

Result coding: 1 = Pass (full functionality with no unexpected errors), 0 = Fail (lack of required functionality or reproducible error during testing), 9 = Conditional (partial functionality, error during testing which cannot be reproduced, poor user experience or other constraints) X = Functionality which is desirable for future iterations of the system. these items are not necessary for user acceptance of this version of the system

All tests  
by Lisa  
26/3/13

#	Test description	Test Protocol	Pass (all items)	Fail (on any item)	Result	Notes
2	<b>STUDIES</b>					
2.1	<b>New Studies</b>					
2.1.1	A user with "Study Administrator" access to a study can define new substudies.	1. Log in as a user with "Study Administrator" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Click the "New Child Study" button. 4. Enter relevant data for required fields marked with an asterisk and click the "Save" button.	1. The user is able to create the new substudy. 2. The new substudy is recognised as a child study of WARTN.	1. The user is unable to create the new substudy. 2. The new substudy is not recognised as a child study of WARTN.	1	
2.1.2	A user with "Study Read-Only" access to a study cannot define new substudies.	1. Log in as a user with "Study Read Only" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Click the "New Child Study" button. 4. Enter relevant data for required fields marked with an asterisk, and click the "Save" button.	1. The user is unable to create the new substudy.	1. The user is able to create the new substudy.	1	
2.1.3	The "Study Administrator" who creates a new substudy gains full Administrative rights to that substudy on its creation.	1. Log in as a user with "Study Administrator" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Click the "New Child Study" button. 4. Enter relevant date for required fields marked with an asterisk and click the "Save" button. 5. In the Study > Manage Users tab, search for the applicable user from the context of WARTN. 6. In the Study > Manage Users tab, search for the applicable user from the context of the new substudy. 7. Compare the access rights	1. The user is able to be located under "Manage Users". 2. The user's access rights for the new substudy are the same as their access rights for the WARTN study.	1. The user is unable to be located under "Manage Users". 2. The user's access rights for the new substudy are different to their access rights for the WARTN study.	1	
2.2	<b>Numbering / IDs.</b>					
2.2.1	On creation of a study, a user with "Study Administrator" access can set the system of subject IDs for a study and all of its substudies.	Method pending.	1. The user is able to set the system of subject IDs for a study and all of its sub-studies	1. The user is unable to set the system of subject IDs for a study and all of its substudies	1	
2.2.2	On creation of a study, a user with "Study Administrator" access can set the system of collection IDs for a study and all of its substudies.	Method pending.	1. The user is able to set the system of collection IDs for a study and all of its sub-studies	1. The user is unable to set the system of collection IDs for a study and all of its substudies	1	
2.2.3	On creation of a study, a user with "Study Administrator" access can set the system of biospecimen IDs for a study and all of its substudies.	Method pending.	1. The user is able to set the system of biospecimen IDs for a study and all of its sub-studies	1. The user is unable to set the system of biospecimen IDs for a study and all of its substudies	X / 9	may not be appropriate for wartn
2.2.4	On creation of a study, a user with "Study Administrator" access can select for a study to generate sequential subject IDs across all substudies it contains.	Method pending.	1. The user is able to set subject IDs to be sequential across all substudies.	1. The user is unable to set subject IDs to be sequential across all substudies.	9	As above
2.2.5	On creation of a study, a user with "Study Administrator" access can select for a study to generate sequential collection IDs across all substudies it contains.	Method pending.	1. The user is able to set collection IDs to be sequential across all substudies.	1. The user is unable to set collection IDs to be sequential across all substudies.	9	As above

2.2.6	On creation of a study, a user with "Study Administrator" access can select for a study to generate sequential biospecimen IDs across all substudies it contains.	Method pending.	1. The user is able to set biospecimen IDs to be sequential across all substudies.	1. The user is unable to set biospecimen IDs to be sequential across all substudies.	9	as above
2.2.7	On creation of a study, a user with "Study Administrator" access can set the collection ID to contain a portion of the substudy ID of the substudy it is associated to.	Method pending.	1. The user is able to set the collection ID to contain a portion of the substudy ID when setting up a new Study.	1. The user is unable to set the collection ID to contain a portion of the substudy ID when setting up a new Study.	X	this is functionality we would consider useful, but which is not required for acceptance of this version
2.2.8	On creation of a study, a user with "Study Administrator" access can set the collection ID to contain a portion of the subject ID of the subject it is associated to.	Method pending.	1. The user is able to set the collection ID to contain a portion of the subject ID when setting up a new Study. 2. This ID numbering system functions across substudies.	1. The user is unable to set the collection ID to contain a portion of the subject ID when setting up a new Study. 2. This ID numbering system does not function across substudies.	X	this is functionality we would consider useful, but which is not required for acceptance of this version
2.2.9	On creation of a study, a user with "Study Administrator" access can set the biospecimen ID to contain a portion of the collection ID of the collection it is associated to.	Method pending.	1. The user is able to set the biospecimen ID to contain a portion of the collection ID when setting up a new Study. 2. This ID numbering system functions across substudies.	1. The user is unable to set the biospecimen ID to contain a portion of the collection ID when setting up a new Study. 2. This ID numbering system does not function across substudies.	1	never intended as functionality of the system
2.3	<b>Sub-study access</b>					
2.3.1	A user with "Study Administrator" access to a study and all of its substudies can modify user access to a specific substudy without altering their access to the parent study.	1. Select a substudy in the Study > Study Details tab. 2. In the Study > Manage Users tab, select a user with "Study Read-Only" access to WARTN and all substudies, and modify their access to the selected substudy. 3. Log out of the Ark and log back in as the selected user. 4. Check that the access to WARTN is independent to the changes to the substudy. 5. Check that the access to other substudies is independent to the changes to the substudy. 6. Check that the access to the target substudy is changed. 7. Repeat steps 2	1. Study Administrator is able to modify substudy specific access for users with access to WARTN. 2. The modified user is able to confirm the appropriate access changes. 3. The user's access to WARTN is unaffected by substudy access modifications. 4. The user's access to a substudy is not governed by WARTN access. 5. Substudy access modifications do not affect the user's access to WARTN. 6. Substudy access modifications do not affect the user's access to other substudies.	1. Study Administrator is unable to modify substudy specific access for users with access to WARTN. 2. The modified user is unable to confirm the appropriate access changes. 3. The user's access to WARTN is affected by substudy access modifications. 4. The user's access to a substudy is governed by WARTN access. 5. Substudy access modifications affect the user's access to WARTN. 6. Substudy access modifications affect the user's access to other substudies.	1	
2.3.2	A user with "Study Read-Only" access to a study and all of its substudies cannot modify user access to a study or substudy	1. Select a substudy in the Study > Study Details tab. 2. In the Study > Manage Users tab, select a user with "Study Read-Only" access to WARTN and all substudies, and modify their access to the selected substudy. 3. Log out of the Ark and log back in as the selected user. 4. Check that the access to WARTN is unchanged. 5. Check that the access to other substudies is unchanged. 6. Check that the access to the target substudy is unchanged.	1. User is unable to modify study or substudy specific access for other users 2. The modified user's access to the target substudy is unchanged 3. The modified user's access to WARTN is unchanged. 4. The modified user's access to other substudies is unchanged.	1. User is able to modify study or substudy specific access for other users 2. The modified user's access to the target substudy has changed 3. The modified user's access to WARTN has changed. 4. The modified user's access to other substudies has changed.	1	
2.3.3	A user with access rights to a study cannot access a substudy for which they do not have access.	1. Log in as a user with "Study Administrator" access to WARTN. 2. Select a substudy in the Study > Study Details tab. 3. In the Study > Manage Users tab, select a user with access to WARTN and the previously selected substudy, and remove their access to the substudy. 4. Log out of the Ark and log back in as the selected user. 5. Check for access to WARTN. 6. Check for access to the selected substudy. 7. Check for access to other substudies.	1. A Study Administrator is able to remove access to a substudy for users with access to WARTN. 2. The modified user is unable to see a substudy for which they do not have access. 3. The user is unable to identify patients, collections, biospecimens, transactions, and freezer allocations associated with a substudy for which they do not have access. 4. The user's access to WARTN is unaffected by substudy access modifications. 5. The user's access to a substudy is not governed by WARTN access. 6. Substudy access modifications do not affect the user's access to WARTN. 7. Substudy access modifications do not affect the user's access to other substudies.	1. A Study Administrator is able to remove access to a substudy for users with access to WARTN. 2. The modified user is unable to see a substudy for which they do not have access. 3. The user is able to identify patients, collections, biospecimens, transactions, or freezer allocations associated with a substudy for which they do not have access. 4. The user's access to WARTN is affected by substudy access modifications. 5. The user's access to a substudy is governed by WARTN access. 6. Substudy access modifications affect the user's access to WARTN. 7. Substudy access modifications affect the user's access to other	1	
2.4	<b>Archiving</b>					
2.4.1	A user with "Study Read-Only" access to a study and all of its substudies cannot set a study or substudy as "archived"	1. Log in as a user with "Study Read-Only" access to WARTN and all of its substudies. 2. Click on a WARTN substudy in the Study Details tab. 3. Alter the "Status" of the study to "Archived", and click the "Save" button.	1. The user is able to see a list of all studies and substudies. 2. The user is able to view the study details. 3. The user is unable to modify study details. 4. The user is unable to set the substudy's status to "Archived".	1. The user is unable to see a list of all studies and substudies. 2. The user is unable to view the study details. 3. The user is able to modify study details. 4. The user is able to set the substudy's status to "Archived".	1	
2.4.2	A user with "Study Administrator" access to a study and all of its substudies can set a study or substudy as "Archived".	1. Log in as a user with "Study Administrator" access to WARTN and all of its substudies. 2. Click on a WARTN substudy in the Study Details tab. 3. Alter the "Status" of the study to "Archived", and click the "Save" button.	1. The user is able to see a list of all studies and substudies. 2. The user is able to view the study details. 3. The user is able to modify study details. 4. The user is able to set the substudy's status to "Archived".	1. The user is unable to see a list of all studies and substudies. 2. The user is unable to view the study details. 3. The user is unable to modify study details. 4. The user is unable to set the substudy's status to "Archived".	1	

2.4.3	A user with "Study Administrator" access to a study and all of its substudies can view a list of all archived substudies in the Study > Study Details tab.	1. Log in as a user with "Study Administrator" access to WARTN and all of its substudies. 2. Identify an archived substudy in the Study > Study Details tab. 3. Identify that the study is Archived.	1. The user is able to identify archived substudies in the Study > Study Details tab. 2. The user is able to identify if a substudy's status is "Archived". 3. The user is able to identify active studies in the Study > Study Details tab.	1. The user is unable to identify archived substudies in the Study > Study Details tab. 2. The user is unable to identify if a substudy's status is "Archived". 3. The user is unable to identify active studies in the Study > Study Details tab.	X/9	study administrator cannot see archived studies in the list on study details page. Access to be determined in future release.
2.4.4	A user with "Study Read-Only" access to a study and all of its substudies cannot view any archived substudies in the Study > Study Details tab.	1. Log in as a user with "Study Read-Only" access to WARTN and all of its substudies. 2. Identify an archived substudy in the Study > Study Details tab. 3. Identify that the study is Archived.	1. The user is unable identify archived substudies in the Study > Study Details tab. 2. The user is able to identify active studies in the Study > Study Details tab.	1. The user is able to identify the archived substudy in the Study > Study Details tab. 2. The user is unable to identify active studies in the Study > Study Details tab.	1	
2.4.5	A user with access to a study and all of its substudies cannot identify Archived substudies in the "Study" value list in the Subject > Demographic Data tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. In the Subject > Demographic Data tab, find the name of an archived substudy in the "Study" value list.	1. The user is able to view the Subject > Demographic Data tab from the context of the WARTN study. 2. The user is unable to identify the archived study in the Subject > Demographic Data "Study" value list. 3. The user is able to identify all active substudies in the Subject > Demographic Data "Study" value list.	1. The user is unable to view the Subject > Demographic Data tab from the context of the WARTN study. 2. The user is able to identify the archived study in the Subject > Demographic Data "Study" value list. 3. The user is unable to identify all active substudies in the Subject > Demographic Data "Study" value list.	1	
2.4.6	A user with access to a study and all of its substudies cannot identify the patients, transactions, or biospecimens associated with archived substudies from within the Subject > Demographic Data tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. In the Subject > Demographic Data tab, find a patient with a known association to an active substudy and an archived substudy. 4. Attempt to identify which substudies the patient is associated with.	1. The user is able to view the Subject > Demographic Data tab from the context of the WARTN study. 2. The user is unable to identify patients assigned to the archived study. 3. The user is able to identify all patients assigned to all active studies.	1. The user is unable to view the Subject > Demographic Data tab from the context of the WARTN study. 2. The user is able to identify patients assigned to the archived study. 3. The user is unable to identify all patients assigned to all active studies.	1	Can not see achived study in Demographic Data page dropdown and can not see it on the Study Detail page. Also tested for an archived study, and no biospecimens were displayed
2.4.7	A user with access to a study and all of its substudies can identify the collections and biospecimens for a patient for all active studies when viewing the Subject > Subject Biospecimen tab from the context of the parent study.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under Subject > Demographic Data, enter the context of a patient with biospecimens associated to multiple active substudies, and an archived substudy. 4. In the Subject > Subject Biospecimen tab, identify the collections associated with active substudies, and the collections associated with archived substudies.	1. The user is able to view the Subject > Subject Biospecimen tab from the context of the parent study. 2. The user is able to see all collections, biospecimens, and transactions assigned to active substudies. 3. The user is unable to identify collections, biospecimens, or transactions assigned to archived substudies.	1. The user is unable to view the Subject > Subject Biospecimen tab from the context of the parent study. 2. The user is unable to see all collections, biospecimens, and transactions assigned to active substudies. 3. The user is able to identify collections, biospecimens, or transactions assigned to archived substudies.	1	accept that you can see a list of substudies the patient has consented to when in the Subject page of the parent study but you have to be in the context of the substudy to see the collections and biospecimens for that substudy. The vast majority of our patients are only in one study and we have no patients in more than two so its not a big deal practically. Happy to
2.4.8	A user with access to a study and all of its substudies can identify the collections and biospecimens for a patient for all active studies when viewing the Subject > Biospecimen tab from the context of the parent study.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under Subject > Demographic Data, enter the context of a patient with biospecimens associated to multiple active substudies, and an archived substudy. 4. In the Subject > Biospecimen tab, identify the collections associated with active substudies, and the collections associated with archived substudies.	1. The user is able to view the Subject > Biospecimen tab from the context of the parent study. 2. The user is able to see all collections, biospecimens, and transactions assigned to active substudies. 3. The user is unable to identify collections, biospecimens, or transactions assigned to archived substudies.	1. The user is unable to view the Subject > Biospecimen tab from the context of the parent study. 2. The user is unable to see all collections, biospecimens, and transactions assigned to active substudies. 3. The user is able to identify collections, biospecimens, or transactions assigned to archived substudies.	1	Lisa; " I am happy to accept that you can see a list of substudies the patient has consented to when in the Subject page of the parent study but you have to be in the context of the substudy to see the collections and biospecimens for that substudy. The vast majority of our patients are only in one study and we have no patients in more than two so its not a big deal practically. Happy to sign off."
2.4.10	A user with access to a study and all of its substudies cannot enter the Subject > Demographic Data page for a subject in the context of an archived substudy.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under Subject > Demographic Data, enter the context of a patient known to have biospecimens associated to an active substudy, and an archived substudy. 3. In the Subject > Demographic Data page for a subject, find and click the name of an archived substudy in the "Link to Child Study Subject" list. 4. Click the Subject > Demographic Data tab. 5. Identify the same patient and enter the Subject > Demographic Data page.	1. The user is unable to view the Subject > Demographic Data page for a subject from the context of an archived study. 2. The user is unable to identify if a patient is associated with an archived study from the Subject > Demographic Data page. 3. The user is able to identify which active studies a patient is associated with from the Subject > Demographic Data page.	1. The user is able to view the Subject > Demographic Data page for a subject from the context of an archived study. 2. The user is able to identify if a patient is associated with an archived study from the Subject > Demographic Data page. 3. The user is unable to identify which active studies a patient is associated with from the Subject > Demographic Data page.	1	user is unable to enter the context of an archived study in the subject demographic data tab.

2.4.11	A user with access to a study and all of its substudies cannot identify Archived substudies in the "Study" value list in the Subject > Biospecimen tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under Subject > Demographic Data, enter the context of a patient known to have biospecimens associated to an active substudy, and an archived substudy. 3. In the Subject > Biospecimen tab, find the name of an archived substudy in the "Study" value list.	1. The user is able to view the Subject > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is unable to identify archived studies in the Subject > Biospecimen "Study" value list. 3. The user is able to identify all active substudies in the Subject > Biospecimen "Study" value list.	1. The user is unable to view the Subject > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is able to identify archived studies in the Subject > Biospecimen "Study" value list. 3. The user is unable to identify all active substudies in the Subject > Biospecimen "Study" value list.	1	
2.4.12	A user with access to a study and all of its substudies cannot identify the patients, transactions, or biospecimens associated with archived substudies from within the Subject > Biospecimen tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under Subject > Demographic Data, enter the context of a patient known to have biospecimens associated to an active substudy, and an archived substudy. 4. In the Subject > Biospecimen tab, find a patient with a known association to an active substudy and an archived substudy. 5. Attempt to identify which	1. The user is able to view the Subject > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is unable to identify patients assigned to archived studies. 3. The user is able to identify all patients, transactions, or biospecimens assigned to all active studies.	1. The user is unable to view the Subject > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is able to identify patients, transactions, or biospecimens assigned to archived studies. 3. The user is unable to identify all patients, transactions, and biospecimens assigned to all active studies.	1	user is unable to enter the context of an archived study in the subject biospecimen tab and view archived collections, biospecimens, and transactions
2.4.13	A user with access to a study and all of its substudies cannot identify Archived substudies in the "Study" value list in the LIMS > Subject Detail tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. In the LIMS > Subject Detail tab, find the name of an archived substudy in the "Study" value list.	1. The user is able to view the LIMS > Subject Detail tab from the context of the WARTN study. 2. The user is unable to identify archived studies in the LIMS > Subject Detail "Study" value list. 3. The user is able to identify all active substudies in the LIMS > Subject Detail "Study" value list.	1. The user is unable to view the LIMS > Subject Detail tab from the context of the WARTN study. 2. The user is able to identify archived studies in the LIMS > Subject Detail "Study" value list. 3. The user is unable to identify all active substudies in the LIMS > Subject Detail "Study" value list.	1	
2.4.14	A user with access to a study and all of its substudies cannot identify the patients, transactions, or biospecimens associated with archived substudies from within the LIMS > Subject Detail tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. In the LIMS > Subject Detail tab, find a patient with a known association to an active substudy and an archived substudy. 4. Attempt to identify which substudies the patient is	1. The user is able to view the LIMS > Subject Detail tab from the context of the WARTN study. 2. The user is unable to identify patients assigned to archived studies. 3. The user is able to identify all patients assigned to all active studies.	1. The user is unable to view the LIMS > Subject Detail tab from the context of the WARTN study. 2. The user is able to identify patients assigned to an archives study. 3. The user is unable to identify all patients assigned to all active studies.	1	
2.4.15	A user with access to a study and all of its substudies cannot identify Archived substudies in the "Study" value list in the LIMS > Biospecimen tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under LIMS > Subject Detail, enter the context of a patient known to have biospecimens associated to an active substudy, and an archived substudy. 3. In the LIMS > Biospecimen tab, find the name of an archived substudy in the "Study" value list.	1. The user is able to view the LIMS > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is unable to identify the archived study in the LIMS > Biospecimen "Study" value list. 3. The user is able to identify all active substudies in the LIMS > Biospecimen "Study" value list.	1. The user is unable to view the LIMS > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is able to identify the archived study in the LIMS > Biospecimen "Study" value list. 3. The user is unable to identify all active substudies in the LIMS > Biospecimen "Study" value list.	1	
2.4.16	A user with access to a study and all of its substudies cannot identify the patients, transactions, or biospecimens associated with archived substudies from within the LIMS > Biospecimen tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the WARTN study. 3. Under LIMS > Subject Detail, enter the context of a patient known to have biospecimens associated to an active substudy, and an archived substudy. 4. In the LIMS > Biospecimen tab, find a patient with a known association to an active substudy and an archived substudy. 5. Attempt to identify which	1. The user is able to view the LIMS > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is unable to identify patients, transactions, or biospecimens assigned to the archived study. 3. The user is able to identify all patients, transactions, and biospecimens assigned to all active studies.	1. The user is unable to view the LIMS > Biospecimen tab from the context of a patient in multiple substudies. 2. The user is able to identify patients, transactions, or biospecimens assigned to the archived study. 3. The user is unable to identify all patients, transactions, and biospecimens assigned to all active studies.	1	user is unable to enter the context of an archived study in the Subject → Biospecimen Search tab and the biospecimen details pages
2.4.17	A user with access to a study and all of its substudies cannot identify Archived substudies in the "Study" value list in the LIMS > Subject Detail tab.	1. Log in as a user with access to WARTN and all of its substudies. 2. Find a previously archived study in the Study > Study Details tab. 3. In the LIMS > Subject Detail tab, find the name of an archived substudy in the "Study" value list.	1. The user is unable to identify the archived study in the Subject > Demographic Data "Study" value list. 2. The user is unable to identify patients assigned to the archived study.	1. The user is able to identify the archived study in the Subject > Demographic Data "Study" value list. 2. The user is able to identify patients assigned to the archived study.	1	
2.5	<b>Fields</b>					
2.5.1	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the "study name"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	

2.5.2	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "primary investigator"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	
2.5.3	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study's "other collaborators"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	X	to be applied in later release
2.5.4	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "contact person"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	
2.5.5	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "contact phone"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	
2.5.9	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "description"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	
2.5.10	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "start date".	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	can use "Date of Application"
2.5.12	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the "parent study"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	1	
2.5.13	The "Study > Study Details" page for a specific study or substudy contains an appropriate field for entry of the study "study end date"	1. Log in as a user with "Study Administrator" access to a study and all of its substudies. 2. Click the first study in the list of studies under the Study > Study Details tab. 3. Identify that an appropriate field exists.	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.	X	to be applied in later release. Can use description for generic fields/data

## CONSENT

A user with "Subject Data Manager" or higher access can modify consent data for a patient.

1. Log in as a user with "Subject Data Manager" access to WARTN and all of its substudies. 2. Under Study > Study Details, enter the context of the Colorectal Cancer Collection study. 3. In the LIMS > Subject Detail tab, find the patient with the surname "Beilin". 4. Modify the consent data for the patient in this study

1. The user is able to modify the consent data. 2. The user is able to identify that the consent history fields are updating appropriately.

1. The user is unable to modify the consent data. 2. The user is unable to identify that the consent history fields are updating appropriately.

1

need to expand test methods for this



A user with "Subject Data Manager" or higher access for a study and its substudies can choose to propagate the consent for a parent study to the child substudies as an independent consent.

A user with "Subject Data Manager" or higher access for a study and its substudies can create consents for substudies which are independent to those of the parent study

A user with "Subject Data Manager" or higher access for a study and its substudies can allocate a consent to select list of studies or substudies

USER EXPERIENCE: The date of the consent can be easily seen

USER EXPERIENCE: The user who is consenting a patient can be easily identified

A user with "Subject Read-Only" or higher access for a study and its substudies can search for a patient's consent status for a study or sub-study. The "Subject > Demographic Data" page for a specific subject contains an appropriate field for entry of subject "consent type"

The "Subject > Demographic Data" page for a specific subject contains an appropriate field for entry of subject "date of consent"

The "Subject > Demographic Data" page for a specific subject contains an appropriate field for listing the studies a subject has consented to.

USER EXPERIENCE: There should be no confusion as to whether a consent is at the study or sub-study level

Lisa stated " I think this means that parent study consent is independent of sub study consent and that is the case. You can auto-consent or not as required."

1. Log in as a user with "Subject Data Manager" access to WARTN and all substudies. 2. In Study > Study Details, enter the context of the WARTN study. 3. In Subject > Demographic Data, find a subject with the surname "Beilin". 4. Remove consent for the WARTN study. 5.

1. Log in as a user with "Subject Data Manager" access to WARTN and all substudies. 2. For allsub -studies that will be auto-consented, select Auto-consent" and click "Save". 3. In Study > Study Details, enter the context of the WARTN study. 4. In Subject > Demographic Data, find a subject with the surname "Beilin". The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

1. Log in as a user with "Subject Read-Only" access to WARTN and its substudies 2. ..see if the CRC sub-study and WARTN study consent status for an individual patient can be searched under the "Subject > Demographic Data" tab. 1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Identify that an appropriate field exists.

1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Identify that an appropriate field exists.

1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Identify that an appropriate field exists.

The user will review user experience items during normal testing and pass or fail this item after completion.

1. The subject is consented to all specified sub-studies.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The user is able to search for a consent status for the study. 2. The user is able to search for a consent status for the sub-study. 3. The user can see a history of the consent status for the study. 1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.

1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.

1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.

1. The location and format of the data is suitable to meet the user's requirements.

1. The subject is consented to all specified sub-studies.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The field does not exists 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.

1. The field does not exists 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.

1. The field does not exists 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.

1. The location and format of the data is not suitable to meet the user's requirements.

1	
1	
1	
1	
X	Create a userid field to record who actually created/saved consent
1	Can run a report to determine all patients/subjects for a particular consent status and a particular subject
1	field consent type exists
1	field consent date exists
1	the corresponding list of child studies indicate the sub-studies the subject is consented to
1	

## SUBJECTS

### 2.1 New Subjects

2.1.1 A user with "Subject Data Manager" access to a study can define new subjects.

1. Log in as a user with "Subject Data Manager" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Click on the "New" button in the Subject > Demographic Data tab. 4. Enter relevant data for required fields marked with an asterisk and click the "Save" button. 1. Log in as a user with "Subject Read-Only" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Click on the "New" button in the Subject > Demographic Data tab. 4. Enter relevant data for required fields marked with an asterisk and click the "Save" button.

1. The user is able to create a new subject. 2. The new subject is unable to be identified as a subject in the WARTN study.

1. The user is unable to create a new subject. 2. The new subject is unable to be identified as a subject in the WARTN study.

2.1.2 A user with "Subject Read-Only" access to a study cannot define new subjects.

1. The user is unable to create a new subject.

1. The user is unable to create a new subject.

1	new subject created successfully
1	unable to create new subjects

## Numbering

## Fields

The "Subject > Demographic Data" page for a specific subject contains an appropriate field for entry of subject "date of death"

1. Log in as a user with access to WARTN and all its substudies.
2. Click WARTN in the list of studies under the Study > Study Details tab.
3. Click the first subject in the list of subjects under the Study > Demographic Data tab.
4. Identify that an appropriate field exists.

1. The field exists
2. The field location and format are suitable to meet the user's requirements.
3. Data entry to the field is possible in a context appropriate to its use.
4. The test user considers all value lists and check box options associated with the field to be appropriate.

1. The field does not exist.
2. The field location and format do not meet the user's requirements.
3. Data entry to the field is not possible in the context appropriate to its use.
4. The test user does not consider all value lists and checkbox options associated with the field to be appropriate.

our I was unable to change  
it so it created the new  
patient with ID WTN-  
00000001 which already

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<p>The "Subject &gt; Demographic Data" page for a specific subject contains an appropriate field for listing the subject "study consent list"</p>	<p>1. Log in as a user with access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. Identify that an appropriate field exists.</p>	<p>1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.</p>	<p>1. The field does not exists 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.</p>	<div></div>
<p><b>Search</b> A user with "Subject Read-Only" or higher access to a study can search for a subject using any field or ID associated with that subject, and view the Subject &gt; Demographic Data form for a found subject.</p>	<p>1. Log in as a user with "Subject Read-Only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Identify if the Subject &gt; Demographic Data tab allows for the user to search for subjects based on data from all subject fields.</p>	<p>1. The user is able to search for data on every subject field. 2. The user is able to find and identify subjects by searching for data from any subject field. 3. The user is able to click into the Subject &gt; Demographic Data form for a subject found by searching any subject field.</p>	<p>1. The user is unable to search for data on one or more subject fields. 2. The user is unable to find and identify subjects by searching for data from a subject field. 3. The user is unable to click into the Subject &gt; Demographic Data form for a subject found by searching any subject field.</p>	<div>x</div> <p>Most common search fields are available ie surname, PID. Part of Data Extraction. To be implemented in future milestone</p>
<p>A user with "Subject Read-Only" or higher access to a study can search for a subject by collection ID or biospecimen ID, and view the Subject &gt; Demographic Data form for a found subject.</p>	<p>1. Log in as a user with "Subject Read-Only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Identify if the Subject &gt; Demographic Data tab allows for the user to search for subjects via collection ID and biospecimen ID.</p>	<p>1. The user is able to search for data on every subject field. 2. The user is able to find and identify subjects by searching for a collection ID 3. The user is able to find and identify subjects by searching for a biospecimen ID. 4. The user is able to click into the Subject &gt; Demographic Data form for a subject found by searching collection ID and biospecimen ID.</p>	<p>1. The user is unable to search for data on one or more subject fields. 2. The user is unable to find and identify subjects by searching for a collection ID. 3. The user is unable to find and identify subjects by searching for a biospecimen ID. 4. The user is unable to click into the Subject &gt; Demographic Data form for a subject found by searching collection ID and biospecimen ID.</p>	<div>1</div> <p>To do this, use the biocollection search, select the bio* and then your subject will be in context.</p>
<p><b>Attachments</b> A user with "Subject Data Manager" or higher access to a study can upload attachments for a subject.</p>	<p>1. Log in as a user with "Subject Data Manager" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. In Subject &gt; Attachments click "New". 5. Click "browse", find a test image file, and click "Save" to upload it. 6. Identify if the attachment exists for the</p>	<p>1. The user is able to upload attachments for a subject. 2. The user is able to see a list of previously uploaded attachments for a subject. 3. The user is able to download attachments for a subject.</p>	<p>1. The user is unable to upload attachments for a subject. 2. The user is unable to see a list of previously uploaded attachments for a subject. 3. The user is unable to download attachments for a subject.</p>	<div>1</div>
<p>A user with "Subject Data Manager" or higher access to a study can delete attachments previously uploaded for a subject.</p>	<p>1. Log in as a user with "Subject Data Manager" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. In Subject &gt; Attachments click "Delete" on an attachment previously uploaded. 5. Identify the attachment</p>	<p>1. The user is able to see a list of previously uploaded attachments for a subject. 2. The user is able to delete attachments previously uploaded for a subject.</p>	<p>1. The user is unable to see a list of previously uploaded attachments for a subject. 2. The user is unable to delete attachments previously uploaded for a subject.</p>	<div>1</div>
<p>A user with "Subject Read-Only" or higher access to a study can view attachments for a subject.</p>	<p>1. Log in as a user with "Subject Read Only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. Identify that previously uploaded attachments exist in the</p>	<p>1. The user is able to see a list of previously uploaded attachments for a subject. 2. The user is able to download attachments previously uploaded for a subject.</p>	<p>1. The user is unable to see a list of previously uploaded attachments for a subject. 2. The user is unable to download attachments previously uploaded for a subject.</p>	<div>1</div>
<p>A user with "Subject Read-Only" access to a study cannot upload attachments for a subject.</p>	<p>1. Log in as a user with "Subject Read-Only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. In Subject &gt; Attachments click "New". 5. Click "browse", find a test image file, and click "Save" to upload it. 6. Identify if the attachment exists for the</p>	<p>1. The user is able to see a list of previously uploaded attachments for a subject. 2. The user is unable to upload attachments for a subject.</p>	<p>1. The user is unable to see a list of previously uploaded attachments for a subject. 2. The user is able to upload attachments for a subject.</p>	<div>1</div>
<p>A user with "Subject Read-Only" access to a study cannot delete attachments previously uploaded for a subject.</p>	<p>1. Log in as a user with "Subject Read-Only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study &gt; Study Details tab. 3. Click the first subject in the list of subjects under the Subject &gt; Demographic Data tab. 4. In Subject &gt; Attachments click "Delete" on an attachment previously uploaded. 5. Identify the attachment</p>	<p>1. The user is able to see a list of previously uploaded attachments for a subject. 2. The user is unable to delete attachments previously uploaded for a subject.</p>	<p>1. The user is unable to see a list of previously uploaded attachments for a subject. 2. The user is able to delete attachments previously uploaded for a subject.</p>	<div>1</div>
<p><b>User Experience</b> USER EXPERIENCE: When a subject is in context, data from the field "surname" should always be visible.  USER EXPERIENCE: When a subject is in context, data from the field "firstname" should always be visible.</p>	<p>The user will review user experience items during normal testing and pass or fail this item after completion.  The user will review user experience items during normal testing and pass or fail this item after completion.</p>	<p>1. The location and format of the data is suitable to meet the user's requirements.  1. The location and format of the data is suitable to meet the user's requirements.</p>	<p>1. The location and format of the data is not suitable to meet the user's requirements.  1. The location and format of the data is not suitable to meet the user's requirements.</p>	<div>1</div> <div>1</div>

USER EXPERIENCE: When a subject is in context, data from the field "date of birth" should always be visible.

USER EXPERIENCE: When a subject is in context, data from the field "subject ID" should always be visible.

USER EXPERIENCE: The "status" field should not automatically enter data

The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1	
1	
1	

### Wish List

Users are able to search patients based on field in patient, collection, biospecimen - including custom fields.

The "Patient" section of the database allows users to add test results against a patient

ability to add treatment results against a patient

1. Log in as a user with "Subject Data Manager" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Click "Study-specific Demographic Data" tab 5. Add/Edit data against the custom fields accordingly

1. Log in as a user with "Subject Data Manager" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Click "Study-specific

1	biocollection search, select the bio* and then your subject will be in context. This will be further expanded in data
1	this is functionality we would consider useful but which is not required for acceptance of this version
1	May also use the "Clinical Data" tab to record custom data

## COLLECTIONS

### New Collections

A user with "LIMS Data Manager" access to a study can define new collections.

A user with "LIMS Read-Only" access to a study cannot define new collections.

### Access

#### Numbering

sequential collection numbering across all studies and substudies (C-01234)

1. Log in as a user with "Subject Read-Only" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Search for a subject, or click any of the subject links available. 4. Select a linked sub-study to bring into context. 5. Click the "Subject Biospecimen" tab 6. Click

1. Log in as a user with "Subject Read-Only" access to WARTN. 2. Click on the WARTN study in the Study Details tab. 3. Search for a subject, or click any of the subject links available. 4. Select a linked sub-study to bring into context. 5. Click the "Subject Biospecimen" tab 6. Click

1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first subject in the list of subjects under the Subject > Demographic Data tab. 4. Click "Study-specific Demographic Data" tab 5. Add/Edit data against the custom fields accordingly

1. The user is able to create a new collection for a subject.

1. The user is unable to create a new subject.

1. The user is able to create a new collection for a subject.

1. The user is unable to create a new subject.

1	new subject created successfully
1	unable to create new subjects

1	
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### Archiving

#### Attachments

#### User Experience

#### Wish List

#### Fields

The "Collection Detail" page contains an appropriate field for entry of "study"

1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Identify that an appropriate field exists.

1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.

1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be appropriate.

X	Collections are always tied to the study in context currently
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A user with sufficient access can maintain study-specific and substudy specific custom fields for collections, on a per-study or per-substudy basis.

TODO

store, access, search, and export collection information from all fields, including custom fields

USER EXPERIENCE: When a study is selected (i.e. WARTN), it should be possible to see all collections and biospecimens for a subject across all substudies (except for archived substudies).

USER EXPERIENCE: When a collection is in context, a list of associated biospecimens should be accessible on every page.

USER EXPERIENCE: When a collection is in context, the study or substudy that the collection is associated with should be readily visible.

USER EXPERIENCE: When a collection is in context, the collection ID should always be visible, with the consent status for the associated substudy.

#### Attachments

A user with "Study Administrator" or higher access to a study can upload attachments for a study.

A user with "Study Administrator" or higher access to a study can delete attachments previously uploaded for a study.

A user with "Study Read-Only" or higher access to a study can view attachments for a study.

A user with "Study Read-Only" access to a study cannot upload attachments for a study.

A user with "Study Read-Only" access to a study cannot delete attachments previously uploaded for a study.

#### Wish List

ability to add test results against a collection

The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

The user will review user experience items during normal testing and pass or fail this item after completion.

1. Log in as a user with "Study Administrator" access to WARTN. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. In Study > Attachments click "New". 4. Click "browse", find a test image file, and click "Save" to upload it. 5. Identify if the attachment exists for the study on the Study >

1. Log in as a user with "Study Administrator" access to WARTN. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. In Study > Attachments click "Delete" on an attachment previously uploaded. 4. Identify the attachment no longer exists for the study on the Study > Attachments tab.

1. Log in as a user with "Study Read Only" access to WARTN. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Identify that previously uploaded attachments exist in the Study > Attachments tab

1. Log in as a user with "Study Read-Only" access to WARTN. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. In Study > Attachments click "New". 4. Click "browse", find a test image file, and click "Save" to upload it. 4. Identify if the attachment exists for the study on the Study >

1. Log in as a user with "Study Read-Only" access to WARTN. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. In Study > Attachments click "Delete" on an attachment previously uploaded. 4. Identify the attachment no longer exists for the study on

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The location and format of the data is suitable to meet the user's requirements.

1. The user is able to upload attachments for a study or substudy. 2. The user is able to see a list of previously uploaded attachments for a study or substudy. 3. The user is able to download attachments for a study or substudy.

1. The user is able to see a list of previously uploaded attachments for a study or substudy. 2. The user is able to delete attachments previously uploaded for a study or substudy.

1. The user is able to see a list of previously uploaded attachments for a study or substudy. 2. The user is able to download attachments previously uploaded for a study or substudy.

1. The user is able to see a list of previously uploaded attachments for a study or substudy. 2. The user is unable to upload attachments for a study or substudy.

1. The user is able to see a list of previously uploaded attachments for a study or substudy. 2. The user is unable to delete attachments previously uploaded for a study or substudy.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The location and format of the data is not suitable to meet the user's requirements.

1. The user is unable to upload attachments for a study or substudy. 2. The user is unable to see a list of previously uploaded attachments for a study or substudy. 3. The user is unable to download attachments for a study or substudy.

1. The user is unable to see a list of previously uploaded attachments for a study or substudy. 2. The user is unable to delete attachments previously uploaded for a study or substudy.

1. The user is unable to see a list of previously uploaded attachments for a study or substudy. 2. The user is unable to download attachments previously uploaded for a study or substudy.

1. The user is unable to see a list of previously uploaded attachments for a study or substudy. 2. The user is able to upload attachments for a study or substudy.

1. The user is unable to see a list of previously uploaded attachments for a study or substudy. 2. The user is able to delete attachments previously uploaded for a study or substudy.

1	
X	
X	
1	use tree to the left
1	
1	
X	this is functionality we would consider useful but which is not required for acceptance of this version
X	this is functionality we would consider useful but which is not required for acceptance of this version
X	this is functionality we would consider useful but which is not required for acceptance of this version
X	this is functionality we would consider useful but which is not required for acceptance of this version
X	this is functionality we would consider useful but which is not required for acceptance of this version
X	this is functionality we would consider useful but which is not required for acceptance of this version

#### BIOSPECIMENS

On creation of a study, a user with "Study Administrator" access can set the biospecimen number to contain the patient number for which it belongs

Method pending.

X	this is functionality we would consider useful but which is not required for acceptance of this version
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The "Biospecimen Detail" page contains an appropriate field for entry of a biospecimen "sample time"	1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Click the first biospecimen in the list of biospecimens on the Subject >	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be	1	
The "Biospecimen Detail" page contains an appropriate field for entry of a biospecimen "processing date"	1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Click the first biospecimen in the list of biospecimens on the Subject >	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be	1	
The "Biospecimen Detail" page contains an appropriate field for entry of a biospecimen "processing time"	1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Click the first biospecimen in the list of biospecimens on the Subject >	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be	1	
The "Biospecimen Detail" page contains an appropriate field for entry of a biospecimen "date frozen"	1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Click the first biospecimen in the list of biospecimens on the Subject >	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be	1	
A user with "Subject Read-Only" or higher access to a study can search for a biospecimen by subject ID, collection ID, or biospecimen ID, and view the "Biospecimen Details" form for a found biospecimen.	1. Log in as a user with "Subject Read-only" access to WARTN and all its substudies. 2. Click WARTN in the list of studies under the Study > Study Details tab. 3. Click the first biospecimen in the list of biospecimens under the Subject > Biospecimen tab. 4. Click the first biospecimen in the list of biospecimens on the Subject >	1. The field exists 2. The field location and format are suitable to meet the user's requirements. 3. Data entry to the field is possible in a context appropriate to its use. 4. The test user considers all value lists and check box options associated with the field to be appropriate.	1. The field does not exist 2. The field location and format do not meet the user's requirements. 3. Data entry to the field is not possible in the context appropriate to its use. 4. The test user does not consider all value lists and check box options associated with the field to be	1	similar to wager.
User has the ability to print labels individually and to be batched by adding a new biospecimen can be done against a patient and then assigned to a collection - similar to	1. Log in as a user with "Study Administrator" access to WARTN and all its substudies. 2. Click	TODO TODO		1	
USER EXPERIENCE: When viewing the Subject > Subject Biospecimen page, the page should note the context visibly.	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
dates should default to empty - not today's date	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
this should be always visible: substudy of collection, substudy consent status, collection ID, biospecimenID, patientID, patient name	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
view and add transaction history for the biospecimen alongside the biospecimen data view/edit	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
process button to create child biospecimen	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
list of sub-aliquots is visible on biospecimen page	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	Tree should indicate which biospecimens have children
location of a biospecimen in storage is visible on biospecimen page	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	
transaction history for a biospecimen always visible	The user will review user experience items during normal testing and pass or fail this item after completion.	1. The location and format of the data is suitable to meet the user's requirements.	1. The location and format of the data is not suitable to meet the user's requirements.	1	

ability to add test results against a biospecimen		X	this is functionality we would consider useful, but which is not required for acceptance of this version
TRANSACTIONS			
treatment field should be a part of biospecimen, not transaction treatment field should not be a required field contains a field to enter reason  contains a field to enter study name  contains a field to enter substudy name contains a field to enter collaborator  collaborator field always visible  contains a field to enter status  contains a field to enter quantity  contains a field to enter date   contains a field to enter available quantity	user experience at time of UAT.	1	subject identification can be set to requested format
	user experience at time of UAT.	1	
		1	
		1	
		X	
		X	
		X	to be applied in later release
	user experience at time of UAT.	X	to be discussed, we could add such a field in the future
		1	status field exists
		1	field exists
		9	current defaults to current date. Would be better to have date selection - future release
	1	field exists	
INVENTORY			
ability to define new inventory sites, and associate them with specific ability to define new containers and associate them with a site ability to define new racks and associate them with a container ability to define new boxes and associate them with a shelf ability to view the inventory in a hierarchial form ability to note the type of storage container (freezer/room, temperature, etc.) ability to upload and view documents against an inventory container	user experience at time of UAT.	1	new sites able to be added by system administrator (super user)
		1	
		1	
		1	
		1	
		X	currently in description. We would prefer being able to see this data as fields.
		1	this is functionality we would consider useful, but which is not required for acceptance of this version
SECURITY & BACKUP			
The database has the capacity to assign roles to users (such as study administrator, data entry, data viewing, etc.) Value lists should not be populated with information for studies, substudies, ID numbers, collections, biospecimens, transactions, etc. that a user does not have the rights to access. (e.g. study names in HTML source) Users of all access levels should only be able to see the studies and substudies they have access to.		1	
		1	
		1	

Users who are not study managers should not be able to see account names, email address, account information, contact details, or access rights for users in studies they are not permitted to access  
 Users who are not study managers should not be able to see account names, email address, information, or access rights for any users - even those in the studies they are permitted to access

Users who are study managers should not be able to see account information and access rights for users not affiliated with studies they manage  
 Study managers should not be able to identify account names, or any security or user account information for users who are not affiliated with the studies they manage  
 Users should only be able to see the patients and collections they have access to see, regardless of entry in multiple studies  
 one login across all user experience at time of UAT.  
 Study managers should have the capacity to designate different roles for a user across the different studies/collections they manage  
 linked/SSO with SJGHC novell accounts  
 daily backups of data  
 remote site backup for disaster

1	
1	will hinder collaboration and sharing of users amongst studies. Furthermore, you cannot change the users details, you cannot revoke or see any other access rights, only your own studies. So this is not such an issue. Perhaps when a user gets created we can allow them to be able to see it.
1	All they can see is username (email) in a read only state. They cannot see projects or access rights
X	As above, however marking as X to allow the "invisible flag" to be coded for future release
1	
1	
1	
n/a	
1	We have strategies in place for this
1	We have strategies in place for this

#### CUSTOM FIELDS

"custom fields" and "phenotypic data" is a really blurry distinction for everyone in the lab

can enter a custom field - description, field type, etc.  
 can group custom fields into "questionnaires"  
 can append new custom fields to existing questionnaires  
 can not remove custom fields from existing questionnaires  
 can rename existing custom field descriptions

can add custom fields as value list, boolean, free text, date entry

1	
1	
X	we'd really kind of need this if you're viewing it by "forms" or "questionnaires"
1	
1	the data dictionary tab. The intent was to make it obvious you are not changing the field name for just the questionnaire/data set that you are looking at, but rather for all questionnaire/data sets that
X	

#### SEARCHING - This is Data

A user with sufficient access can search data for all fields for a subject. Method pending.

1. The user is able to search for certain results entered in any number of the relevant fields. 1. The user is unable to search for certain results entered in any number of the relevant fields.

X	be able to search it - lisa's catchphrase. We will analyse and test this for the next realease when
X	be able to search it - lisa's catchphrase. We will analyse and test this for the next realease when

A user with sufficient access can search data for all custom fields entered against a subject. Method pending.

1. The user is able to search for certain results entered in any number of the relevant custom fields. 1. The user is unable to search for certain results entered in any number of the relevant custom fields.



A user with sufficient access can search data for all fields for a collection.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant fields.	1. The user is unable to search for certain results entered in any number of the relevant fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all custom fields entered against a collection.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant custom fields.	1. The user is unable to search for certain results entered in any number of the relevant custom fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all fields for a biospecimen.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant fields.	1. The user is unable to search for certain results entered in any number of the relevant fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all custom fields entered against a biospecimen.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant custom fields.	1. The user is unable to search for certain results entered in any number of the relevant custom fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all fields for a transaction.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant fields.	1. The user is unable to search for certain results entered in any number of the relevant fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all fields for a study or substudy.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant fields.	1. The user is unable to search for certain results entered in any number of the relevant fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all custom fields entered against a study or substudy.	Method pending.	1. The user is able to search for certain results entered in any number of the relevant custom fields.	1. The user is unable to search for certain results entered in any number of the relevant custom fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all fields for an inventory object (freezer, site, etc).	Method pending.	1. The user is able to search for certain results entered in any number of the relevant fields.	1. The user is unable to search for certain results entered in any number of the relevant fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
A user with sufficient access can search data for all custom fields entered against an inventory object (freezer, site, etc).	Method pending.	1. The user is able to search for certain results entered in any number of the relevant custom fields.	1. The user is unable to search for certain results entered in any number of the relevant custom fields.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when
All custom fields can be searched in a manner similar to the existing functionality in wger.	Method pending.	1. The user is able to search for certain results entered in any custom field.	1. The user is unable to search for certain results entered in any custom field.	X	be able to search it - lisa's catchphrase. We will analyse and test this for the next release when

## EXPORTING

A user with sufficient access can export data from any subject field for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all fields entered against a subject.	1. The user is unable to export data from all fields entered against a subject.	X	as per wger
A user with sufficient access can export data from any custom field entered against a subject, for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all custom fields entered against a subject.	1. The user is unable to export data from all custom fields entered against a subject.	X	as per wger
A user with sufficient access can export data from any collection field for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all fields entered against a collection.	1. The user is unable to export data from all fields entered against a collection.	X	as per wger
A user with sufficient access can export data from any custom field entered against a collection, for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all custom fields entered against a collection.	1. The user is unable to export data from all custom fields entered against a collection.	X	as per wger
A user with sufficient access can export data from any biospecimen field for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all fields entered against a biospecimen.	1. The user is unable to export data from all fields entered against a biospecimen.	X	as per wger
A user with sufficient access can export data from any custom field entered against a biospecimen, for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all custom fields entered against a biospecimen.	1. The user is unable to export data from all custom fields entered against a biospecimen.	X	as per wger
A user with sufficient access can export data from any transaction field for a set of found subjects, collections, biospecimens, or transactions.	Method pending.	1. The user is able to export data from all fields entered against a transaction.	1. The user is unable to export data from all fields entered against a transaction.	X	this is functionality we would consider useful, but which is not required for acceptance of this version

A user with sufficient access can export data from any study or substudy field for a set of found studies. A user with sufficient access can export data for any field relating to the LIMS inventory objects (sites, freezers, etc.)	Method pending.	1. The user is able to export data from all fields entered against a study or substudy.	1. The user is unable to export data from all fields entered against a study or substudy.	X	as per wager (sort of)
	Method pending.			1. The user is unable to export data from all fields entered against a LIMS inventory object.	1. The user is unable to export data from all fields entered against a LIMS inventory object.
<b>REPORTS</b> summary of patients in a selected study. summary of patients in a selected substudy summary of a patient (name, dob, all collections, all biospecimens, etc.)  summary of specimens in a selected inventory container					
				1	wager does something similar to this
				1	
				X	Should be available with Data extraction
				1	wish list
<b>USER EXPERIENCE</b> same substudy context between lims, user experience at time of UAT. subject, study, reporting, and patient context remains unchanged until a new subject search is performed. heirarchy of patient collections and biospecimens should state the study "WÄRTN" LIMS CONTEXT SHOULD SHOW ALL SUBSTUDY BIOSPECIMENS  documentation about what is needed in non-custom fields. i.e. status					
				1	
				1	
				1	Always in context
				X	
				X	