

Associated Policy:	OCR
Policy Name	Research Study Submission, Review & Feasibility
Version 6.0 Date:	12/27/2019

Research Study Technology Feasibility Worksheet

INSTRUCTIONS

The purpose of this Research Study Technology Feasibility Worksheet is to assist the study team to request approval for data to be transferred externally, to access a restricted website, to add software to the TGH network, or to add or attach hardware to a TGH computer or equipment for research purposes only.

STEPS

1. Complete Section I: Study Information
2. Complete Section II: Data Transfers Externally, if applicable
3. Complete Section III: Software Addition, if applicable
4. Complete Section IV: Hardware Addition, if applicable
5. Complete Section V: Access to Restricted Website, if applicable
6. Complete Section VI: Submitter Information. This is the information for the person completing and submitting this Worksheet.
7. Submit the completed Research Study Technology Feasibility Worksheet to research@tgh.org and the OCR Program Coordinator.

Section VII will be completed by the reviewer.

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Section I: Study Information	
TGH RO #:	
Full Study Title:	
Short Study Title:	
Study Protocol Number:	
Projected Enrollment:	
Principal Investigator's (PI) Name <i>(responsible for the study)</i> and Contact Information:	
Study Coordinator's Name and Contact Information:	
Sponsor:	
Sponsor Representative's Name and Contact Information:	
Vendor:	
Vendor Representative's Name and Contact Information:	
Study Summary:	
Is data to be transferred externally?	Yes <input type="checkbox"/> Please complete Section II. No <input type="checkbox"/>
Is software to be added to TGH computers or network?	Yes <input type="checkbox"/> Please complete Section III. No <input type="checkbox"/>
Is hardware to be added/attached to TGH computers or equipment?	Yes <input type="checkbox"/> Please complete Section IV. No <input type="checkbox"/>
Is access to a currently blocked or restricted website being requested?	Yes <input type="checkbox"/> Please complete Section IV. No <input type="checkbox"/>



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Section II: Data Transfers Externally

N/A

Data to Be Transferred Externally	Who will de-identify the data?	Mode of Transfer	Who will Transfer the Data to External Recipient?	Who is Receiving the Data? (External Recipient)
<input type="checkbox"/> CT/ CAT/ CTA scans <input type="checkbox"/> MRIs/ MRAs <input type="checkbox"/> DEXA scans <input type="checkbox"/> X-rays <input type="checkbox"/> Mammograms <input type="checkbox"/> Stereotactic breast biopsies <input type="checkbox"/> Fluoroscopic <input type="checkbox"/> Cardiac catheterization	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE <input type="checkbox"/> Other:	<input type="checkbox"/> PowerShare <input type="checkbox"/> Upload to website Specify: _____ <input type="checkbox"/> Encrypted CD <input type="checkbox"/> Entered in software Specify: _____ <input type="checkbox"/> Entered in hardware Specify: _____ <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Echocardiograms	TGH Radiology Imaging	<input type="checkbox"/> Encrypted CD	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Ultrasounds	TGH Radiology Imaging	<input type="checkbox"/> Encrypted CD	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team



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				<input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Bone scans (not DEXAs)	TGH Radiology Imaging	<input type="checkbox"/> Encrypted CD	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Nuclear medicine images	TGH Radiology Imaging	<input type="checkbox"/> Encrypted CD	<input type="checkbox"/> TGH Radiology Imaging <input type="checkbox"/> TGH CORE	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Photographs (no faces)	<input type="checkbox"/> TGH CORE <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> Upload to website Specify: _____ <input type="checkbox"/> Encrypted CD <input type="checkbox"/> Entered in software Specify: _____ <input type="checkbox"/> Entered in hardware Specify: _____ <input type="checkbox"/> Other:	<input type="checkbox"/> TGH CORE <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:



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Other:		<input type="checkbox"/> Upload to website Specify: _____ <input type="checkbox"/> Encrypted CD <input type="checkbox"/> Entered in software Specify: _____ <input type="checkbox"/> Entered in hardware Specify: _____ <input type="checkbox"/> Other:	<input type="checkbox"/> TGH CORE <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Other:		<input type="checkbox"/> Upload to website Specify: _____ <input type="checkbox"/> Encrypted CD <input type="checkbox"/> Entered in software Specify: _____ <input type="checkbox"/> Entered in hardware Specify: _____ <input type="checkbox"/> Other:	<input type="checkbox"/> TGH CORE <input type="checkbox"/> Other: Specify: _____	<input type="checkbox"/> USF Study Team <input type="checkbox"/> USF Study Team to then transfer to Sponsor <input type="checkbox"/> Non-TGH Study Team <input type="checkbox"/> Non-TGH Study Team to then transfer to Sponsor <input type="checkbox"/> Sponsor <input type="checkbox"/> Other:
Comments:				



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Section III: Software Addition

N/A

Section III: Software Addition <input type="checkbox"/> N/A	
Vendor Name:	
Software/System Name:	
Software/System Purpose:	
List Vendor/Sponsor 21CRF Part 11 compliance information, if applicable:	
Does TGH already have this software?	Yes <input type="checkbox"/> No <input type="checkbox"/>
How will this software work in conjunction with the existing TGH network?	
Will the software be removed once the research study is complete?	Yes <input type="checkbox"/> No <input type="checkbox"/>
What are the internal and external interfaces that may be present?	
List the type of data to be exported using this software. Include a description of the patient identifiers that will be included in the data transfer.	
How will the data be transferred (e.g. system upload; transmittal form completion)? Include if the data transfer is manual or automated and who will be responsible for the data transfer.	
Documents included to support this request (such as training manuals, user manuals, etc.)	



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Section IV: Hardware Addition

N/A

Vendor Name:	
Software/System Name:	
Software/System Purpose:	
List Vendor/Sponsor 21CRF Part 11 compliance information, if applicable:	
Does TGH already have this hardware?	Yes <input type="checkbox"/> No <input type="checkbox"/>
How will this hardware work in conjunction with the existing TGH network, computers, and equipment?	
Will the hardware be removed once the research study is complete?	Yes <input type="checkbox"/> No <input type="checkbox"/>
What are the internal and external interfaces that may be present?	
List the type of data to be exported using this hardware. Include a description of the patient identifiers that will be included in the data transfer.	
How will the data be transferred (e.g. system upload; transmittal form completion)? Include if the data transfer is manual or automated, and who will be responsible for the data transfer.	
Documents included to support this request (such as training manuals, user manuals, device manuals, etc.)	



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Section V: Access to Restricted Website

N/A

Website (URL) to be Accessed	Explanation and Justification
Website:	
Website:	
Documents included to support this request (such as training manuals, user manuals, device manuals, etc)	
Comments:	

Section VI: Submitter Information

Name	Role	Date
Signature:		

----- STUDY TEAM STOPS HERE-----



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Section VII: Determination of Technology Feasibility

- Yes, feasible
- No, not feasible
- Requires additional information

Comments

Section VIII: Reviewer Information

Name	Role	Date
Signature: _____		

TGH OCR Updates to the Worksheet:

Name	Date	Sections Updated	Comment