

Data Transfer SOP – QA Labs

By: Ran Klein, University of Ottawa Heart Institute.

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Last Updated: 2012-11-20

Intended Audience:

These operating procedures are intended for participating imaging sites in the IMAGE-HF project, including:

- Interpreting physicians
- Research coordinators
- Research support staff

Background:

Standardization of image interpretation is a key feature of the IMAGE-HF project. Standardization is conducted by QA labs of respective imaging modalities and indicators as listed below. All participating sites are responsible for image interpretation and reporting. A subset of images will be selected and sent to the corresponding QA lab for interpretation. Feedback will be provided to the imaging site, to standardize image quality and interpretation. For cases with discordant interpretations, consensus will be reached and documented.

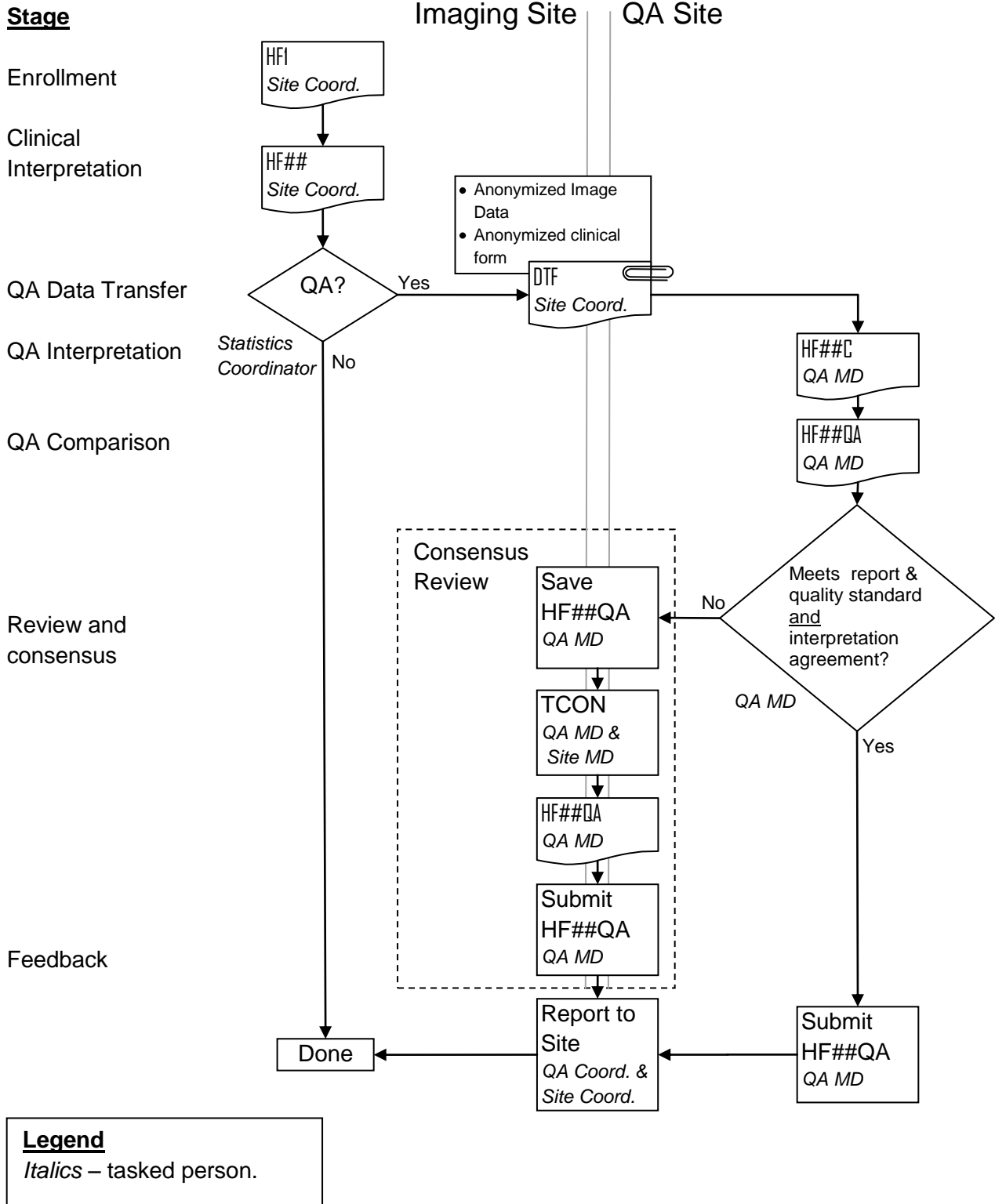
The following table summarizes the IMAGE-HF QA lab sites and contact persons.

Study	CRF	Modality	Indication	QA Lab	QA lab director	QA Contact
1A	HF-15	PET, SPECT	Ischemia	UOHI	Rob Beanlands	Ran Klein
	HF-12	PET, SPECT	Viability	UOHI	Rob Beanlands	Ran Klein
	HF-15	CMRi	Ischemia	London	James White	Irene Pauchard
	HF-13	CMRi	Viability	London	James White	Irene Pauchard
1B	HF-18	Echo	Non-ischemics	UOHI	Kwan Chan	Ran Klein
	HF-19	CMRi	Non-ischemics	Edmonton	Ian Paterson	Ian Paterson
1C	HF-21	CTA	Anatomy	UOHI	Ben Chow	Ran Klein
	HF-22	ICA	Anatomy	MHICC	Philippe L'Allier	Philippe L'Allier

The IMAGE-HF database will automatically flag patients to be used as QA when the modality forms (i.e. HF 12, HF13, HF15, HF18, HF19, HF21, & HF22) are entered to the APA system (via the web interface).

Procedure Overview:

The following flow diagram summarizes the QA procedure step-by-step from top to bottom. Detailed explanations follow.



Retrieving QA Data

Data Transfer Form: The DTF CRF will be used to track image data that has been transferred from the imaging site to the QA lab using DICOM transfer or FTP. An email is sent to a designated QA site representative from the APA system or administrator notifying that a DTF has been submitted by the Imaging Site. The DTF contains information on transmission of key QA data and how they were transmitted to the QA site. This data includes:

- Anonymized image data
- Anonymized clinical reports
- The IMAGE-HF image interpretation CRF.

The DTF also contains contact information for the imaging site representative.


- 1) Click on the *Inbox* tab.
- 2) Select an *HF_DTF* subject message, as shown below.



- 3) Click on the *form icon* to view the DTF-CRF or the *paperclip icon* to view the attachments.




- 4) Clicking on the  will display the DTF, as shown below:



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HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

IMAGE HF DATA TRANSFER FORM



Randomization #:

00020

1A

01

0007

Patient ID #: Project Site Number

Date Sent: Sender: Name:
dd/mm/yyyy E-mail Address:
 Telephone:

Data

1) Image data

Modality:

Indication:

If Modality is Echo + CMR, which one are you sending (choose one only): OR Echo
 CMR

Core Lab: UOHI London Montreal Edmonton

Anonymized Identifiers (DICOM fields) if different from guidelines:

Name:

ID:

DOB: dd/mm/yyyy

Transfer method:

Direct DICOM

FTP Folder:

 Label:

Please anonymize the patient information according to the guidelines to ensure that the patient is not identifiable

2) Clinical Interpretation Report & CRF(s)

Transfer method: Attachment via APA Web

FTP File name:

 Folder:

Fax

Core Lab Contact Information


Person:

Telephone:

FTP: Address: [Help](#)

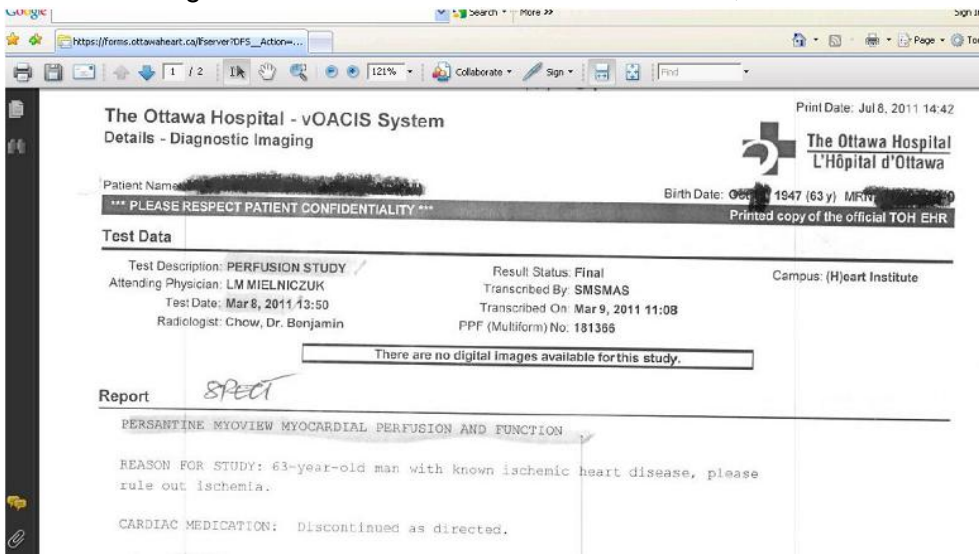
 Port:

 User Name:



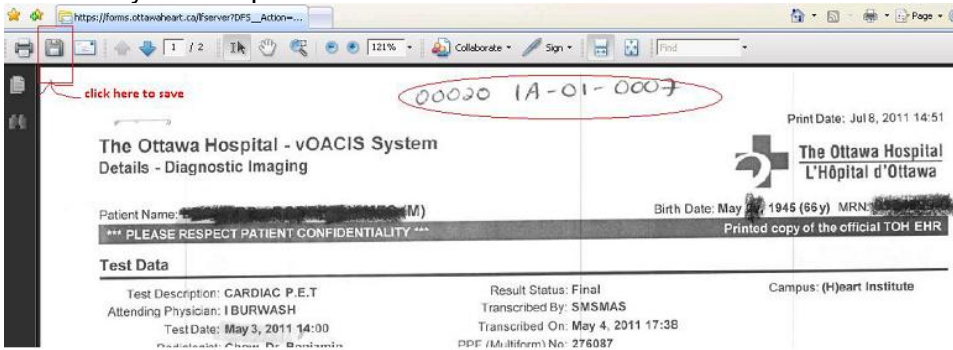
! NOTE – The DTF is your reference for locating key data for image interpretation and imaging site contact information.

5) Double clicking on the  icon will view the attachment, as demonstrated below:

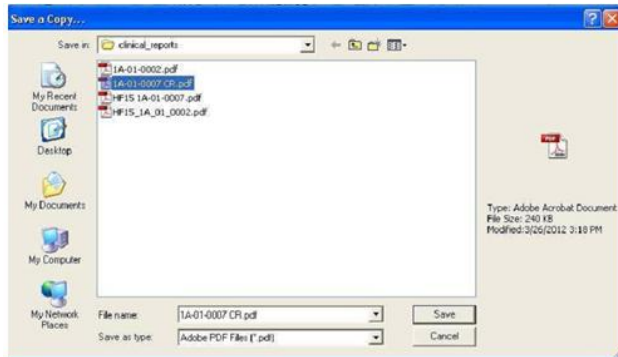


OPTIONAL: Saving attachments to file for your record

a) After the attachment is opened from the DTF form, click on the Save button to save the file to your computer.



b) Choose the location where you would like to save your file, and rename the file if necessary (e.g. form id –project – site – number) and click the Save button.



Retrieving Additional Data

Refer to the DTF for details on how the images and supporting documentation (e.g. clinical report forms) have been transferred to the QA site. The QA site core lab coordinator should be contacted for site specific information.

In general, anonymized image data is transferred by secure FTP, but in the same institution DICOM transfer may also be used. Clinical report forms may be attached to the DTF and retrieved using APA as described above, but in some cases may also be faxed or transferred by FTP (with the image data).

Complete IMAGE-HF Core Image Interpretation CRF

- Completion of e-form via the forms portal (<https://forms.ottawaheart.ca/isp/login.jsp>).
- Each QA lab will be assigned a user account in order to complete the Image HF CRF online.
- Applies to respective core lab interpretation (HF-XXC) CRFs.


1) Click on the *IMAGE_HF_QA* folder listed under the Folders tab, as shown below:



2) A list of CRF(s) names appears under the IMAGE_HF_QA folder, as shown below:



Select the desired form, (e.g. HF15C_IA_Stress_Perfusion_report) by either clicking on the

icon  or on the name of the file (HF15C_IA_Stress_Perfusion_Report). For detailed information, please refer to the modality specific SOP (available at <http://www.image-hf.ca/imaging-technology-sops.htm>)

Complete the corresponding IMAGE-HF QA CRF.


Complete IMAGE-HF Quality Assurance CRF

- Completion of e-form via the forms portal (<https://forms.ottawaheart.ca/jsp/login.jsp>).
- Each QA lab will be assigned a user account in order to complete the Image HF CRF online.
- Applies to respective quality assurance (HF-XXQA) CRFs.

1) Select the appropriate HF QA form to complete for QA (e.g. HF15_QA_update).



2) Complete all fields of the QA form comparing the imaging site and QA lab interpretation CRFs (e.g. HF15 and HF15C CRFs respectively), indicating N/A where data is not available.


PROJECT I-A
HF15QA- STRESS PERFUSION REPORT- PET, SPECT OR CMR

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 INSTITUT DE CARDIOLOGIE
 DE L'UNIVERSITÉ D'OTTAWA

Randomization #:

Patient ID #:

IMAGE-HE

RECOMMENDATION:	Agreement	Consensus review results
III. Revascularization benefit category (likely, may, unlikely, uncertain, other)	<input type="radio"/> Yes <input type="radio"/> No → (If no , requires consensus review)	<input type="radio"/> Patient LIKELY to benefit from revascularization or angiography <input type="radio"/> Patient MAY benefit from revascularization or angiography <input type="radio"/> Patient UNLIKELY to benefit from revascularization <input type="radio"/> Patient UNCERTAIN to benefit from revascularization, recommend viability imaging <input type="radio"/> Other: <input type="text"/>
Reason for disagreement: <input type="text"/>		

3) In the *Mandatory Consensus Fields* section, complete whether the imaging site and QA lab interpretations agreed.

MANDATORY CONSENSUS FIELDS (I, II, III)		Consensus review results																									
I. Global LV Scar category (Normal/None, Mild/Small, Moderate, Severe/Large)	<input type="radio"/> N/A <input type="radio"/> Yes <input type="radio"/> No → (If no , requires consensus review)	<table border="1"> <thead> <tr> <th></th> <th>Normal/None (<5%)</th> <th>Mild/Small (<10%)</th> <th>Moderate (11-20%)</th> <th>Severe/Large (>20%)</th> </tr> </thead> <tbody> <tr> <td>Whole Heart</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>LAD</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>RCA</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>LCx</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> </tbody> </table>		Normal/None (<5%)	Mild/Small (<10%)	Moderate (11-20%)	Severe/Large (>20%)	Whole Heart	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	LAD	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	RCA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	LCx	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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II. Global LV Ischemia category (Normal/None, Mild/Small, Moderate, Severe/Large)	<input type="radio"/> N/A <input type="radio"/> Yes <input type="radio"/> No → (If no , requires consensus review)	<table border="1"> <thead> <tr> <th></th> <th>Normal/None (<5%)</th> <th>Mild/Small (<10%)</th> <th>Moderate (11-20%)</th> <th>Severe/Large (>20%)</th> </tr> </thead> <tbody> <tr> <td>Whole Heart</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>LAD</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>RCA</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> <tr> <td>LCx</td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> <td><input type="radio"/></td> </tr> </tbody> </table>		Normal/None (<5%)	Mild/Small (<10%)	Moderate (11-20%)	Severe/Large (>20%)	Whole Heart	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	LAD	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	RCA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	LCx	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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RCA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>																							
LCx	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>																							

HF15QA- Stress Perfusion Report: PET, SPECT or CMR V6- 17Jul2012 Page 1 of 2

4) **Agreement** - If the all mandatory interpretations **agree**, submit the form by selecting *Submit* from the pull down menu and clicking the *Submit* button. Send a copy of the completed QA CRF to the imaging site as feedback on the QA by following steps below.

CONSENSUS REVIEW REQUIRED Yes No

Date of consensus review:
Year Month Day

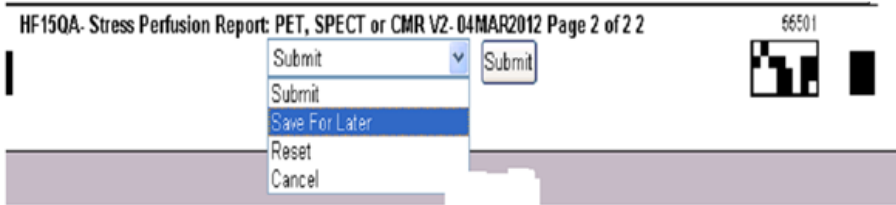
Site Initials: QA Initials:

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Submit 56501

Submit
 Save For Later
 Reset
 Cancel

Disagreement - If one or more of the mandatory interpretations **disagree**, a consensus review is required as explained in the next section (Consensus Reviews Procedure on page 12). Save the form by selecting *Save For Later* from the pull down menu and clicking the *Submit* button. This case will be saved in the INBOX tab to be retrieved for review at a later time.



- 5) After you click on the *Submit* option, another window (Routing for Form: HF15_QA) will display, as shown below:

A screenshot of a web form titled "Routing for Form: HF15_QA". The "Send to:" section has two radio buttons: "User" (selected) and "Routing Completed". The "User" option has a dropdown menu showing "IHF_QA_Centre1" and a "Search" button. Below this are "Send", "Back", and "Cancel" buttons. The "Notes:" section has a "Subject" field with "1A - 01 - 0002 - HF15QA" and a "Notes" text area. The "Copy Final Document:" section has an "Add Recipients" field and "Search" and "Remove" buttons. At the bottom are "Send", "Back", and "Cancel" buttons.

- 6) Under the "Send to" section, please click on the Routing Completed option, as shown below:

A screenshot of the same "Routing for Form: HF15_QA" form. In this view, the "Routing Completed" radio button is selected and circled in red. The "User" option is now unselected. The "Send", "Back", and "Cancel" buttons are visible at the bottom.

- 7) Under the *Notes* section, you can write some notes, as shown in the example below:

Notes:

Subject: IA - 01 - 0002 - HF15QA

Notes: All agreement, copy of final HF15QA for your record

- 8) Under the *Copy Final Document* section, please click on the *Search* button to retrieve the list of the site you are choosing to send a copy of the QA to:

Copy Final Document:

Add Recipients

Search

Remove

Send Back Cancel

- 9) A list of users or centres will be displayed as below:

Autonomy Process Automation™ Web Desktop - Windows Internet Explorer

Search Users

OK Reset Cancel << < 1 of 7 > >>

Search in Everywhere contains

	<input type="checkbox"/>	User Name	UserID
1	<input type="checkbox"/>	IHF- 1ACMR Corelab	1acmr_core
2	<input type="checkbox"/>	IHF_QA_Centre1	IHF_QA_Centre1
3	<input type="checkbox"/>	IHF_QA_Centre2	IHF_QA_Centre2
4	<input type="checkbox"/>	IHF_QA_Centre3	IHF_QA_Centre3
5	<input type="checkbox"/>	IHF_QA_Centre4	IHF_QA_Centre4
6	<input type="checkbox"/>	IHF_QA_Centre5	IHF_QA_Centre5
7	<input type="checkbox"/>	IHF_QA_Centre6	IHF_QA_Centre6
8	<input type="checkbox"/>	IHF_QA_Centre7	IHF_QA_Centre7
9	<input type="checkbox"/>	IHF_QA_Centre8	IHF_QA_Centre8
10	<input type="checkbox"/>	IHF_QA_Centre9	IHF_QA_Centre9

- 10) Please choose the centre you wish to send a copy of the QA form to. For example, if site 1, then choose IHF_QA_Centre1. Doing this will send a copy of the QA form to the Work Queue tab of the user for site 1. IHF_QA_Centre1 is a folder which stores all the QA forms in a separate tab called Work-Queue for each centre.

Data Transfer SOP – QA Labs

Search Users

OK Reset Cancel << < 1 of 7 > >>

Search is Everywhere contains

	User Name	UserID
1	IHF- IACMR Corelab	Iacmr_core
2	IHF_QA_Centre1	IHF_QA_Centre1
3	IHF_QA_Centre2	IHF_QA_Centre2
4	IHF_QA_Centre3	IHF_QA_Centre3
5	IHF_QA_Centre4	IHF_QA_Centre4
6	IHF_QA_Centre5	IHF_QA_Centre5
7	IHF_QA_Centre6	IHF_QA_Centre6
8	IHF_QA_Centre7	IHF_QA_Centre7
9	IHF_QA_Centre8	IHF_QA_Centre8
10	IHF_QA_Centre9	IHF_QA_Centre9

11) Here is an example of how to send a final copy of QA to site

Routing for Form: HF15_QA

Send to:

If you are the final approver, click *Routing Completed*.
Otherwise, select the user to whom you would like to route the form. Then click *Send*.

User Search

Routing Completed

Send Back Cancel

Notes:

Subject: IA-01-0002-HF15QA

Notes: All agreement, copy of final HF15QA for your record

Copy Final Document:

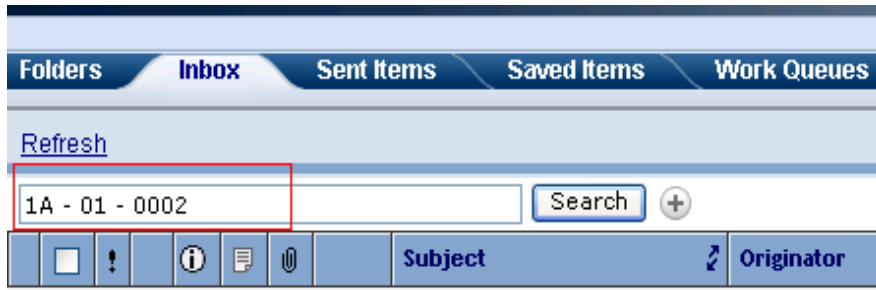
Add Recipients: Search Remove


Send Back Cancel

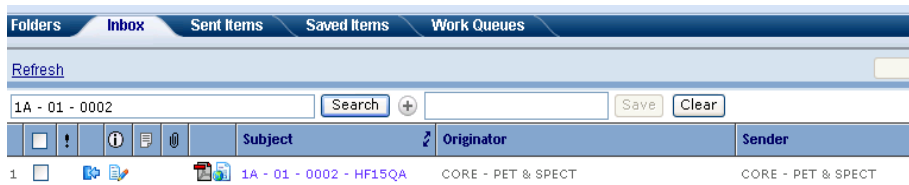
Consensus Reviews Procedure

In the event of a disagreement in the mandatory fields on the quality assurance CRF, a consensus review is required. The QA site and imaging site must coordinate the consensus review. Based on the particular needs of the modality a web conferencing (e.g. GoToMeeting, WebEx) session may be used. Contact the respective core lab manager for technical support.

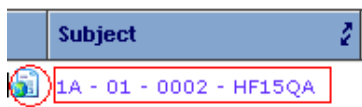
- 1) The QA lab reviewers and the imaging site will schedule a time to review the interpretation and reach a consensus.
- 2) Retrieve the previously saved: HFXXQA, HFXX, and HFXXC CRFs as well as any other relevant data (e.g. images, clinical reports, technical reports).
- 3) To retrieve the QA CRF go to the *Inbox Tab*, and find the Randomization # using the search feature as shown below the below and click on the *Search* button



*Notice that your Saved for Later record has a pad and a pencil icon  and it will be displayed in the first row after the *Search* button is pressed.



Once you have located your case, click on the subject line or the icon to open the form as shown below:



- 4) Complete the right hand column of the QA form for all fields which have indicated disagreement by indicating consensus results.

MANDATORY CONSENSUS FIELDS (I, II, III)		Consensus review results				
I. Global LV <u>Scar</u> category (Normal/None, Mild/Small, Moderate, Severe/Large)	<input type="radio"/> N/A <input checked="" type="radio"/> Yes <input type="radio"/> No → (If no , requires consensus review)	Normal/None (<5%)	Mild/Small (<10%)	Moderate (11-20%)	Severe/Large (>20%)	
		Whole Heart				
		LAD				
		RCA				
		LCx				
II. Global LV <u>Ischemia</u> category (Normal/None, Mild/Small, Moderate, Severe/Large)	<input type="radio"/> N/A <input type="radio"/> Yes <input checked="" type="radio"/> No → (If no , requires consensus review)	Normal/None (<5%)	Mild/Small (<10%)	Moderate (11-20%)	Severe/Large (>20%)	
		Whole Heart				
		LAD				
		RCA				
		LCx				

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5) In the text fields at the bottom of the form indicate remarks and recommendations.

COMMENTS

Clinical:	
Technical:	
Action:	

!Note – In the event that a consensus cannot be reached by the two readers, a third reader should be consulted. The majority agreement should be documented in the consensus review column. A note should be recorded in the text field.

6) Indicate the initials of the reviewers.

Date of QA: Year Month Day

QA Initials:

CONSENSUS REVIEW REQUIRED Yes No

Date of consensus review: Year Month Day

Site Initials:

QA Initials:

- 7) After the consensus review process is completed, submit the form, and send a copy of the QA report to the site. Follow the same procedure as before to submit the form (see below steps):
 - a) After you click on the *Submit* button, another window (Routing for Form: HF15_QA) will display, as shown below:

Routing for Form: HF15_QA

Send to:

If you are the final approver, click *Routing Completed*.
Otherwise, select the user to whom you would like to route the form. Then click *Send*.

User

Routing Completed

Notes:

Subject:

Notes:

Copy Final Document:

Add Recipients:

- b) Under the *Send to* section, click on the *Routing Completed* option, as shown below:

Routing for Form: HF15_QA

Send to:

If you are the final approver, click *Routing Completed*.
Otherwise, select the user to whom you would like to route the form. Then click *Send*.

User

Routing Completed

Notes:

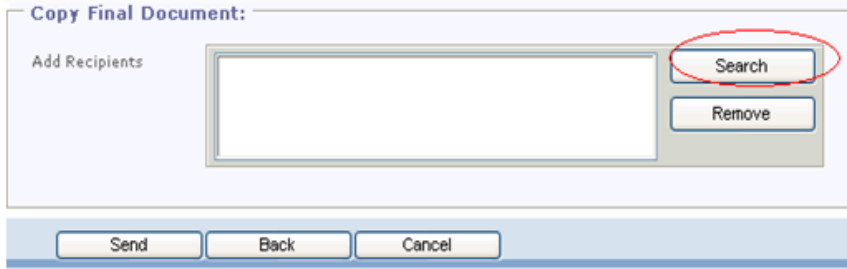
- c) Under the *Notes* section, you can write some notes, as shown in the example below:

Notes:

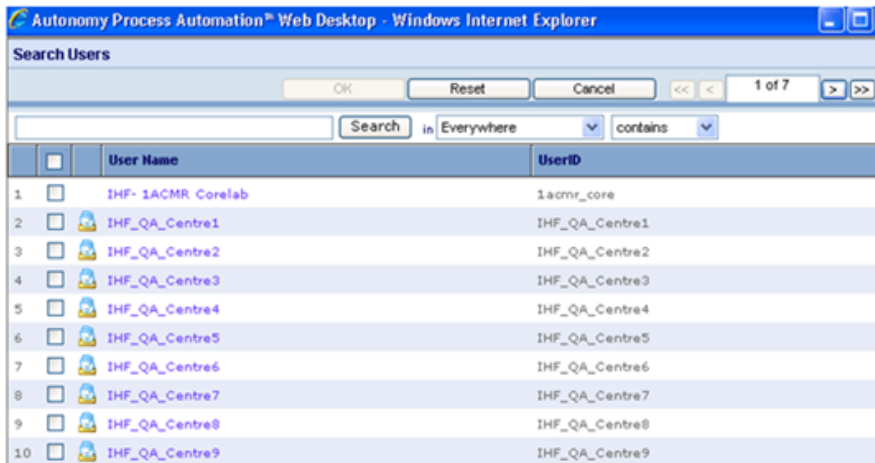
Subject:

Notes:

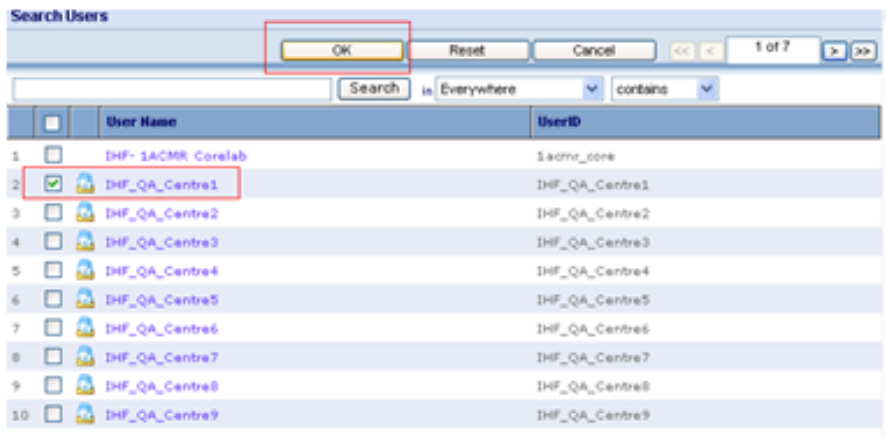
Under the *Copy Final Document* section, click on the *Search* button to retrieve the list of the site you are choosing to send a copy of the QA to:



d) A list of users or centre will be displayed as below:



e) Choose the centre you wish to send a copy of the QA form to. For example, if site 1, then choose IHF_QA_Centre1. Doing this will send a copy of the QA form to the Work Queue tab of the user for site 1. IHF_QA_Centre1 is a folder which stores all the QA forms in a separate tab called Work-Queue for each centre.



f) In summary, after you have submitted your form, in the Routing for Form: HF15QA window, select *Routing Completed* button, add appropriate notes (if any), and click the Send button (6), as shown below.

Data Transfer SOP – QA Labs

Routing for Form: HF15_QA

Send to:

If you are the final approver, click *Routing Completed*.
Otherwise, select the user to whom you would like to route the form. Then click *Send*.

User Search

Routing Completed

Send Back Cancel

Notes:

Subject:

Notes:

Copy Final Document:

Add Recipients: Search Remove

Send Back Cancel

-END-