Clinical Research Improvement In Systems and Processes

Project Update

May 17*

* A few slides are updated thanks to the feedback received after the meeting.

Clinical Research Connect

Agenda

Clinical Research Connect: Launch June 5

First adopters:
Anesthesiology, Neurosurgery, Surgery

Scope: what's included and excluded for June

Planning next steps and timeline

Clinical Research Connect is a workflow with abilities to capture data once,
auto-generate documents and forms,
submit electronically,
sign documents electronically using DocuSign,
send email notifications, and more.

Clinical Research Connect

Clinical Research Connect is a new workflow within the SOM Workflow Platform

Study Start-up Future State

Electronic Submission and Approval

Compliance Requirements
- CIRB
- Conflict of Interest
- ESCRO
- CoC (FDA, NIH)
- FERPA/SBS
- Investigational Drug Services
- IBC
- IRB Reliance Agreement(s)
- ISPRO
- Neonatal ICU
- New Medical Device
- Non-UVA Institutional Approval
- Protocol Review Committee
- Radioactive Drug Research Committee
- RSC/HIRE
- SOM CTO Review

+ Requirements after IRB Approval

Ancillary Services
- Ambulatory Clinic/Hospital Nursing Unit/Cancer Center Infusion
- Biorepository and Tissue Research Facility (BTRF)
- Clinical Laboratories
- Continuum Home Health
- Clinical Research Unit
- Health South
- Radiology and Medical Imaging
- Supply Chain Management
- Therapy Services (Physical Therapy, Occupational Therapy)

Clinical Research Connect

Common Information

Feasibility Assessment

Compliance Requirements

Institutional Review Board

Budget

Grant Pricing Request

Contract,

Proposal Routing Form

PTAO set-up

Ancillary Services

Billing Coverage Analysis

✓**Ready for Enrollment**

System Integrations

IRB Protocol Builder

IRB Online

ResearchUVa

OnCore Clinical Trials Mgmt System

June rollout

Electronic Submission and Approval

Compliance Requirements
- CIRB
- Conflict of Interest
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- RSC/HIRE
- SOM CTO Review

+ Requirements after IRB Approval

Ancillary Services
- Ambulatory Clinic/Hospital Nursing Unit/Cancer Center Infusion

Biorepository and Tissue Research Facility (BTRF)

All other Ancillary Services are Informational
- Health South
- Radiology and Medical Imaging
- Supply Chain Management
- Therapy Services (Physical Therapy, Occupational Therapy)

Clinical Research Connect

Common Information
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Grant Pricing Request
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✓**Ready for Enrollment**

System Integrations

IRB Protocol Builder

IRB Online

ResearchUVa

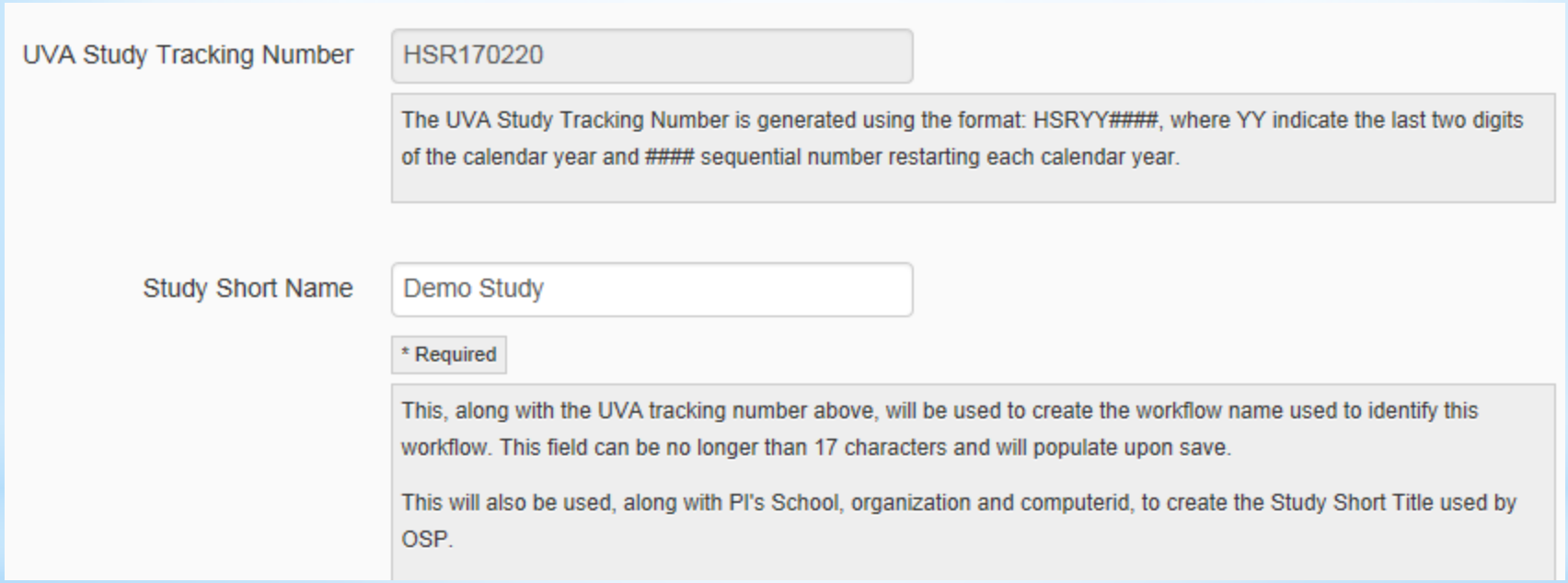
OnCore
Clinical Trials Mgmt
System

Clinical Research Connect – Study Start-up Phases, Steps and Statuses

Process Phase	Step	Current Status
BEGIN HERE FOR ALL HSR STUDIES	Study Workflow Name Creation	Not Ready Not Applicable Open In Progress Complete Informational
PRINCIPAL INVESTIGATOR	Principal Investigator Contact Information	
ORGANIZATION(s) and TITLE(s)	Study Organizations and Titles	
Personnel (Provides WORKFLOW ACCESS)	Principal Investigator: Key Personnel	
	Study Personnel and Key Personnel Information	
General	Protocol Owner	
	Dates, Study Type, Contract Acknowledgment	
Study Reports	Study Reports	
Study Notes	Study Notes	
Study Documents	Study Documents - General	
	Study Documents - Required by IRB, locked when submit	
	Study Documents - Sent to IRB, not locked when submitte	
	Study Documents - Provided by IRB Protocol Builder	
IRB REVIEW TYPE	IRB Review Type	

Every study in the workflow will have a unique UVa Study Tracking Number, auto-generated based on: “HSRYY####”

Process Phase	Step
BEGIN HERE FOR ALL HSR STUDIES	Study Workflow Name Creation



After Study Workflow Name Creation:

Clinical Research Connect: HSR170220-Demo Study

Principal Investigator and Study Personnel Information, Study Organizations

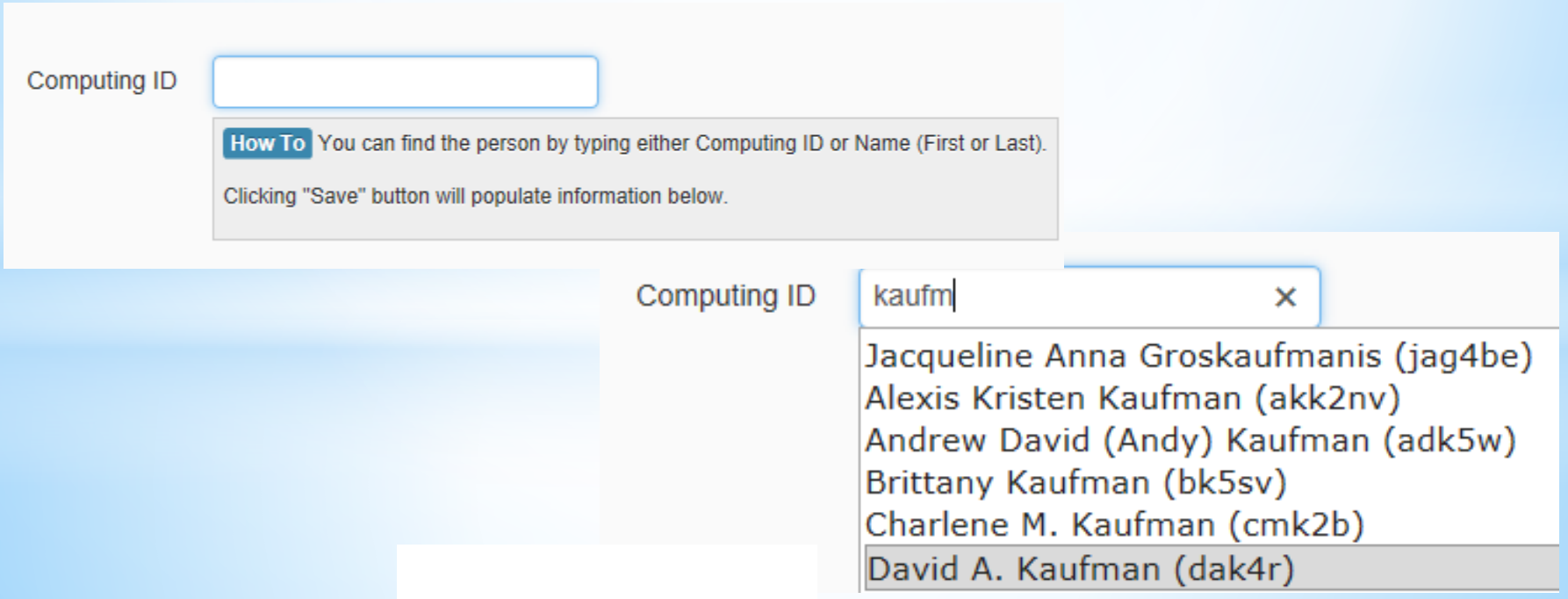
Process Phase	Step
BEGIN HERE FOR ALL HSR STUDIES	Study Workflow Name Creation
PRINCIPAL INVESTIGATOR	Principal Investigator Contact Information
ORGANIZATION(s) and TITLE(s)	Study Organizations and Titles
Personnel (Provides WORKFLOW ACCESS)	Principal Investigator: Key Personnel
	Study Personnel and Key Personnel Information

- Capturing Principal Investigator Computing ID/Name; the system populates Primary Appointment.
- Capturing Responsible Organization and Award Owning Organization; the system populates Department Chairs' information, certain study roles and information.
- Capturing Study Personnel.

Main reason: Clinical Research Connect Access and Populating Proposal Routing Form

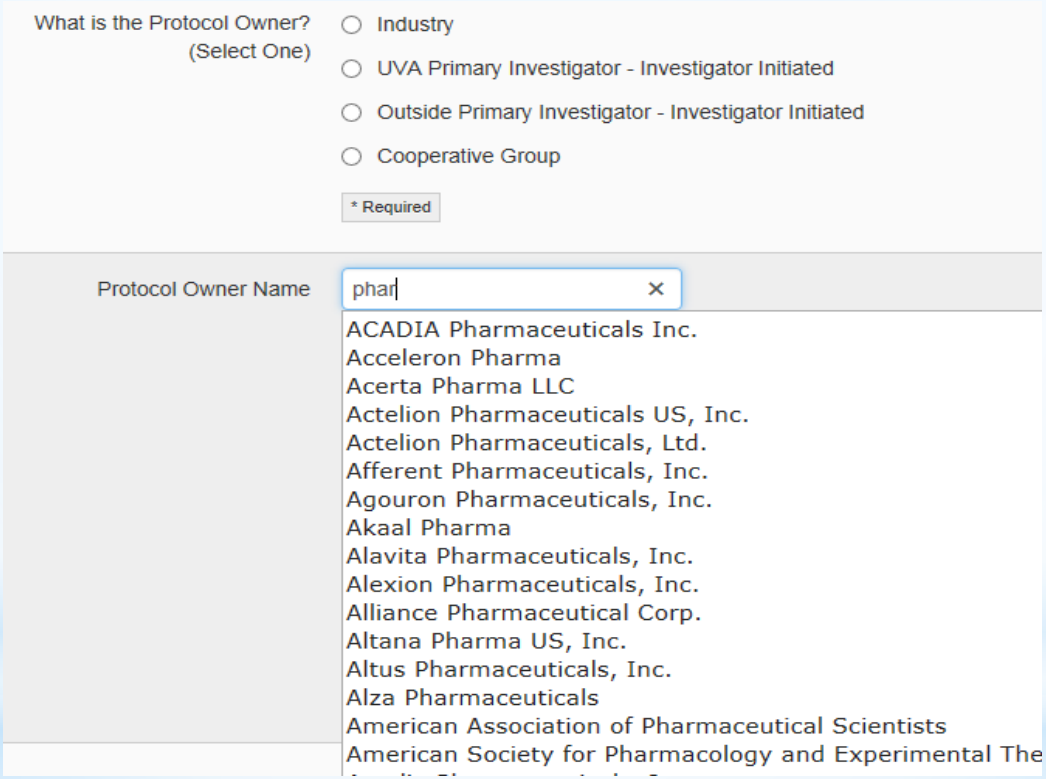
Find the person and other contact information will be populated

PRINCIPAL INVESTIGATOR	Principal Investigator Contact Information
ORGANIZATION(s) and TITLE(s)	Study Organizations and Titles
Personnel (Provides WORKFLOW ACCESS)	Principal Investigator: Key Personnel
	Study Personnel and Key Personnel Information



Capturing additional study information, such as Protocol Owner Name

General	Protocol Owner
	Dates, Study Type, Contract Acknowledgment



Customer list from the Integrated System (Oracle) available for selection.

Capturing additional study information, such as Study Type for reporting

General	Protocol Owner
	Dates, Study Type, Contract Acknowledgment

Study Type: Select

* Required

- Basic Science (BAS): Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.
- Diagnostic (DIA): Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.
- Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
- Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
- Screening (SCR): Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
- Supportive Care (SUP): Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
- Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.
- Other (OTH): Not in other categories
- Retrospective ONLY (sub-category of HSR)

Capturing Study Population for reporting

Study Population (choose all that apply)

- ☐ Bacterial and Fungal Diseases
- ☐ Behaviors and Mental Disorders
- ☐ Blood and Lymph Conditions
- ☐ Cancers and Other Neoplasms
- ☐ Digestive System Diseases
- ☐ Diseases and Abnormalities at or Before Birth
- ☐ Disorders of Environmental Origin
- ☐ Ear, Nose, and Throat Diseases
- ☐ Eye Diseases
- ☐ Gland and Hormone Related Diseases
- ☐ Heart and Blood Diseases
- ☐ Immune System Diseases
- ☐ Mouth and Tooth Diseases
- ☐ Muscle, Bone, and Cartilage Diseases
- ☐ Nervous System Diseases
- ☐ Nutritional and Metabolic Diseases
- ☐ Occupational Diseases
- ☐ Parasitic Diseases
- ☐ Respiratory Tract (Lung and Bronchial) Diseases
- ☐ Skin and Connective Tissue Diseases
- ☐ Substance Related Disorders
- ☐ Symptoms and General Pathology
- ☐ Urinary Tract, Sexual Organs, and Pregnancy Conditions
- ☐ Viral Diseases
- ☐ Wounds and Injuries

This list of values is taken directly from https://www.clinicaltrials.gov.

Study Reports providing executive summary for a particular component, used to create PRF Study Notes for common communication

Study Reports	Study Reports
Study Notes	Study Notes

KEY PERSONNEL 5/17/2017

Principal Investigator

Computing ID	First Name	Last Name	Key Personnel?	COI Investigator?
nbf2p	Nathan	Fountain	Yes	Yes

Sub-Investigator(s)

Computing ID	First Name	Last Name	Key Personnel?	COI Investigator?
ag7h	Alban	Gaultier	Yes	No
pd9d	Parchayi	Dalal	No	No
sf9a	Steve	Fetcho	No	

Study-Coordinator(s)

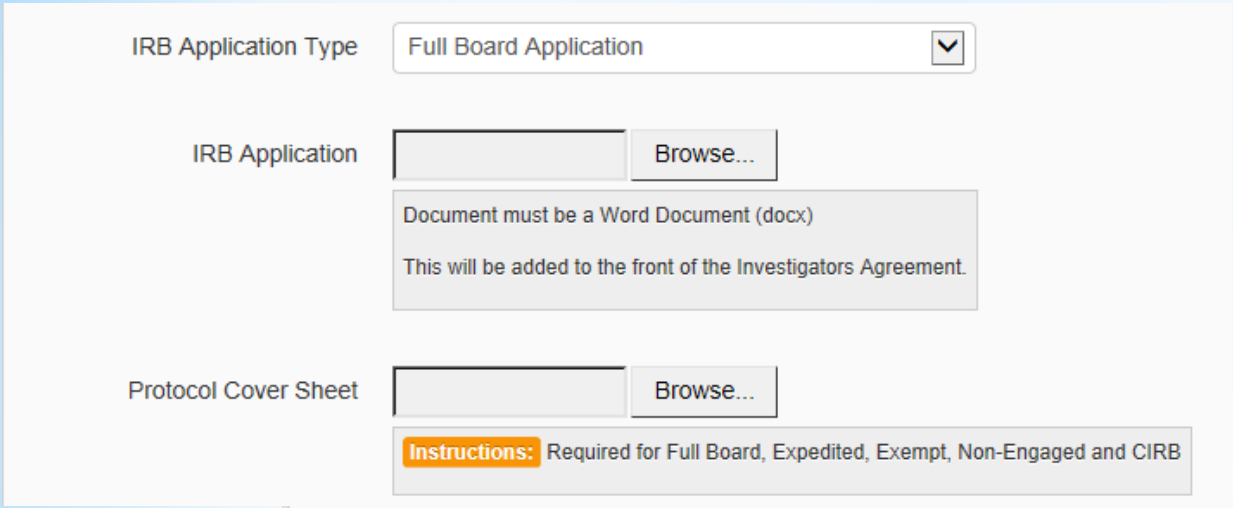
Computing ID	First Name	Last Name	Key Personnel?	COI Investigator?
jjl4d	Johanna	Loomba	No	No
ja4na	Junaid	Ahmad	Yes	Yes
se6ta	Sara	Elizabeth	Yes	No

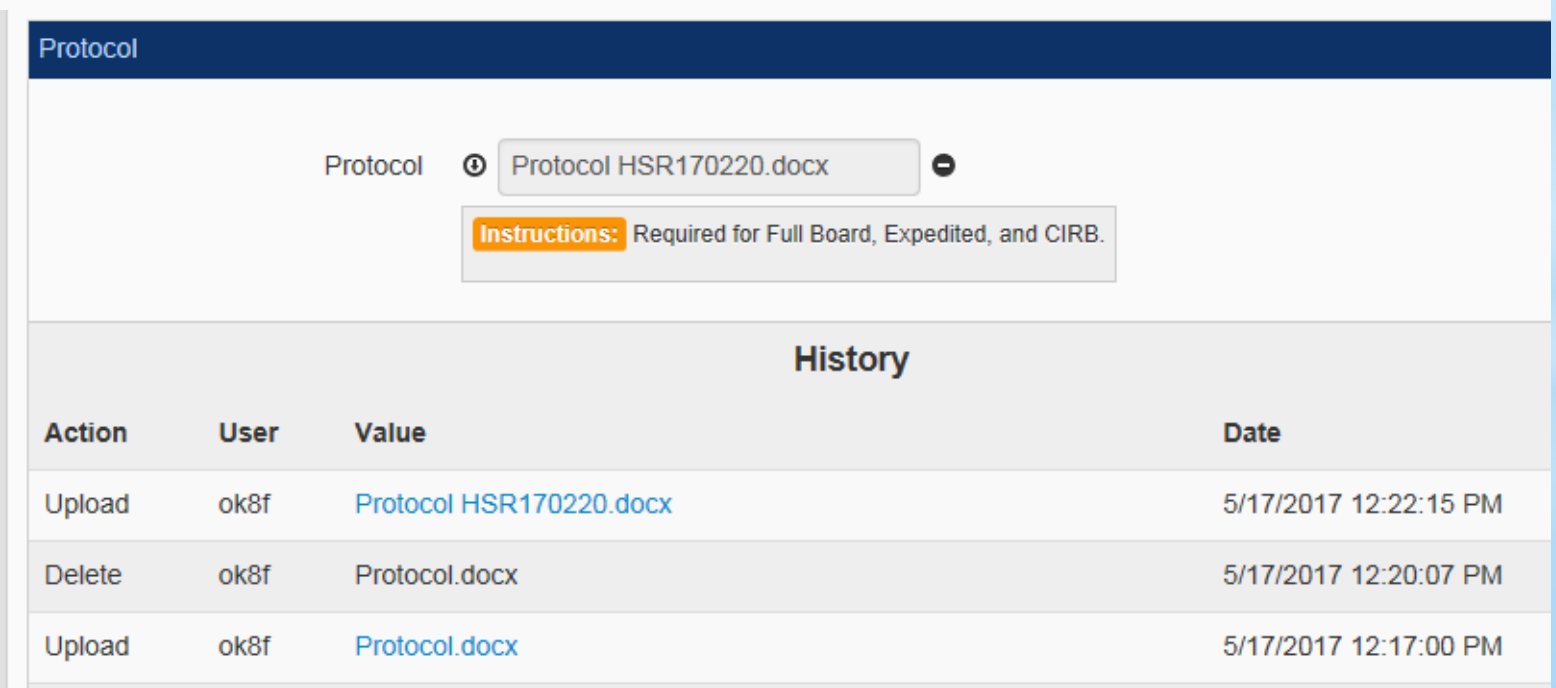
Short Title	Integration Test
Proposal Type:	New
Proposal Org/Dept No:	40410 MD-CELL Cell Biology
Award Owning Org/Dept No:	40730 MD-INMD Allergy
Primary Activity Type:	Organized Research
This project will occur:	On-Grounds
Check all that apply:	Basic/Bench Research, Clinical Research
Proposal Period From:	7/17/2017
Proposal Period To:	7/21/2024
SBIR	No
STTR	No
Limited submission opportunity	
3. SPONSOR DETAILS	
Immediate Sponsor:	Men's 4-Miler
Sponsor Type:	Industry
Originating Sponsor (if applicable)	
Solicitation #:	
CFDA #:	6003

Study Documents

Study Documents	Study Documents - General
	Study Documents - Required by IRB, locked when submitted to IRB
	Study Documents - Sent to IRB, not locked when submitted to IRB
	Study Documents - Provided by IRB Protocol Builder

Study Documents: Easy Upload function, previous versions are available





Identifying IRB Review Type

Instructions

This step is Open when "PI - Appointment and Study - Organizations and Titles" Step is Complete.

Important: Identifying IRB Review Type is important as there are many steps which are dependent on this selection. Use IRB Review Type Table. If you are not confident, contact IRB-HSR staff to confirm your selection.

Submit the step only when you are ready. After you "Submit" the step, the information will not be available for editing.

IRB Review Type

IRB Review Type

- ○ Emergency Use of an Unapproved Drug or Device - For clinical care of a single patient
- ○ Humanitarian Device Exemptions (HDE) - Exemption for use of a Humanitarian Use Device
- ○ Non-Human Subject Research Determination- Does not meet definition of human subject research or is not a clinical investigation of a test article
- ○ Non-UVA Agent - Human Subject Research but not conducted on behalf of UVa
- ○ Exempt - Not any of the above & meets an Exempt Criteria
- ○ Non-Engaged - Not any of the above, & does not engage UVa in human subject research.
- ○ Expedited - Not any of the above, must be Minimal Risk & meet an Expedited Criteria
- ○ Full Board - Does not qualify for another review type.

* Required

Steps change status depending on actions and completion of prerequisites.

IRB Review Type	Complete 5/15/2017 12:42:11 PM
Multi-Site, Study Subject	Open 5/15/2017 12:42:12 PM
Funding Source, Other Support Sources	Open 5/15/2017 12:42:12 PM
IDS, IND Holder, IDE Holder	In Progress 5/17/2017 10:55:57 AM

For example:

- Submission of IRB Review Type “Completes” the IRB Review Type step.
- Dependent steps, such as three shown above became “Open”.
- Saving information on a step changed the status to “In Progress”.

Feasibility Assessment Submission	Open 5/15/2017 12:31:52 PM
Feasibility Assessment Committee	Not Ready 5/15/2017 12:04:51 PM

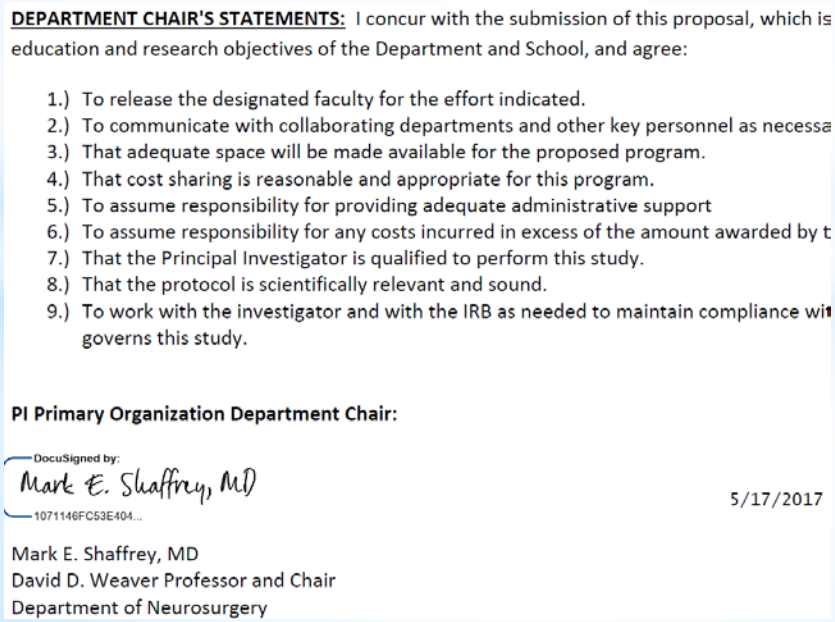
For example:

- The “Committee” step is “Not Ready” until the “Submission” is complete.

Certification is an automatically generated document.
It will be signed electronically by PI, PI's Primary Appointment Department Chair, Responsible Department Chair, Award Owning Department Chair, and the SOM Dean's Office.

Certification	Certification
	Certification DocuSign Creation
	Certification DocuSign Status
	MILESTONE: Certification Signed Document

Replacing signatures on the Proposal Routing Form and Department Chairs' signatures on IRB Application



DEPARTMENT CHAIR'S STATEMENTS: I concur with the submission of this proposal, which is education and research objectives of the Department and School, and agree:

1.) To release the designated faculty for the effort indicated.
2.) To communicate with collaborating departments and other key personnel as necessa
3.) That adequate space will be made available for the proposed program.
4.) That cost sharing is reasonable and appropriate for this program.
5.) To assume responsibility for providing adequate administrative support
6.) To assume responsibility for any costs incurred in excess of the amount awarded by t
7.) That the Principal Investigator is qualified to perform this study.
8.) That the protocol is scientifically relevant and sound.
9.) To work with the investigator and with the IRB as needed to maintain compliance wi governs this study.

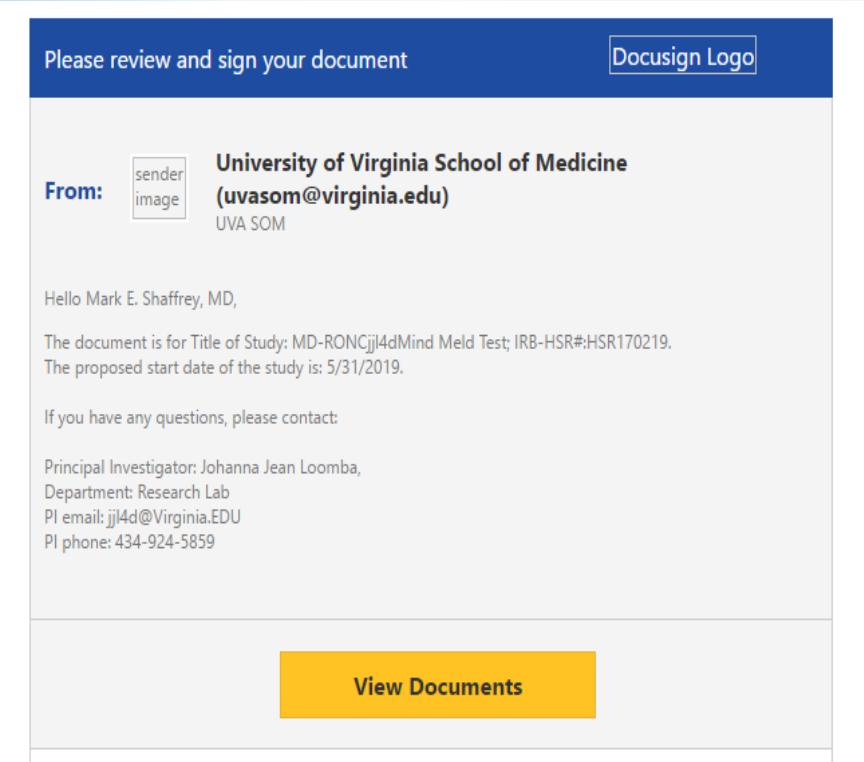
PI Primary Organization Department Chair:

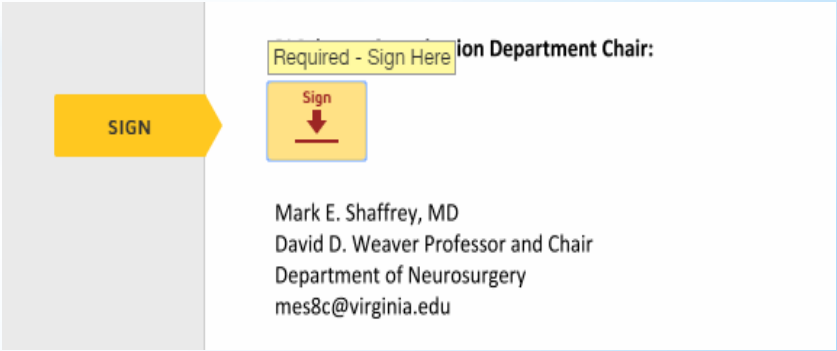
DocuSigned by:
Mark E. Shaffrey, MD
1071146FC53E404...

5/17/2017

Mark E. Shaffrey, MD
David D. Weaver Professor and Chair
Department of Neurosurgery

How to “DocuSign”





Additional important steps: Contract and creation of PRF, PTAO Budget and Grant Pricing Request

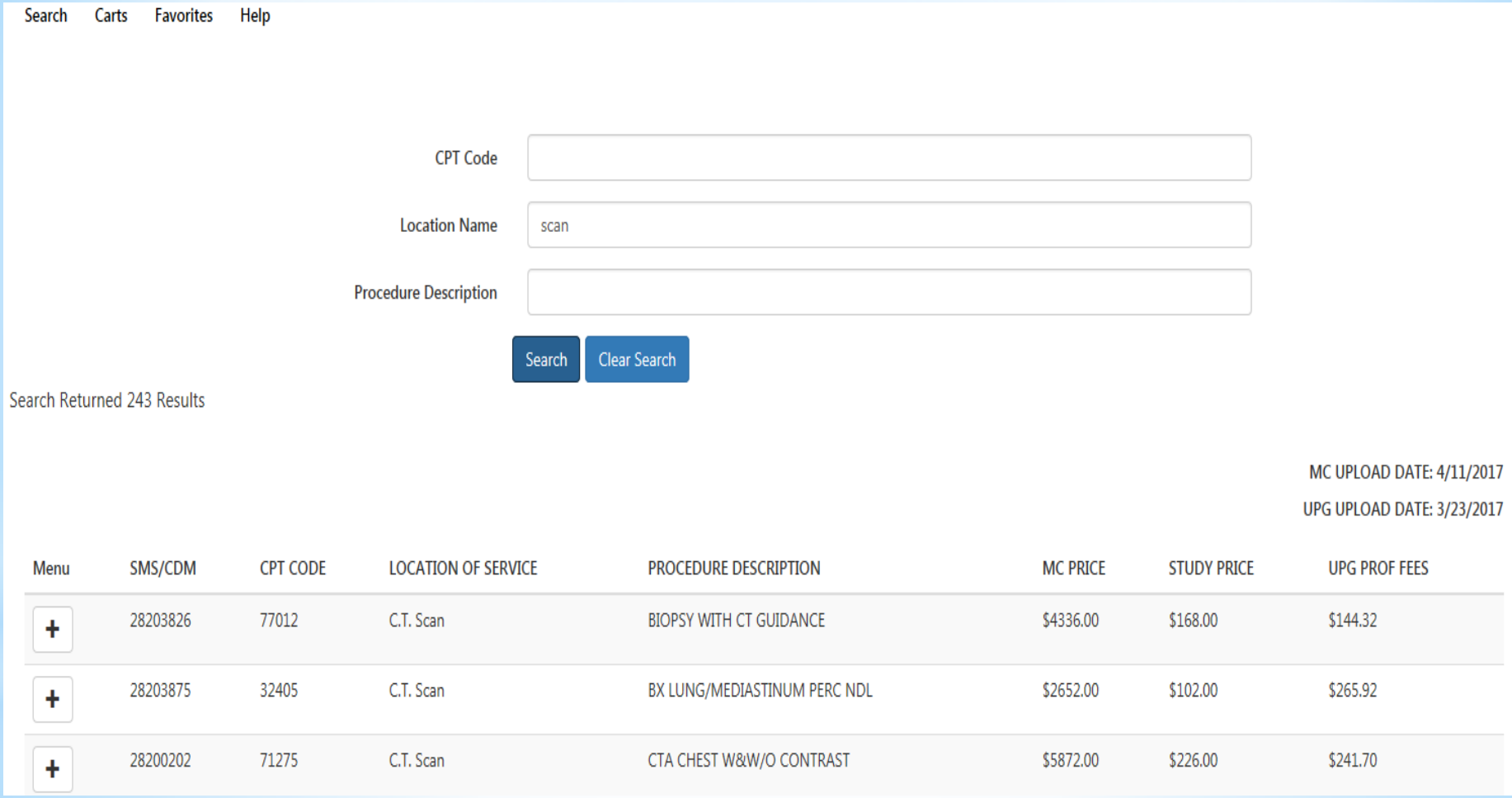
CONTRACT	Contract
	MILESTONE: Contract Execution
PTAO	PTAO Request (by OGC/OSP)
	MILESTONE: PTAO Entry

Generating At-Risk PTAO for Industry studies earlier in the process.

Budget and Grant Pricing Request	Grant Pricing Request
	Budget

Grant Pricing Request has a link to a new application allowing study team search for procedures and identify their pricing.

Grant Pricing Request – New Application
Allowing to search for procedures and access pricing



Managed by the SOM Clinical Trials Office

Compliance Requirements: IRB Protocol Builder → Clinical Research Connect

COMPLIANCE REQUIREMENTS	MILESTONE: Completion in IRB Protocol Builder
	Compliance Requirements Checklist (Provided by IRB)

Institutional Biosafety Committee (IBC) - IBC Number	◉ Applicable	○ Not Applicable
Investigational Drug Services (IDS)	○ Applicable	◉ Not Applicable
IRB Reliance Agreement: IRB-HSR is IRB of Record	○ Applicable	◉ Not Applicable
IRB Reliance Agreement: IRB-HSR not IRB of Record	○ Applicable	◉ Not Applicable
New Medical Device	○ Applicable	◉ Not Applicable

Requires study team's acknowledgment that they have completed related questions in IRB Protocol Builder and have indicated UVa Study Tracking Number

Automatically setting "Applicable" and "Not Applicable" for each requirement.

Electronic Submissions and Outcomes Prior to submitting to IRB

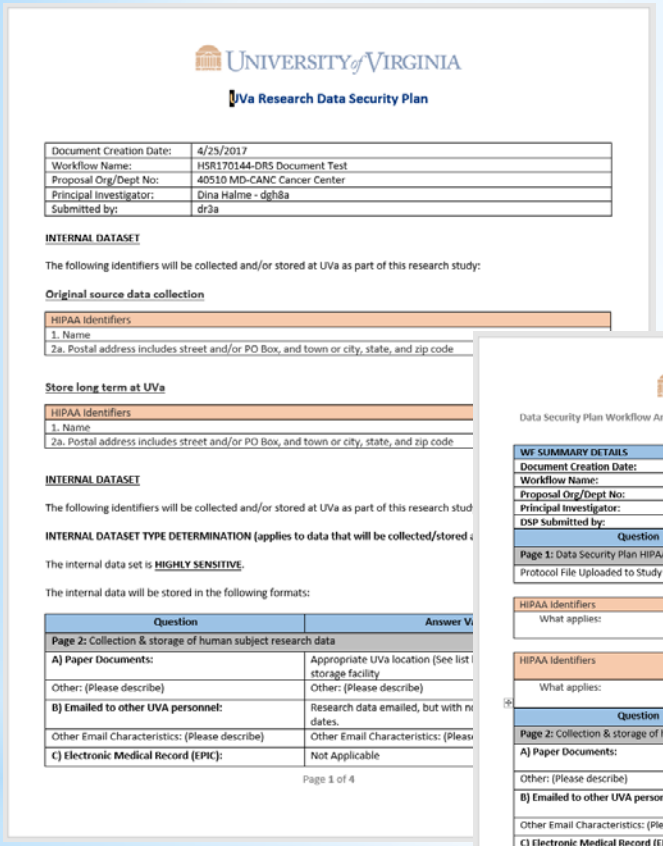
Submissions and Outcomes Prior to IRB Pre-Review	Central Institutional Review Board (CIRB)
	Conflict of Interest Committee Outcome
	ESCRO Submission
	ESCRO Outcome
	FDA Certificate of Confidentiality
	FERPA/SBS Submission
	FERPA/SBS Outcome
	IDS Submission
	IDS Committee
	IDS Status
	Institutional Biosafety (IBC) Submission
	Institutional Biosafety (IBC) Outcome
	Institutional Biosafety Committee (IBC Number)
	IRB Reliance Agreement: IRB-HSR is IRB of Record
	IRB Reliance Agreement: IRB-HSR not IRB of Record

Compliance requirements steps will become “Open” if were identified as “Applicable”; “Not Applicable” otherwise.

Electronic Submissions and Outcomes Prior to submitting to IRB (continue)

Submissions and Outcomes Prior to IRB Pre-Review	
	Neonatal ICU Submission
	Neonatal ICU Committee
	New Medical Device
	Non-UVA Institutional Approval
	Protocol Review Committee (PRC) Submission
	Protocol Review Committee (PRC) Committee
	Radioactive Drug Research Committee (RDRC)
	RSC/HIRE Standard Radiation Language
	RSC/HIRE Submission
	RSC/HIRE Committee
	SOM CTO Review and Outcome
DATA SECURITY PLAN	Data Security Plan
	Data Security Plan Outcome

Data Security Plan and Highly Sensitive Data Storage Request are Auto-generated



UNIVERSITY of VIRGINIA

UVa Research Data Security Plan

Document Creation Date:	4/25/2017
Workflow Name:	HSR170144-DRS Document Test
Proposal Org/Dept No:	40510 MD-CANC Cancer Center
Principal Investigator:	Dina Halme - dgh8a
Submitted by:	dr3a

INTERNAL DATASET

The following identifiers will be collected and/or stored at UVa as part of this research study:

Original source data collection

HIPAA Identifiers
1. Name
2a. Postal address includes street and/or PO Box, and town or city, state, and zip code

Store long term at UVa

HIPAA Identifiers
1. Name
2a. Postal address includes street and/or PO Box, and town or city, state, and zip code

INTERNAL DATASET

The following identifiers will be collected and/or stored at UVa as part of this research stud

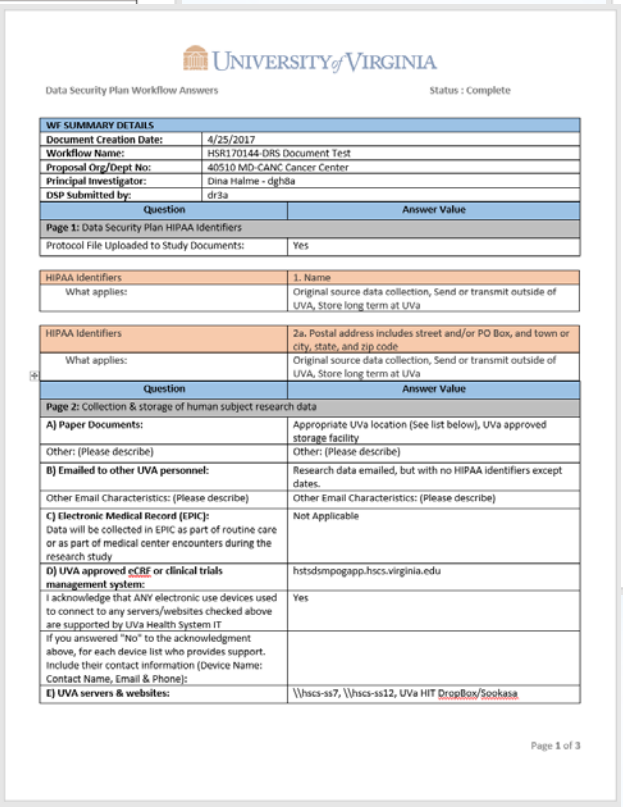
INTERNAL DATASET TYPE DETERMINATION (applies to data that will be collected/stored

The internal data set is **HIGHLY SENSITIVE**.

The internal data will be stored in the following formats:

Question	Answer V
Page 2: Collection & storage of human subject research data	
A) Paper Documents:	Appropriate UVa location (See list storage facility
Other: (Please describe)	Other: (Please describe)
B) Emailed to other UVA personnel:	Research data emailed, but with n dates.
Other Email Characteristics: (Please describe)	Other Email Characteristics: (Pleas
C) Electronic Medical Record (EPIC):	Not Applicable

Page 1 of 4



UNIVERSITY of VIRGINIA

Data Security Plan Workflow Answers — Status : Complete

WF SUMMARY DETAILS	
Document Creation Date:	4/25/2017
Workflow Name:	HSR170144-DRS Document Test
Proposal Org/Dept No:	40510 MD-CANC Cancer Center
Principal Investigator:	Dina Halme - dgh8a
DSP Submitted by:	dr3a

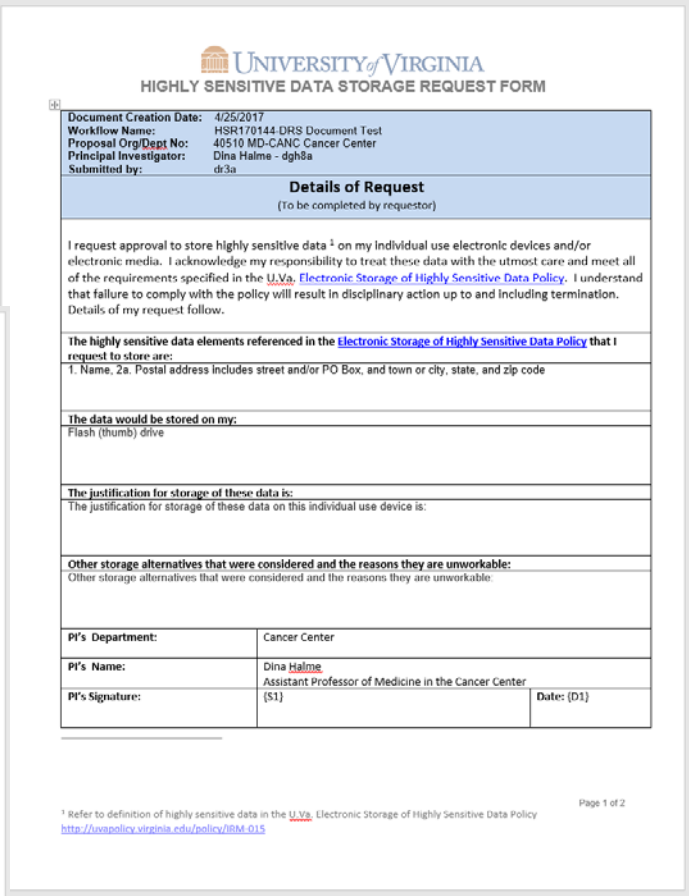
Question	Answer Value
Page 1: Data Security Plan HIPAA Identifiers	
Protocol File Uploaded to Study Documents:	Yes

HIPAA Identifiers	1. Name
What applies:	Original source data collection, Send or transmit outside of UVA, Store long term at UVa

HIPAA Identifiers	2a. Postal address includes street and/or PO Box, and town or city, state, and zip code
What applies:	Original source data collection, Send or transmit outside of UVA, Store long term at UVa

Question	Answer Value
Page 2: Collection & storage of human subject research data	
A) Paper Documents:	Appropriate UVa location (See list below), UVa approved storage facility
Other: (Please describe)	Other: (Please describe)
B) Emailed to other UVA personnel:	Research data emailed, but with no HIPAA identifiers except dates.
Other Email Characteristics: (Please describe)	Other Email Characteristics: (Please describe)
C) Electronic Medical Record (EPIC): Data will be collected in EPIC as part of routine care or as part of medical center encounters during the research study	Not Applicable
D) UVA approved eCRF or clinical trials management system:	hstsdsmpogapp.hscs.virginia.edu
I acknowledge that ANY electronic use devices used to connect to any servers/websites checked above are supported by UVa Health System IT	Yes
If you answered "No" to the acknowledgment above, for each device list who provides support. Include their contact information (Device Name: Contact Name, Email & Phone):	
E) UVA servers & websites:	\\hscs-ss7, \\hscs-ss12, UVa HIT DropBox/Sopkasa

Page 1 of 3



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HIGHLY SENSITIVE DATA STORAGE REQUEST FORM

Document Creation Date:	4/25/2017
Workflow Name:	HSR170144-DRS Document Test
Proposal Org/Dept No:	40510 MD-CANC Cancer Center
Principal Investigator:	Dina Halme - dgh8a
Submitted by:	dr3a

Details of Request

(To be completed by requestor)

I request approval to store highly sensitive data [1] on my individual use electronic devices and/or electronic media. I acknowledge my responsibility to treat these data with the utmost care and meet all of the requirements specified in the U.Va. Electronic Storage of Highly Sensitive Data Policy. I understand that failure to comply with the policy will result in disciplinary action up to and including termination. Details of my request follow.

The highly sensitive data elements referenced in the Electronic Storage of Highly Sensitive Data Policy that I request to store are:

1. Name, 2a. Postal address includes street and/or PO Box, and town or city, state, and zip code

The data would be stored on my:

Flash (thumb) drive

The justification for storage of these data is:

The justification for storage of these data on this individual use device is:

Other storage alternatives that were considered and the reasons they are unworkable:

Other storage alternatives that were considered and the reasons they are unworkable:

PI's Department:	Cancer Center	
PI's Name:	Dina Halme Assistant Professor of Medicine in the Cancer Center	
PI's Signature:	{S1}	**Date:** {D1}

Page 1 of 2

[1] Refer to definition of highly sensitive data in the U.Va. Electronic Storage of Highly Sensitive Data Policy http://uvapolicy.virginia.edu/policy/IRM-015

ISPRO Approval of the Data Security Plan and Highly Sensitive Data Storage Form, which will be signed electronically

Submissions and Outcomes Prior to IRB Pre-Review

	ISPRO Committee (Data Security Plan)
	ISPRO Highly Sensitive Data Storage Form DocuSign Creation
	ISPRO Highly Sensitive Data Storage Form DocuSign Status
	ISPRO Highly Sensitive Data Storage Form Signed Document

IRB-HSR: Submission, Signing, Status and Information

IRB Submission: Clinical Research Connect → IRB (auto-generated email)
IRB Status and Information: IRB Online → Clinical Research Connect

INSTITUTIONAL REVIEW BOARD for HEALTH SCIENCE RESEARCH (IRB-HSR)	MILESTONE: IRB-HSR Submission
	IRB-HSR Status and Information (Provided by IRB)
	IRB-HSR Investigator Agreement
	IRB-HSR DocuSign Creation
	IRB-HSR DocuSign Signature Status
	IRB-HSR DocuSign Status
	IRB-HSR Investigator Agreement Signed
	MILESTONE: IRB-HSR Approval

Electronic Submissions and Outcomes After IRB Approval

Submissions and Outcomes After IRB Approval	NIH Certificate of Confidentiality
	HIRE Notification
	GRIME Submission
	GRIME Outcome
	GMEC Submission
	GMEC Outcome

Ancillary Services – starting point

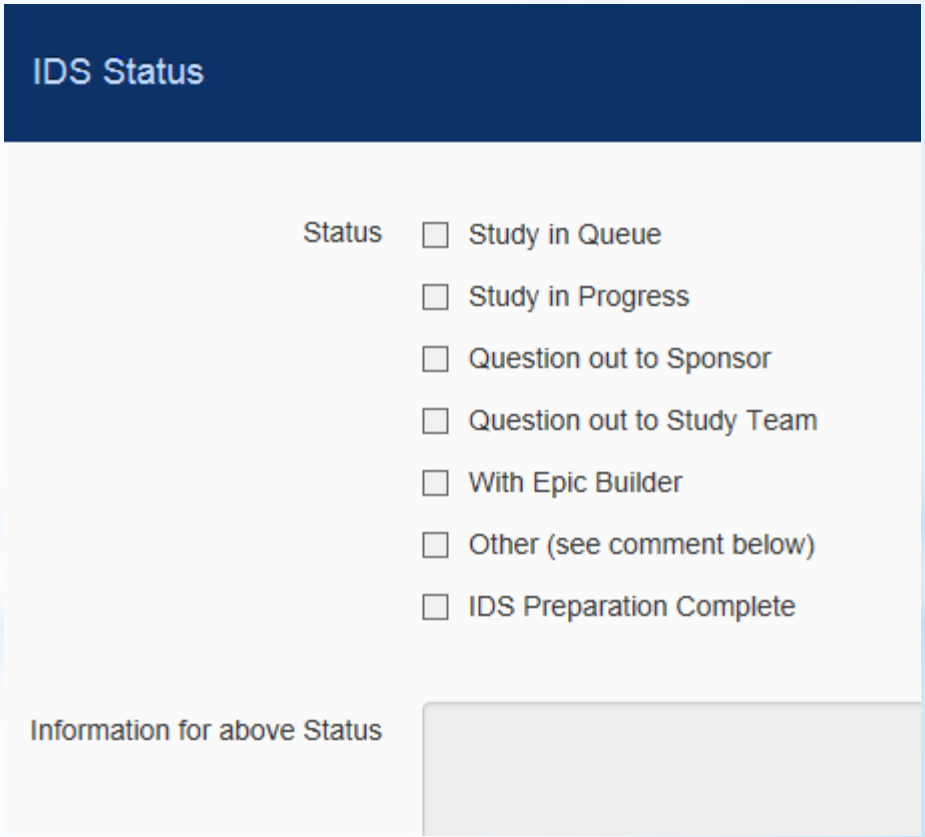
Ancillary Services	Biorepository and Tissue Research Facility
	Clinical Labs
	Radiology and Medical Imaging, including Snyder Research Imaging
	Ambulatory Clinic/Hospital Nursing Unit/Cancer Center Infusion
	New Medical Device/Supply Chain Management
	Continuum Home Health
	Therapy Services (Physical Therapy, Occupational Therapy)
	Clinical Research Unit
	Health South

For June rollout: only BTRF step provides electronic submission.
Other steps do not provide electronic submission to the ancillary services; they are informational only, providing instructions on the submission/review process.

Preliminary and actual submission to Investigational Drug Services, IDS Status

- Preliminary IDS Submission
- Preliminary IDS Committee

- IDS Submission
- IDS Committee
- IDS Status



Billing Coverage Analysis and Final steps to Completion

ClinicalTrials.gov	ClinicalTrials.gov
BILLING COVERAGE ANALYSIS (BCA)	Billing Coverage Analysis (BCA) - by CTO
	BCA DocuSign Creation - by CTO
	BCA DocuSign Status
	MILESTONE: BCA Signed Document
Billing Set-up	MILESTONE: Billing Set-up
START-UP COMPLETION	MILESTONE: READY FOR ENROLLMENT

Clinical Research Connect Process and System Highlights

- WE HAVE A PLATFORM to connect study team to all the steps in the highly complex process
- Automated 100 study start-up components
- Moved toward single point of data entry, provided visibility and increased awareness
- Eliminated more than 10 signatures and allowed electronic signing
- Automated 25 compliance requirements prior to submission to IRB
- Created Feasibility Assessment framework
- Allowed generation of At Risk PTAO earlier in the process
- Provided access to research pricing throughout the study management
- Reengineered Data Security Plan generation
- Established foundation for reporting, analytics, and decision making

Planning Next Steps

July-August: review, assessment, finalizing Phase 2 scope and timeline

September: starting Phase 2 development

Fall 2017: Decisions on rollout to SOM and beyond

THANK YOU!

Clinical Research Connect