

Integrating the Healthcare Enterprise



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IHE Quality, Research and Public Health (QRPH) Technical Framework Supplement

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Retrieve Process for Execution (RPE)

Trial Implementation

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Foreword

25 This is a supplement to the IHE Quality, Research and Public Health (QRPH) Trial Implementation Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of September 2, 2011 and will be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results
30 of testing. Following successful testing it will be incorporated into the QRPH Final Text Technical Framework. Comments are invited and can be submitted at <http://www.ihe.net/qrph/qrphcomments.cfm> or by email to qrph@ihe.net.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as
35 addition of large new sections introduced by editor’s instructions to “add new text” or similar, which for readability are not bolded or underlined.

“Boxed” instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

40

<i>Replace Section X.X by the following:</i>
--

General information about IHE can be found at: www.ihe.net

Information about the IHE QRPH domain can be found at: <http://www.ihe.net/Domains/index.cfm>

Information about the structure of IHE Technical Frameworks and Supplements can be found at:
45 <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>

The current version of the IHE Technical Framework can be found at:
http://www.ihe.net/Technical_Framework/index.cfm

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Introduction

Retrieve Process for Execution (RPE) is a proposed IHE profile for *collaborative workflow* or *collaborative process management* involving three main actors:

1. the manager of process definitions
- 175 2. the manager of runtime processes
3. the performer of process activities

Note that the process definition contains specification for all activities to be performed. An activity defines a specific act, several of which define the entire process.

180 RPE started as Retrieve *Protocol* for Execution Profile, a proposed automated mechanism for an Electronic Health Record (EHR) to retrieve a complex set of clinical research instructions (a study protocol) from a research sponsor's Electronic Data Capture (EDC) system and to execute these instructions within the EHR. Interest has since grown to expand RPE to support processes from other domains involving collaborative workflow like quality, public health and patient care support. RPE now does this consistent with accepted IT standards for process management. This
185 specification is a substantial re-write, and all transactions should be re-examined.

RPE defines the transport mechanism for process definitions, but does not provide the definitions per se. Additional profiles that define specific processes will complement RPE, and bring the process automation capability to completion.

Open Issues and Questions

190 Should the current version of RPE be more distinctly renamed and distinguished from the original clinical research-specific Retrieve *Protocol* for Execution version 1.0?

Closed Issues

No closed issues at this time.

195

Volume 1 – Integration Profiles

Add the following to section 1.1.5

1.n Copyright Permissions

200 *To be completed*

Add the following to section 2.5

2.5 Dependencies of the RPE Integration Profile

205 Retrieve Process for Execution (RPE) is not strictly dependent on any IHE profile but, for performance of activities, the Retrieve Form for Data-capture (RFD) and Redaction Services profiles can be used very synergistically for form-based submission of appropriately redacted EHR data.

Add the following to section 2.7

210

2.7 History of Annual Changes

To be completed

Add Section X to the QRPH Technical Framework

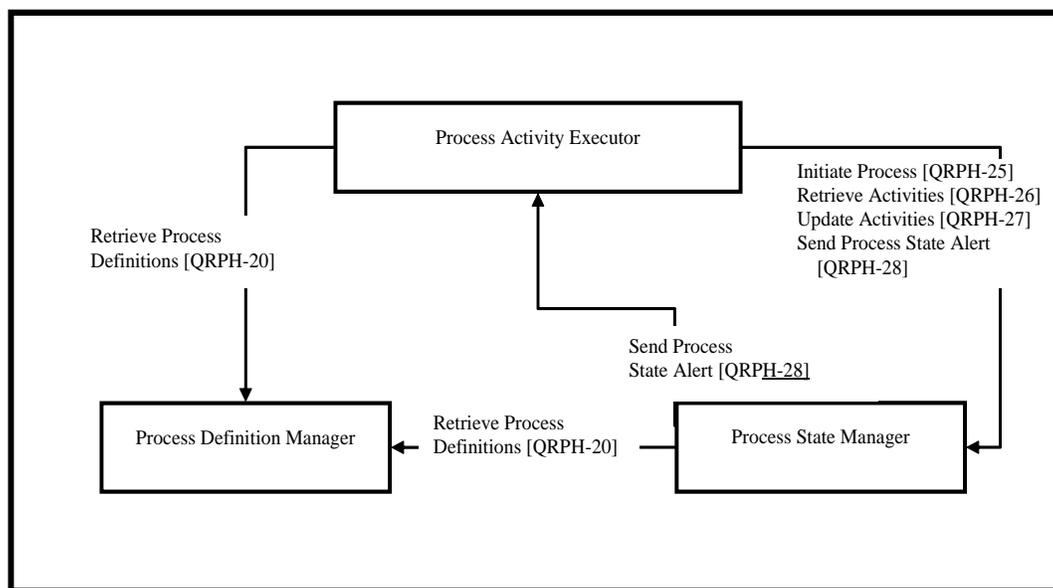
215 **X Retrieve Process for Execution (RPE) Profile**

Retrieve Process for Execution (RPE) is a proposed IHE profile for *collaborative workflow* or *collaborative process management* involving three main actors:

1. the manager of process definitions
2. the manager of runtime processes
- 220 3. the performer of process activities

X.1 RPE Actors/Transactions

Figure X.1-1 shows the actors directly involved in the Retrieve Process for Execution Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other profiles are not necessarily shown.



225 **Figure X.1-1: RPE Actor Diagram**

Table X.1-1 lists the transactions for each actor directly involved in the RPE Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume 1, Section X.2.

230

Table X.1-1: RPE Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Process Definition Manager	Retrieve Process Definitions [QRPH-20]	R	QRPH TF-2:3.Y1
Process State Manager	Retrieve Process Definitions [QRPH-20]	O	QRPH TF-2:3.Y1
	Initiate Process [QRPH-25]	R	QRPH TF-2:3.Y2
	Retrieve Activities [QRPH-26]	O	QRPH TF-2:3.Y3
	Update Activity [QRPH-27]	O	QRPH TF-2:3.Y4
	Send Process State Alert [QRPH-28]	R	QRPH TF-2:3.Y5
Process Activity Executor	Retrieve Process Definitions [QRPH-20]	R	QRPH TF-2:3.Y1
	Initiate Process [QRPH-25]	R	QRPH TF-2:3.Y2
	Retrieve Activities [QRPH-26]	O	QRPH TF-2:3.Y3
	Update Activity [QRPH-27]	O	QRPH TF-2:3.Y4
	Send Process State Alert [QRPH-28]	R	QRPH TF-2:3.Y5

235 X.1.1 Actor Descriptions and Requirements

X.1.1.1 Process Definition Manager

The Process Definition Manager manages access to a repository of process definitions allowing for search and retrieval.

240 An example would be a research sponsor providing access to the clinical research protocols it has developed. Another would be a provider of evidence-based clinical practice guidelines.

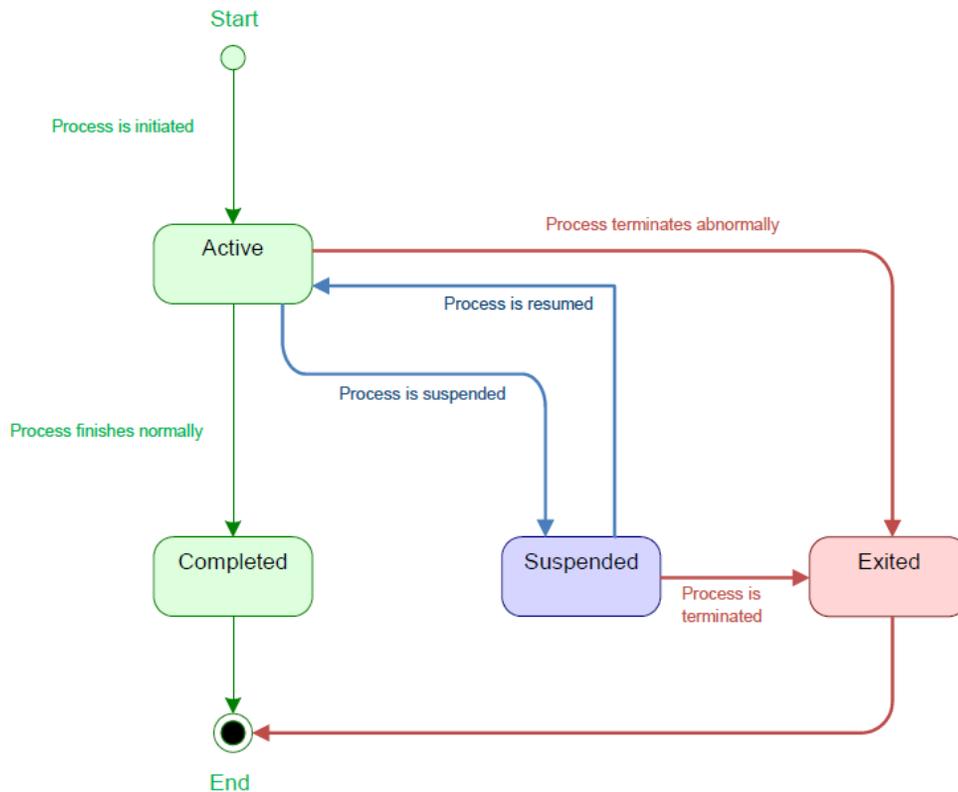
X.1.1.2 Process State Manager

245 The Process State Manager manages the initiation and state of runtime process instances. The Process State Manager typically also supports the initiation and lifecycle management of task activities associated with a process while providing the ability for task performers to retrieve and update activities.

An example would be a research sponsor conducting clinical trials in conjunction with its EHR participants. Another would be an EHR performing clinical care in accord with executable guideline-based processes.

The states of a process from the perspective of RPE actors¹ are indicated below:

¹ A BPMN 2.0 process and its activities may undergo more complex state transitions as per the BPMN 2.0 specification, Section 13.2.2, but these are the ones of interest to the Process Activity Executor. (Note the “Exited” state is any non-normal end state reached by a process or activity.)



250

All state transitions above are managed by the Process State Manager which can then use the Send Process State Alert transaction to notify the Process Activity Executor.

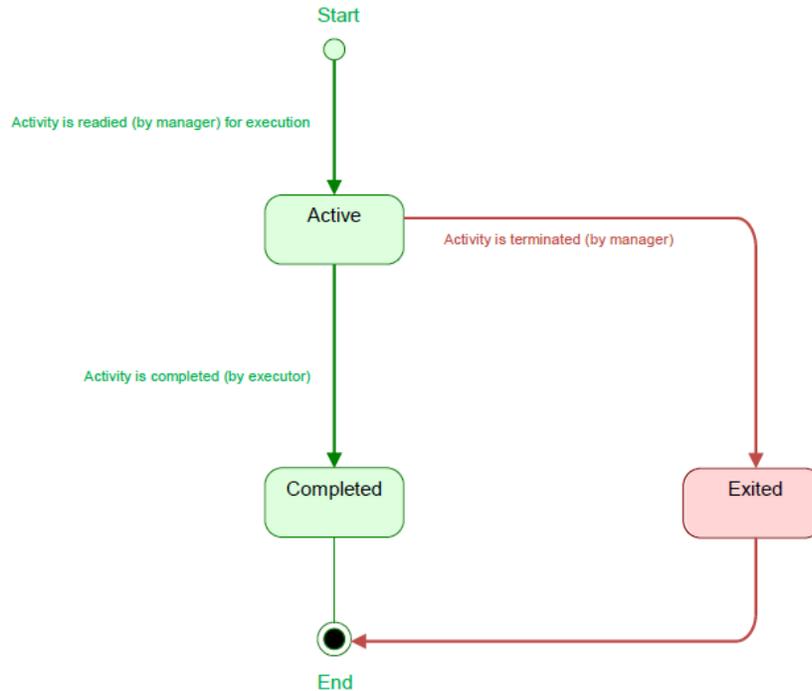
X.1.1.3 Process Activity Executor

255 The Process Activity Executor performs activities as prescribed by a running process being managed by a Process State Manager. The Process Activity Executor retrieves current activity or task lists, works its list, updating the Process State Manager on activity state until completion. This cycle is repeated until all process activities have been worked and the process itself completes.

260 An example would be an EHR performing activities as part of a clinical trial being managed by a research sponsor. Another example would be an EHR performing guideline-based care process activities.

The states of an activity from the perspective of RPE actors² are indicated below:

² A BPMN 2.0 activity may undergo more complex state transitions as per the BPMN 2.0 specification, Section 13.2.2, but these ones are of interest to the Process Activity Executor. (Note the “Exited” state is any non-normal end state reached by an activity.)



265 The Process State Manager is responsible for transitioning the activity into the “Active” state and possibly forcing it into a non-normal end state, i.e., “Exited” and using the Send Process State Alert transaction to notify the Process Activity Executor.

The Process Activity Executor is responsible for marking the activity “Completed” and using the Update Activity transaction to update the Process State Manager with this change as well as any associated output data.

270 **X.2 RPE Actor Options**

Table X.2-1: RPE Actor Options

Actor	Options	Vol & Section
Process State Manager	Retrieve Process Definitions [QRPH-20]	QRPH TF-2:3.Y1
Process State Manager	Retrieve Activities [QRPH-26]	QRPH TF-2:3.Y3
Process State Manager	Update Activity [QRPH-27]	QRPH TF-2:3.Y4
Process Activity Executor	Retrieve Activities [QRPH-26]	QRPH TF-2:3.Y3
Process Activity Executor	Update Activity [QRPH-27]	QRPH TF-2:3.Y4

The optional transactions extend the capabilities of the participating actor. Each actor can participate in any or all appropriate optional transactions.

275 **X.2.1 Retrieve Process Definitions Option**

The Retrieve Process Definitions option allows a Process State Manager to retrieve the process definition. A Process State Manager that supports the Retrieve Process Definitions option shall support the QRPH-20 transaction.

X.2.2 Retrieve Activities Option

280 The Retrieve Activities option allows a Process State Manager or a Process Activity Executor to retrieve the current set of activities it needs to execute as part of processes it is a participant in and managed by the given Process State Manager. A Process State Manager or Process Activity Executor that supports the Retrieve Activities option shall support the QRPH-26 transaction."

X.2.3 Update Activity Option

285 Update Activity allows a Process Activity Executor to provide an update on activity's state or data to a Process State Manager for a process it is a participant in. A Process Activity Executor that supports the Update Activity option shall support the QRPH-27 transaction.

X.3 Groupings

No groupings specified.

290 **X.4 RPE Process Flow**

X.4.1 Use Cases

The clinical research uses case below describes the before and after effects of implementing the Retrieve Process for Execution (RPE) profile for an investigational new drug clinical trial scenario.

- Scenario
- 295 • The setting for the clinical trial use case is a physicians' practice where patient care is delivered side-by-side with clinical research. The site, Fictitious Medical Group, is a multi-site physician practice, employing over 100 physicians in a variety of specialties. The Fictitious CEO encourages the physicians to participate as site investigators for pharmaceutical-sponsored clinical trials.

300 **Before RPE**

Preconditions

1. A Clinical Research Protocol is defined by a clinical trials expert at Sponsor, a biopharma research company.
- 305 2. Fictitious provides support for clinical research activities in the form of a Research Department of twelve dedicated study coordinators, mostly RNs, along with clerical and data-entry support personnel.

3. Fictitious Medical Group uses an Electronic Health Record (EHR) and a number of sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial activities.

310

Clinical Research Site's Involvement:

Fictitious involvement in a clinical study begins when the Research Department receives a request for proposal (RFP) from Sponsor. A Study Coordinator, Patricia Zone, RN, evaluates the RFP for business viability and clinical appropriateness, provides the requested documentation back to the sponsor, and agrees to participate. After being approved as a site for the Sponsor #1234 trial, the Fictitious Medical Group provides the required regulatory documentation to the sponsor.

315

Following trial set up, Patricia contacts Corey Jones, a patient at Fictitious, about participating in the trial and Corey agrees to participate as a subject. A number of tasks deal with this individual patient:

1. Obtain proper consent and other documentation from study candidate Corey Jones.
2. Register Corey in the EHR as a candidate in trial #1234, using the EHR's patient index.
3. Register Corey as a candidate in the EDC system.
4. Schedules Corey's study screening visits using the EHR scheduling module, and flag the visits as pertaining to the trial #1234.
5. Examine screening results to confirm continued enrollment in the trial.

320

After screening, Patricia obtains and schedules the next set of study activities corresponding to the path (arm) of the Sponsor #1234 trial.

325

Postconditions

1. Fictitious Medical Group uses an EHR and the EDC system to document the Sponsor #1234 trial activities.

330

After RPE

Preconditions

1. A Clinical Research Protocol is defined by the clinical trials expert at Sponsor using a study design tool.
2. The resulting study design definition document is stored and made available for access by a Process Definition Manager (implemented by an EDC or other system).
3. A Process State Manager (implemented by an EDC or other system) is available to deploy, run and manage the execution of the clinical trial process.
4. The Fictitious EHR (or other system) can implement the Process Activity Executor role.

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Clinical Research Site's Involvement:

The Process Activity Executor uses the Retrieve Process Definitions transaction to obtain a list of protocols from the Process Definition Manager.

345 Screening:

Process Activity Executor uses the Initiate Process transaction to notify the Process State Manager that the site wishes to enter a patient into the study.

Process Activity Executor uses the Retrieve Activities transaction to obtain from the Process State Manager the set of screening activities.

350 Process Activity Executor uses the Update Activity transaction to send the Process State Manager the screening results. (Note if activities have associated RFD forms then Update Activity may be replaced by RFD form retrieval and submission.)

Process State Manager uses the Send Process State Alert transaction to notify the Process Activity Executor that the patient passed screening and has been enrolled in the trial.

355 Treatment:

Process Activity Executor uses the Retrieve Activities transaction again to obtain from the Process State Manager the next set of study activities for this patient.

Process Activity Executor uses the Update Activity transaction to send the Process State Manager updates of activities as they are performed. (Note if activities have associated RFD forms then

360 Update Activity may be replaced by RFD form retrieval and submission.)

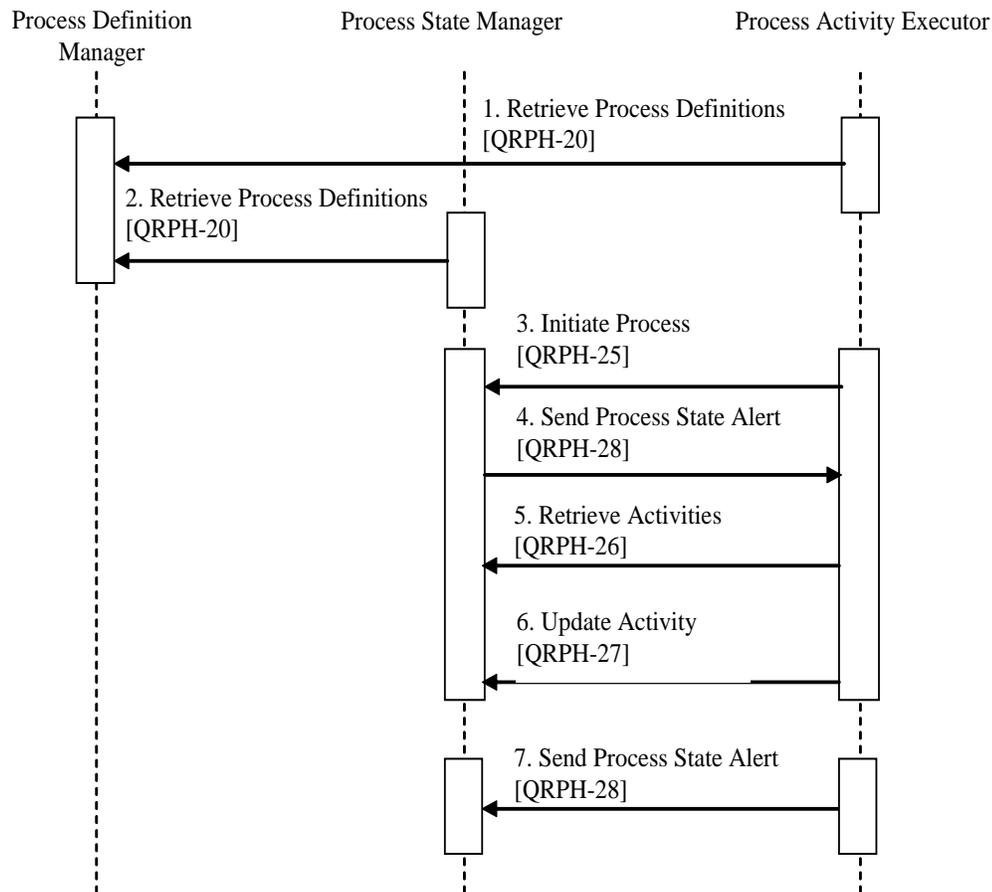
Process Activity Executor can at any time use the Send Process State Alert transaction to notify the Process State Manager that the patient has withdrawn from the trial.

Process State Manager can at any time use the Send Process State Alert transaction to notify the Process Activity Executor that the trial has been placed on hold.

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X.4.2 Process Flow

The basic process flow for RPE is shown below:



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Figure X.4.2-1: Basic Process Flow in RPE Profile

1. The Process Activity Executor retrieves process definitions of potential interest from the Process Definition Manager.
2. The Process State Manager may have previously retrieved the same process definition(s) from the same or different Process Definition Manager.
3. The Process Activity Executor requests process initiation by the Process State Manager forwarding a given process definition identifier as well as other required data, e.g., a patient identifier, demographics or eligibility criteria.
4. The Process State Manager notifies the Process Activity Executor that the process is actively proceeding or otherwise, e.g., after initial screening of patient data.
5. The Process Activity Executor retrieves the current activity it has to perform.
6. After completion of an activity, the Process Activity Executor sends the Process State Manager the updated activity state and output data.
7. The Process Activity Executor can always notify the Process State Manager of unscheduled events that may affect the process state, e.g., patient withdrawal from a clinical trial.

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385 **X.5 RPE Security Considerations**

The risk analysis for RPE enumerates assets, threats, and mitigations. The complete risk data is stored and available from IHE³.

390 The purpose of this risk assessment is to notify vendors of some of the risks that they are advised to consider when implementing RPE actors. For general IHE risks and threats, please see ITI TF-1: Appendix L. The vendor is also advised that many risks cannot be mitigated by the IHE profile and instead responsibility for mitigation is transferred to the vendor, and occasionally to the affinity domains, individual enterprises and implementers. In these instances, IHE fulfills its responsibility to notify affected parties through the use of the following sections.

395 **Table X.5-1: Risk Issues**

Risk Scenario	Type of Impact	Probability
S1: Patient is misidentified during process initiation, activity retrieval initiation or update. Demographic or identification information is intermixed with that of another patient.	Loss of Data Integrity resulting in potentially incorrect diagnosis, treatment and/or data analysis, possibly resulting in loss of life or quality of life for the patient and/or errant analysis in the context of research, public health or quality processes.	M
S2: A malicious attacker may attempt to compromise the system to obtain wrongful access to patient identity, clinical, financial or insurance data.	Loss of Privacy, Legal Liability / Compensation, Loss / Decrease of Funding, Loss of Public Trust or Reputation for Patient, Provider, Agency, Institution or Organization, Accountable Employee Loses Job	M
S3: Accidental release of personal health information (PHI) protected by consent agreements, regulation or law.	Loss of Privacy, Legal Liability / Compensation, Loss / Decrease of Funding, Loss of Public Trust or Reputation for Patient, Provider, Agency, Institution or Organization, Accountable Employee Loses Job	M
S4: Activity results data with negative indications may be prematurely exposed to patient prior to direct communication.	Decreased Effectiveness of Provider, Agency, Institution or Organization in the conduct of its processes.	M

³ The full risk analysis data may be found at:
[ftp://ftp.ihe.net/Quality/2010_2011_YR_4/QRPH%20Technical%20Committee/Maintenance%20work/RPE/RPE Risk Analysis 2010-05-21.xls](ftp://ftp.ihe.net/Quality/2010_2011_YR_4/QRPH%20Technical%20Committee/Maintenance%20work/RPE/RPE%20Risk%20Analysis%202010-05-21.xls)

Risk Scenario	Type of Impact	Probability
S5: Identify of certain profile actors needs to be kept secret during conduct of a process, e.g., a double-blind study.	Decreased Effectiveness of Provider, Agency, Institution or Organization in the conduct of its processes.	M
S6: In the event of inappropriate disclosure or other incident, auditing and investigation time becomes prohibitively long.	Increased Cost and Decreased Effectiveness of Provider, Agency, Institution or Organization in the conduct of its processes.	M

X.5.1 Recommendations

The high impact risks include:

- mismatch between patient and patient data
- 400 • malicious system attack
- inappropriate or premature disclosure of personal health information
- patient and organization identity protection

For risk mitigation, the following profiles from the ITI-TF are referred:

- Audit Trail and Node Authentication (ATNA)
- 405 • Basic Patient Privacy Consents (BPPC)
- Cross-Enterprise User Assertion (XUA)
- Consistent Time (CT)
- Enterprise User Authentication (EUA)
- Document Digital Signature (DSG)

410 This profile includes the mitigations:

M1: Ensure additional demographics are available to verify patient identity (e.g., address, other identifiers)

M2: Identify actors, ensure secure login and access control to protected data, e.g., using XUA and grouping with EUA for protected applications.

415 **M3:** Use secured communication for any patient data e.g., as per ATNA.

M4: Audit access to PHI, e.g., as per ATNA.

M5: Obtain patient consent to release protected data, e.g., using BPPC and DSG.

M6: Use pseudonymized identifiers for organizations in transactions as supported by RPE.

These mitigations are transferred to vendors and clients:

420 **T1:** Verify demographics other than patient name, birth date and gender.

- 425 **T2:** Providers evaluate and review activity data before submission to ensure data is entered correctly for the correct patient. Providers are cautioned not to use RPE for unmediated treatment or diagnosis, i.e., a doctor must always intervene prior to treatment or diagnosis to ensure that errors that may occur in submission are checked by a human prior to engaging in any treatment or diagnosis of a patient.
- T3:** Secure internal networks from unauthorized access.
- T4:** Ensure strong password use for applications with access to PHI.
- T5:** Employ a restrictive RBAC scheme for applications providing access to PHI.
- 430 **T6:** Obtain patient consents and ensure patient data requiring increased protection is clearly identified.
- T7:** Workflow processes should be designed to ensure provider to patient communication occurs prior to sharing results with negative implications.
- T8:** Assign pseudonymized identifiers in processes when it is required to shield real identities.
- 435 **T9:** Actors are advised to consider the usability of their logging and audit repository implementation.

Appendix A: Actor Summary Definitions

440 **Process Definition Manager** – A system that manages access to a repository of process definitions allowing for search and retrieval. An example would be a research sponsor providing access to the clinical research protocols it has developed. Another would be a provider of evidence-based clinical practice guidelines.

445 **Process State Manager** – A system that manages the initiation and state of runtime process instances. The Process State Manager typically also supports the initiation and lifecycle management of task activities associated with a process while providing the ability for task performers to retrieve and update activities. An example would be a research sponsor conducting clinical trials in conjunction with its EHR participants. Another would be an EHR performing clinical care in accord with executable guideline-based processes.

450 **Process Activity Executor** – A system that performs activities as prescribed by a running process being managed by a Process State Manager. The Process Activity Executor retrieves current activity or task lists, works its list, updating the Process State Manager on activity state until completion. This cycle is repeated until all process activities have been worked and the process itself completes. An example would be an EHR performing activities as part of a clinical trial being managed by a research sponsor. Another would be an EHR performing guideline-based care process activities.

455 Appendix B: Transaction Summary Definitions

460 **Retrieve Process Definitions** – enables access to one or more process definitions specified by an identifier or other query criteria. This transaction is implemented by the Process Definition Manager and used by both the Process State Manager – to deploy processes it wishes to manage – and the Process Activity Executor – to examine processes it may be interested in becoming an activity participant.

Initiate Process – enables a Process Activity Executor to initiate a new process to be managed by a Process State Manager, e.g., an EHR entering a new patient candidate in a clinical trial being managed by a research sponsor.

465 **Retrieve Activities** – enables a Process Activity Executor to retrieve the current set of activities it needs to execute as part of a process managed by a Process State Manager.

Update Activity – allows a Process Activity Executor to provide an update on activity's state or data to a Process State Manager for a process it is a participant in.

470 **Send Process State Alert** – provides the Process State Manager and Process Activity Executor the ability to notify each other of unscheduled events that affect the state of the process, e.g., an EHR patient withdrawing from a clinical trial or, a study being placed on hold.

Glossary

Add the following terms to the Glossary:

475 **Process Definition** – A design definition of a process flow of activities involving one or more role-based activity performers. A process definition is implemented in XML and deployable to a runtime process engine.

Process – A specific instance of a process definition running in a process engine.

480 **Activity Definition** – A definition of an individual task activity which is deployable to a runtime task processor. Typically an activity is defined as part of a process definition but standalone activities may also be defined.

Activity – A specific instance of an activity created in, and available from, a task processor.

Volume 2 - Transactions

485 3 IHE Transactions

Add Section 3.Y

3.Y1 Retrieve Process Definitions

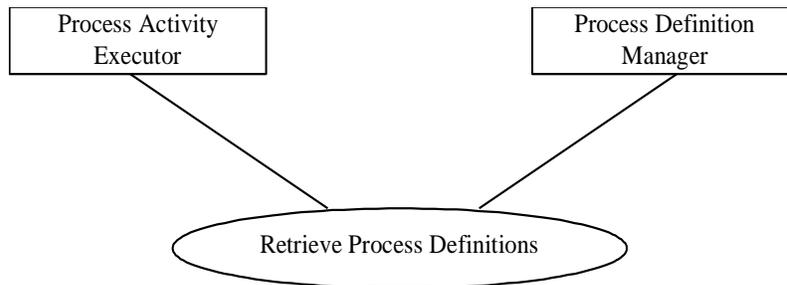
490 This section corresponds to transaction QRPH TF-Y1 of the IHE QRPH Transaction Framework
QRPH TFY1 is used by the Process Definition Manager and Process Activity Executor actors.

3.Y1.1 Scope

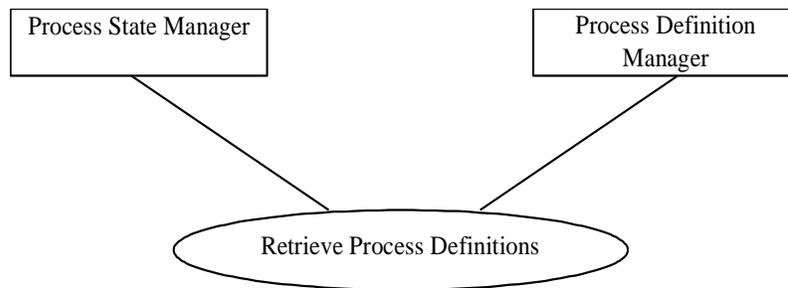
495 This transaction involves a Process Activity Executor or Process State Manager requesting one or
more process definitions from a Process Definition Manager. The Process Activity Executor or
Process State Manager has one or more process definition identifiers obtained by means outside the
scope of this profile.

The Process Definition Manager returns a list of matching process definitions or else it returns an
error response.

3.Y1.2 Use Case Roles



500



505

Actor: Process Activity Executor

Role: A system that knows how to execute activities that are part of a process.

Actor: Process State Manager

Role: A system that manages the runtime state of a process.

510 **Actor:** Process Definition Manager

Role: A system that provides a set of process definitions upon request.

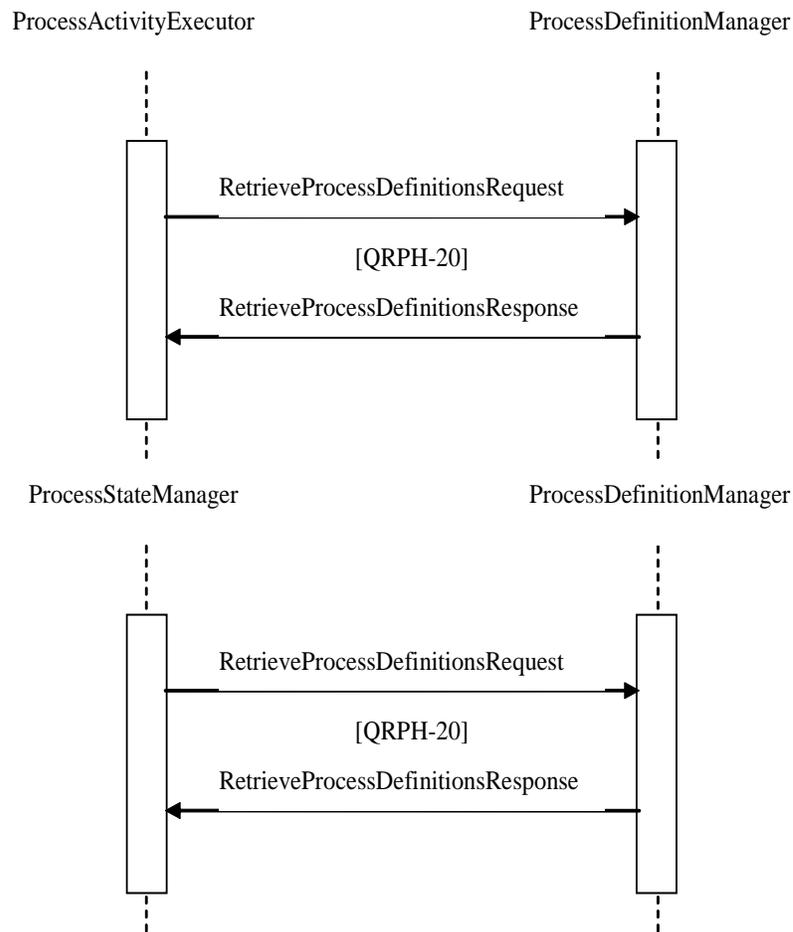
3.Y1.3 Referenced Standards

Implementers of this transaction shall comply with all requirements where applicable described in:

- 515
- ITI TF-2X: Appendix V Web Services for IHE Transactions
 - OMG Business Process Model and Notation (BPMN) Version 2.0 available at: <http://www.omg.org/spec/BPMN/2.0/>
 - Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>

520

3.Y1.4 Interaction Diagram



525

3.Y1.4.1 Retrieve Process Definitions Message

3.Y1.4.1.1 Trigger Events

The Process Activity Executor or Process State Manager, based upon human decision or application of a rule for automatic operation, wants to obtain from the Process Definition Manager one or more process definitions matching a set of supplied ids.

530

3.Y1.4.1.2 Message Semantics

The following parameters are specified for the body of this transaction.

Table 3.Y1.4.1.2–1: Retrieve Process Definitions Request Parameters

Parameter Name	REQ	Description	Value
processDefinitionIdentifier (list)	R	An identifier (or list of identifiers) for the process definition(s) to be	The identifier is an XML element of simple type string.

Parameter Name	REQ	Description	Value
		retrieved.	
maxOccurs	O	If specified, the number of items returned by either of the above 3 options MUST NOT exceed this limit.	An XML element of simple type int.
startIndex	O	The startIndex can be used to perform multiple identical queries and iterate over result sets where the maxOccurs size exceeds the query limit.	An XML element of simple type int.

535 Section 3.Y1.6 describes the Web Services protocol requirements and the format of the message in full detail.

3.Y1.4.1.3 Expected Actions

540 Upon reception of the Retrieve Process Definitions Message, the Process Definition Manager shall parse the request and return the requested process definitions in the Retrieve Process Definitions Response message.

The successful response shall be one or more well-formed XML documents matching the supplied identifiers.

Otherwise SOAP faults shall be generated accordingly:

- 545 • If there is missing information, such as no process definition identifier list, the request is otherwise malformed. The fault should include:
 - faultcode: Client
 - faultstring: Invalid Request
 - and may provide further information in the details element.
- 550 • If no matching process definition is available The fault should include:
 - faultcode: Client
 - faultstring: No Matching Process Definition

3.Y1.4.2 Retrieve Process Definitions Response Message

3.Y1.4.2.1 Trigger Events

555 The delivery of a set of process definitions is triggered by a Process Definition Manager actor responding to a Retrieve Process Definitions message.

3.Y1.4.2.2 Message Semantics

560 A matching list of one or more process definitions is returned. The format of each process definition is a well-formed XML document.

Table 3.Y1.4.1.2–2: Retrieve Process Definitions Response Parameter

Parameter Name	REQ	Description	Value
processDefinition	R	One process definition per process definition identifier requested.	A complex XML element of type specified per optional processDefinitionLanguage attribute
processDefinitionLanguage	O	XML attribute	Default value: http://www.omg.org/spec/BPMN/20100524/MODEL

3.Y1.4.2.3 Expected Actions

The Process Activity Executor shall consume the set of process definitions. If a SOAP fault is received then this fault should be handled based on the business rules of the system.

565 3.Y1.5 Security Considerations

See section QRPH TF-1:X.6.

3.Y1.6 Protocol Requirements

570 The Retrieve Process Definitions request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2: Appendix V Web Services for IHE Transactions.

Table 3.Y1.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsaw	http://www.w3.org/2005/08/addressing
xsd	http://www.w3.org/2001/XMLSchema

575 These are the requirements for the Retrieve Process Definitions transaction presented in the order in which they would appear in the WSDL definition:

- The following types shall be imported (xds:import) in the /definitions/types section:
- namespace="urn:ihe:qrph:rpe:2009", schema="RPE.xsd"
- The /definitions/message/part/@element attribute of the Retrieve Process Definitions request message shall be defined as: "ihe:RetrieveProcessDefinitionsRequest"
- 580 • The /definitions/message/part/@element attribute of the Retrieve Process Definitions response message shall be defined as: "ihe:RetrieveProcessDefinitionsResponse"
- The /definitions/portType/operation/input/@wsaw:Action attribute for the Retrieve Process Definitions request message shall be defined as "urn:ihe:qrph:2009:RetrieveProcessDefinitions"

- The /definitions/portType/operation/output/@wsaw:Action attribute for the Retrieve Process Definitions response message shall be defined as:
585 “urn:ihe:qrph:2009:RetrieveProcessDefinitionsResponse”
- The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as
595 “urn:ihe:qrph:2009:RetrieveProcessDefinitions”

590 These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in the section 3.Y1.6.1 Sample SOAP Messages.

3.Y1.6.1 Sample SOAP Messages

595 The samples in the following two sections show a typical request and corresponding response as contained in a SOAP Body. *Note the SOAP Header should be populated according to the IHE Appendix V: Web Services for IHE Transactions.*

A full WSDL for the Process Definition Manager actor is found on the IHE FTP site at:
ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH Technical Committee/Profiles in Progress/RPE/metadata

3.Y1.6.1.1 Sample Retrieve Process Definitions SOAP Request

600 *Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.*

```
605 <soap:Body>
  <rpe:RetrieveProcessDefinitionsRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
    <rpe:processDefinitionIdentifier>1006</rpe:processDefinitionIdentifier>
  </rpe:RetrieveProcessDefinitionsRequest>
</soap:Body>
```

610 3.Y1.6.1.2 Sample Retrieve Process Definitions SOAP Response

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

```
615 <soap:Body>
  <rpe:RetrieveProcessDefinitionsResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
    <rpe:processDefinition processDefinitionLanguage="http://www.omg.org/spec/BPMN/20100524/MODEL">
      <definitions targetNamespace="http://www.examples.org" xmlns:tns="http://www.examples.org"
620 xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
      xsi:schemaLocation="http://www.omg.org/spec/BPMN/20100524/MODEL BPMN-20100501/BPMN20.xsd
      xmlns:di="http://www.omg.org/spec/DD/20100524/DI
      xmlns:bpmndi="http://www.omg.org/spec/BPMN/20100524/DI"
625 xmlns:dc="http://www.omg.org/spec/DD/20100524/DC xmlns:hl7="urn:hl7-org:v3"
      xmlns:rpe="urn:ihe:qrph:rpe:2009" id="_1312929184333">

      <!-- Import schemas and define RPE and HL7 element items for reference by process data
      object variables -->
      <import importType="http://www.w3.org/2001/XMLSchema" location="RPE.xsd"
630 namespace="urn:ihe:qrph:rpe:2009"/>
```

```

        <import importType="http://www.w3.org/2001/XMLSchema" location="HL7-SD/StudyDesign.xsd"
        namespace="urn:hl7-org:v3"/>
        <itemDefinition id="InitiateProcessRequestItem"
        structureRef="rpe:InitiateProcessRequest"></itemDefinition>
635     <itemDefinition id="RequestContextItem"
        structureRef="rpe:requestContext"></itemDefinition>
        <itemDefinition id="PatientDataItem" structureRef="rpe:patientData"></itemDefinition>
        <itemDefinition id="EligibilityCriterionItem"
640     structureRef="hl7:eligibilityCriterion"></itemDefinition>
        <itemDefinition id="ObservationItem" structureRef="hl7:observation"></itemDefinition>
        <itemDefinition id="SubstanceAdministrationItem"
        structureRef="hl7:substanceAdministration"></itemDefinition>

        <message id="InitiateProcessRequest" itemRef="tns:InitiateProcessRequestItem"
645     name="Initiate Process Request"/>

        <process isExecutable="false" id="_6" name="IHE RPE Study Design" >
        <documentation id="Title">IHE RPE Study Design</documentation>
650     <documentation id="Description">A simple single arm example consisting of Screen,
        Treatment and Followup epochs with 3 activities total:
        a screening visit, a treatment visit and a followup visit 6 months
        later.</documentation>
        <ioSpecification>
655     <dataInput isCollection="true" name="Eligibility Criteria"
        id="EligibilityCriteria" itemSubjectRef="tns:EligibilityCriterionItem"/>
        <dataInput name="Request Context" id="RequestContext"
        itemSubjectRef="tns:RequestContextItem"/>
        <dataInput name="Patient Data" id="PatientData"
660     itemSubjectRef="tns:PatientDataItem"/>
        <dataInput name="Substance Administration" id="SubstanceAdministration"
        itemSubjectRef="tns:SubstanceAdministrationItem"/>
        <dataOutput isCollection="true" name="Screening Observations"
        id="ScreeningObservations" itemSubjectRef="tns:ObservationItem"/>
665     <dataOutput isCollection="true" name="Treatment Observations"
        id="TreatmentObservations" itemSubjectRef="tns:ObservationItem"/>
        <dataOutput isCollection="true" name="Follow-up Observations"
        id="FollowUpObservations" itemSubjectRef="tns:ObservationItem"/>

        ...
670     </definitions>
    </rpe:processDefinition>
  </rpe:RetrieveProcessDefinitionsResponse>
</soap:Body>

```

675 3.Y2 Initiate Process

This section corresponds to transaction QRPH-Y2 of the IHE QRPH Transaction Framework. QRPH-Y2 is used by the Process State Manager and Process Activity Executor actors.

3.Y2.1 Scope

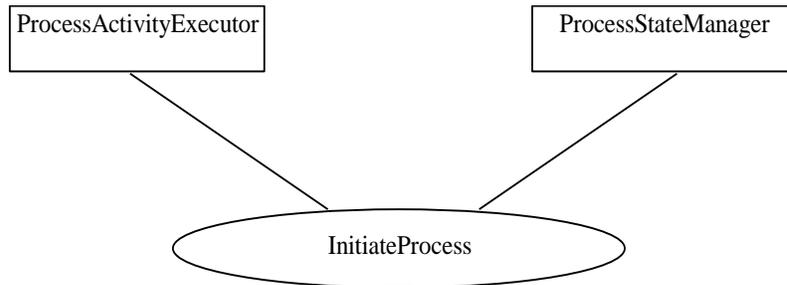
680 This transaction involves a Process Activity Executor requesting initiation of a process with a Process State Manager.

In its request the Process Activity Executor supplies an initial context including:

- an identifier for the process definition of interest
- an organizational identifier
- a patient identifier

- 685
- an endpoint reference for callback notifications (alerts)
 - other optional patient data (such as demographics)

3.Y2.2 Use Case Roles



690 **Actor:** Process Activity Executor

Role: A system that knows how to execute activities that are part of a process.

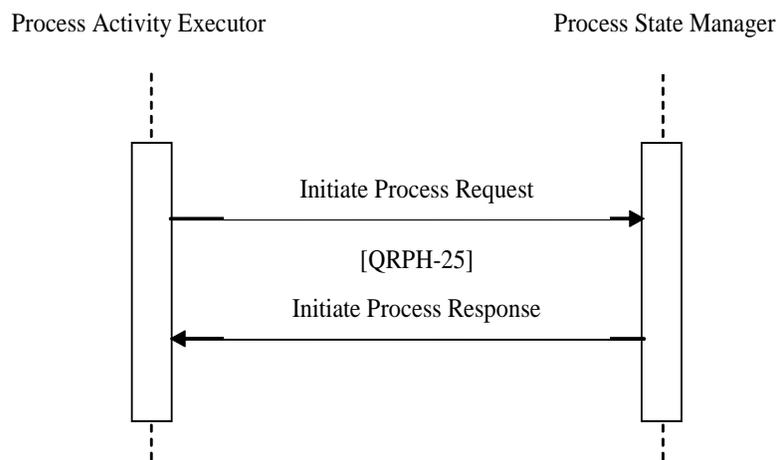
Actor: Process State Manager

Role: A system that manages the runtime state of a process.

695 **3.Y2.3 Referenced Standards**

See section 3.Y1.3.

3.Y2.4 Interaction Diagram



700

3.Y2.4.1 Initiate Process Message

3.Y2.4.1.1 Trigger Events

The Process Activity Executor, based upon human decision or application of a rule for automatic operation, wants to initiate a process with a Process State Manager.

705 3.Y2.4.1.2 Message Semantics

The following parameters are specified for the body of this transaction.

Table 3.Y2.4.1.2-1: Initiate Process Request Parameters

Parameter Name	REQ	Description	Value
requestContext	R	The <i>initial</i> request context being sent consisting of:	A complex XML element as specified below.
processDefinitionIdentifier	R	Identifier for the process definition.	XML string type
organizationIdentifier	R	Identifier for involved organization.	XML string type
patientIdentifier	R	Identifier for the patient.	XML string type
requestorReference	R	The Process Activity Executor callback endpoint for the Process State Manager to use in sending alerts.	WS-Addressing EndpointReferenceType
patientData	O	Patient data, e.g., a CRD-conforming CCD.	An XML element of complex type specified per patientDataLanguage attribute with default value (CCD): http://xreg2.nist.gov:8080/hitspValidation/schema/cdar2c32/infrastructure/cda/C32_CDA.xsd

710 Section 3.Y2.6 describes the Web Services protocol requirements and the format of the message in full detail.

3.Y2.4.1.3 Expected Actions

715 The Process State Manager parses the Initiate Process request and if well-formed, initiates an instance of the given process and acknowledges the request with a returned process context to be used in subsequent transactions.

Otherwise SOAP faults shall be generated accordingly:

- If request is not well-formed, a SOAP fault shall be generated and shall include:
 - faultcode: Client

- 720
 - faultstring: Invalid Request
 - and may provide further information in the details element.
- If the process failed to initiate due to a Process State Manager system error, a SOAP fault shall be generated and shall include:
 - faultcode: Server
 - faultstring: System Error
- 725
 - and may provide further information in the details element.

3.Y2.4.2 Initiate Process Response Message

3.Y2.4.2.1 Trigger Events

730 The message is triggered by a Process State Manager receiving an Initiate Process request from a Process Activity Executor and after successful initiation of the process.

3.Y2.4.2.2 Message Semantics

The following output parameter is the body of the response.

Table 3.Y2.4.2.2-1: Initiate Process Response Parameter

Parameter Name	REQ	Description	Value
processContext	R	The returned context to be included in subsequent Retrieve Activities, Update Activity and Send Process State Alert transactions, consisting of the following assigned identifiers:	A complex XML element as specified below.
processIdentifier	R	Identifier for process instance.	XML string type
assignedOrganizationIdentifier	O	Assigned identifier for organization.	XML string type
assignedPatientIdentifier	O	Assigned identifier for patient.	XML string type

735

3.Y2.4.2.3 Expected Actions

The Process State Manager shall generate the response code based on the business rules of the system. If a SOAP fault is received then this fault should also be handled based on the business rules of the system.

740 3.Y2.5 Security Considerations

See section QRPH TF-1:X.6.

3.Y2.6 Protocol Requirements

745 The Initiate Process request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2: Appendix V Web Services for IHE Transactions.

Table 3.Y2.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsaw	http://www.w3.org/2005/08/addressing
xsd	http://www.w3.org/2001/XMLSchema

These are the requirements for the Initiate Process transaction presented in the order in which they would appear in the WSDL definition:

- 750 • The following types shall be imported (xds:import) in the /definitions/types section:
- namespace="urn:ihe:qrph:rpe:2009", schema="RPE.xsd"
- The /definitions/message/part/@element attribute of the Initiate Process request message shall be defined as: "ihe:InitiateProcessRequest"
- 755 • The /definitions/message/part/@element attribute of the Initiate Process response message shall be defined as: "ihe:InitiateProcessResponse"
- The /definitions/portType/operation/input/@wsaw:Action attribute for the Initiate Process request message shall be defined as "urn:ihe:qrph:2009:InitiateProcess"
- The /definitions/portType/operation/output/@wsaw:Action attribute for the Initiate Process response message shall be defined as: "urn:ihe:qrph:2009:InitiateProcessResponse"
- 760 • The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:2009:InitiateProcess"

These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in the section 3.Y2.6.1 Sample SOAP Messages.

765 3.Y2.6.1 Sample SOAP Messages

The samples in the following two sections show a typical request and corresponding response as contained in a SOAP Body. *Note the SOAP Header should be populated according to the IHE Appendix V: Web Services for IHE Transactions and in accord with section 3.Y2.5 Security Considerations.*

770 A full WSDL for the Process State Manager actor is found on the IHE FTP site at: [ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH Technical Committee/Profiles in Progress/RPE/metadata](ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH%20Technical%20Committee/Profiles%20in%20Progress/RPE/metadata)

3.Y2.6.1.1 Sample Initiate Process SOAP Request

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

```

775 <soap:Body>
780   <rpe:InitiateProcessRequest xmlns:rpe="urn:ihe:qrph:rpe:2009"
      xmlns:wsa="http://schemas.xmlsoap.org/ws/2004/03/addressing">
      <rpe:requestContext>
        <rpe:processDefinitionIdentifier>Connectathon2011RPEStudyDesign
        </rpe:processDefinitionIdentifier>
785   <rpe:organizationIdentifier>CIS_CE_CB</rpe:organizationIdentifier>
      <rpe:patientIdentifier>997685070</rpe:organizationIdentifier>
      <rpe:requestorReference>
        <wsa:Address>http://example.com/fabrikam/acct</wsa:Address>
        </rpe:requestorReference>
790   </rpe:requestContext>
      <rpe:patientData>
        <ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xsi:schemaLocation="urn:hl7-org:v3
http://xreg2.nist.gov:8080/hitspValidation/schema/cdar2c32/infrastructure/cda/C32_CDA.xsd
">
795   ...
      <recordTarget>
        <patientRole>
          <id root="2.16.840.1.113883.3.72" extension="997685070" assigningAuthorityName="NIST
Healthcare Project"/>
800   <addr>
          <streetAddressLine>145 Adams Lane</streetAddressLine>
          <city>Palatine</city>
          <state>IL</state>
          <postalCode>60067</postalCode>
805   </addr>
          <telecom/>
          <patient>
            <name use="L">
              <given qualifier="CL">Carol</given>
              <family qualifier="BR">Stroke</family>
              <suffix>the 7th</suffix>
            </name>
            <administrativeGenderCode code="F" displayName="Female"
codeSystem="2.16.840.1.113883.5.1" codeSystemName="HL7 AdministrativeGender"/>
815   <birthTime value="19840704"/>
            <maritalStatusCode code="S" displayName="Single"
codeSystem="2.16.840.1.113883.5.2" codeSystemName="HL7 Marital status"/>
            <languageCommunication>
              <templateId root="2.16.840.1.113883.3.88.11.83.2"
assigningAuthorityName="HITSF/C83"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.2.1"
assigningAuthorityName="IHE/PCC"/>
              <languageCode code="en-US"/>
            </languageCommunication>
825   </patient>
          </patientRole>
        </recordTarget>
        ...
      </ClinicalDocument>
830   </rpe:patientData>
    </rpe:InitiateProcessRequest>
  </soap:Body>

```

3.Y2.6.1.2 Sample Initiate Process SOAP Response

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

835

```
<soap:Body>
  <rpe:InitiateProcessResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
    <rpe:processContext>
      <rpe:processIdentifier>Connectathon2011RPEStudyDesign-CIS_CE_CB-997685070
      </rpe:processIdentifier>
      <rpe:assignedOrganizationIdentifier>CIS_CE_CB</rpe:assignedOrganizationIdentifier>
      <rpe:assignedPatientIdentifier>997685070</rpe:assignedPatientIdentifier>
    </rpe:processContext>
  </rpe:InitiateProcessResponse>
</soap:Body>
```

840

845

3.Y3 Retrieve Activities

850

This section corresponds to transaction QRPH-Y3 of the IHE QRPH Transaction Framework. QRPH-Y3 is used by the Process State Manager and Process Activity Executor actors.

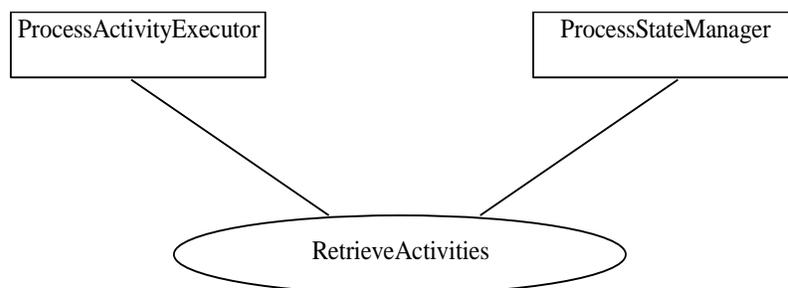
3.Y3.1 Scope

855

Retrieve Activities enables a Process Activity Executor to retrieve the current set of activities it needs to execute as part of processes it is a participant in and managed by the given Process State Manager.

In its request, the Process Activity Executor supplies the current process context as per table 3.Y2.4.2.2.

3.Y3.2 Use Case Roles



860

Actor: Process Activity Executor

Role: A system that knows how to execute activities that are part of a process.

Actor: Process State Manager

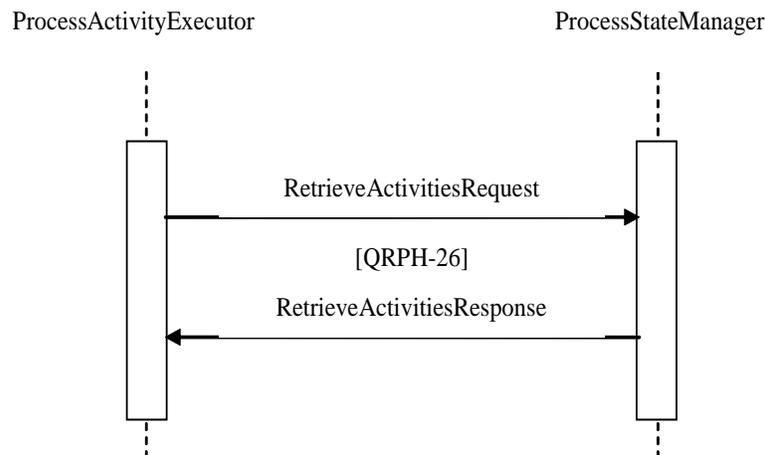
Role: A system that manages the runtime state of a process.

865

3.Y3.3 Referenced Standards

See section 3.Y1.3.

3.Y3.4 Interaction Diagram



870

3.Y3.4.1 Retrieve Activities Message

3.Y3.4.1.1 Trigger Events

The Process Activity Executor, based upon human decision or application of a rule for automatic operation, wants to retrieve the current set of process activities it needs to perform from a Process State Manager.

875

3.Y3.4.1.2 Message Semantics

The current process context (see table 3.Y2.4.2.2) is the sole input parameter.

Section 3.Y3.6 describes the Web Services protocol requirements and the format of the message in full detail.

3.Y3.4.1.3 Expected Actions

The Process State Manager parses the Retrieve Activities request and if well-formed, returns the current set of activities for the given organization and patient. If no activities are outstanding an empty response is returned.

Otherwise SOAP faults shall be generated accordingly:

- 885
- If the request is not well-formed, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: Invalid Request

- and may provide further information in the details element.
- If there is no matching process identifier for the organization, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: No Matching Process
- If the supplied process has previously completed or otherwise terminated, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: Process Terminated

3.Y3.4.2 Retrieve Activities Response Message

3.Y3.4.2.1 Trigger Events

The message is triggered by a Process State Manager receiving a Retrieve Activities request from a Process Activity Executor.

3.Y3.4.2.2 Message Semantics

A list of zero or more process activities is returned. The format of each activity is a well-formed XML document of the type supported by the process of which they are part.

Table 3.Y3.4.2.2-2: Retrieve Activities Response Parameter

Parameter Name	REQ	Description	Value
activity	R	One or more process activities.	A complex XML element representing an activity within a process as specified per optional activityLanguage attribute, the default value being: http://www.omg.org/spec/BPMN/20100524/MODEL

3.Y3.4.2.3 Expected Actions

The Process State Manager shall generate the list of activities based on the business rules of the system. If a SOAP fault is received then this fault should also be handled based on the business rules of the system.

3.Y3.5 Security Considerations

See section QRPH TF-1:X.6.

3.Y3.6 Protocol Requirements

915 The Retrieve Activities request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2: Appendix V Web Services for IHE Transactions.

Table 3.Y3.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsaw	http://www.w3.org/2005/08/addressing
xsd	http://www.w3.org/2001/XMLSchema

920 These are the requirements for the Retrieve Activities transaction presented in the order in which they would appear in the WSDL definition:

- The following types shall be imported (xds:import) in the /definitions/types section:
- namespace="urn:ihe:qrph:rpe:2009", schema="RPE.xsd"
- The /definitions/message/part/@element attribute of the Retrieve Activities request message shall be defined as: "ihe:RetrieveActivitiesRequest"
- 925 • The /definitions/message/part/@element attribute of the Retrieve Activities response message shall be defined as: "ihe:RetrieveActivitiesResponse"
- The /definitions/portType/operation/input/@wsaw:Action attribute for the Retrieve Activities request message shall be defined as "urn:ihe:qrph:2009:RetrieveActivities"
- The /definitions/portType/operation/output/@wsaw:Action attribute for the Retrieve Activities response message shall be defined as: "urn:ihe:qrph:2009:RetrieveActivitiesResponse"
- 930 • The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:2009:RetrieveActivities"

935 These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in the section 3.Y3.6.1 Sample SOAP Messages.

3.Y3.6.1 Sample SOAP Messages

940 The samples in the following two sections show a typical request and corresponding response as contained in a SOAP Body. Note the SOAP Header should be populated according to the IHE Appendix V: Web Services for IHE Transactions and in accord with section 3.Y3.5 Security Considerations.

A full WSDL for the Process State Manager actor is found on the IHE FTP site at: [ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH Technical Committee/Profiles in Progress/RPE/metadata](ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH%20Technical%20Committee/Profiles%20in%20Progress/RPE/metadata)

3.Y3.6.1.1 Sample Retrieve Activities SOAP Request

945 *Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.*

```
945 <soap:Body>
950   <rpe:RetrieveActivitiesRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
      <rpe:processContext>
        <rpe:processIdentifier>Connectathon2011RPEStudyDesign-CIS_CE_CB-997685070
        </rpe:processIdentifier>
        <rpe:assignedOrganizationIdentifier>CIS_CE_CB</rpe:assignedOrganizationIdentifier>
        <rpe:assignedPatientIdentifier>997685070</rpe:assignedPatientIdentifier>
955     </rpe:processContext>
      </rpe:RetrieveActivitiesRequest>
    </soap:Body>
```

3.Y3.6.1.2 Sample Retrieve Activities SOAP Response

960 *Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.*

```
965 <soap:Body>
      <rpe:RetrieveActivitiesResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
        <rpe:activity activityLanguage=" http://www.omg.org/spec/BPMN/20100524/MODEL">
          <userTask xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL" implementation="##unspecified"
            name="Screening Activity" id="ScreeningActivity"/>
          </rpe:activity>
970     </rpe:RetrieveActivitiesResponse>
    </soap:Body>
```

3.Y4 Update Activity

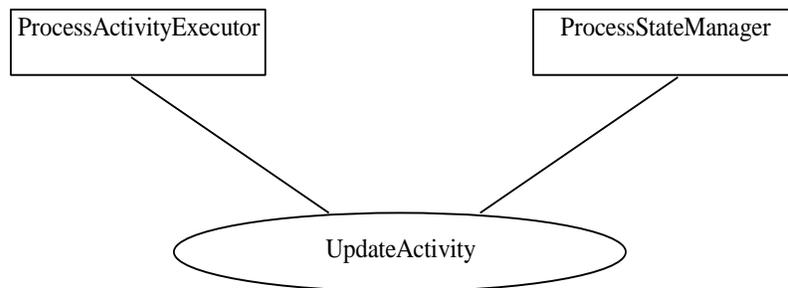
975 This section corresponds to transaction QRPH-Y4 of the IHE QRPH Transaction Framework. QRPH-Y4 is used by the Process State Manager and Process Activity Executor actors.

3.Y4.1 Scope

Update Activity allows a Process Activity Executor to provide an update on activity's state or data to a Process State Manager for a process it is a participant in.

980 In its request, the Process Activity Executor supplies the current process context as per table 3.Y2.4.2.2 and the updated activity.

3.Y4.2 Use Case Roles



985 **Actor:** Process Activity Executor

Role: A system that knows how to execute activities that are part of a process.

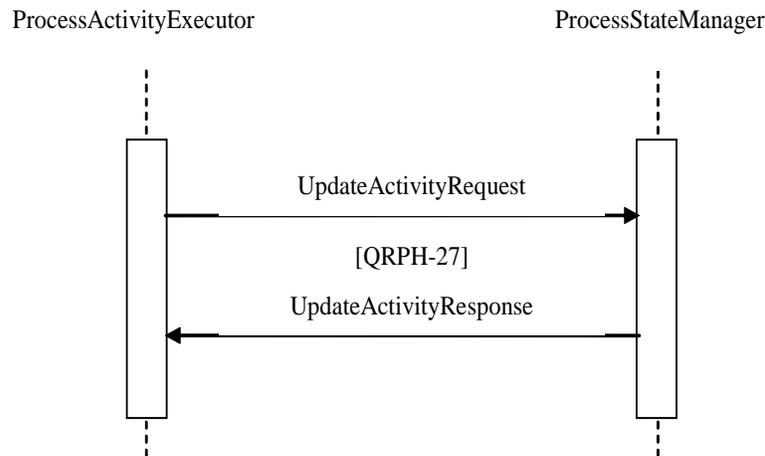
Actor: Process State Manager

Role: A system that manages the runtime state of a process.

990 **3.Y4.3 Referenced Standards**

See section 3.Y1.3.

3.Y4.4 Interaction Diagram



995 **3.Y4.4.1 Update Activity Message**

3.Y4.4.1.1 Trigger Events

The Process Activity Executor, based upon human decision or application of a rule for automatic operation, wants to update the Process State Manager with the current state or data associated with an activity it is performing.

1000 **3.Y4.4.1.2 Message Semantics**

The following parameters are specified for the body of this transaction.

Table 3.Y4.4.1.2-1: Update Activity Request Parameters

Parameter Name	REQ	Description	Value
processContext	R	(see Table 3.Y2.4.2.2-1)	
activity	R	A process activity.	A complex XML element representing an activity within a process as specified per optional activityLanguage attribute.
activityLanguage	O	XML attribute	Default value: http://www.omg.org/spec/BPMN/20100524/MODEL

1005 Section 3.Y4.6 describes the Web Services protocol requirements and the format of the message in full detail.

3.Y4.4.1.3 Expected Actions

The Process State Manager parses the Update Activity request and if well-formed, updates the given activity for the state and/or data supplied.

1010 If the activity is updated as a result of this transaction the Process State Manager acknowledges the request with a response code of “ACTIVITY_UPDATED”.

Otherwise SOAP faults shall be generated accordingly:

- If the request is not well-formed, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: Invalid Request
 - and may provide further information in the details element.

1015

- If there is no matching activity identifier, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: No Matching Activity

1020

- If the process failed to update the activity due to a Process State Manager system error, a SOAP fault shall be generated and shall include:
 - faultcode: Server
 - faultstring: System Error
 - and may provide further information in the details element.

1025

3.Y4.4.1 Update Activity Response Message

3.Y4.4.2.1 Trigger Events

The message is triggered by a Process State Manager receiving an Update Activity request from a Process Activity Executor.

1030 3.Y4.4.2.2 Message Semantics

A responseCode XML element of type string is returned which confirms successful update of the activity with a value of “ACTIVITY_UPDATED”.

3.Y4.4.2.3 Expected Actions

1035 The Process State Manager shall update the activity based on the business rules of the system. If a SOAP fault is received then this fault should also be handled based on the business rules of the system.

3.Y4.5 Security Considerations

See section QRPH TF-1:X.6.

3.Y4.6 Protocol Requirements

1040 The Update Activity request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2: Appendix V Web Services for IHE Transactions.

Table 3.Y4.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsaw	http://www.w3.org/2005/08/addressing
xsd	http://www.w3.org/2001/XMLSchema

1045 These are the requirements for the Update Activity transaction presented in the order in which they would appear in the WSDL definition:

- The following types shall be imported (xds:import) in the /definitions/types section:
- namespace=”urn:ihe:qrph:rpe:2009”, schema=”RPE.xsd”
- 1050 • The /definitions/message/part/@element attribute of the Update Activity request message shall be defined as: “ihe:UpdateActivityRequest”
- The /definitions/message/part/@element attribute of the Update Activity response message shall be defined as: “ihe:UpdateActivityResponse”

- 1055 • The /definitions/portType/operation/input/@wsaw:Action attribute for the Update Activity request message shall be defined as “urn:ihe:qrph:2009:UpdateActivity”
 - The /definitions/portType/operation/output/@wsaw:Action attribute for the Update Activity response message shall be defined as: “urn:ihe:qrph:2009:UpdateActivityResponse”
 - The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as “urn:ihe:qrph:2009:UpdateActivity”
- 1060 These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in the section 3.Y4.6.1 Sample SOAP Messages.

3.Y4.6.1 Sample SOAP Messages

1065 The samples in the following two sections show a typical request and corresponding response as contained in a SOAP Body. *Note the SOAP Header should be populated according to the IHE Appendix V: Web Services for IHE Transactions and in accord with section 3.Y4.5 Security Considerations.*

1070 A full WSDL for the Process State Manager actor is found on the IHE FTP site at: ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH Technical Committee/Profiles in Progress/RPE/metadata.

3.Y4.6.1.1 Sample Update Activity SOAP Request

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

```

1075 <soap:Body>
      <rpe:UpdateActivityRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
        <rpe:processContext>
          <rpe:processIdentifier>Connectathon2011RPEStudyDesign-CIS_CE_CB-997685070
1080          </rpe:processIdentifier>
          <rpe:assignedOrganizationIdentifier>CIS_CE_CB</rpe:assignedOrganizationIdentifier>
          <rpe:assignedPatientIdentifier>997685070</rpe:assignedPatientIdentifier>
        </rpe:processContext>
        <rpe:activity activityLanguage=" http://www.omg.org/spec/BPMN/20100524/MODEL">
          <userTask xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL"
1085          implementation="##unspecified" name="Screening Activity" id="ScreeningActivity">
            <dataOutputAssociation id="ScreeningObservations_DataOutput">
              <targetRef>ScreeningObservations</targetRef>
              <assignment>
                <from><![CDATA[
1090                <hl7:observation xmlns:hl7="urn:hl7-org:v3" classCode="OBS"
                moodCode="CRT">
                  <id root="1.2.5.2.3.4" extension="DBP"/>
                  <code code="8462-4" codeSystem="2.16.840.1.113883.6.1"
1095                  codeSystemName="LOINC" displayName="BP Diastolic">
                    <originalText>Diastolic Blood Pressure</originalText>
                  </code>
                  <statusCode code="active"/>
                  <value xsi:type="PQ" value="120" unit="mmHg"/>
                </hl7:observation>
1100                ]]>
              ]>

```

```

1105         </from>
            <to>ScreeningObservations</to>
        </assignment>
    </dataOutputAssociation>
</userTask>
</rpe:activity>
</rpe:UpdateActivityRequest>
</soap:Body>

```

3.Y4.6.1.2 Sample Update Activity SOAP Response

1110 *Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.*

```

1115 <soap:Body>
    <rpe:UpdateActivityRequestResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
        <rpe:responseCode>ACTIVITY_UPDATED</rpe:responseCode>
    </rpe:UpdateActivityRequestResponse>
</soap:Body>

```

3.Y5 Send Process State Alert

1120 This section corresponds to transaction QRPH-Y5 of the IHE QRPH Transaction Framework. QRPH-Y5 is used by the Process State Manager and Process Activity Executor actors.

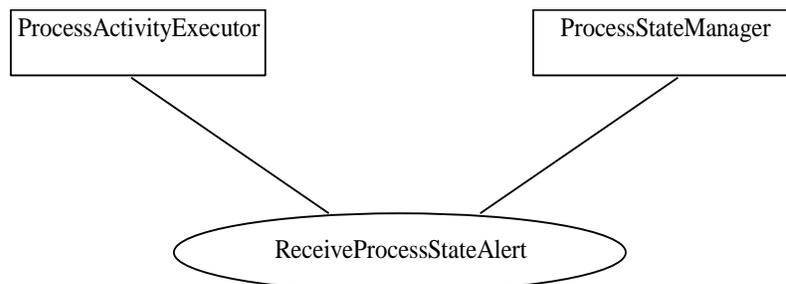
3.Y5.1 Scope

This transaction involves either:

- 1125 • a Process Activity Executor alerting a Process State Manager of a change that affects the state of a process it initiated,
- OR
- a Process State Manager alerting a Process Activity Executor of a change associated with a process it initiated with the Process State Manager, in which case the alert contains.

1130 In either case, the request passed by the actor supplies the current process context as per table 3.Y2.4.2.2 and a process state value.

3.Y5.2 Use Case Roles



Actor: Process Activity Executor

1135 **Role:** A system that knows how to execute activities that are part of a process.

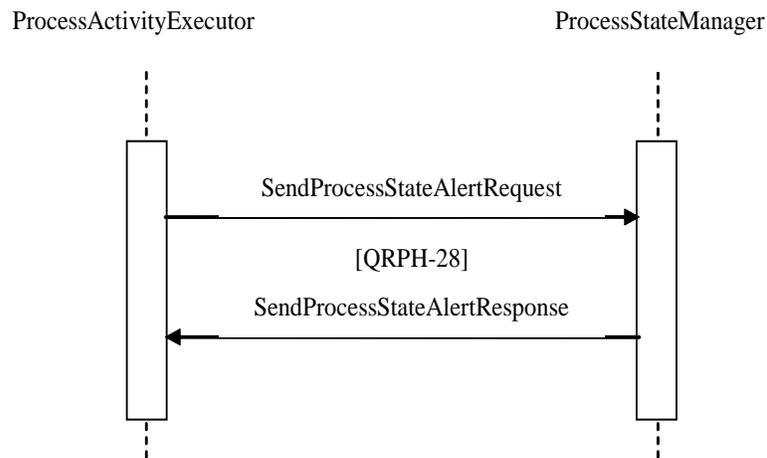
Actor: Process State Manager

Role: A system that manages the runtime state of a process.

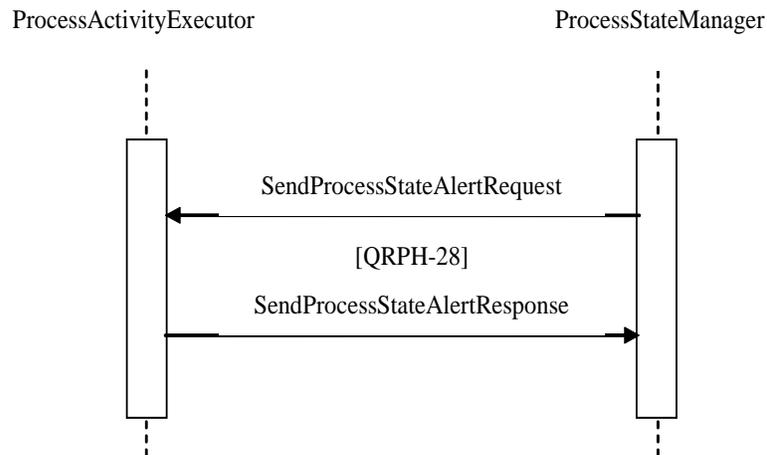
3.Y5.3 Referenced Standards

1140 See section 3.Y1.3.

3.Y5.4 Interaction Diagram



OR:



1145

3.Y5.4.1 Send Process State Alert Message

3.Y5.4.1.1 Trigger Events

Either:

- 1150 • the Process Activity Executor, based upon human decision or application of a rule for automatic operation, wants to alert the Process State Manager of a change that affects a process it initiated OR
- the Process State Manager, based upon human decision or application of a rule for automatic operation, wants to alert the Process Activity Executor of a change associated with a process it initiated with the Process State Manager.

1155 3.Y5.4.1.2 Message Semantics

The following parameters are specified for the body of this transaction.

Table 3.Y5.4.1.2–1: Send Process State Alert Request Parameters

Parameter Name	REQ	Description	Value
processContext	R	(see Table 3.Y1.4.1.2–2)	
processState	R	The process state change being alerted.	An XML attribute of type enumerated string with (current) possible values: PROCESS_ACTIVE – the process is now active, e.g., a patient has been enrolled in a clinical study PROCESS_SUSPENDED – the process has been suspended and is currently inactive, e.g., a hold has been placed on a clinical study PROCESS_EXITED – the process has been terminated abnormally, e.g., a clinical study has been discontinued PROCESS_COMPLETED – the process has completed as expected, e.g., a clinical study has concluded ACTIVITY_EXITED – a process activity has been terminated, e.g., completion of a study activity is no longer required

1160 Section 3.Y5.6 describes the Web Services protocol requirements and the format of the message in full detail.

3.Y5.4.1.3 Expected Actions

The Process Activity Executor or Process State Manager parses the Send Process State Alert request and if well-formed acknowledges the request with a response code of “PROCESS_STATE_ALERT_RECEIVED”.

1165 Otherwise SOAP faults shall be generated accordingly:

- If request is not well-formed, a SOAP fault shall be generated and shall include:
 - faultcode: Client
 - faultstring: Invalid Request
 - and may provide further information in the details element.

1170 **3.Y5.4.2 Send Process State Alert Response Message**

3.Y5.4.2.1 Trigger Events

The message is triggered by a Process Activity Executor or Process State Manager receiving a well-formed Send Process State Alert request.

3.Y5.4.2.2 Message Semantics

1175 A responseCode XML element of type string is returned to confirm receipt of the alert with a value of “PROCESS_STATE_ALERT_RECEIVED”.

3.Y5.4.2.3 Expected Actions

The Process State Manager shall generate the response code based on the business rules of the system. If a SOAP fault is received then this fault should also be handled based on the business rules of the system.

1180

3.Y5.5 Security Considerations

See section QRPH TF-1:X.6.

3.Y5.6 Protocol Requirements

The Send Process State Alert request and response shall be transmitted using Synchronous Web Services Exchange, according to the requirements specified in ITI TF-2: Appendix V Web Services for IHE Transactions.

1185

Table 3.Y5.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap12	http://schemas.xmlsoap.org/wsdl/soap12/
wsaw	http://www.w3.org/2005/08/addressing
xsd	http://www.w3.org/2001/XMLSchema

1190 These are the requirements for the Send Process State Alert transaction presented in the order in which they would appear in the WSDL definition:

- The following types shall be imported (xds:import) in the /definitions/types section:

- namespace="urn:ihe:qrph:rpe:2009", schema="RPE.xsd"
- 1195 • The /definitions/message/part/@element attribute of the Send Process State Alert request message shall be defined as: "ihe:SendProcessStateAlertRequest"
- The /definitions/message/part/@element attribute of the Send Process State Alert response message shall be defined as: "ihe:SendProcessStateAlertResponse"
- The /definitions/portType/operation/input/@wsaw:Action attribute for the Send Process State Alert request message shall be defined as "urn:ihe:qrph:2009:SendProcessStateAlert"
- 1200 • The /definitions/portType/operation/output/@wsaw:Action attribute for the Send Process State Alert response message shall be defined as: "urn:ihe:qrph:2009:SendProcessStateAlertResponse"
- The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:2009:SendProcessStateAlert"

1205 These are the requirements that affect the wire format of the SOAP message. The other WSDL properties are only used within the WSDL definition and do not affect interoperability. Full sample request and response messages are in the section 3.Y5.6.1 Sample SOAP Messages.

3.Y5.6.1 Sample SOAP Messages

1210 The samples in the following two sections show a typical request and corresponding response as contained in a SOAP Body. *Note the SOAP Header should be populated according to the IHE Appendix V: Web Services for IHE Transactions and in accord with section 3.Y5.5 Security Considerations.*

A full WSDL for the Process State Manager actor is found on the IHE FTP site at: [ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH Technical Committee/Profiles in Progress/RPE/metadata](ftp://ftp.ihe.net/Quality/2011_2012_YR_5/QRPH%20Technical%20Committee/Profiles%20in%20Progress/RPE/metadata).

1215 3.Y5.6.1.1 Sample Send Process State Alert SOAP Request

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

1220 Process State Manager to Process Activity Executor (notification of patient enrollment):

```
1220 <soap:Body>
1225   <rpe:SendProcessStateAlertRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
1225     <rpe:processContext>
1225       <rpe:processIdentifier>Connectathon2011RPEStudyDesign-CIS_CE_CB-997685070
1225       </rpe:processIdentifier>
1225       <rpe:assignedOrganizationIdentifier>CIS_CE_CB</rpe:assignedOrganizationIdentifier>
1225       <rpe:assignedPatientIdentifier>997685070</rpe:assignedPatientIdentifier>
1225     </rpe:processContext>
1225     <rpe:processState>PROCESS_ACTIVE</rpe:processState>
1230   </rpe:SendProcessStateAlertRequest>
1230 </soap:Body>
```

1235 Process Activity Executor to Process State Manager (notification of patient withdrawal):

```
1235 <soap:Body>
1235   <rpe:SendProcessStateAlertRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
1235     <rpe:processContext>
```

```
1240     <rpe:processIdentifier>Connectathon2011RPEStudyDesign-CIS_CE_CB-997685070
        </rpe:processIdentifier>
        <rpe:assignedOrganizationIdentifier>CIS_CE_CB</rpe:assignedOrganizationIdentifier>
        <rpe:assignedPatientIdentifier>997685070</rpe:assignedPatientIdentifier>
    </rpe:processContext>
    <rpe:processState>PROCESS_EXITED</rpe:processState>
1245 </rpe:SendProcessStateAlertRequest>
</soap:Body>
```

3.Y5.6.1.2 Sample Send Process State Alert SOAP Response

Note to the editor: please keep the following format for the sample text – courier new, 8pt, no spacing before and after the paragraph, tab stops every 1/8 of an inch for the first inch.

```
1250 <soap:Body>
    <rpe:SendProcessStateAlertResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
        <rpe:responseCode>PROCESS_STATE_ALERT_RECEIVED</rpe:responseCode>
    </rpe:SendProcessStateAlertResponse>
</soap:Body>
```