

UTSouthwestern

Medical Center

Human Research Protection Program

Adding UTSW Affiliates to Studies

Stephanie Francisco, CIP, Sr. Regulatory Analyst

UTSouthwestern

Medical Center

Human Research Protection Program

Who are UTSW affiliates?

Children's Health



Parkland Health & Hospital System



Texas Health Resources



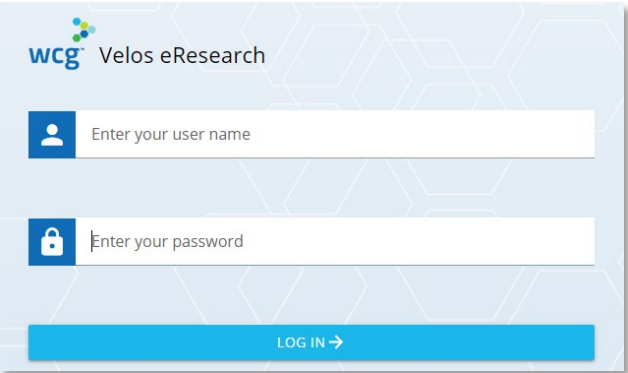
Texas Scottish Rite for Children



Adding UTSW Affiliate Sites: Velos

Log in to Velos

Log in to Velos using your single sign on username and password



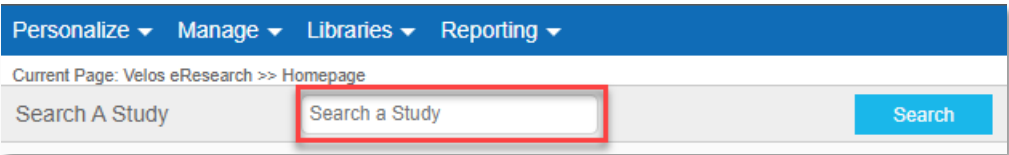
The login form for Velos eResearch features a light blue background with a hexagonal pattern. It includes the WCG logo and the text "Velos eResearch". There are two input fields: "Enter your user name" with a person icon and "Enter your password" with a lock icon. A blue "LOG IN →" button is at the bottom.

Important Info & Tips

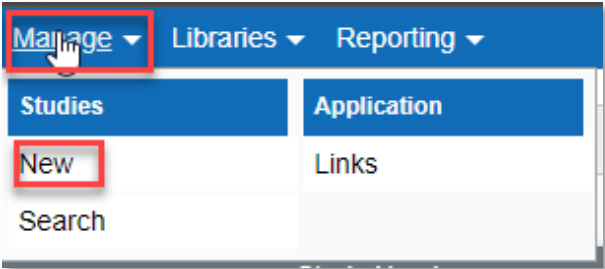
- You must enter your Username in all lowercase letters, but your password as you would normally enter it.
- The Velos default e-Signature is **1234**.
- You should allow for pop-ups from the Velos system in your internet browser.

Locate/Build Your Study

If you have already created a study in Velos, use the Velos ID number in the search field



The search bar is part of a blue navigation header. It includes a breadcrumb trail "Current Page: Velos eResearch >> Homepage". Below the header is a search section with the text "Search A Study", a text input field containing "Search a Study", and a blue "Search" button. A red box highlights the search input field.



The dropdown menu is open for the "Manage" option in the navigation header. It shows a table with two columns: "Studies" and "Application". Under "Studies", there are options for "New" (highlighted with a red box) and "Search". Under "Application", there is a "Links" option.

If you need to create a study, use the drop-down menu option “manage” and select “new.”

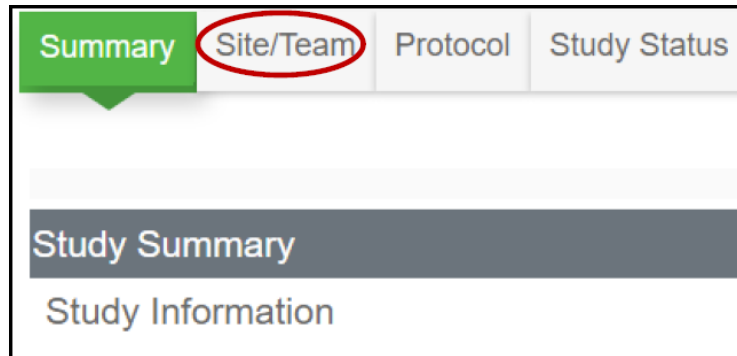
For the purposes of this presentation, we will not discuss how to set up a new study in

Velos.

Adding UTSW Affiliate Sites: Velos

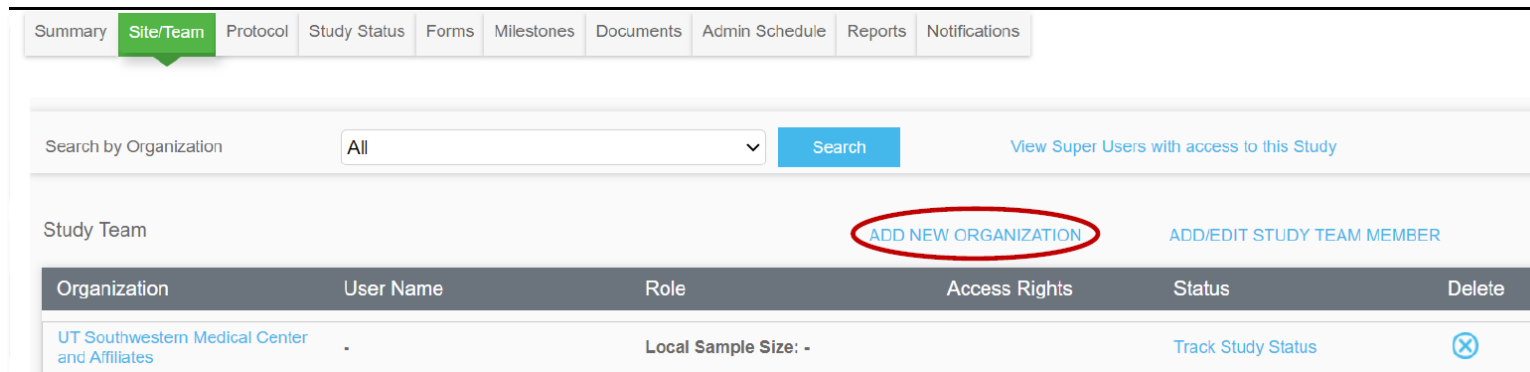
Complete the Site/Team Tab

To access the **Site/Team** tab, locate the study and then from the Summary tab, click on the **Site/Team** tab.



Add Organization or Performance Site

1. In the **Site/Team** tab, click the **Add New Organization** link



Important Info & Tips

Site/Team Tab

- Users must be on the **Site/Team** tab to access the study.
- UT Southwestern Medical Center and Affiliates should be listed (populates automatically).
- Performance sites listed in eIRB Question 5.1 will populate on the **Site/Team** tab when IRB Approval is received.
- Children's and Parkland must be listed to interface with their respective Epic system.
- You will manually add performance sites **IF**:
 - The study is cancer related (SCCC must be added).
 - Performance Site is external (will not be populated from eIRB Question 5.1).

Adding UTSW Affiliate Sites: Velos

Add Organization or Performance Site (Cont'd)

2. Select the **Organization** from the drop-down list

Add/ Edit Organization Details

Organization *

Select an option

▼

Type

Select an option

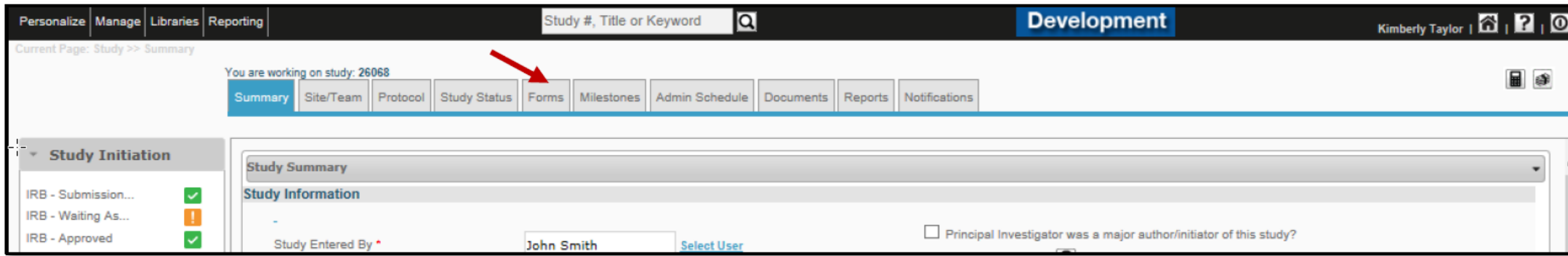
▼

Adding UTSW Affiliate Sites: Velos

Complete the Performance Site Approval Form(s) for each Applicable Site

You will need to submit Performance Site Review forms for each of the applicable sites. For example, if enrolling subjects at UTSW, Parkland, and Children's you will request performance site approvals for all sites using three different forms. **Important note:** Performance site review forms must be completed and **approved** BEFORE any research-related activities can begin at each site.

Click on the “Forms” tab



The screenshot displays the Velos system interface. At the top, there is a navigation bar with tabs: Personalize, Manage, Libraries, and Reporting. A search bar labeled 'Study #, Title or Keyword' is next to the 'Development' tab. The user 'Kimberly Taylor' is logged in. Below the navigation bar, the current page is 'Study >> Summary'. A red arrow points to the 'Forms' tab in the 'You are working on study: 26068' section. The 'Forms' tab is highlighted. On the left, under 'Study Initiation', there are three items: 'IRB - Submission...' with a green checkmark, 'IRB - Waiting As...' with a yellow warning icon, and 'IRB - Approved' with a green checkmark. The main content area shows 'Study Summary' and 'Study Information'. The 'Study Entered By' field is populated with 'John Smith' and a 'Select User' link. A checkbox for 'Principal Investigator was a major author/initiator of this study?' is also visible.

Adding UTSW Affiliate Sites: UTSW

UTSW Site

1. When UTSW is selected as a Performance Site in eIRB and the eIRB is in a “Waiting Assignment” state, Velos will send a reminder notification to the study author, PI, and Primary Research Coordinator every Monday and Thursday to complete the UTSW Performance Site Review Form. The email reminder will stop once the UTSW Performance Site Review Form status is set to “completed.”
2. Select the “**UTSW Performance Site Review Form**” in the “**Form Name**” field and click on the “**Go**” button.

The screenshot shows the Velos eIRB interface. At the top, there is a navigation bar with tabs: Summary, Site/Team, Protocol, Study Status, Forms, Milestones, Admin Schedule, Documents, Reports, and Notifications. The 'Forms' tab is highlighted with a red circle. Below the navigation bar, there is a section titled 'Jump to Form' with a dropdown menu. The dropdown menu is open, showing the option 'UTSW Performance Site Review Form' selected, which is also circled in red. To the right of the dropdown menu is a 'Go' button, also circled in red. Below the dropdown menu, there is a text field labeled 'Open Form Name:' with the value 'UTSW Performance Site Review Form' entered.

Adding UTSW Affiliate Sites: UTSW

3. The **UTSW Performance Site Review Form** will open. Complete the fields as they apply to your study at the performance site.
4. Once the questions have been answered from the form, you will need to confirm that the information in the form is complete and correct.
5. Change the form status to **Completed**
6. Enter your **e-signature** and click on **Submit** to save the form.
7. After a few minutes Velos will automatically add the **Performance Site-Submitted** status under the **UTSW** site.
8. The **Office of Clinical Trial Management** (OCTM) team will review the **UTSW Performance Site Review Form** and add the respective Ancillary-Submitted status.
9. Upon receiving the approval statuses from all the requested ancillaries, **OCTM** will add the final **Performance Site – Approved** status in Velos under the site **UTSW**.

Adding UTSW Affiliate Sites: UTSW

AIRC Site

NOTE: If the AIRC Checkbox is checked anywhere on the UTSW Performance Site Form status and the UTSW Performance Site Review Form has the Form status as “Completed”, Velos will send an email reminder notification to the Study Author, PI and the Primary Research Coordinator every Monday and Thursday until the form **AIRC Application for Research – Human Subjects** is submitted and has a “Completed” form status.

The screenshot shows a navigation bar with tabs: Summary, Site/Team, Protocol, Study Status, Forms (selected), Milestones, Admin Schedule, Documents, Reports, and Notifications. Below the tabs is a search bar with the text "Jump to Form: AIRC Application for Research - Human Subjects" and a "Go" button. A red circle highlights the search text, and a red arrow points to the "Go" button. Another red arrow points to the "Forms" tab.

Important Note

Note: Do not add the Performance Site - Submitted status separately under any of the below sites as the UTSW site encompasses all of the below sites:

1. UTSW - Advance Imaging Research Center (AIRC)
2. UTSW - Ambulatory Services
3. UTSW - CTRC Inpatient (CRU)
4. UTSW - CTRC Outpatient (CRU)
5. UTSW - University Hospitals (Zale and Clements)
6. UTSW - Other

The study team should complete the **AIRC Application for Research – Human Subjects** Form and add the status **UTSW Ancillary – AIRC – Submitted** under the **UTSW – Advance Imaging Research Center (AIRC)**. This status will send an email notification to the AIRC approvers for approval.

Adding UTSW Affiliate Sites: Children's Medical Center (CMC)

Children's Medical Center (CMC) Site

The CMC site requires you to complete the **Children's Health Performance Site Approval Application** BEFORE any research-related activities can begin at this site.

1. Complete the CMC REDCap form to start the performance site approval process:

Link: redcap.childrens.com/redcap/surveys/?s=W7KLMXLTXTAHDFMW

2. The **Performance Site Review Form** will open. Complete the fields as they apply to your study at the performance site.

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)

Parkland Health and Hospital System (PHHS) Site

The PHHS site requires you to complete the REDCap Performance Site Review Form BEFORE any research-related activities can begin at this site.

Link: <https://rc.phhs.org/redcap/surveys/?s=TRR7XXMRAX>

In UTSW Velos, click the **REDCap link** to access and complete the form

The screenshot shows the UTSW Velos interface for the 'Performance Site Review Form'. A red box highlights the 'Administrative Information' section, which contains a note about the form's effective date and a 'CLICK HERE' link. A red arrow points from the text 'In UTSW Velos, click the REDCap link' to the 'CLICK HERE' link. Below the red box, the form fields are visible, including 'Data Entry Date' (03/22/2019), 'Principal Investigator', 'Primary Administrative Contact', 'Primary Research Coordinator', 'Research Participants', and 'Services/Locations'. The REDCap logo is also visible in the bottom right corner of the form area.


REDCap: Secure web platform
<https://rc.phhs.org/redcap/surveys/?s=TRR7XXMRAX>

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)

The screenshot shows a web browser window with the URL `rc.phhs.org/redcap/surveys/?s=TRR7XXMRAX`. The browser's address bar and tabs are visible at the top. The main content area displays the Parkland logo and the title "Parkland Performance Site Review Form". Below the title, a paragraph states that the Parkland Office of Research Administration (ORA) will begin review of the study once all requirements are completed. A list of three requirements follows: 1) Final Institutional Review Board (IRB) approval, 2) Clinical Trial Coverage Analysis (CTCA) approval by the Principal Investigator (PI) or a waiver, and 3) Completion and receipt of the PSR Form. A note specifies that study activities may not begin until written site approval is received. Contact information for the Parkland ORA is provided. An attachment link for "PSR Form Instructions.docx" is shown. A section titled "Instructions for completing this form." contains a thank-you message and a list of requirements for the form, including completion, thorough answers, and awareness of the consequences of incomplete submissions. At the bottom, a legend indicates that red asterisks denote required values, and two radio buttons are provided for the user to indicate their understanding and agreement.

rc.phhs.org/redcap/surveys/?s=TRR7XXMRAX

Apps REDCap eIRB eIRB Research Administr... Velos eResearch : U... Velos PHHS Parkland ORA Refor... 20" X 60" Cubicle P... Cubicle Wall & Pan... LUX DIVWT Reclaim... Reading list

 **Parkland**

Parkland Performance Site Review Form

The Parkland Office of Research Administration (ORA) will begin review of your study once ALL the following is completed:

- 1) Final Institutional Review Board (IRB) approval.
- 2) Clinical Trial Coverage Analysis (CTCA) is approved by Principal Investigator (PI), or a waiver is issued for the CTCA.
- 3) Performance Site Review (PSR) Form is completed and received.

*PLEASE NOTE: Study activities MAY NOT begin until after you receive written site approval from Parkland ORA.

For questions, please contact Parkland ORA at 214-590-1170 or ParklandSiteResApp@phhs.org.

Instructions for completing this form.

Attachment: [PSR Form Instructions.docx](#) (0.02 MB)

Thank you for choosing Parkland as a study performance site. The Performance Site Review (PSR) form is designed to provide study operational, fiscal and regulatory information to Parkland departments and leadership for approval.

The Parkland Office of Research Administration (ORA) is committed to ensuring feasibility of your study and patient safety; therefore, to facilitate the timely approval of your study the following requirements are crucial.

- Completion of this form in its entirety.
- Answer each question thoroughly.
- Provide as much detail as possible.
- Please be aware an incomplete form submission will result in delaying your study approval because the PSR form may be returned to you for further information.

* must provide value

☐ I understand and agree ☐ I disagree

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)


resources or other support: ☐ No reset

17.0 Final Confirmation

17.1 Prior to submission, you attest that the information on this form is complete and accurate to the best of your knowledge. By submitting the Parkland PSR form, you acknowledge that research fees per the Parkland Research Fee Schedule may apply to this study. Please note that this form is not submitted until you receive an email confirmation.
* must provide value

☐ Yes
☐ No reset


Parkland Research Fee Schedule.

Attachment:  [2020 Parkland Research Fee Schedule.pdf](#) (0.11 MB)

17.2 Printed Name of Person Completing Form
First Name:
Last Name:

17.3 Signature of Person Completing Form: _____
* must provide value
[Add signature](#)

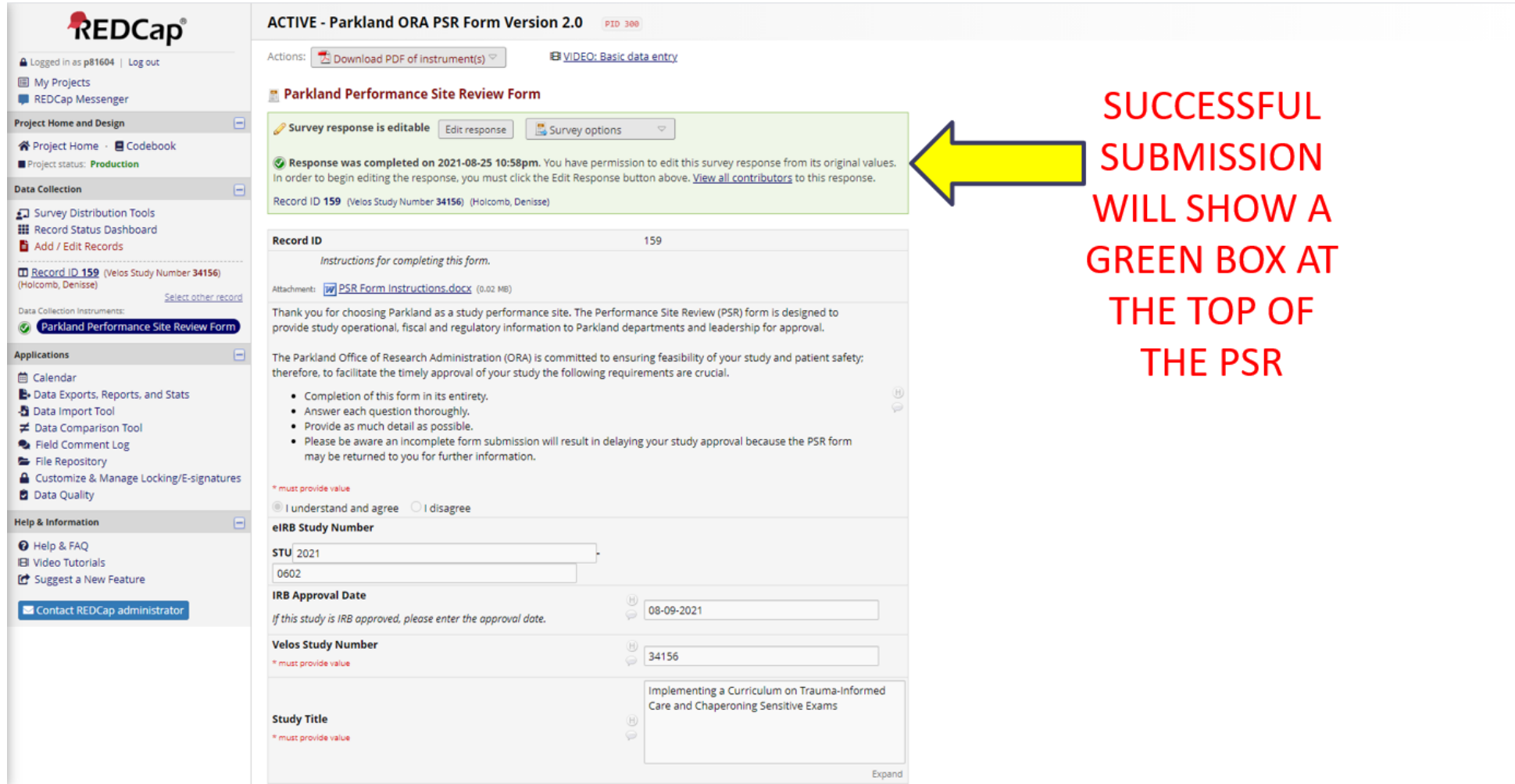
17.4 Contact Email
* must provide value

17.5 Date Form Completed
* must provide value  Today M-D-Y

Submit Save & Return Later

***YOU MUST SUBMIT for Parkland to receive the PSR**

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)



REDCap

Logged in as p81604 | Log out

My Projects

REDCap Messenger

Project Home and Design

Project Home · Codebook

Project status: **Production**

Data Collection

Survey Distribution Tools

Record Status Dashboard

Add / Edit Records

Record ID 159 (Velos Study Number 34156) (Holcomb, Denisse)

Select other record

Data Collection Instruments:

Parkland Performance Site Review Form

Applications

Calendar

Data Exports, Reports, and Stats

Data Import Tool

Data Comparison Tool

Field Comment Log

File Repository

Customize & Manage Locking/E-signatures

Data Quality

Help & Information

Help & FAQ

Video Tutorials

Suggest a New Feature

Contact REDCap administrator

ACTIVE - Parkland ORA PSR Form Version 2.0 PID 300

Actions: Download PDF of Instrument(s) VIDEO: Basic data entry

Parkland Performance Site Review Form

Survey response is editable Edit response Survey options

Response was completed on 2021-08-25 10:58pm. You have permission to edit this survey response from its original values. In order to begin editing the response, you must click the Edit Response button above. View all contributors to this response.

Record ID 159 (Velos Study Number 34156) (Holcomb, Denisse)

Record ID 159

Instructions for completing this form.

Attachment: PSR Form Instructions.docx (0.02 MB)

Thank you for choosing Parkland as a study performance site. The Performance Site Review (PSR) form is designed to provide study operational, fiscal and regulatory information to Parkland departments and leadership for approval.

The Parkland Office of Research Administration (ORA) is committed to ensuring feasibility of your study and patient safety; therefore, to facilitate the timely approval of your study the following requirements are crucial.

- Completion of this form in its entirety.
- Answer each question thoroughly.
- Provide as much detail as possible.
- Please be aware an incomplete form submission will result in delaying your study approval because the PSR form may be returned to you for further information.

* must provide value

☒ I understand and agree ☐ I disagree

eIRB Study Number

STU 2021

0602

IRB Approval Date

If this study is IRB approved, please enter the approval date.

08-09-2021

Velos Study Number

* must provide value

34156

Study Title

* must provide value

Implementing a Curriculum on Trauma-Informed Care and Chaperoning Sensitive Exams

Expand

**SUCCESSFUL
SUBMISSION
WILL SHOW A
GREEN BOX AT
THE TOP OF
THE PSR**

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)

REDCap

Logged in as p81604 | Log out

My Projects
REDCap Messenger

Project Home and Design

Project Home · Codebook

Project status: **Production**

Data Collection

Survey Distribution Tools
Record Status Dashboard
Add / Edit Records

Record ID 168 (Velos Study Number 12345)
[Select other record](#)

Data Collection Instruments:

Parkland Performance Site Review Form

Applications

Calendar
Data Exports, Reports, and Stats
Data Import Tool
Data Comparison Tool
Field Comment Log
File Repository
Customize & Manage Locking/E-signatures
Data Quality

Help & Information

Help & FAQ
Video Tutorials
Suggest a New Feature

Contact REDCap administrator

ACTIVE - Parkland ORA PSR Form Version 2.0 PID 300

Actions: [Download PDF of Instrument\(s\)](#) [VIDEO: Basic data entry](#)

Parkland Performance Site Review Form

Survey response is editable [Edit response](#) [Survey options](#)

Response is only partial and is not complete. Response was added on 2021-09-15 8:20am. You have permission to edit this survey response from its original values. In order to begin editing the response, you must click the Edit Response button above. [View all contributors](#) to this response.

Record ID 168 (Velos Study Number 12345)

Record ID 168

Instructions for completing this form.

Attachment: [PSR Form Instructions.docx](#) (0.02 MB)

Thank you for choosing Parkland as a study performance site. The Performance Site Review (PSR) form is designed to provide study operational, fiscal and regulatory information to Parkland departments and leadership for approval.

The Parkland Office of Research Administration (ORA) is committed to ensuring feasibility of your study and patient safety; therefore, to facilitate the timely approval of your study the following requirements are crucial.

- Completion of this form in its entirety.
- Answer each question thoroughly.
- Provide as much detail as possible.
- Please be aware an incomplete form submission will result in delaying your study approval because the PSR form may be returned to you for further information.

* must provide value

☐ I understand and agree ☐ I disagree

eIRB Study Number

STU

IRB Approval Date

If this study is IRB approved, please enter the approval date.

Velos Study Number

* must provide value

Study Title

* must provide value

IF YOU CHOOSE TO SAVE AND RETURN LATER

There will be an orange box at the top of the PSR stating that the form has not been completed and submitted.

Adding UTSW Affiliate Sites: Parkland Health and Hospital System (PHHS)

After you complete and submit the survey you must request a link to access for revisions

REDCap Research Electronic Data Capture

Parkland

**Parkland Office of Research Administration
Performance Site Review Form**

The ORA will begin review of your study once ALL the following is completed:

- 1) Final Institutional Review Board (IRB) approval.
- 2) Clinical Trial Coverage Analysis (CTCA) is approved by Principal Investigator (PI), or a waiver is issued for the CTCA.
- 3) PSR is completed and received.

***PLEASE NOTE:** Study activities **MAY NOT** begin until after you receive written site approval from Parkland ORA.

For questions, please contact the Office of Research Administration at [214-590-1170](tel:214-590-1170) or ParklandSiteResApp@phhs.org.

Study eIRB Number
* must provide value

Velos Number
* must provide value

Parkland

**Parkland Office of Research Administration
Performance Site Review Form**

The ORA will begin review of your study once ALL the following is completed:

- 1) Final Institutional Review Board (IRB) approval.

Survey Queue [Get link to my survey queue](#)

Listed below is your survey queue, which lists any other surveys that you have not yet completed.
To begin the next survey, click the 'Begin survey' button next to the title.

Status	Survey Title
Begin survey	Parkland Office of Research Administration Performance Site Review Form

[Close](#)

For questions, please contact the Office of Research Administration at [214-590-1170](tel:214-590-1170) or ParklandSiteResApp@phhs.org.

Study eIRB Number
* must provide value

11

Adding UTSW Affiliate Sites: CMC and PHHS

Add Performance Submitted Study Status

Now, add the “**Performance Review-Submitted**” study status for **CMC and PHHS** performance sites. This will generate an email to the performance site reviewers, notifying them that performance site approval has been requested.

1. Click on the “**Study Status**” tab.
2. Click on the “**ADD NEW STATUS**” link.

The screenshot displays the UTSW Research Portal interface. At the top, there is a navigation bar with tabs: Personalize, Manage, Libraries, and Reporting. A search bar is present with the placeholder text 'Study #, Title or Keyword'. The user's name, Kimberly Taylor, is displayed on the right. Below the navigation bar, the current page is identified as 'Study >> Status'. The main content area shows a tabbed interface with the 'Study Status' tab selected. A search bar for 'Search by Organization' is visible, with a dropdown menu set to 'All' and a 'Search' button. To the right of the search bar, there is a table with columns: Current Status, Study Start Date, Study End Date, and a 'Change Dates' link. The table contains one row with the status 'IRB - Approved'. In the bottom right corner, the 'ADD NEW STATUS' link is circled in red. The bottom of the interface shows a 'Study Status History' table with columns: Organization, Study Status, Status Valid From, Status Valid Until, Meeting Date, Notes, and Delete.

Current Status	Study Start Date	Study End Date	
IRB - Approved			Change Dates

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
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Adding UTSW Affiliate Sites: CMC and PHHS

Add Performance Submitted Study Status – Con'd

3. Complete the following fields:

Organization: Select the performance site (e.g. Children's Medical Center or Parkland Health and Hospital System

***NEVER** select "UT Southwestern Medical Center and Affiliates."*

Status type: Select "**Performance Site**"

Study status: Select "**Performance Site – Submitted**"

Status valid form: Enter the current date.

Remember to add the
"Performance Site—Submitted"
study status for **EACH**
performance site.

Adding UTSW Affiliate Sites: CMC and PHHS

Add Performance Submitted Study Status – Con'd

Personalize | Manage | Libraries | Reporting | Study #, Title or Keyword **Development**

Current Page: Study >> Status Details

You are working on study: 26068

Summary | Site/Team | Protocol | **Study Status** | Forms | Milestones | Admin Schedule | Documents | Reports | Notifications

Study Initiation

- IRB - Submission... ☒
- IRB - Waiting As... ☐
- IRB - Approved ☒

Study Activation

- Study - Active/E... ☐

Study Closure

- IRB - Study Closed ☐

Study Start Date : Study End Date :

Please enter status details:

Organization Parkland Health and Hospital System

Status Type Performance Site

Study Status Performance Site - Submitted

Documented By * Kimberly Taylor [Select User](#)

Assigned To [Select User](#)

Status Valid From * 05/10/2019

Status Valid Until

Meeting Date

Notes

☒ This is study's Current Status

☐ Organization specific current reportable status

e-Signature *

If you do not see your performance site listed when selecting the performance site from the drop down list, verify that the performance site is listed on the study in the eIRB.

Adding UTSW Affiliate Sites: CMC and PHHS

Add Performance Submitted Study Status – Con'd

4. Enter your **e-Signature** and click **Submit**.

5. The request for performance site approval has been submitted. A system generated email will be sent to the performance site approver, notifying them of the request.

6. Once the performance site approver receives the request notification, they will add the status of **Performance Site – Received – Pending Review** or **Performance Site – Application Form Incomplete**. A system generated email will be sent to the PI, Primary Research Coordinator and Study Author, notifying them that the request is pending review by the Performance Site Approver or that it has been returned due to insufficient information.

(Note: If the form is incomplete, the study team will edit the form and then notify the performance site approver, outside of Velos, that the form has been edited and is ready for review.)

7. The performance site reviewer will review the request and will add the status **Performance Site-Approved** once approved, or **Performance Site – Disapproved** if not approved. These statuses will also generate an email notification to the PI, Primary Research Coordinator and Study Author.

Special note about PHHS and EPIC

EPIC QUESTION UNDER THE SUMMARY TAB

In order for the study to come across to our Parkland Velos, please do the following:

- Go to the **Study Summary** tab in UTSW Velos system. Scroll down to **More Study Details** and find the **Epic Interface Fields** section. Then click the box to **Include Study & Patients in Epic.** Set to **Yes.**

Adding UTSW Affiliate Sites: PHHS

Special note about PHHS and EPIC

Personalize

Manage

Libraries

Reporting

Study #, Title or Keyword

Current Page: Study >> Summary

Study Initiation

IRB - Submis...
IRB - Waitin...
IRB - Approv...
IRB - Approv...

Study Activation

Study - Acti...

Study Closure

IRB - Study ...

You are working on study: 34156

Summary

Site/Team

Protocol

Study Status

Forms

Documents

Admin Schedule

Reports

Notifications

Send Study to Investigational Drug System

Select an option

Study Number for Investigational Drug System

Is this a ClinicalTrialsXpress study?

Select an option

Principal Investigator's Home Affiliated Institution

UT Southwestern

IRB ID

STU-2021-0602

Legacy IRB ID

Epic Interface Fields

Include Study & Patients in Epic?

Yes

This study has a Certificate of Confidentiality

Short Study Title (shows in Epic)

Study Contact

Study Contact Phone(s)

ClinicalTrials.gov Number Not Required?

Select an option

ClinicalTrials.gov Number

Radiology

To request radiology review, please use Study Status tab to add UTSW Ancillary Services - Radiology - Submitted.

Financials

UT Southwestern University Hospital - St. Paul (UHSP) Account Number

UT Southwestern University Hospital - Zale Lipshy (UH2L) Account Number

UT Southwestern Ambulatory Services Account Number

Parkland Health and Hospital System (PHHS) EPIC SAR Account

Adding UTSW Affiliate Sites: Scottish Rite for Children (SRC)

Adding a performance site at Texas Scottish Rite Hospital

- To be added as a performance site, the project needs to be submitted to the Scottish Rite for Children Research Advisory Panel (RAP) for review and approval. There must be a SRC researcher on the project. All documents must be submitted via the SRC REDCap database. Courtney Hartman, RAP Administrator, is the contact for access/assistance.

Courtney Hartman, M.S.

Regulatory Analyst

Coordinator - Research Advisory Panel

Department of Research

Scottish Rite for Children

214-559-7870 (office)

Courtney.Hartman@tsrh.org

rap@tsrh.org

- Courtney Hartman is the CRU approver for the UTSW IRB. A new study will NOT be approved with SRC as a performance site until the RAP has approved.
- The deadline for new submissions is the last Friday of each month.
- The links to the REDCap database and RAP submission system are not publicly available. Please use the contact information provided for Courtney Hartman for questions about performance site approvals at SRC.

Adding UTSW Affiliate Sites: Texas Health Resources (THR)

Adding a performance site at Texas Health Resources

A THR Performance Site Approval review will be initiated following notification to the THR HRPP & RA offices.

- For proper notification to occur, researchers will need to both select THR as a performance site within the eIRB application and within Velos.

Typically, notification to THR of a Performance Site Review will occur in one of the following methods:

- Submission of a new study application through the eIRB which lists THR as a performance site
- Submission of a modification through the eIRB adding THR as a performance site
- Direct contact by researchers to the THR HRPP or RA offices

Entity Review Form and Study Questionnaire

- Submission of a completed/signed THR Entity Review Form to indicate local approval of the research by applicable THR facilities
 - THR Entity Review Form will need to be uploaded into eIRB application
 - THR Entity Review Form link: <https://redcap.vanderbilt.edu/surveys/?s=CKRELTHMMXEKMKYA>
- THR requires that a Study Questionnaire be completed for either a new study where THR is listed as a Performance Site or a MOD has been issued adding THR as a Performance Site
 - THR Study Questionnaire link: <https://redcap.vanderbilt.edu/surveys/?s=4YX8FEEP9L8ERXTC>



DO NOT START ANY RESEARCH-RELATED ACTIVITIES WITHOUT BOTH IRB AND SITE APPROVAL!

UTSouthwestern

Medical Center

Human Research Protection Program

Adding or Modifying Performance Sites in eIRB

Adding UTSW Affiliate Sites: eIRB – New Studies

After you have completed your study set up and submitted it through Velos, it should populate in eIRB. The following steps are for new studies; modifications will be detailed in later slides.

Section 5.0 Performance Sites

This is the section where all sites engaged in research should be listed.

In Section 5.1, use the “Add” button to select performance sites

5.0 Performance Sites

Please note the following for affiliated performance site(s): selecting the Parkland Health & Hospital System includes the imaging/radiology services at Meadows MRI and the PHHS Breast Imaging Center. Selecting Clements University Hospital includes the imaging/radiology services at Aston, Rogers MRI, the Outpatient Building, Vascular Interventional Radiology, the PET Center and Breast Imaging Center.

* 5.1 Add all UT Southwestern affiliated performance sites:

<div>+ Add</div>				
Performance Site		Recruitment	Procedures	Resources
<div><div>Update</div></div>	UTSW	no	no	yes
<div><div>Update</div></div>	Children's Health (Dallas, Plano)	yes	yes	yes

Adding UTSW Affiliate Sites: eIRB – New Studies

When you select the “**Add**” button, a pop-up will appear and allow you to select each study location. Please note, this step will need to be repeated for each site:

Add ST_UTSW_StudyLocations

Please select one study site from the list below followed by the research-related activities to be conducted at that site. For studies involving more than one local performance site, please select OK and Add Another.

*** Please select UTSW Study Location:**

- ☐ UTSW
- ☐ Children's Health (Dallas, Plano)
- ☐ Parkland Health & Hospital System
- ☐ Retina Foundation of the Southwest
- ☐ Texas Health Resources
- ☐ Institute for Exercise and Environment Medicine (IEEM)
- ☐ Texas Scottish Rite Hospital for Children
- ☐ Other Non-Affiliated Sites

[Clear](#)

Site Activities: *(select all that apply)*

Recruitment: ☐

Procedures: ☐

Resources: ☐

You will need to select all activities that will be performed at each site.

Adding UTSW Affiliate Sites: eIRB – Modifications

Section 1.1 of the Modification Smartform is where changes to performance sites may be made.

*** 1.1 Check all that apply:**

- ☐ Principal Investigator
- ☒ Protocol/Smart Form Changes
- ☐ Investigator Brochure
- ☐ Consent Form
- ☐ HIPAA Authorization
- ☐ Waivers of Consent and Authorization
- ☐ Target Enrollment
- ☐ Recruitment Materials
- ☐ Study Status
- ☐ Conflict of Interest Changes
- ☐ Performance Sites
- ☐ Other

Section 11.0 will populate in the Modification Smartform and will look something like this:

11.0 Performance Sites

* 11.0 Performance Sites: Make your changes below:

Performance Site		I don't want to make any changes				no				no				yes			
<input type="button" value="+ Add"/>																	
<input type="button" value="Update"/>	Parkland Health & Hospital System																
<input type="button" value="Update"/>	UTSW																

Select "Add" to add a new site

Select "Update" to remove or modify activities at an existing site

Adding UTSW Affiliate Sites: eIRB – Modifications

Section 11.1 of the Modification Smartform will pop-up when adding a new site or modifying an existing site. When adding a new site, this form will be identical to the form in Section 5.1

Add ST_UTSW_StudyLocations

Please select one study site from the list below followed by the research-related activities to be conducted at that site. For studies involving more than one local performance site, please select OK and Add Another.

* Please select UTSW Study Location:

☐ UTSW

☐ Children's Health (Dallas, Plano)

☐ Parkland Health & Hospital System

☐ Retina Foundation of the Southwest

☐ Texas Health Resources

☐ Institute for Exercise and Environment Medicine (IEEM)

☐ Texas Scottish Rite Hospital for Children

☐ Other Non-Affiliated Sites

[Clear](#)

You will need to select all activities that will be performed at each site.

Site Activities: *(select all that apply)*

Recruitment: ☐

Procedures: ☐

Resources: ☐

When making a modification or removing a site using the “Update” button, this form will appear:

Edit ST_UTSW_StudyLocations

11.0 Performance Sites: Make your changes below:

* 11.1 What change do you want to make to this site?

☒ I don't want to make any changes

☐ I need to change activities at the site, change location, and/or add/remove procedures

☐ I want to remove this site from my application

[Clear](#)

11.2 Performance Site:
Parkland Health & Hospital System

Adding UTSW Affiliate Sites: eIRB – Modifications Con'd

Continuing with making changes to existing sites, if you need to change activities, location, and/or remove procedures, you will be presented with the screen below. Please note the option of “I want to remove this site from my application,” does just that – it removes the site.

Changes made to sites in the Modification Smartform automatically update the Parent Smartform!

11.0 Performance Sites: Make your changes below:

* 11.1 What change do you want to make to this site?

☐ I don't want to make any changes

☒ I need to change activities at the site, change location, and/or add/remove procedures

☐ I want to remove this site from my application

[Clear](#)

11.2 Performance Site:

Parkland Health & Hospital System

* By selecting Parkland as a study site, you acknowledge that you must obtain prior performance site approval from Parkland before beginning research at Parkland. The performance site approval is complete in Velos. More information about the performance site approval process can be found [here](#). ☒

Contact Research@phhs.org for additional information.

11.3 Site Activities: *(select all that apply)*

Recruitment: ☐

Procedures: ☐

Resources: ☒

11.4 Detail the changes at this Performance Site:

* 11.4.1 Are you changing any location (e.g., adding a new clinic, removing a location, etc.) to be performed at this Performance Site?

☐ Yes

☐ No

[Clear](#)

* 11.4.2 Are you adding or removing any procedures (e.g., new test, updated frequency, etc.) to be performed at this Performance Site?

☐ Yes

☐ No

[Clear](#)

Adding UTSW Affiliate Sites: Modifications in Velos

What happens to the sites listed in Velos when making a change in eIRB?

Velos is automatically updated when sites are removed from eIRB.

If you're adding a site to eIRB, you will still need to complete all the steps for adding a site and requesting performance site approval in Velos.

Adding UTSW Affiliate Sites: References

The content for part of this presentation was used from the Velos Performance Site Approval Tip Sheet

Link: <https://www.utsouthwestern.net/intranet/administration/information-resources/products-services/assets/utsw-performance-site-approval.pdf>

Also, special thanks to the Research Offices at Parkland, Scottish Rite, and Texas Health Resources for sharing their performance site approval slides/processes



Questions?

Thank you for attending.

We'd love to hear your feedback. We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

Visit: <https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW>

