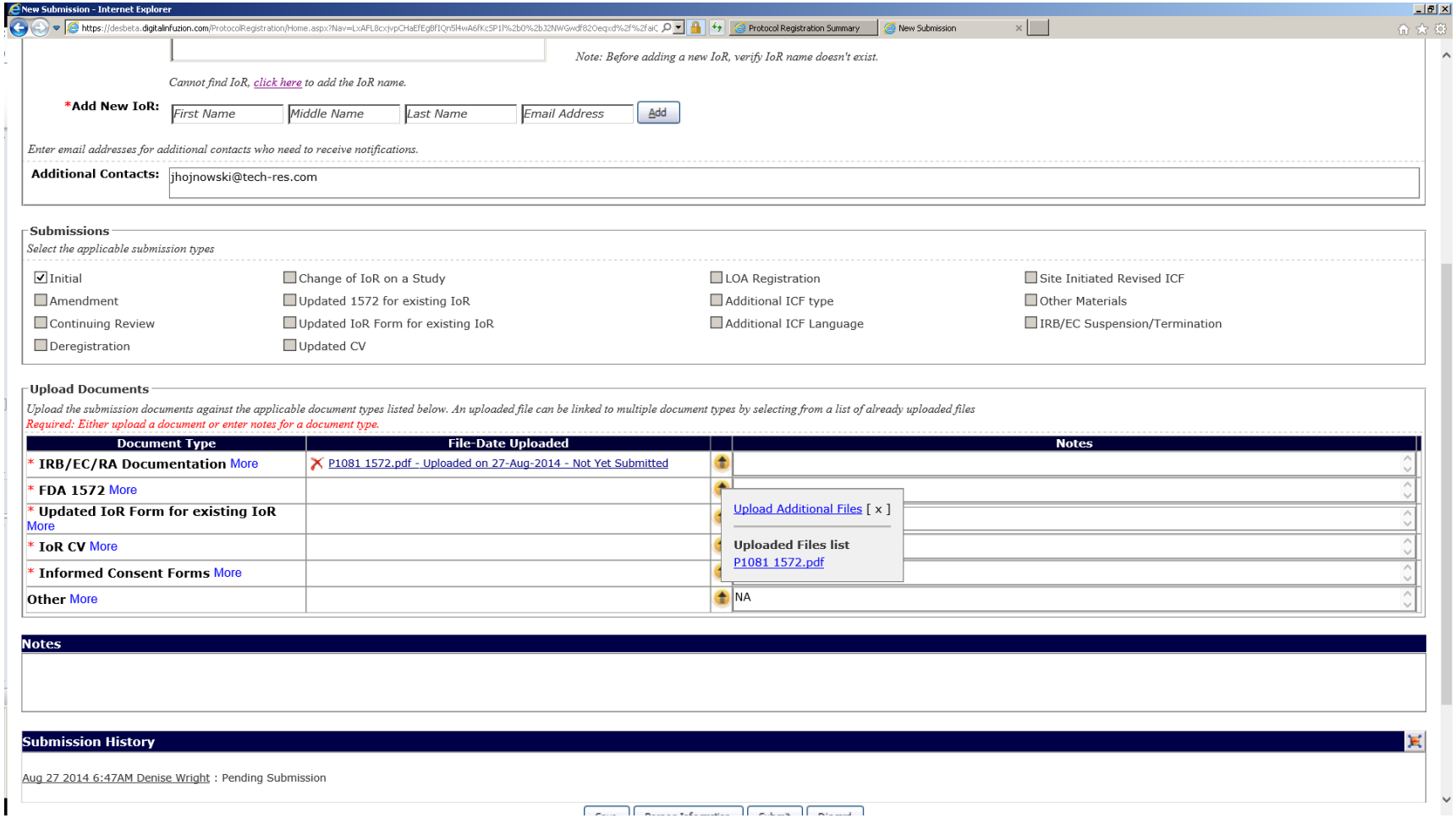
DPRS – Creating an Initial Registration



DPRS – Creating an Initial Registration



DPRS – Creating an Initial Registration



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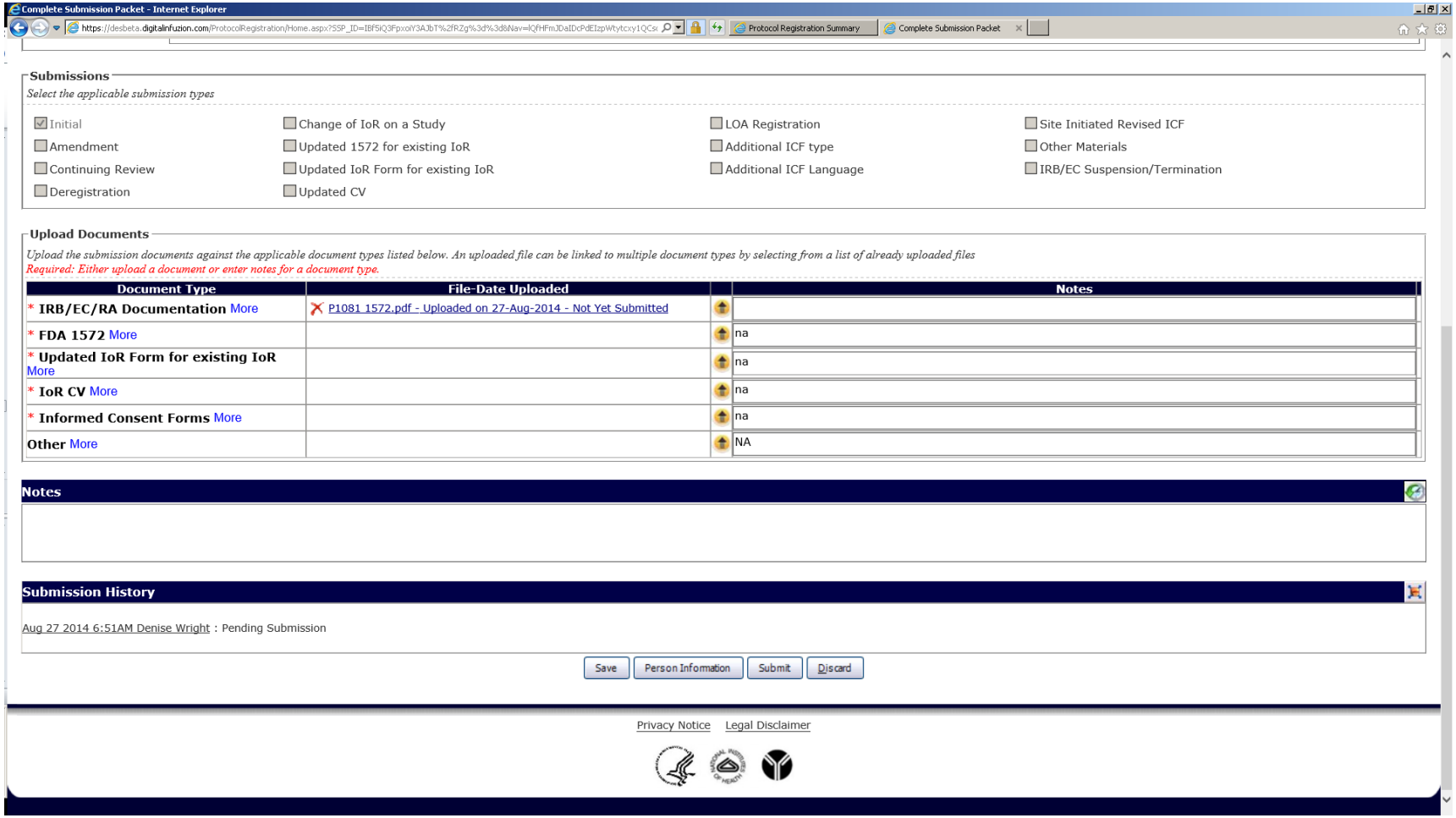

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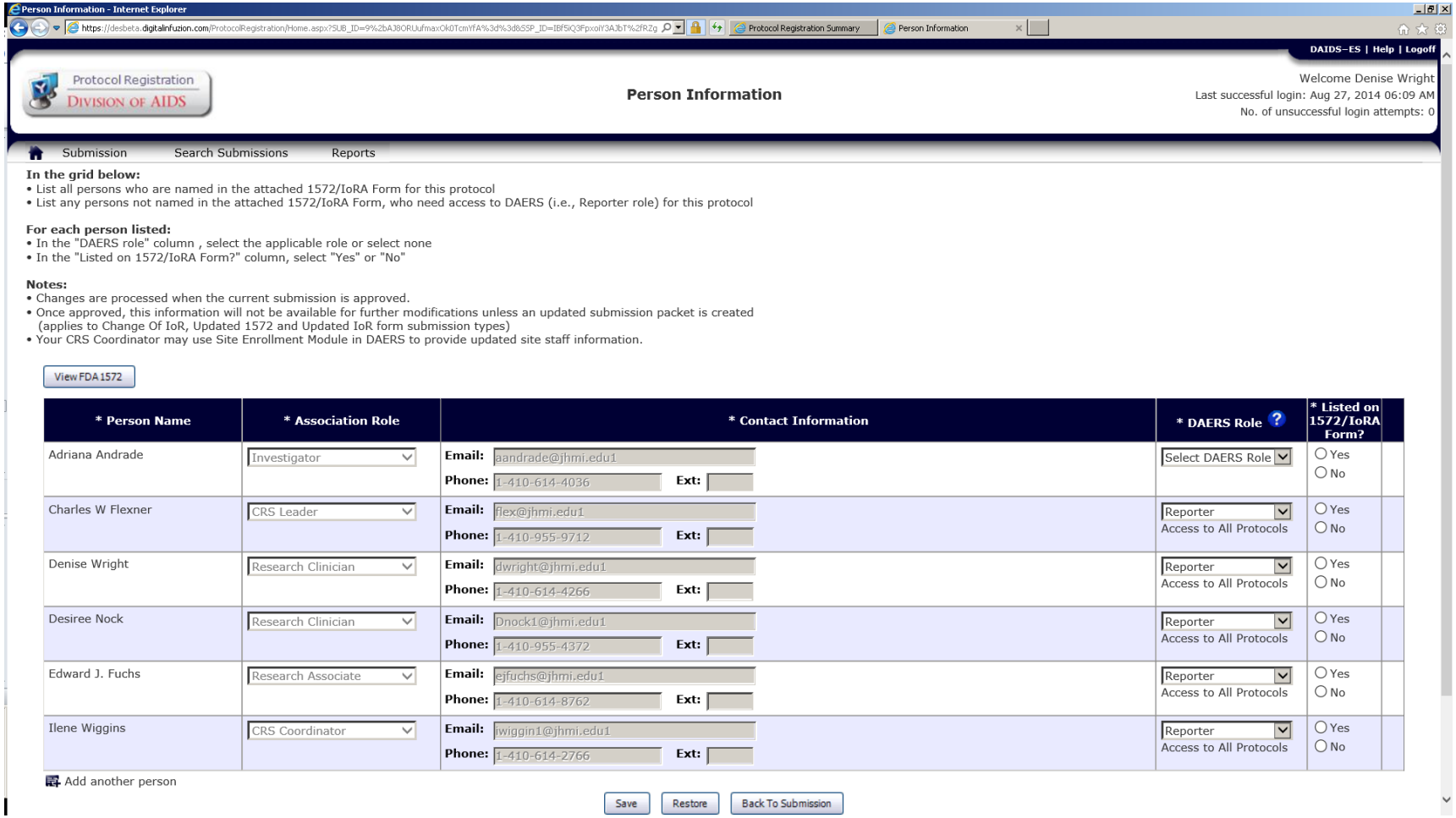

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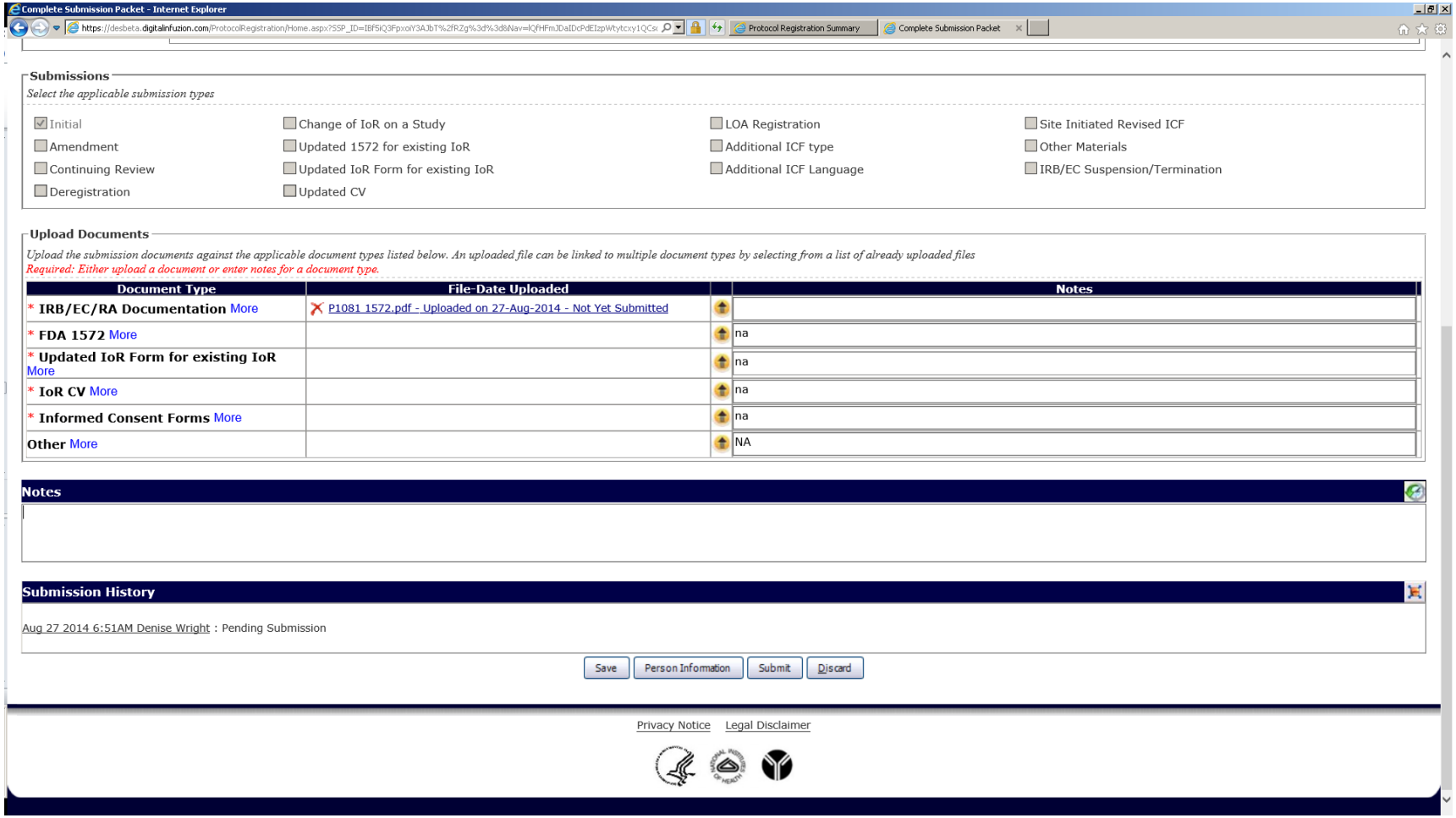

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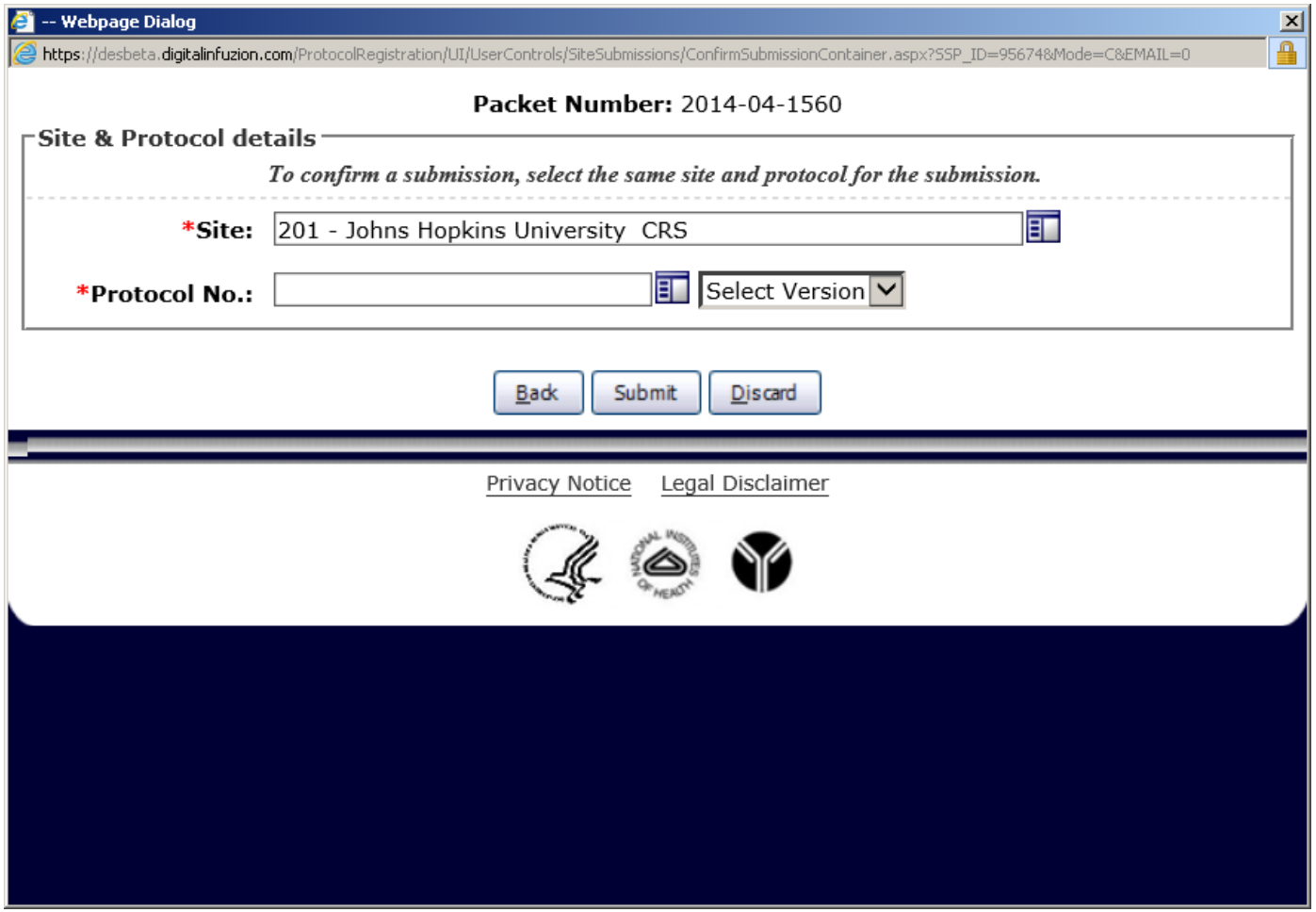

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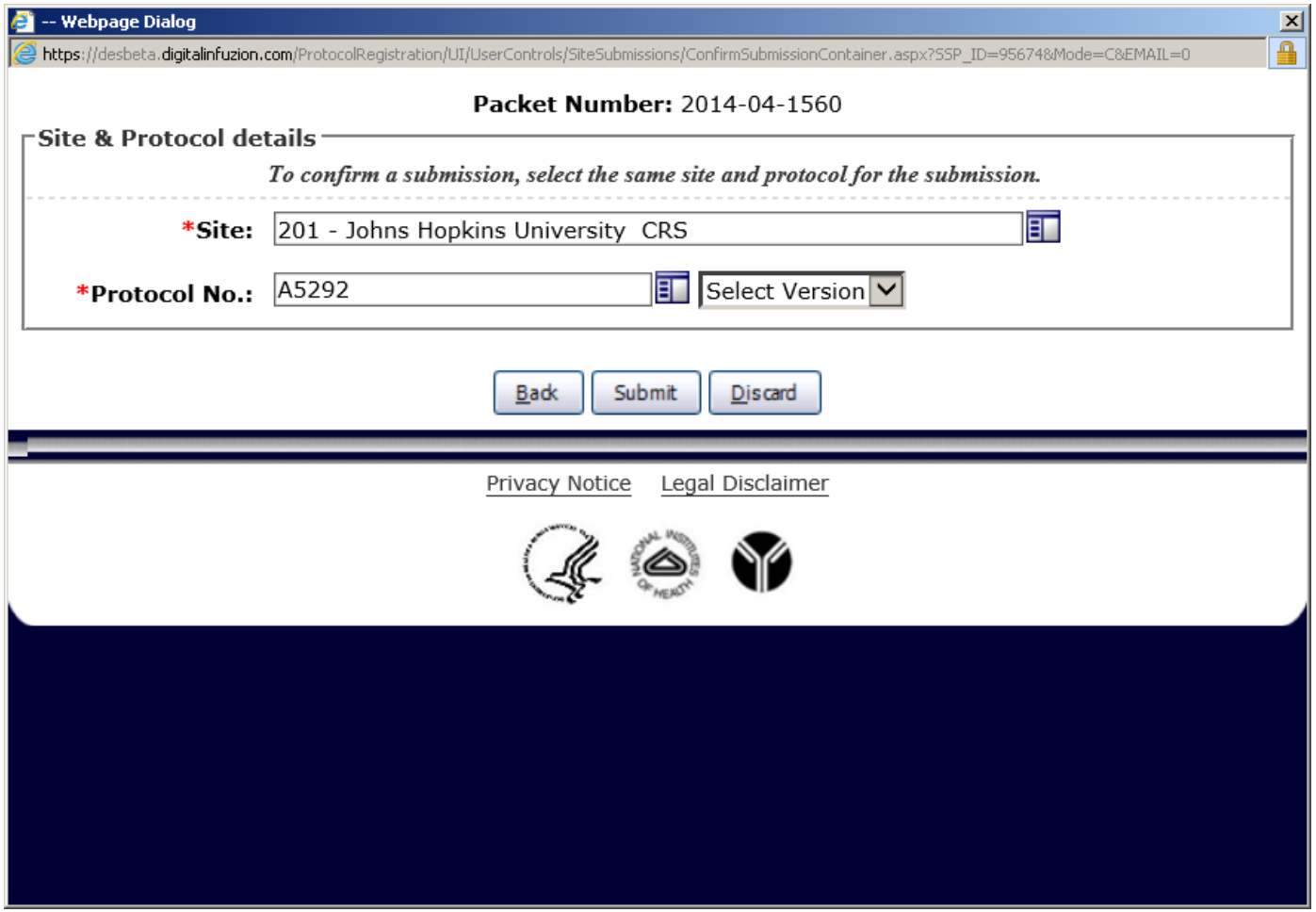

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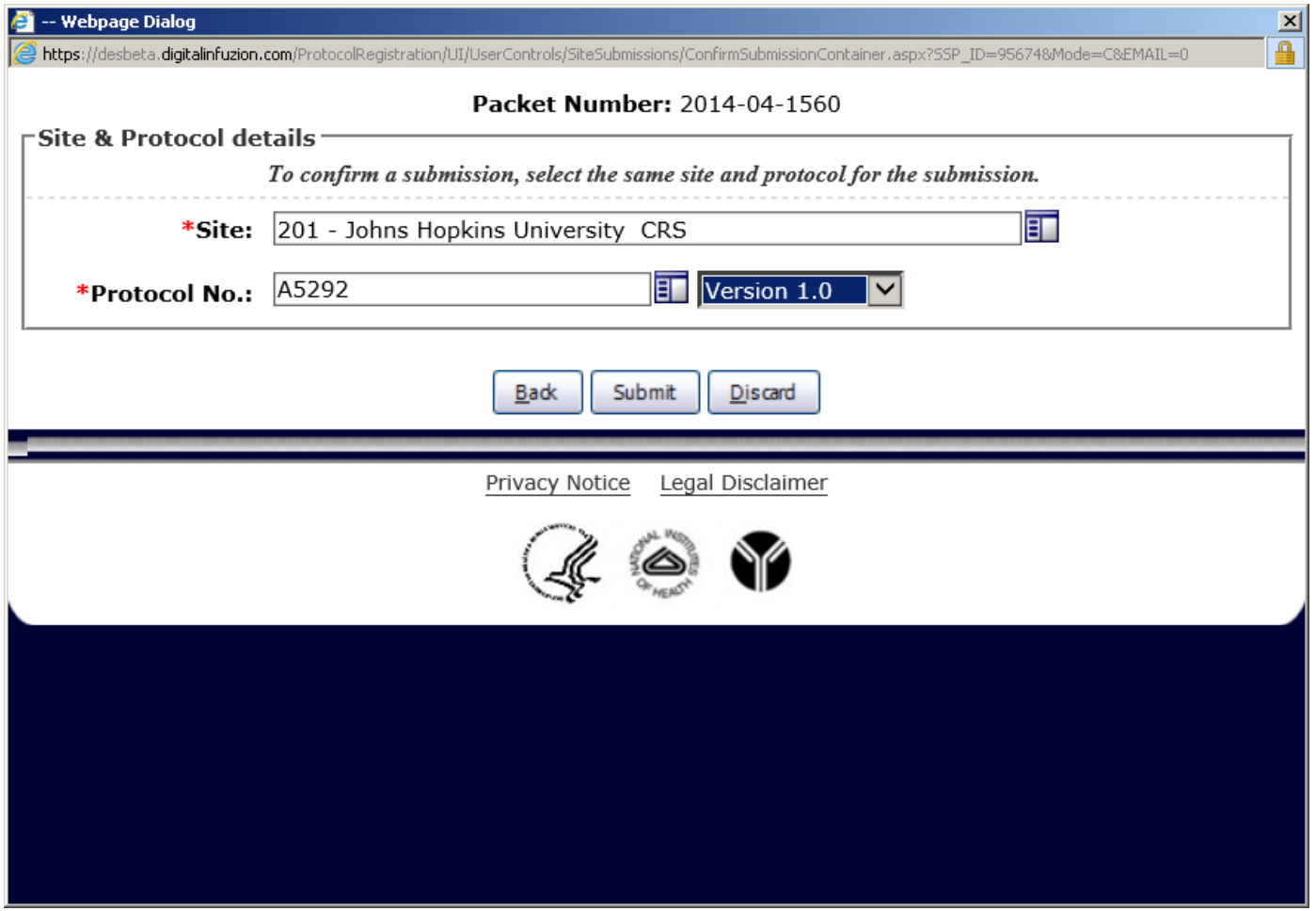

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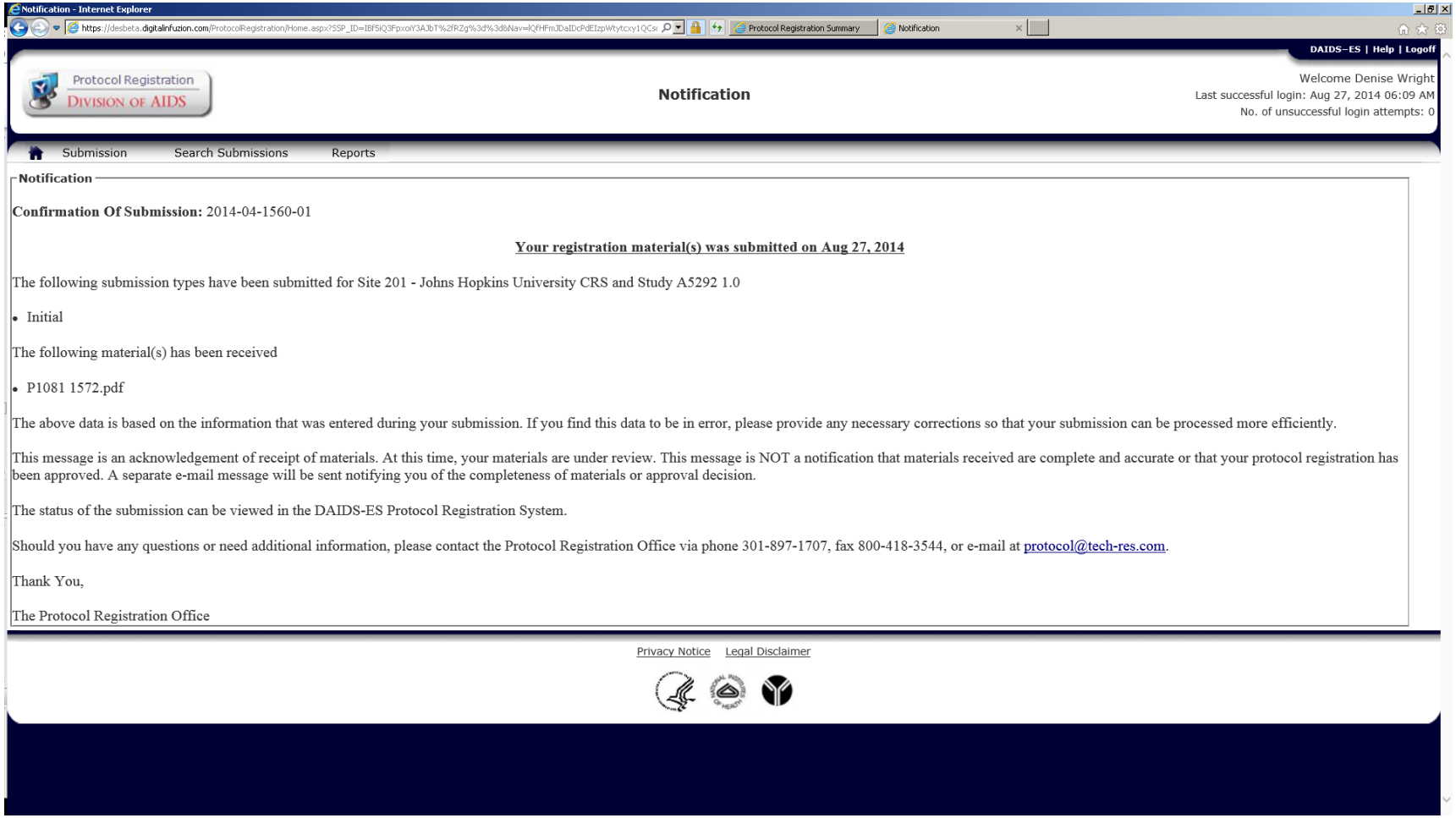

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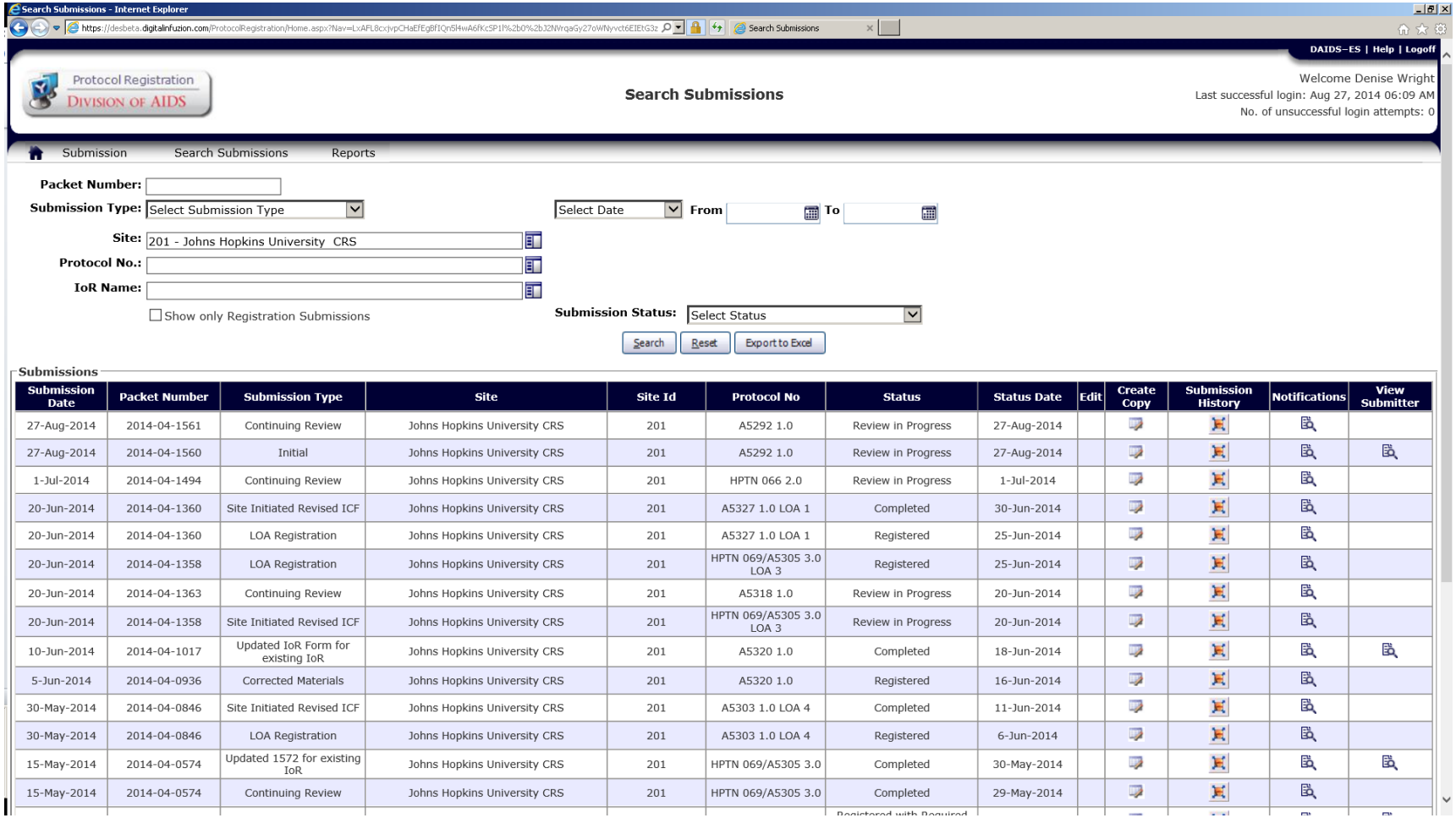

Submission Date	Packet Number	Submission Type	Site	Site Id	Protocol No	Status	Status Date	Edit	Create Copy	Submission History	Notifications	View Submitter
27-Aug-2014	2014-04-1561	Continuing Review	Johns Hopkins University CRS	201	A5292 1.0	Review in Progress	27-Aug-2014					
27-Aug-2014	2014-04-1560	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					
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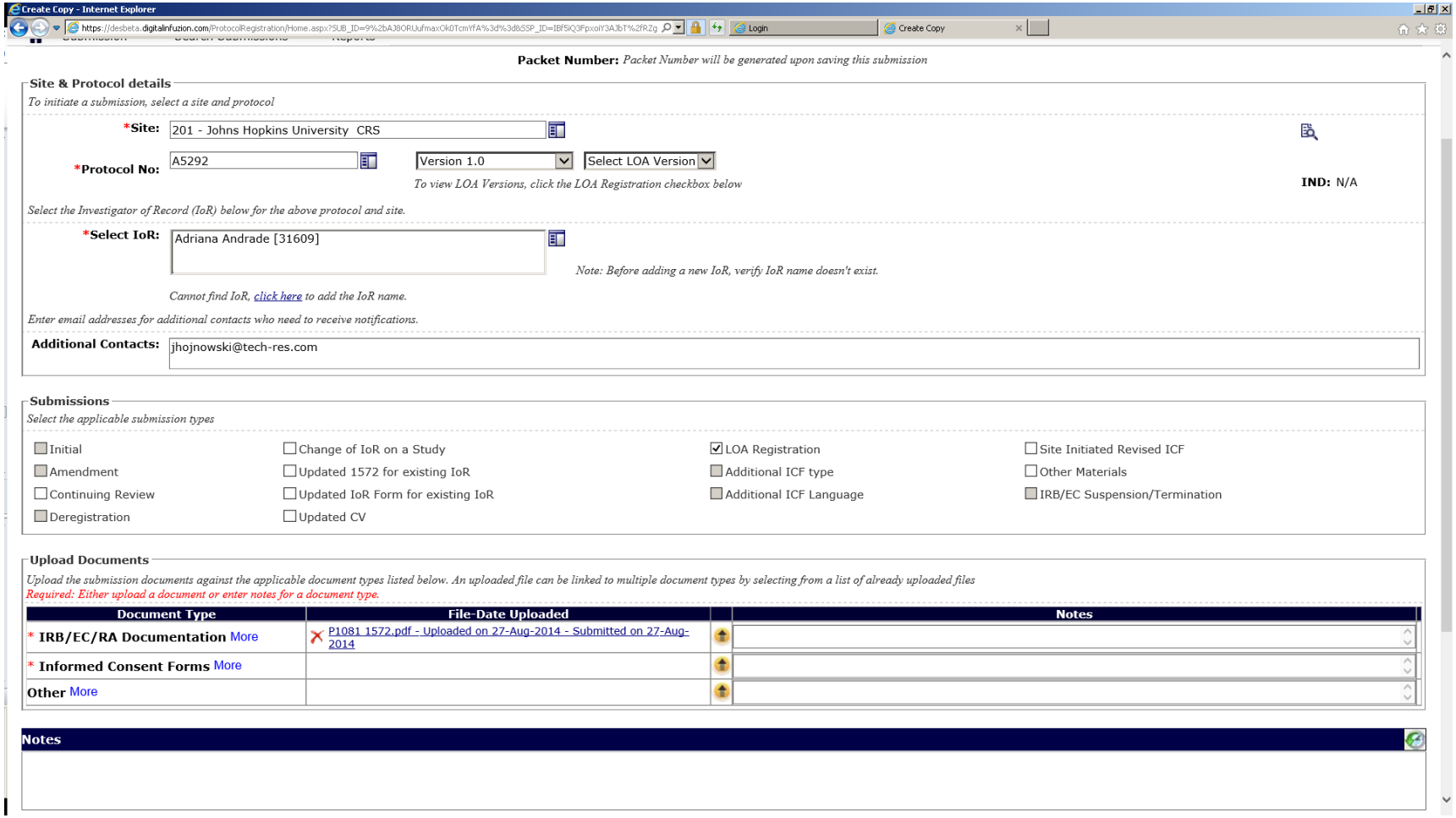

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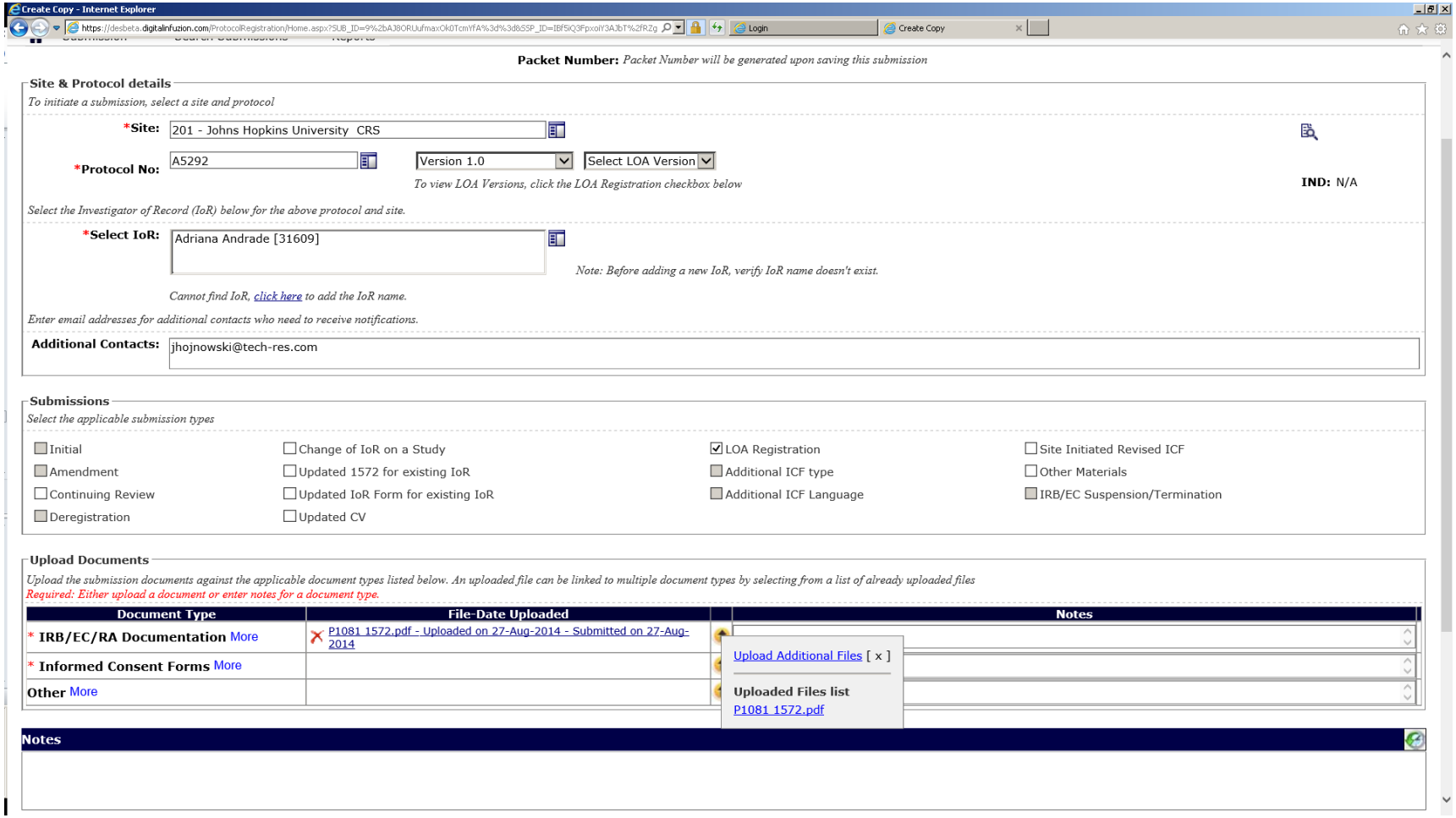

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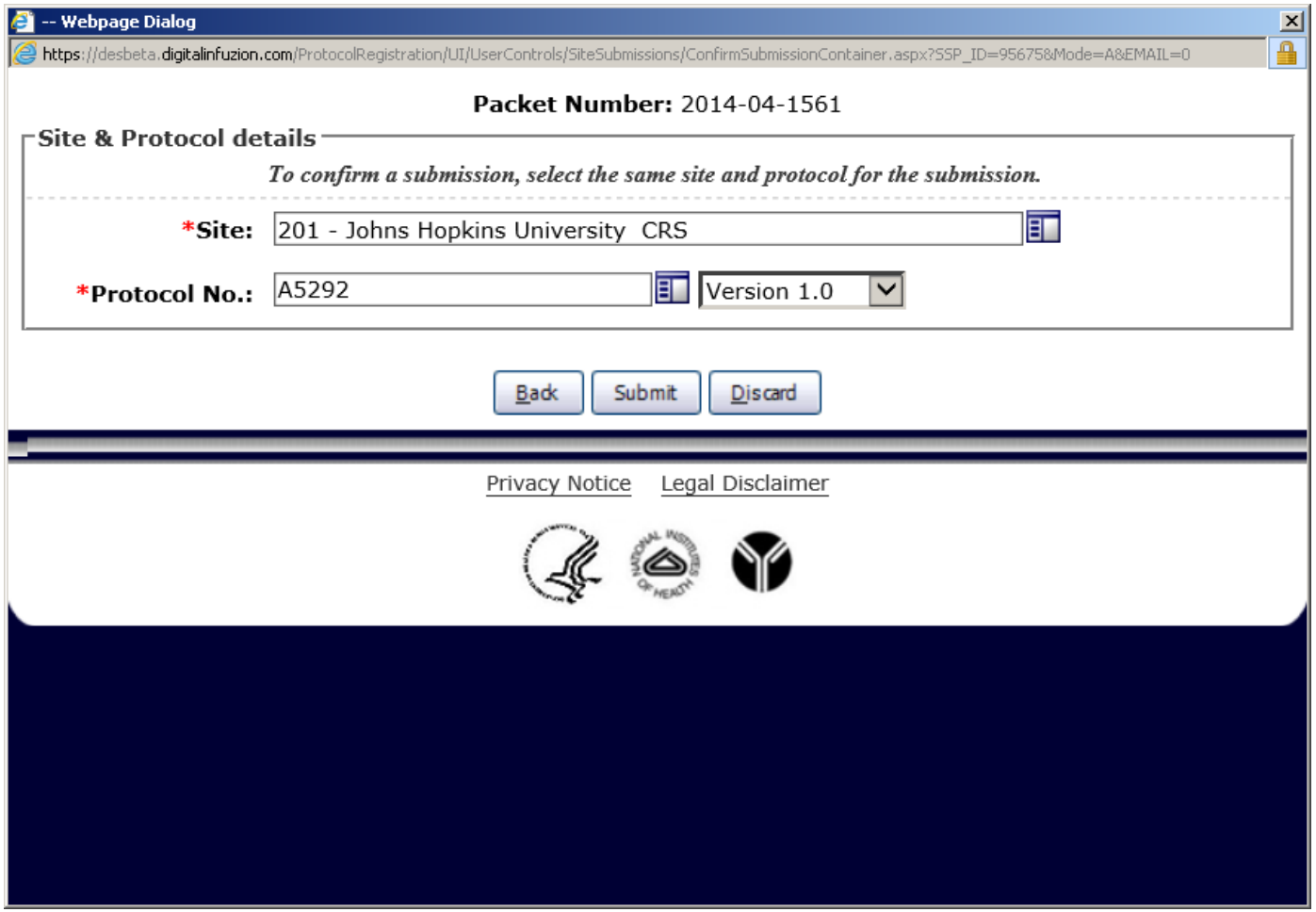

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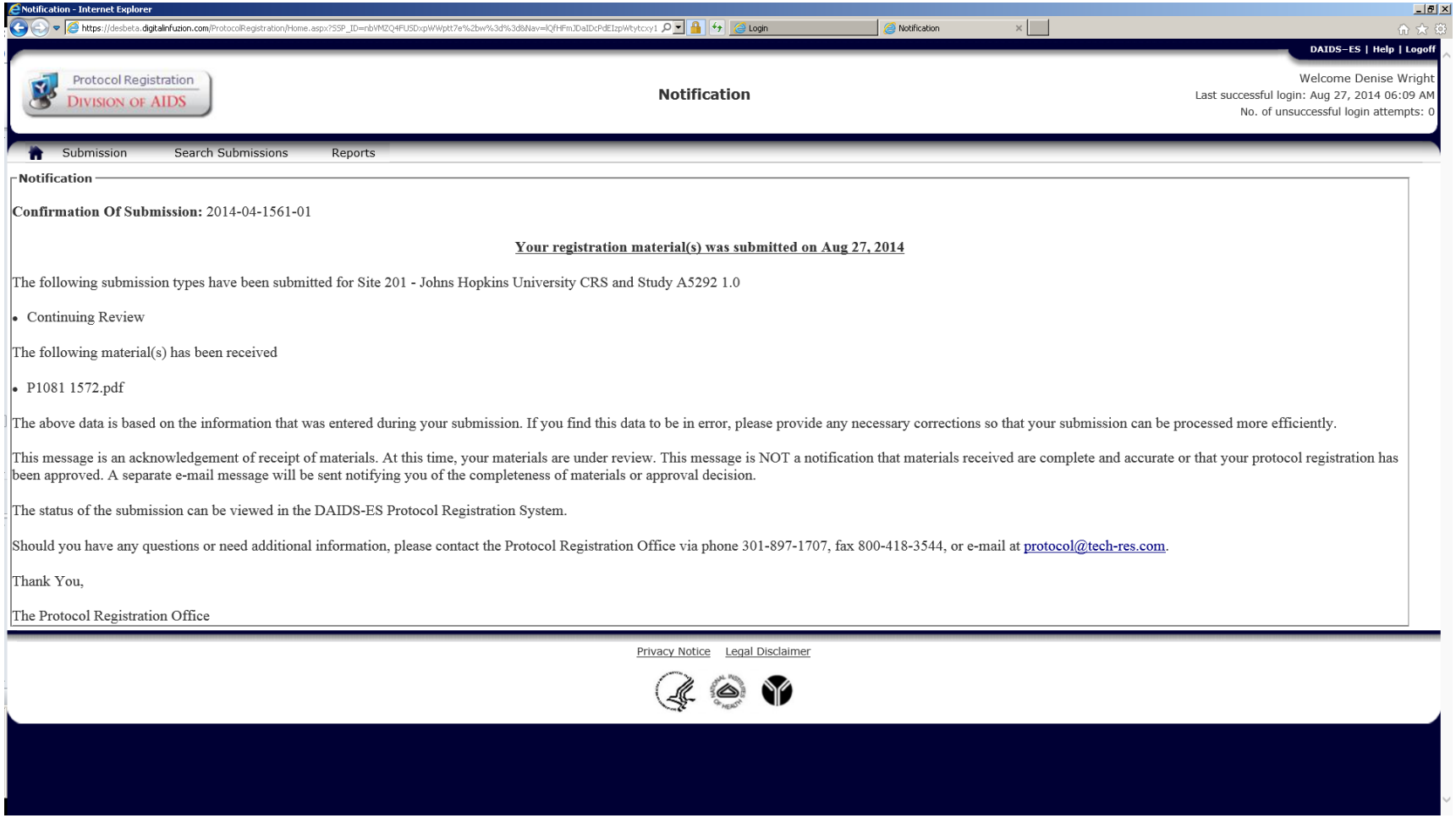
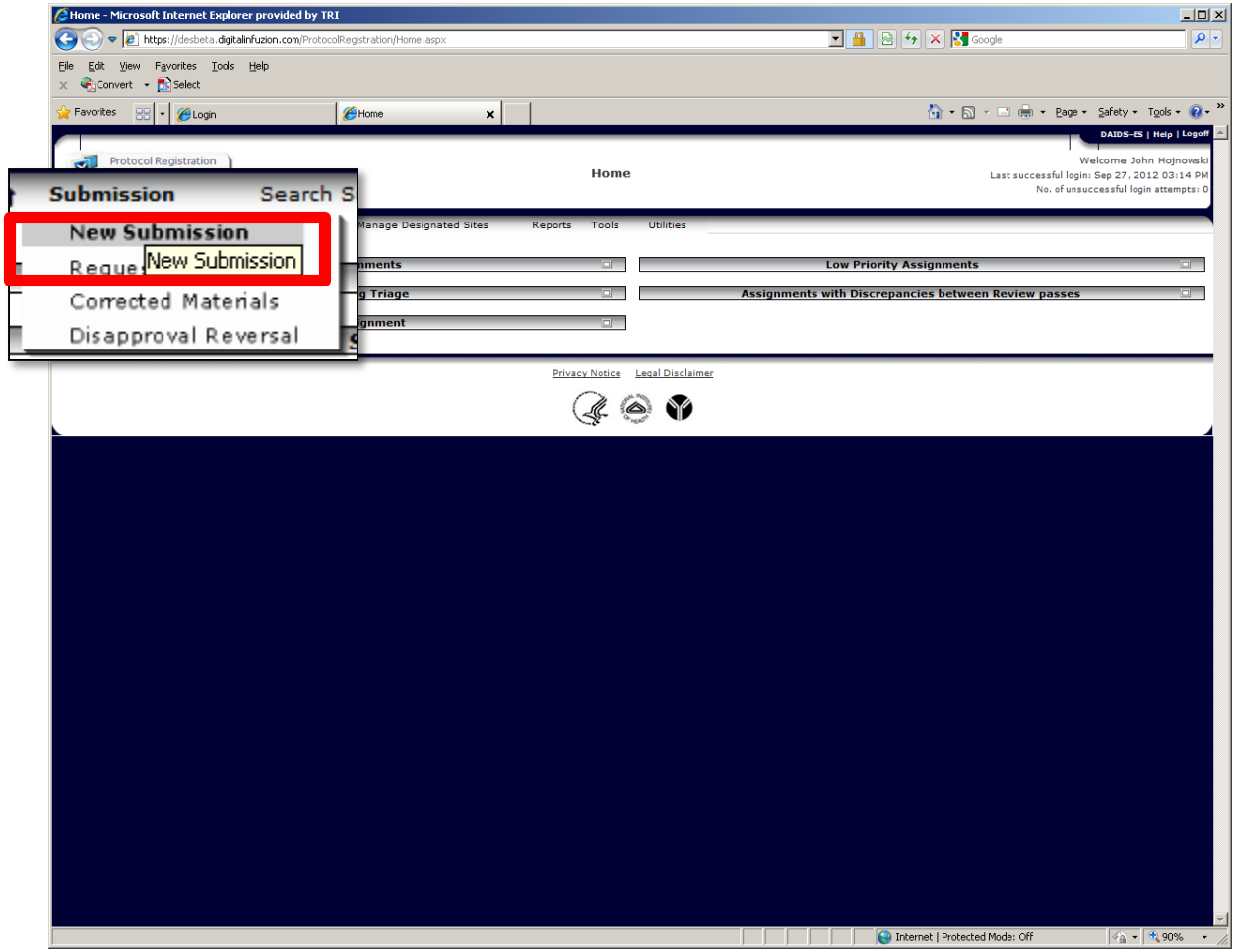


DPRS –
Creating a Multi-Purpose Submission



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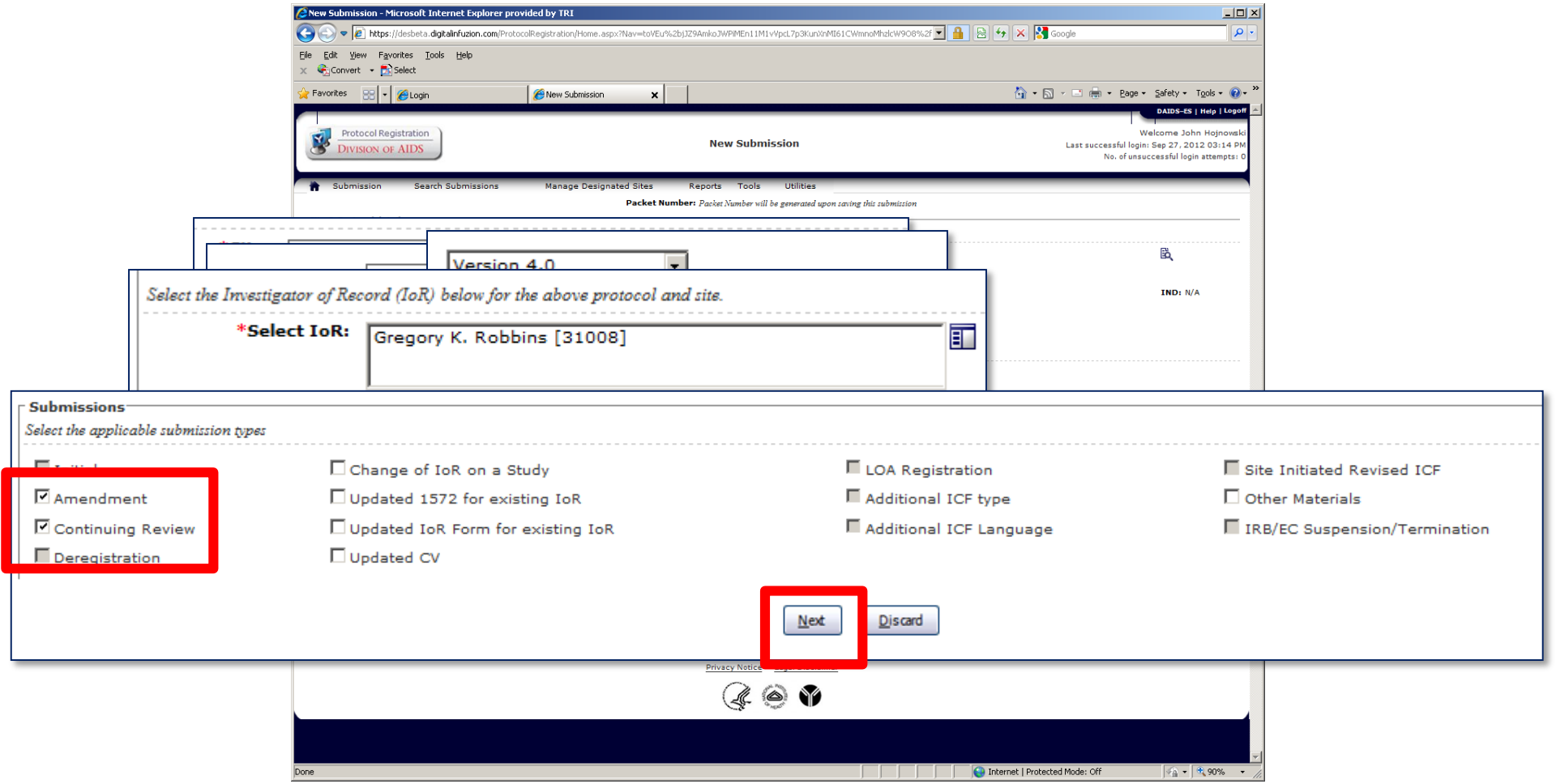

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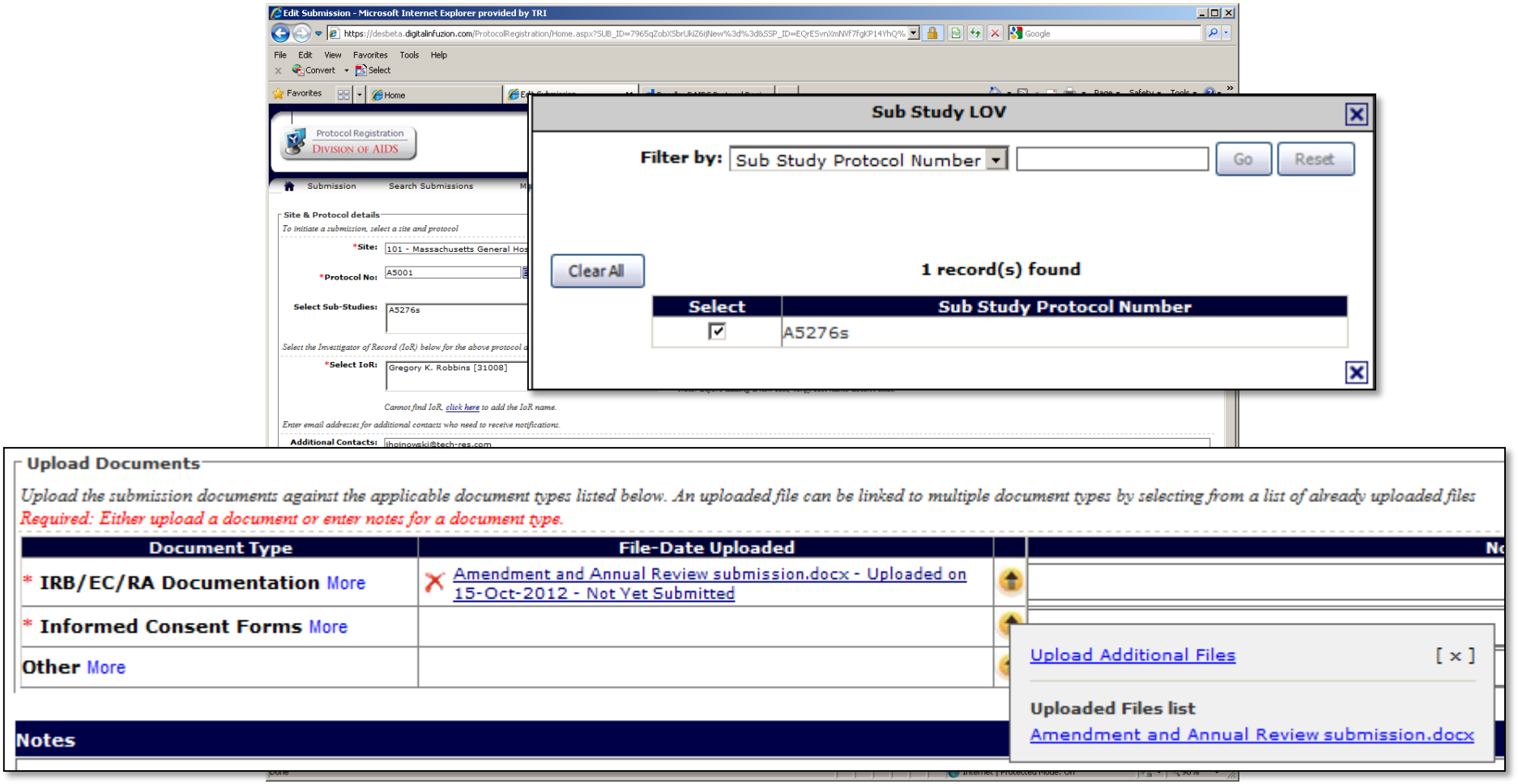

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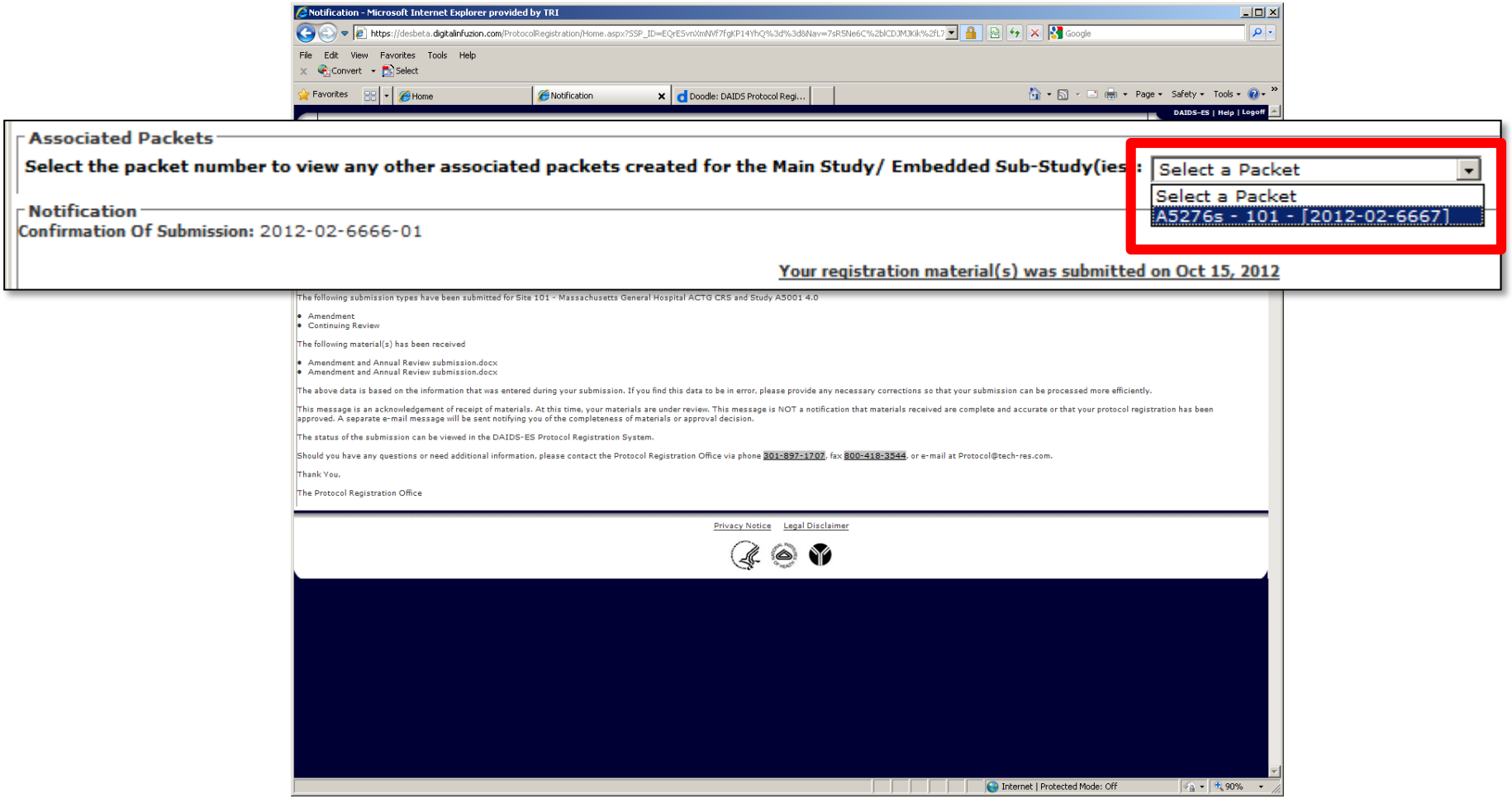
Creating a Multi-Purpose Submission



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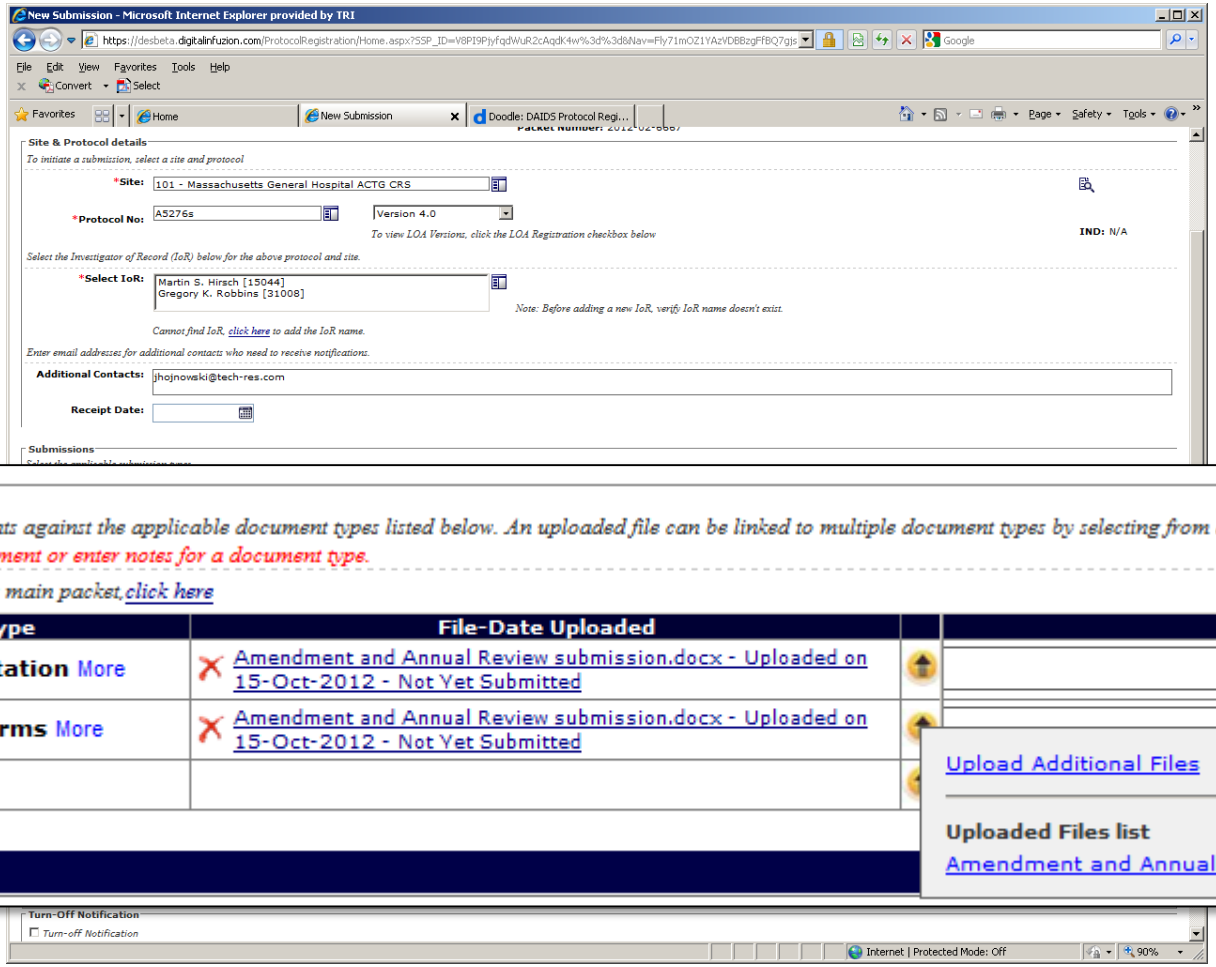

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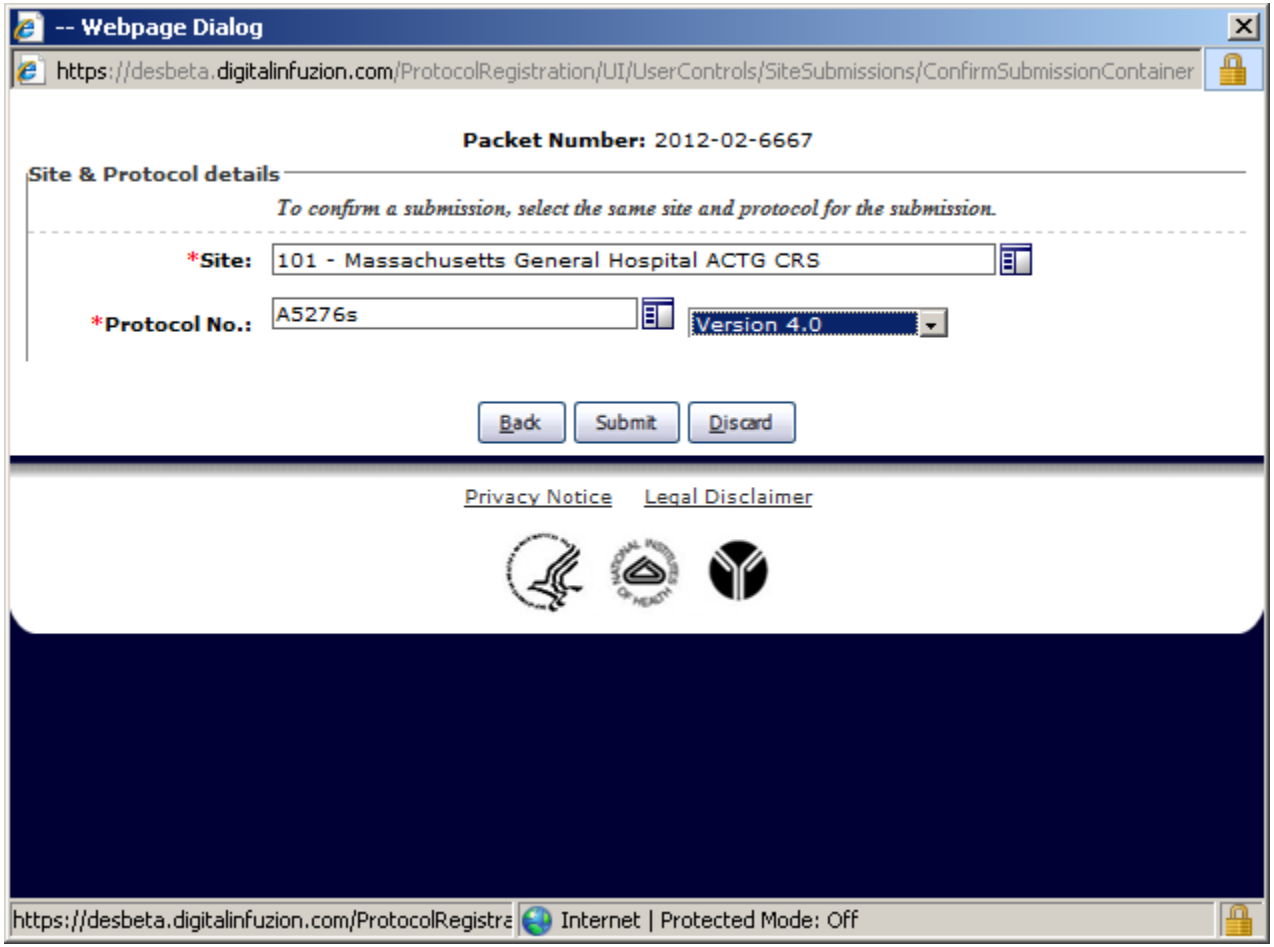
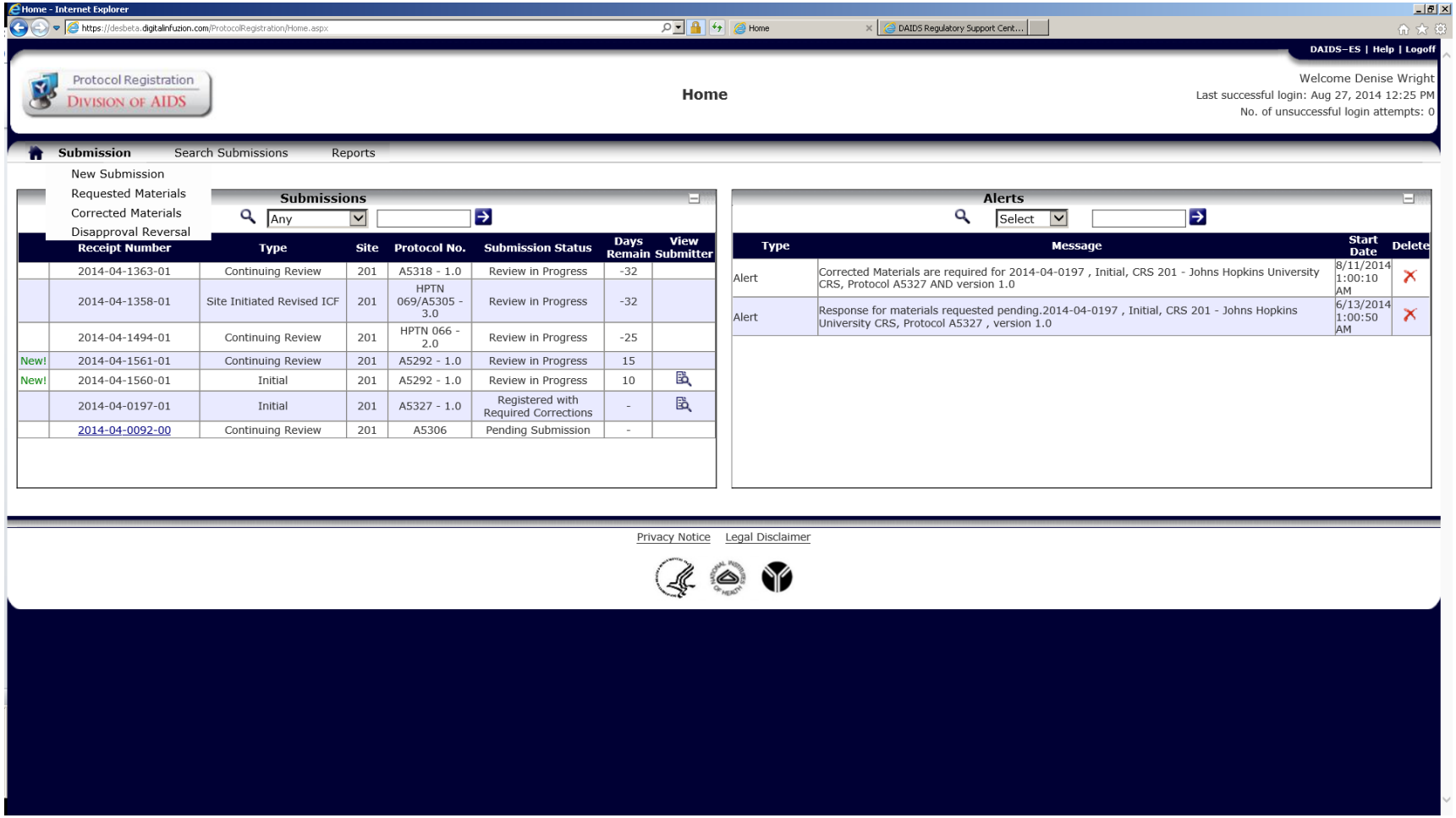


DPRS –
Requested/Corrected Material Submissions



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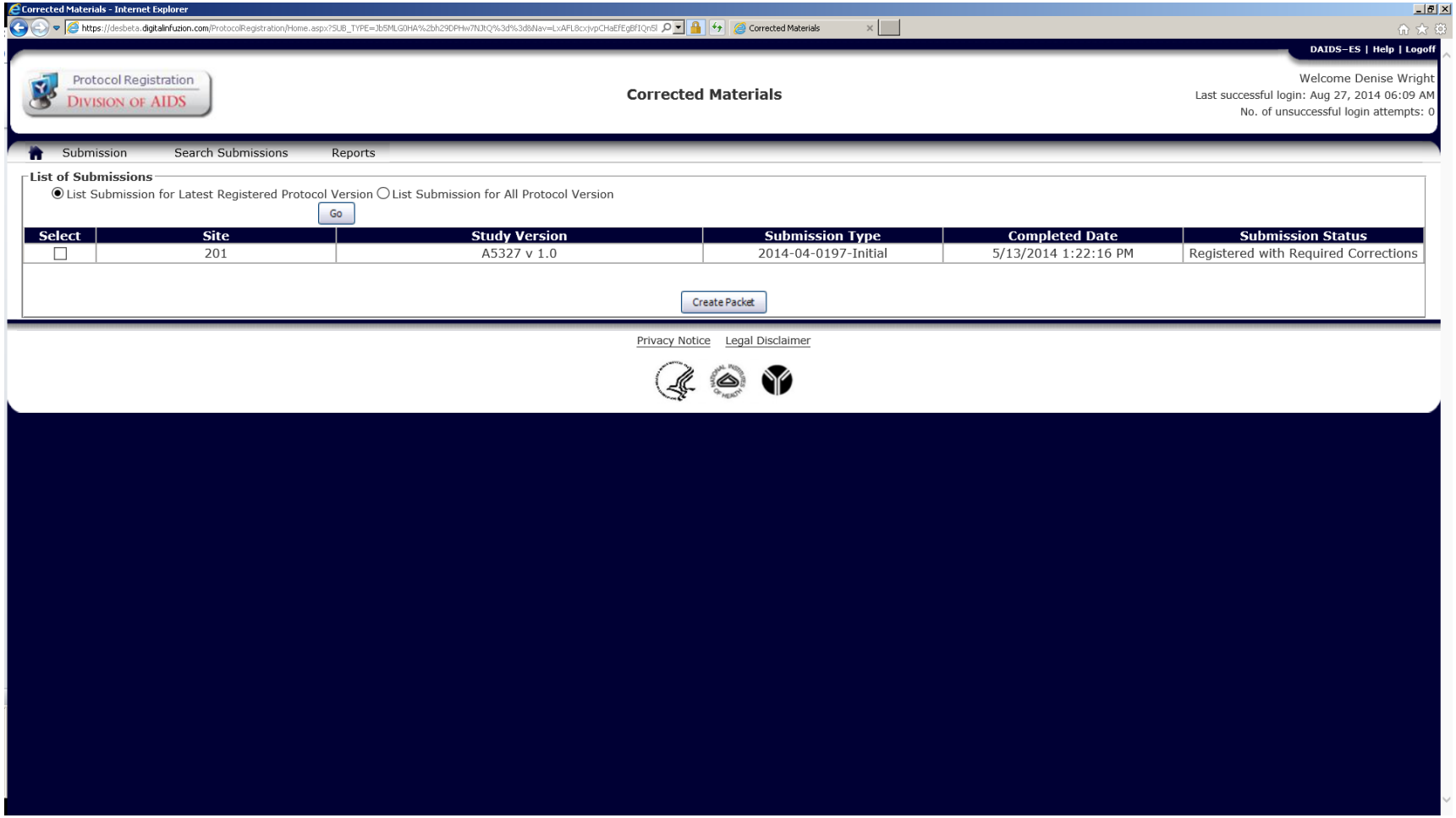
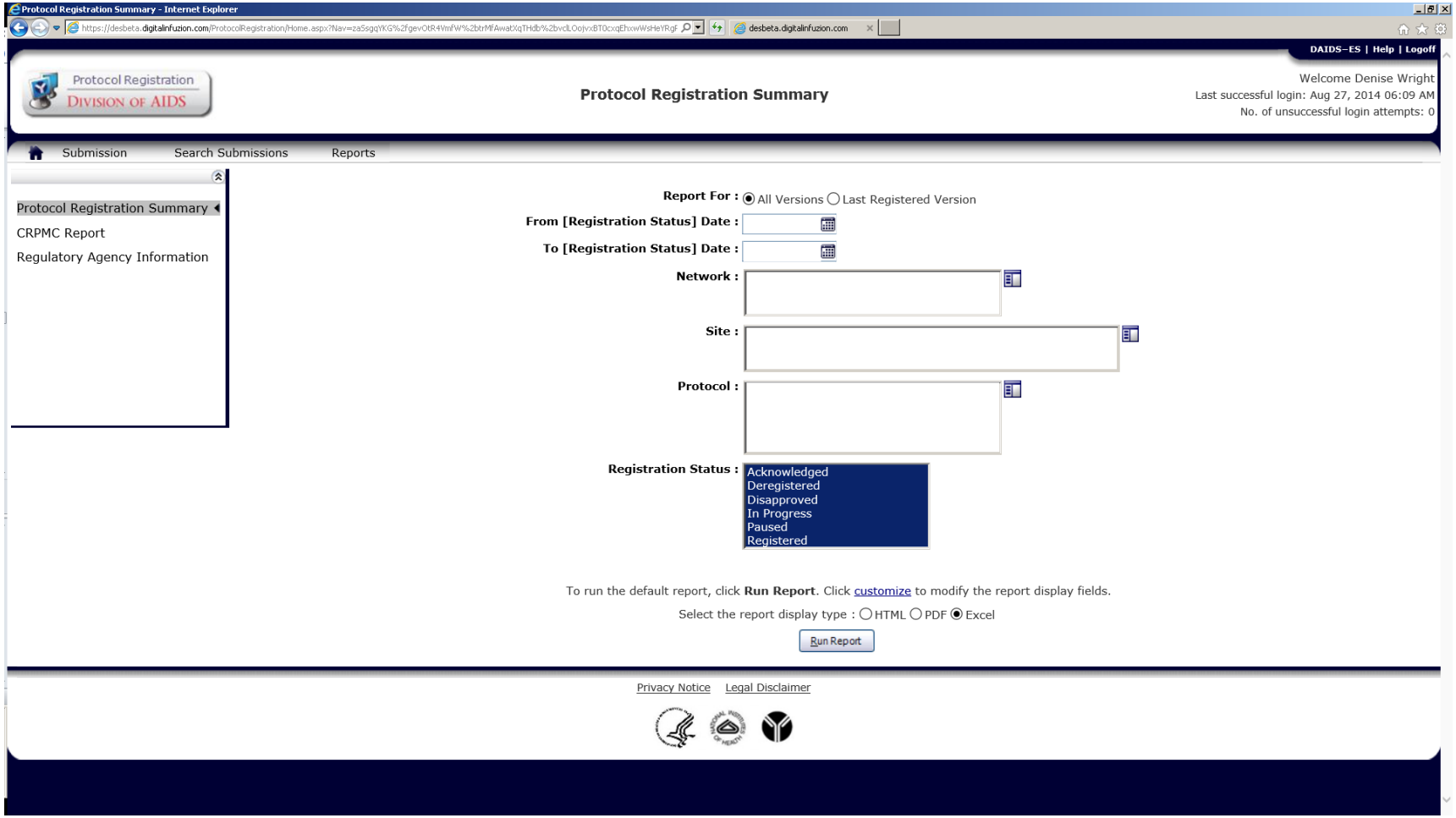
Requested/Corrected Material Submissions



DPRS

Reports

DPRS – Reports



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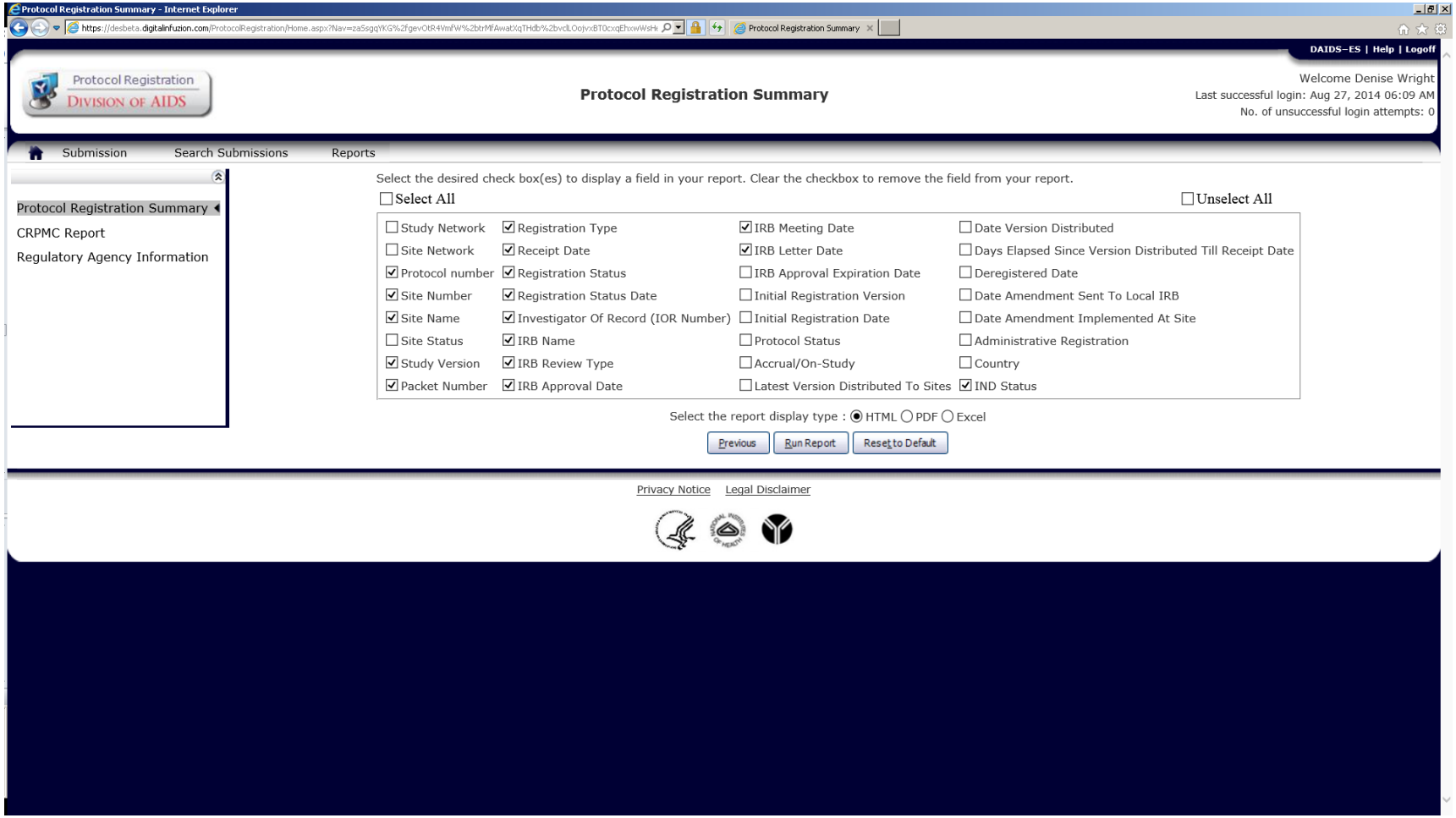

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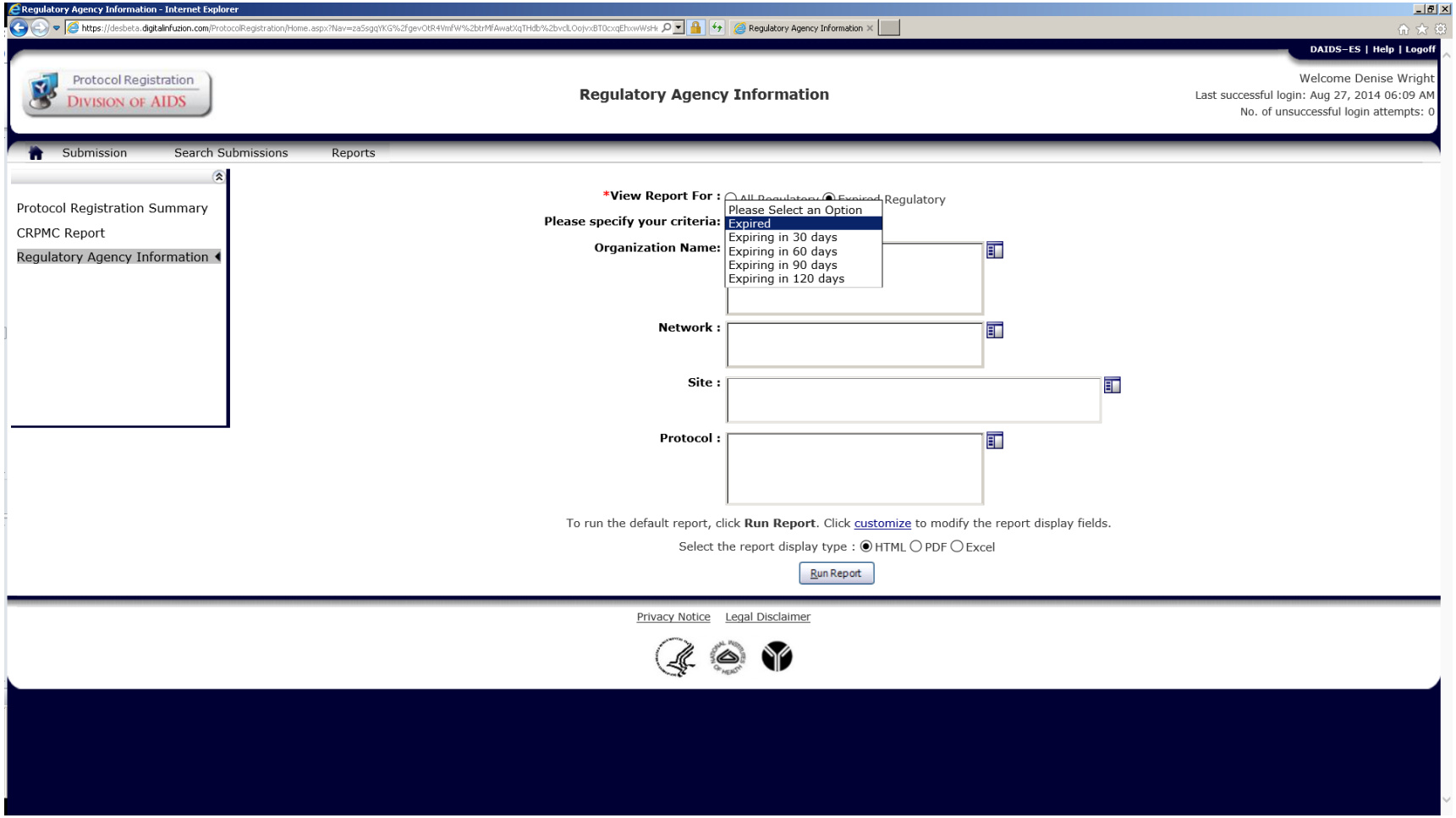


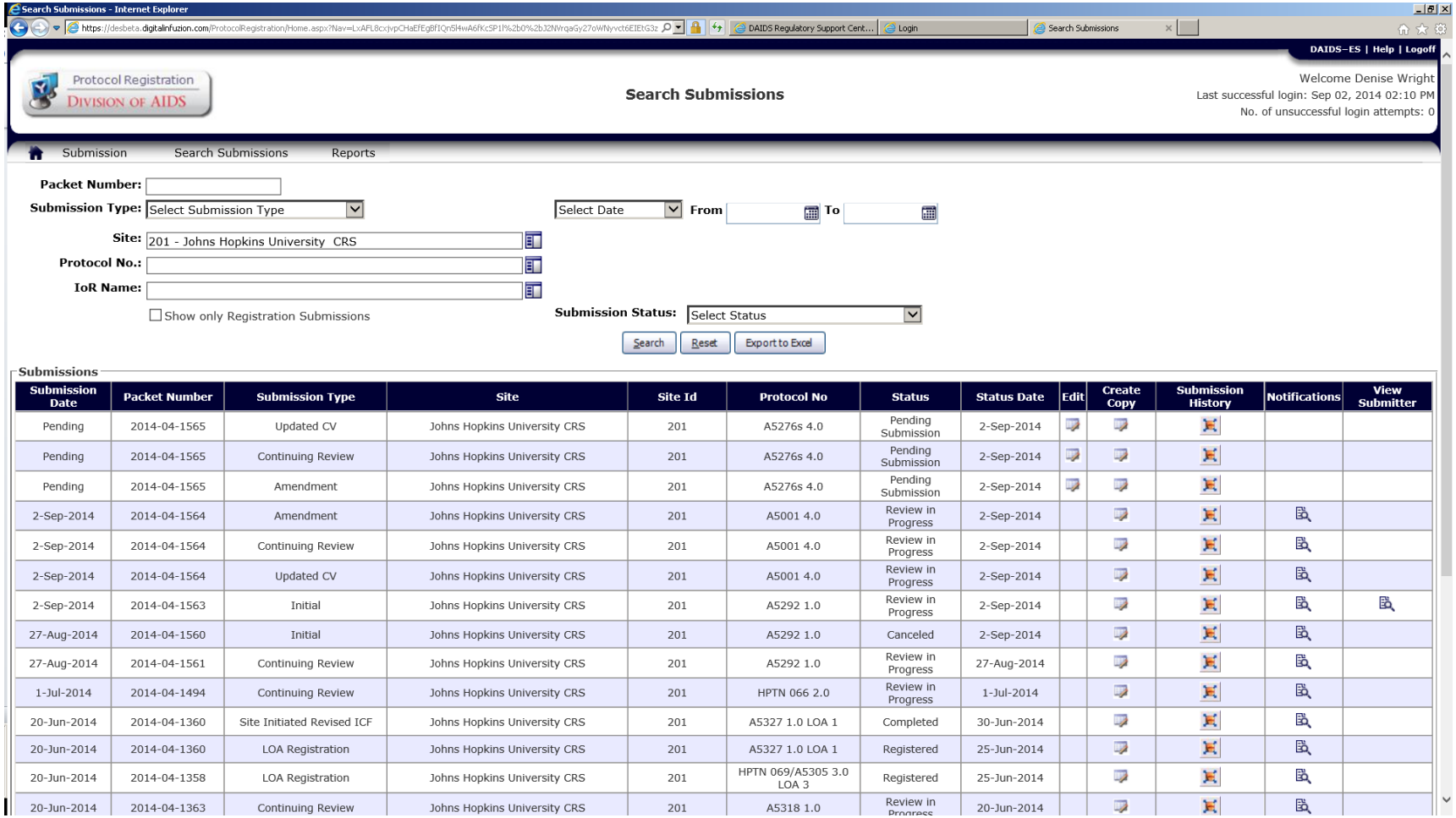
DPRS

Search

National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

DPRS – Search Submissions



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

Resources

Contacts and Important Links

Resources - Contacts

The Protocol Registration Office

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

DAIDS-ES Support

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

Important Links

Protocol Registration Manual and Policy

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

DAIDS RSC Website

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

Important Links

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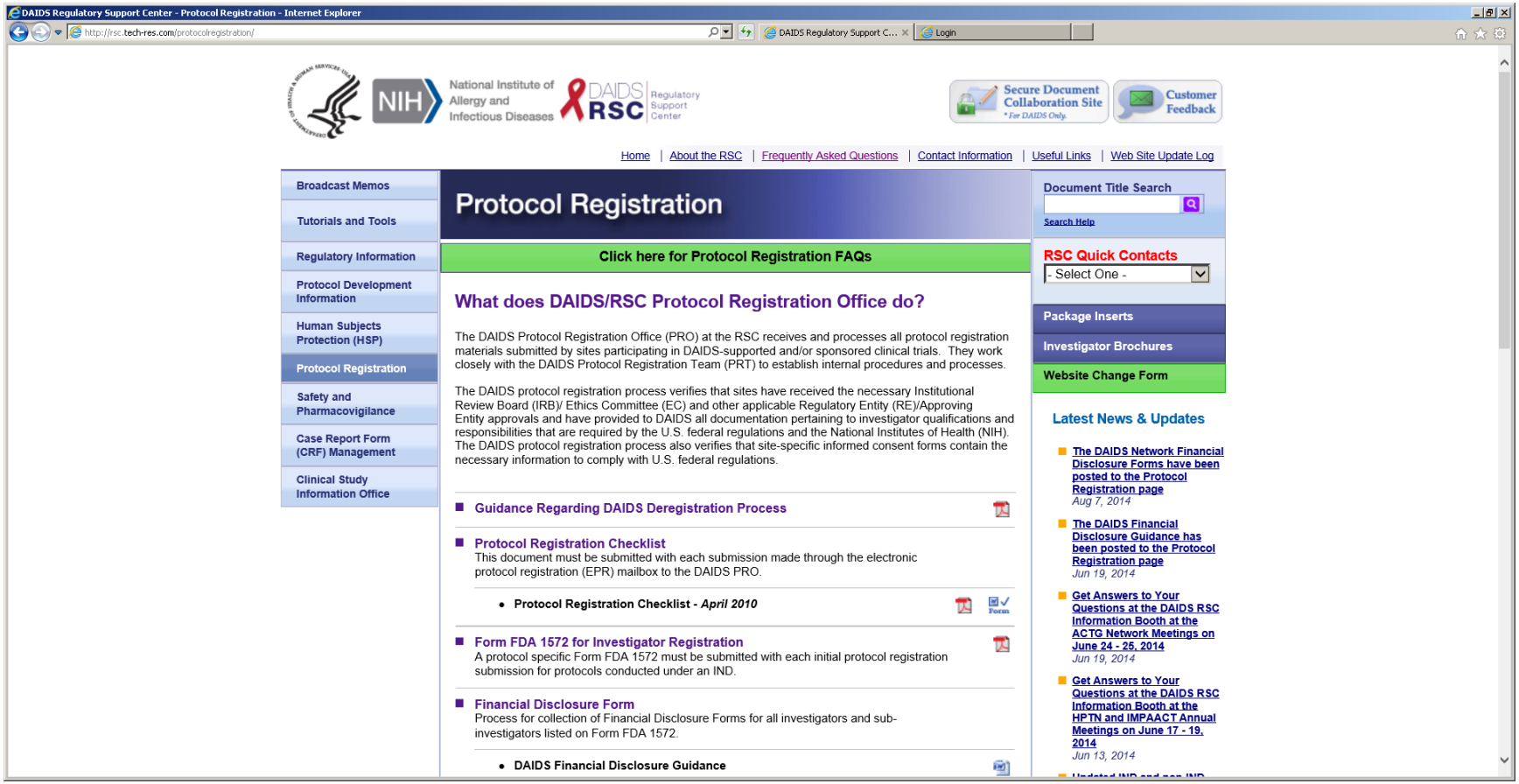
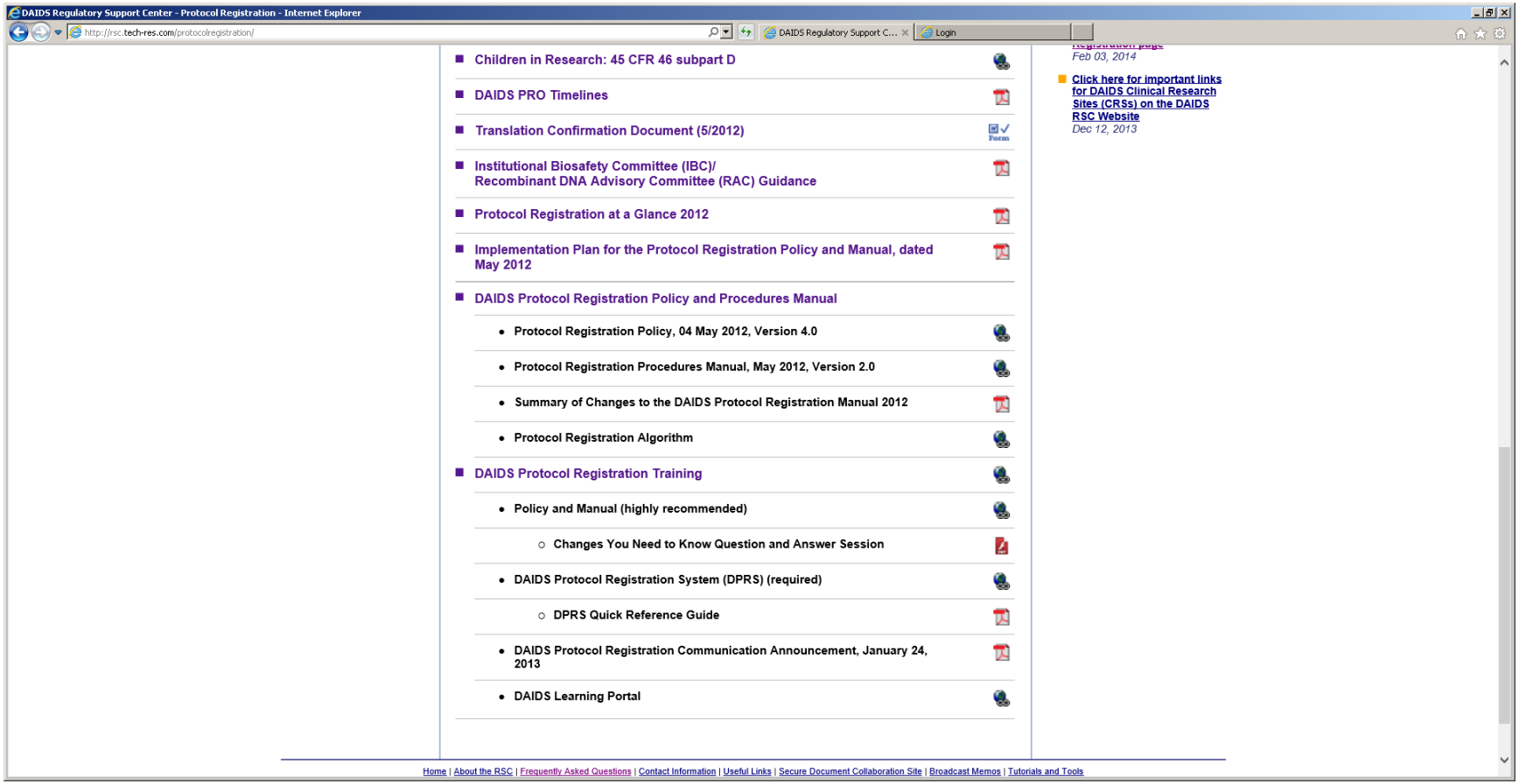


Important Links



Conclusion

- **THANK YOU**

  The DAIDS Protocol Registration Team