# **Integrating the Healthcare Enterprise**



# IHE Quality, Research and Public Health Technical Framework Supplement

# Retrieve Process for Execution (RPE)

# **Trial Implementation**

20 Date: September 9, 2016

10

15

25

Author: QRPH Technical Committee

Email: qrph@ihe.net

Please verify you have the most recent version of this document. See <u>here</u> for Trial Implementation and Final Text versions and <u>here</u> for Public Comment versions.

#### Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework 0.1. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on September 9, 2016 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Quality, Research and Public Health Technical Framework. Comments are invited and may be submitted at <a href="http://www.ihe.net/QRPH\_Public\_Comments">http://www.ihe.net/QRPH\_Public\_Comments</a>. This supplement describes changes to the existing technical framework documents.

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

#### *Amend Section X.X by the following:*

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold-strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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/IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <a href="http://www.ihe.net/IHE Process">http://www.ihe.net/Profiles</a>.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: <a href="http://www.ihe.net/IHE Process">http://www.ihe.net/IHE Process</a> and <a href="http://www.ihe.net/Profiles">http://www.ihe.net/Profiles</a>.

The current version of the IHE QRPH Technical Framework can be found at: <a href="http://www.ihe.net/Technical\_Frameworks">http://www.ihe.net/Technical\_Frameworks</a>.

55

35

40

11

# **CONTENTS**

	Introduction	6
	Open Issues and Questions	6
60	Closed Issues	6
	Volume 1 – Integration Profiles	7
	1.n Copyright Permissions	7
	2.5 Dependencies of the RPE Integration Profile	7
	2.7 History of Annual Changes	7
65	X Retrieve Process for Execution (RPE) Profile	8
	X.1 RPE Actors/Transactions	8
	X.1.1 Actor Descriptions and Requirements	9
	X.1.1.1 Process Definition Manager	9
	X.1.1.2 Process State Manager	9
70	X.1.1.3 Process Activity Executor	10
	X.2 RPE Actor Options	11
	X.2.1 Retrieve Process Definitions Option	12
	X.2.2 Retrieve Activities Option	
	X.2.3 Update Activity Option	12
75	X.3 Groupings	12
	X.4 RPE Process Flow	
	X.4.1 Use Cases	12
	X.4.2 Process Flow	14
	X.5 RPE Security Considerations	16
80	X.5.1 Recommendations	17
	X.6 RPE Version mapping	18
	Appendix A: Actor Summary Definitions	19
	Appendix B: Transaction Summary Definitions	
	Glossary	
85	Volume 2 - Transactions	22
	3 IHE Transactions	22
	3.20 Retrieve Process Definitions [QRPH-20]	22
	3.20.1 Scope	
	3.20.2 Use Case Roles	22
90	3.20.3 Referenced Standards	23
	3.20.4 Interaction Diagram	23
	3.20.4.1 Retrieve Process Definitions Message	
	3.20.4.1.1 Trigger Events	
	3.20.4.1.2 Message Semantics	
95	3.20.4.1.3 Expected Actions	
	3.20.4.2 Retrieve Process Definitions Response Message	
	3.20.4.2.1 Trigger Events	
	3.20.4.2.2 Message Semantics	

The Quality reminent Francisco Supplement Reduced Frocess for Execution (Rd E)

3.20.5 Security Considerations   3.20.6 Protocol Requirements   3.20.6.1 Sample SOAP Messages   3.20.6.1.1 Sample Retrieve Process Definitions SOAP Request   3.20.6.1.2 Sample Retrieve Process Definitions SOAP Response   105   3.25 Initiate Process [QRPH-25]   3.25.1 Scope   3.25.2 Use Case Roles   3.25.3 Referenced Standards   3.25.4 Interaction Diagram   110   3.25.4.1 Initiate Process Message   3.25.4.1.1 Trigger Events   3.25.4.1.2 Message Semantics   3.25.4.1.3 Expected Actions   3.25.4.2 Initiate Process Response Message   115   3.25.4.2.1 Trigger Events   3.25.4.2.1 Trigger Events   3.25.4.2.2 Message Semantics   3.25.4.2.3 Expected Actions   3.25.4.2.3 Expected Actions   3.25.5 Security Considerations   3.25.6 Protocol Requirements   3.25.6 Protocol Requirements   120   3.25.6.1 Sample SOAP Messages   3.25.6.1.2 Sample Initiate Process SOAP Request   3.25.6.1.2 Sample Initiate Process SOAP Response   1.25.6.1.2 Sample Initiate Process SOAP Response	
3.20.6.1 Sample SOAP Messages   3.20.6.1.1 Sample Retrieve Process Definitions SOAP Request   3.20.6.1.2 Sample Retrieve Process Definitions SOAP Response   105   3.25 Initiate Process [QRPH-25]   3.25.1 Scope   3.25.2 Use Case Roles   3.25.3 Referenced Standards   3.25.4 Interaction Diagram   110   3.25.4.1 Initiate Process Message   3.25.4.1.1 Trigger Events   3.25.4.1.2 Message Semantics   3.25.4.1.2 Message Semantics   3.25.4.1.3 Expected Actions   3.25.4.2 Initiate Process Response Message   115   3.25.4.2.1 Trigger Events   3.25.4.2.1 Trigger Events   3.25.4.2.2 Message Semantics   3.25.4.2.3 Expected Actions   3.25.5 Security Considerations   3.25.6 Protocol Requirements   3.25.6 Protocol Requirements   3.25.6.1.1 Sample Initiate Process SOAP Request   3.25.6.1.2 Sample Initiate Process SOAP Response	
3.20.6.1.1 Sample Retrieve Process Definitions SOAP Request 3.20.6.1.2 Sample Retrieve Process Definitions SOAP Response  3.25 Initiate Process [QRPH-25]	26
3.20.6.1.2 Sample Retrie ve Process Definitions SOAP Response  3.25 Initiate Process [QRPH-25]	26
3.25 Initiate Process [QRPH-25]	27
3.25 Initiate Process [QRPH-25]	27
3.25.1 Scope         3.25.2 Use Case Roles         3.25.3 Referenced Standards         3.25.4 Interaction Diagram         110         3.25.4.1 Initiate Process Message         3.25.4.1.1 Trigger Events         3.25.4.1.2 Message Semantics         3.25.4.1.3 Expected Actions         3.25.4.2 Initiate Process Response Message         115         3.25.4.2.1 Trigger Events         3.25.4.2.2 Message Semantics         3.25.4.2.3 Expected Actions         3.25.5 Security Considerations         3.25.6 Protocol Requirements         120         3.25.6.1 Sample SOAP Messages         3.25.6.1.2 Sample Initiate Process SOAP Request         3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.2 Use Case Roles   3.25.3 Referenced Standards   3.25.4 Interaction Diagram   110   3.25.4.1 Initiate Process Message   3.25.4.1.1 Trigger Events   3.25.4.1.2 Message Semantics   3.25.4.1.3 Expected Actions   3.25.4.2 Initiate Process Response Message   115   3.25.4.2.1 Trigger Events   3.25.4.2.1 Trigger Events   3.25.4.2.2 Message Semantics   3.25.4.2.3 Expected Actions   3.25.4.2.3 Expected Actions   3.25.6 Protocol Requirements   3.25.6 Protocol Requirements   3.25.6.1 Sample SOAP Messages   3.25.6.1.1 Sample Initiate Process SOAP Request   3.25.6.1.2 Sample Initiate Process SOAP Response   3.25.6.1.	
3.25.4 Interaction Diagram	
3.25.4.1 Initiate Process Message         3.25.4.1.1 Trigger Events         3.25.4.1.2 Message Semantics         3.25.4.1.3 Expected Actions         3.25.4.2 Initiate Process Response Message         3.25.4.2.1 Trigger Events         3.25.4.2.2 Message Semantics         3.25.4.2.3 Expected Actions         3.25.5 Security Considerations         3.25.6 Protocol Requirements         3.25.6.1 Sample SOAP Messages         3.25.6.1.2 Sample Initiate Process SOAP Response	29
3.25.4.1.1 Trigger Events 3.25.4.1.2 Message Semantics 3.25.4.1.3 Expected Actions 3.25.4.2 Initiate Process Response Message  3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.4.2.3 Expected Actions 3.25.6 Protocol Requirements 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	29
3.25.4.1.1 Trigger Events 3.25.4.1.2 Message Semantics 3.25.4.1.3 Expected Actions 3.25.4.2 Initiate Process Response Message  3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.4.2.3 Expected Actions 3.25.6 Protocol Requirements 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	29
3.25.4.1.2 Message Semantics 3.25.4.1.3 Expected Actions 3.25.4.2 Initiate Process Response Message 3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.5 Security Considerations 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.4.2 Initiate Process Response Message  3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.5 Security Considerations 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.5 Security Considerations 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	30
3.25.4.2.1 Trigger Events 3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.5 Security Considerations 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	30
3.25.4.2.2 Message Semantics 3.25.4.2.3 Expected Actions 3.25.5 Security Considerations 3.25.6 Protocol Requirements 3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.5 Security Considerations 3.25.6 Protocol Requirements  3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.5 Security Considerations 3.25.6 Protocol Requirements  3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	31
3.25.6.1 Sample SOAP Messages 3.25.6.1.1 Sample Initiate Process SOAP Request 3.25.6.1.2 Sample Initiate Process SOAP Response	
3.25.6.1.1 Sample Initiate Process SOAP Request	31
3.25.6.1.2 Sample Initiate Process SOAP Response	32
	32
3.26 Retrieve Activities [QRPH-26]	
3.26.1 Scope	33
125 3.26.2 Use Case Roles	
3.26.3 Referenced Standards	34
3.26.4 Interaction Diagram	34
3.26.4.1 Retrieve Activities Message	34
3.26.4.1.1 Trigger Events	
130 3.26.4.1.2 Message Semantics	34
3.26.4.1.3 Expected Actions	
3.26.4.2 Retrieve Activities Response Message	35
3.26.4.2.1 Trigger Events	35
3.26.4.2.2 Message Semantics	35
3.26.4.2.3 Expected Actions	35
3.26.5 Security Considerations	
3.26.6 Protocol Requirements	35
3.26.6.1 Sample SOAP Messages	36
3.26.6.1.1 Sample Retrieve Activities SOAP Request	37
3.26.6.1.2 Sample Retrieve Activities SOAP Response	
3.27 Update Activity [QRPH-27]	
3.27.1 Scope	20

Telline Transwork Supplement Telline Trocess for Execution (Table)

	3.27.2 Use Case Roles	38
	3.27.3 Referenced Standards	38
145	3.27.4 Interaction Diagram	38
	3.27.4.1 Update Activity Message	39
	3.27.4.1.1 Trigger Events	39
	3.27.4.1.2 Message Semantics	39
	3.27.4.1.3 Expected Actions	39
150	3.27.4.2 Update Activity Response Message	40
	3.27.4.2.1 Trigger Events	
	3.27.4.2.2 Message Semantics	40
	3.27.4.2.3 Expected Actions	40
	3.27.5 Security Considerations	40
155	3.27.6 Protocol Requirements	40
	3.27.6.1 Sample SOAP Messages	
	3.27.6.1.1 Sample Update Activity SOAP Request	41
	3.27.6.1.2 Sample Update Activity SOAP Response	
	3.28 Send Process State Alert [QRPH-28]	42
160	3.28.1 Scope	42
	3.28.2 Use Case Roles	43
	3.28.3 Referenced Standards	43
	3.28.4 Interaction Diagram	43
	3.28.4.1 Send Process State Alert Message	44
165	3.28.4.1.1 Trigger Events	44
	3.28.4.1.2 Message Semantics	44
	3.28.4.1.3 Expected Actions	45
	3.28.4.2 Send Process State Alert Response Message	
	3.28.4.2.1 Trigger Events	45
170	3.28.4.2.2 Message Semantics	45
	3.28.4.2.3 Expected Actions	45
	3.28.5 Security Considerations	45
	3.28.6 Protocol Requirements	45
	3.28.6.1 Sample SOAP Messages	
175	3.28.6.1.1 Sample Send Process State Alert SOAP Request	
	3.28.6.1.2 Sample Send Process State Alert SOAP Response	47

#### Introduction

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

- 1. the manager of process definitions
- 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.

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 or research

- site's Clinical Trials Management System (CTMS) and to execute these instructions within the EHR. Interest has since grown to expand RPE to support processes from other domains involving collaborative workflows like quality, public health and patient care support. RPE now does this consistent with accepted IT standards for process management. In September of 2011, RPE underwent a substantial re-write that required current users of RPE to re-develop their
- implementations of the profile. The current version harmonizes the original Retrieve *Protocol* for Execution and the new Retrieve *Process* for Execution to lessen the burden on users of the profile to conform to the profile.

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. One of these profiles is the Clinical Research Process Content (CRPC) Profile.

# **Open Issues and Questions**

No open issues at this time.

#### Closed Issues

No closed issues at this time.

# **Volume 1 – Integration Profiles**

Add the following to Section 1.1.5

210

# 1.n Copyright Permissions

To be completed

Add the following to Section 2.5

215

220

# 2.5 Dependencies of the RPE Integration Profile

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

Add the following to Section 2.7

# 2.7 History of Annual Changes

225 To be completed

Add Section X to the QRPH Technical Framework

# X Retrieve Process for Execution (RPE) Profile

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

- 1. the manager of process definitions
- 2. the manager of runtime processes
- 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 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.

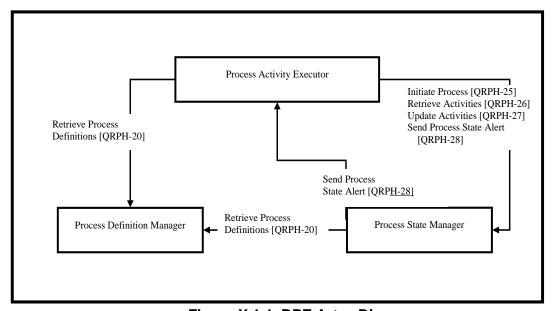


Figure X.1-1: RPE Actor Diagram

240

245

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, which implementations may choose to support, is listed in Section X.2.

\_\_\_\_\_

			. —
Table X	1-1· RPF	Actors and	Transactions

Actors	Transactions	Optionality	Reference
Process Definition Retrieve Process Definitions [QRPH-20]		R	QRPH TF-2: 3.20
Process State	Retrieve Process Definitions [QRPH-20]	О	QRPH TF-2: 3.20
Manager	Initiate Process [QRPH-25]	R	QRPH TF-2: 3.25
	Retrieve Activities [QRPH-26]	О	QRPH TF-2: 3.26
	Update Activity [QRPH-27]	О	QRPH TF-2: 3.27
	Send Process State Alert [QRPH-28]	R	QRPH TF-2: 3.28
Process Activity	Retrieve Process Definitions [QRPH-20]	R	QRPH TF-2: 3.20
Executor	Initiate Process [QRPH-25]	R	QRPH TF-2: 3.25
	Retrieve Activities [QRPH-26]	О	QRPH TF-2: 3.26
	Update Activity [QRPH-27]	О	QRPH TF-2: 3.27
	Send Process State Alert [QRPH-28]	R	QRPH TF-2: 3.28

# 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.

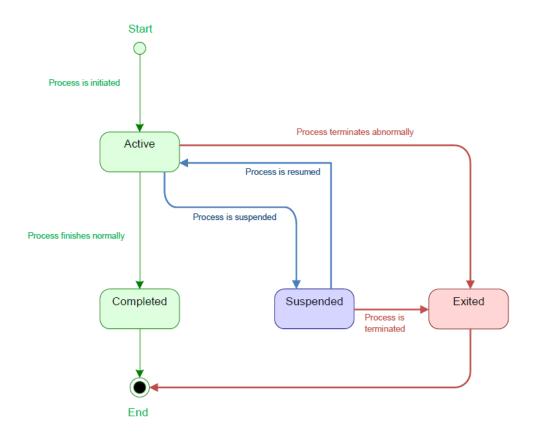
An example would be a research sponsor providing access to the clinical research protocols it has developed. Another would be a provider of evidence-based clinical practice guidelines.

# X.1.1.2 Process State Manager

- 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 accordance with executable guideline-based processes.

The states of a process from the perspective of RPE actors<sup>1</sup> are indicated below:

<sup>1</sup> 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.)



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

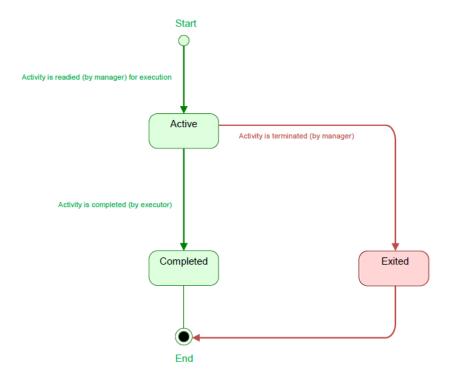
The Process Activity Executor performs activities as prescribed by a running process being managed by a Process State Manager. The Process Activity Executor retrieves current activity or task lists, works its list, updating the Process State Manager on activity state until completion. This cycle is repeated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

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 actors<sup>2</sup> are indicated below:

o reactive by an activity.)

<sup>&</sup>lt;sup>2</sup> 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.)



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.

# 285 X.2 RPE Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1.

ActorOptionsReferenceProcess State ManagerRetrieve Process DefinitionsSection X.2.1Process State ManagerRetrieve ActivitiesSection X.2.2Process State ManagerUpdate ActivitySection X.2.3Process Activity ExecutorRetrieve ActivitiesSection X.2.2

**Table X.2-1: RPE Actor Options** 

\_\_\_\_

Actor	Options	Reference
Process Activity Executor	Update Activity	Section X.2.3

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

#### 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.

# 295 X.2.2 Retrieve Activities Option

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.

## 300 X.2.3 Update Activity Option

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.

#### X.4 RPE Process Flow

#### X.4.1 Use Cases

The clinical research use 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

310

315

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.

#### **Before RPE**

#### Preconditions

- 1. A Clinical Research Protocol is defined by a clinical trials expert at Sponsor, a biopharma research company.
  - 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.

#### **Clinical Research Site's Involvement:**

325

340

345

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.

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

#### Post conditions

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

#### After RPE

#### 350 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.

#### Clinical Research Site's Involvement:

#### Initial:

355

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

#### Screening:

- 1. 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.
- 2. Process Activity Executor uses the Retrieve Activities transaction to obtain from the Process State Manager the set of screening activities.
  - 3. 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.)
- 4. 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.

#### Treatment:

380

- 1. 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.
- 2. 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 Update Activity may be replaced by RFD form retrieval and submission.)
  - 3. 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.
  - 4. 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.

#### X.4.2 Process Flow

The basic process flow for RPE is shown below:

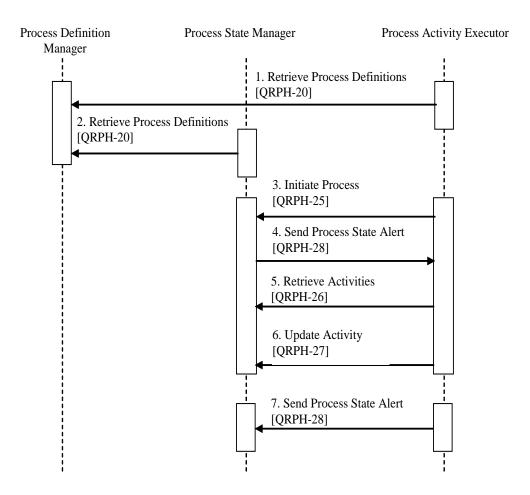


Figure X.4.2-1: Basic Process Flow in RPE Profile

- 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 400 Manager the updated activity state and output data.

385

390

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.

# X.5 RPE Security Considerations

410

The risk analysis for RPE enumerates assets, threats, and mitigations. The complete risk data is stored and available from IHE<sup>3</sup>.

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.

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
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

<sup>&</sup>lt;sup>3</sup> The full risk analysis data may be found at: ftp://ftp.ihe.net/Quality/2010\_2011\_YR\_4/QRPH% 20Technical% 20Committee/Maintenance% 20wo rk/RPE/RPE Risk Analysis 2010-05-21.xls

\_\_\_\_

Risk Scenario	Type of Impact	Probability
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

415

#### X.5.1 Recommendations

The high impact risks include:

- mismatch between patient and patient data
- 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 Technical Framework are referred:

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

This profile includes the mitigations:

- 430 **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.
  - M3: Use secured communication for any patient data e.g., as per ATNA.
- 435 **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:

- **T1**: Verify demographics other than patient name, birth date and gender.
- 440 **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.

- 445 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.
  - **T6**: Obtain patient consents and ensure patient data requiring increased protection is clearly identified.
- 450 **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.
  - **T9**: Actors are advised to consider the usability of their logging and audit repository implementation.

# 455 X.6 RPE Version mapping

The following tables specify mappings from the original Retrieve *Protocol* for Execution to the new Retrieve *Process* for Execution to assist implementers in translating their original RPE actors, transactions, and parameters to the new actors, transactions, and parameters.

# 460 Table X.6-1: Actor Mapping

Retrieve <i>Protocol</i> for Execution	Retrieve <i>Process</i> for Execution
Actor	Actor
ProtocolDefManager	Process Definition Manager
ProtocolExecutor	Process Activity Executor
ProtocolStateManager	Process State Manager

**Table X.6-2: Transaction Mapping** 

Retrieve <i>Protocol</i> for Execution	Retrieve <i>Process</i> for Execution
Transaction	Transaction
RetrieveProtocolDef – Retired [QRPH-10]	Retrieve Process Definitions [QRPH-20]
EnterPatientRequest – Retired [QRPH-11]	Initiate Process [QRPH-25]
PatientScreeningVisitsScheduled – Retired [QRPH-12]	UpdateActivity [QRPH-27]
RecordPatientScreeningVisit – Retired [QRPH-13]	UpdateActivity [QRPH-27]
EnrollPatientRequest – Retired [QRPH-14]	Send Process State Alert [QRPH-28]

Retrieve <i>Protocol</i> for Execution	Retrieve <i>Process</i> for Execution
Transaction	Transaction
PatientStudy Visits Scheduled – Retired [QRPH-15]	UpdateActivity [QRPH-27]
RecordPatientStudyVisit – Retired [QRPH-16]	UpdateActivity [QRPH-27]
AmendProtocolDef – Retired [QRPH-17]	Publish Process Definitions [QRPH-22]
AlertProtocolState – Retired [QRPH-18]	Send Process State Alert [QRPH-28]

**Table X.6-3: Parameter Mapping** 

Retrieve <i>Protocol</i> for Execution	Retrieve <i>Process</i> for Execution
Parameter	Parameter
query	processDefinitionIdentifier
ProtocolDefs	process Definition
contentType	processDefinitionLanguage
study/id	processDefinitionIdentifier
subjectID	processIdentifier
schedule	activity
visit	activity

# 465

470

475

480

# Appendix A: Actor Summary Definitions

**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.

**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.

**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.

\_\_\_\_\_

# **Appendix B: Transaction Summary Definitions**

- Retrieve Process Definitions [QRPH-20] 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.
- 490 **Initiate Process [QRPH-25]** 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.
  - **Retrieve Activities** [QRPH-26] 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.
- 495 **Update Activity [QRPH-27]** 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.
  - **Send Process State Alert [QRPH-28]** 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:

**Process Definition** – A designed flow of activities involving one or more role-based activity performers, implemented in XML and deployable to a runtime process consumer.

505 **Process** – A specific instance of a process definition running in a process consumer.

**Activity Definition** – A designed task which is deployable to a runtime activity processor, typically as part of a process definition.

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

# **Volume 2 - Transactions**

#### 3 IHE Transactions

Add Sections 3.20, 3.25, 3.26, 3.27, and 3.28

# **3.20 Retrieve Process Definitions [QRPH-20]**

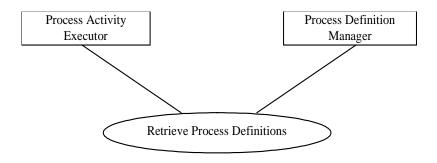
This section corresponds to transaction QRPH-20 of the IHE QRPH Transaction Framework. QRPH-20 is used by the Process Definition Manager and Process Activity Executor Actors.

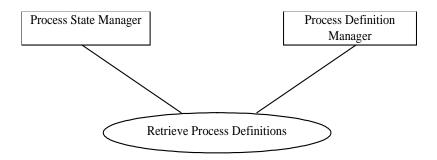
# 3.20.1 Scope

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 either a list of matching process definitions or an error response.

#### 525 **3.20.2 Use Case Roles**





**Actor:** Process Activity Executor

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

535 **Actor:** Process State Manager

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

**Actor:** Process Definition Manager

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

#### 3.20.3 Referenced Standards

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

- ITI TF-2x: Appendix V Web Services for IHE Transactions
- Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml

Implementers of this transaction shall comply with *one of the following* reference standards:

• OMG Business Process Model and Notation (BPMN) Version 2.0 [http://www.omg.org/spec/BPMN/2.0/]

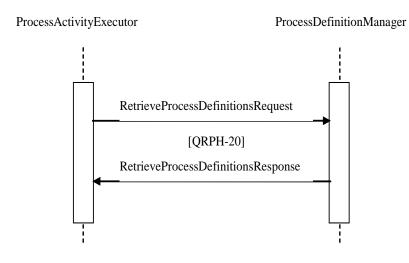
OR

545

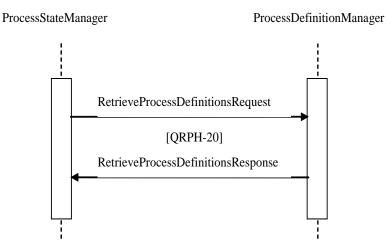
550

• HL7<sup>®4</sup> Study Design
[http://www.hl7.org/v3ballot/html/domains/uvrt/uvrt\_StudyDesign.htm] AND HL7 Study
Participation
[http://www.hl7.org/v3ballot/html/domains/uvrt/uvrt\_StudyParticipation.htm]

# 3.20.4 Interaction Diagram



<sup>&</sup>lt;sup>4</sup> HL7 is the registered trademark of Health Level Seven International.



555

565

#### 3.20.4.1 Retrieve Process Definitions Message

#### 3.20.4.1.1 Trigger Events

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

# 3.20.4.1.2 Message Semantics

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

 Table 3.20.4.1.2-1: 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 retrieved.	HL7 element of type InstanceIdentifier.
maxOccurs	О	If specified, the number of process definitions returned MUST NOT exceed this limit.	An XML element of simple type int.
startIndex	0	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.

Section 3.20.6 describes the Web Services protocol requirements and the format of the message in full detail.

#### 3.20.4.1.3 Expected Actions

- Upon receipt 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.

#### 3.20.4.2 Retrieve Process Definitions Response Message

## 3.20.4.2.1 Trigger Events

The delivery of a set of process definitions is triggered by a Process Definition Manager Actor in response to a Retrieve Process Definitions message.

# 3.20.4.2.2 Message Semantics

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

585

Table 3.20.4.1.2-2: Retrieve Process Definitions Response Parameter

Parameter Name	Option ality	Description	Value
processDefinition	R	One process definition per process definition identifier requested.	A complex XML element of type specified per optional processDefinitionLanguage attribute
processDefinitionLanguage	R	XML attribute	Options: http://www.omg.org/spec/BPMN/ 2.0/ (BPMN) PORT_RM100002UV (HL7 Study Design)

#### 3.20.4.2.3 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.

#### 3.20.5 Security Considerations

See QRPH TF-1:X.5.

\_\_\_\_\_

#### 3.20.6 Protocol Requirements

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

**Table 3.20.6-1: 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 Retrieve Process Definitions transaction presented in the order in which they would appear in the WSDL definition:
  - The following types shall be imported (xsd: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"
  - 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: "urn:ihe:qrph:2009:RetrieveProcessDefinitionsResponse"
  - The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:2009:RetrieveProcessDefinitions"

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 Section 3.20.6.1 Sample SOAP Messages.

#### 3.20.6.1 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 ITI TF-2x: Appendix V: Web Services for IHE Transactions.* 

\_\_\_\_

605

610

A full WSDL for the Process Definition Manager Actor is found on the IHE FTP site at: <a href="mailto:ftp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH">ftp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH</a> Technical Committee/Profiles in <a href="mailto:Progress/RPE/metadata">Progress/RPE/metadata</a>

# 3.20.6.1.1 Sample Retrieve Process Definitions 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.

## 3.20.6.1.2 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.

```
<soap: Body>
         <rpe:RetrieveProcessDefinitionsResponse xmlns:rpe="urn:ihe:grph:rpe:2009">
             <rpe:processDefinition processDefinitionLanguage="http://www.omg.org/spec/BPMN/2.0/">
645
                 <definitions targetNamespace="http://www.examples.org"</pre>
                xmlns:tns="http://www.examples.org" 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
650
                 xmlns:bpmndi="http://www.omg.org/spec/BPMN/20100524/DI"
                 xmlns:dc=http://www.omg.org/spec/DD/20100524/DC xmlns:h17="urn:h17-org:v3"
                 xmlns:rpe="urn:ihe:qrph:rpe:2009" id="_1312929184333">
                     <!-- Import schemas and define RPE and HL7 element items for reference by process
655
                data object variables -->
                    <import importType="http://www.w3.org/2001/XMLSchema" location="RPE.xsd"</pre>
                 namespace="urn:ihe:qrph:rpe:2009"/>
                     <import importType="http://www.w3.org/2001/XMLSchema" location="HL7-</pre>
                 SD/StudyDesign.xsd" namespace="urn:hl7-org:v3"/>
660
                     <itemDefinition id="InitiateProcessRequestItem"</pre>
                 structureRef="rpe: InitiateProcessRequest"></itemDefinition>
                    <itemDefinition id="RequestContextItem"</pre>
                 structureRef="rpe:requestContext"></itemDefinition>
                     <itemDefinition id="PatientDataItem"</pre>
665
                 structureRef="rpe:patientData"></itemDefinition>
                    <itemDefinition id="EligibilityCriterionItem"</pre>
                 structureRef="hl7:eligibilityCriterion"></itemDefinition>
                     <itemDefinition id="ObservationItem"</pre>
                 structureRef="hl7:observation"></itemDefinition>
670
                     <itemDefinition id="SubstanceAdministrationItem"</pre>
                 structureRef="hl7:substanceAdministration"></itemDefinition>
                     <message id="InitiateProcessRequest" itemRef="tns:InitiateProcessRequestItem"</pre>
                name="Initiate Process Request"/>
675
                     <documentation id="Title">IHE RPE Study Design</documentation>
                         <documentation id="Description">A simple single arm example consisting of
                 Screen, Treatment and Followup epochs with 3 activities total:
680
                         a screening visit, a treatment visit and a followup visit 6 months
```

625

later.</documentation> <ioSpecification> <dataInput isCollection="true" name="Eligibility Criteria"</pre> id="EligibilityCriteria" itemSubjectRef="tns:EligibilityCriterionItem"/> 685 <dataInput name="Request Context" id="RequestContext"</pre> itemSubjectRef="tns:RequestContextItem"/> <dataInput name="Patient Data" id="PatientData"</pre> itemSubjectRef="tns:PatientDataItem"/> <dataInput name="Substance Administration" id="SubstanceAdministration"</pre> 690 itemSubjectRef="tns:SubstanceAdministrationItem"/> <dataOutput isCollection="true" name="Screening Observations"</pre> id="ScreeningObservations" itemSubjectRef="tns:ObservationItem"/> <dataOutput isCollection="true" name="Treatment Observations"</pre> id="TreatmentObservations" itemSubjectRef="tns:ObservationItem"/> 695 <dataOutput isCollection="true" name="Follow-up Observations"</pre> id="FollowUpObservations" itemSubjectRef="tns:ObservationItem"/> </definitions> </rpe:processDefinition> 700 </rpe:RetrieveProcessDefinitionsResponse> </soap:Body> <soap:Body> 705 <rpe:RetrieveProcessDefinitionsResponse xmlns:rpe="urn:ihe:grph:rpe:2009"> <rpe:processDefinition processDefinitionLanguage="PORT\_RM100002UV">

# 3.25 Initiate Process [QRPH-25]

</rpe:RetrieveProcessDefinitionsResponse>

</plannedStudy>

</rpe:processDefinition>

This section corresponds to transaction QRPH-25 of the IHE QRPH Transaction Framework. QRPH-25 is used by the Process State Manager and Process Activity Executor Actors.

#### 3.25.1 Scope

</soap:Body>

710

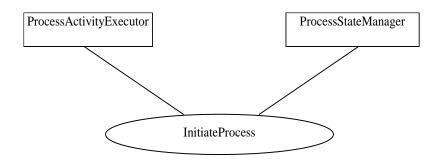
This transaction involves a Process Activity Executor requesting the initiation of a process with a Process State Manager.

- 720 In its request the Process Activity Executor supplies an initial context, including:
  - an identifier for the process definition of interest

<plannedStudy xmlns:hl7="urn:hl7-org:v3">

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

#### 3.25.2 Use Case Roles



730 **Actor:** Process Activity Executor

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

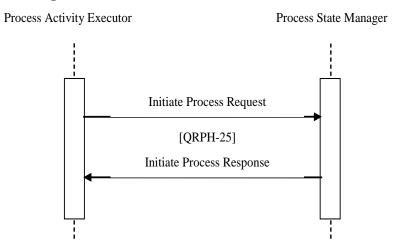
**Actor:** Process State Manager

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

#### 735 **3.25.3 Referenced Standards**

See Section 3.20.3.

# 3.25.4 Interaction Diagram



## 740 **3.25.4.1 Initiate Process Message**

# 3.25.4.1.1 Trigger Events

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

#### 3.25.4.1.2 Message Semantics

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

Table 3.25.4.1.2-1: Initiate Process Request Parameters

Parameter Name	Optionality	Description	Value
patient	R	Basic demographics for the patient.	Simple patient definition, of type rpe:PatientType.
candidateID	R	List of patient identities.	HL7 element of type InstanceIdentifier.
			HL7 patient name type
name	О	Patient name	HL7 address type
address	O	Patient address	HL7 datetime type
dob	О	Patient date of birth	
processDefinitionIdentifier	R	Identifier for the process definition to be initiated.	HL7 element of type InstanceIdentifier.
processState	R	Initial state of the process	An XML element of type enumerated string.
organizationIdentifier	О	Identifier for the involved organization.	HL7 element of type InstanceIdentifier.
requestorReference	0	The Process Activity Executor callback endpoint for the Process State Manager to use in sending alerts.	WS Addressing EndpointReferenceType
patientData	0	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

Section 3.25.6 describes the Web Services protocol requirements and the format of the message in full detail.

#### 3.25.4.1.3 Expected Actions

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.

#### 3.25.4.2 Initiate Process Response Message

#### 3.25.4.2.1 Trigger Events

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.

# 3.25.4.2.2 Message Semantics

The following output parameters are the body of the response.

Table 3.25.4.2.2-1: Initiate Process Response Parameters

Parameter Name	Optionality	Description	Value
processIdentifier	R	Identifier for process instance	HL7 element of type InstanceIdentifier.
processState	R	Initial state of the process	An XML element of type enumerated string.
assignedOrganizationIdentifier	О	Assigned identifier for organization.	HL7 element of type InstanceIdentifier.
patient	О	Provided if additional identifiers are assigned to the patient.	Simple patient definition, of type rpe:PatientType.

765

775

#### 3.25.4.2.3 Expected Actions

The Process Activity Executor shall consume 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.

# 770 **3.25.5 Security Considerations**

See QRPH TF-1:X.5.

# 3.25.6 Protocol Requirements

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

Table 3.25.6-1: 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:

- The following types shall be imported (xsd: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"
- 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"
  - 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 3.25.6.1 Sample SOAP Messages.

#### 3.25.6.1 Sample SOAP Messages

785

790

800

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 ITI TF-2x: Appendix V: Web Services for IHE Transactions and in accord with Section 3.25.5 Security Considerations.

A full WSDL for the Process State Manager Actor is found on the IHE FTP site at: <a href="mailto:ttp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH\_Technical\_Committee/Profiles\_in\_Progress/RPE/metadata">ttp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH\_Technical\_Committee/Profiles\_in\_Progress/RPE/metadata</a>

#### 805 3.25.6.1.1 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.

```
810
       <soap:Body>
         <rpe:InitiateProcessRequest xmlns:rpe="urn:ihe:qrph:rpe:2009" xmlns:hl7="urn:hl7-org:v3"</pre>
         xmlns:wsa="http://schemas.xmlsoap.org/ws/2004/03/addressing">
               <rpe:patient>
                   <rpe:candidateID root="" extension="" />
815
                   <rpe:name>
                       <hl7:given>John</hl7:given>
                       <hl7:family>Smith</hl7:family>
                   </rpe:name>
                   <rpe:address />
820
                   <rpe:dob value="19990101" />
               </rpe:patient>
               <rpe:processDefinitionIdentifier root="1.2.3.4" extension="1006" />
                <rpe:processState>INTERESTED</rpe:processState>
               <rpe:organizationIdentifier root="1.2.3.5" extension="CIS_CE_CB" />
825
               <rpe:requestorReference>
                   <wsa:Address>http://example.com/fabrikam/acct</wsa:Address>
               </rpe:requestorReference>
```

```
</rpe:InitiateProcessRequest>
</soap:Body>
```

#### 3.25.6.1.2 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.

# 3.26 Retrieve Activities [QRPH-26]

This section corresponds to transaction QRPH-26 of the IHE QRPH Transaction Framework. QRPH-26 is used by the Process State Manager and Process Activity Executor Actors.

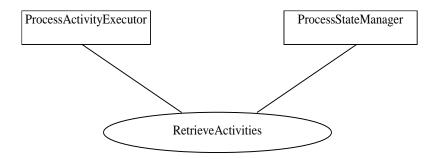
## 845 **3.26.1 Scope**

830

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

In its request, the Process Activity Executor supplies the current process context, per Table 3.25.4.2.2-1.

#### 3.26.2 Use Case Roles



855 **Actor:** Process Activity Executor

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

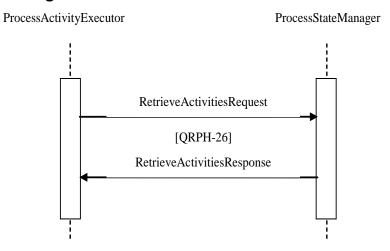
**Actor:** Process State Manager

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

#### 3.26.3 Referenced Standards

860 See Section 3.20.3.

#### 3.26.4 Interaction Diagram



#### 3.26.4.1 Retrieve Activities Message

# 865 **3.26.4.1.1 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.

# 3.26.4.1.2 Message Semantics

The current process context (see Table 3.25.4.2.2-1) is the sole input.

Section 3.26.6 describes the Web Services protocol requirements and the format of the message in full detail.

#### 3.26.4.1.3 Expected Actions

The Process State Manager parses the Retrieve Activities Request message 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.

#### 3.26.4.2 Retrieve Activities Response Message

#### 880 **3.26.4.2.1** Trigger Events

The message is triggered by a Process State Manager in response to a Retrieve Activities Request from a Process Activity Executor.

# 3.26.4.2.2 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 3.26.4.2.2-1: Retrieve Activities Response Parameters

Parameter Name	Optionality	Description	Value
activity	R	Current process activity	A complex XML element representing an activity within a process as specified per the activity Language attribute
activity Language	R	XML attribute	Options: http://www.omg.org/spec/BPMN/ 2.0.2/PDF/ (BPMN) PORT_RM 100002UV (HL7 Study Design)
processIdentifier	R	Identifier for process instance	HL7 element of type InstanceIdentifier.
processState	R	Initial state of the process	An XML element of type enumerated string.
assignedOrganizationIdentifier	0	Assigned identifier for organization.	HL7 element of type InstanceIdentifier.
patient	0	Provided if additional identifiers are assigned to the patient.	Simple patient definition, of type rpe:PatientType.

#### 3.26.4.2.3 Expected Actions

The Process Activity Executor shall consume 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.

## 3.26.5 Security Considerations

See QRPH TF-1:X.5.

#### 3.26.6 Protocol Requirements

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

\_\_\_\_\_

#### Table 3.26.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009	
soap 12	http://schemas.xmlsoap.org/wsdl/soap12/	
wsaw	http://www.w3.org/2005/08/addressing	
xsd	http://www.w3.org/2001/XMLSchema	

900

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 (xsd:import) in the /definitions/types section:
- namespace="urn:ihe:qrph:rpe:2009", schema="RPE.xsd"

905

- The /definitions/message/part/@element attribute of the Retrieve Activities request message shall be defined as: "ihe:RetrieveActivitiesRequest"
- The /definitions/message/part/@element attribute of the Retrieve Activities response message shall be defined as: "ihe:RetrieveActivitiesResponse"

910

- 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"

915

• The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:qrph:2009:RetrieveActivities"

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 Section 3.26.6.1 Sample SOAP Messages.

# 3.26.6.1 Sample SOAP Messages

920

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 3.26.5 Security Considerations.* 

925

A full WSDL for the Process State Manager Actor is found on the IHE FTP site at: <a href="mailto:ttp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH\_Technical\_Committee/Profiles\_in\_Progress/RPE/metadata">ttp://ftp.ihe.net/Quality/2011\_2012\_YR\_5/QRPH\_Technical\_Committee/Profiles\_in\_Progress/RPE/metadata</a>

# 3.26.6.1.1 Sample Retrieve Activities SOAP Request

930

950

980

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.

```
<soap:Body>
         <rpe:RetrieveActivitiesRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
               <rpe:patient>
                   <rpe:candidateID root="" extension="" />
935
                   <rpe:name>
                       <hl7:given>John</hl7:given>
                        <hl7:family>Smith</hl7:family>
                   </rpe:name>
                   <rpe:address />
940
                   <rpe:dob value="19990101" />
               </rpe:patient>
                <rpe:processIdentifier root="1.2.3.5" extension="1006-1" />
                <rpe:processDefinitionIdentifier root="1.2.3.4" extension="1006" />
               <rpe:processState>SCREENING</rpe:processState>
945
               <rpe:assignedOrganizationIdentifier root="1.2.3.5" extension="CIS_CE_CB" />
       </rpe:RetrieveActivitiesRequest>
       </soap:Body>
```

# 3.26.6.1.2 Sample Retrieve Activities 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.

```
<soap: Body>
955
         <rpe:RetrieveActivitiesResponse xmlns:rpe="urn:ihe:qrph:rpe:2009">
           <rpe:activity activityLanguage="http://www.omg.org/spec/BPMN/2.0/">
               <userTask xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL"</pre>
               implementation="##unspecified" name="Screening Activity" id="ScreeningActivity"/>
           </rpe:activity>
960
         </rpe:RetrieveActivitiesResponse>
       </soap:Body>
       <soap: Body>
965
         <rpe:RetrieveActivitiesResponse xmlns:rpe="urn:ihe:qrph:rpe:2009" xmlns:hl7="urn:hl7-org:v3">
           <rpe:activity activityLanguage="PORT_RM100001UV">
               <hl7:study>
                 <hl7:instantiation>
                   <hl7:plannedStudy>
970
                   </hl7:plannedStudy>
                 </hl7:instantiation>
               </hl7:study>
           </rpe:activity>
975
         </rpe:RetrieveActivitiesResponse>
       </soap:Body>
```

# 3.27 Update Activity [QRPH-27]

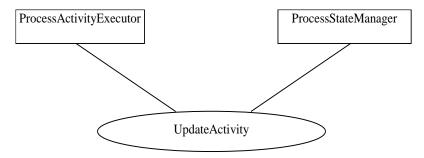
This section corresponds to transaction QRPH-27 of the IHE QRPH Transaction Framework. QRPH-27 is used by the Process State Manager and Process Activity Executor Actors.

# 3.27.1 Scope

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

In its request, the Process Activity Executor supplies the current process context, per Table 3.25.4.2.2-1, and the updated activity.

#### 3.27.2 Use Case Roles



**Actor:** Process Activity Executor

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

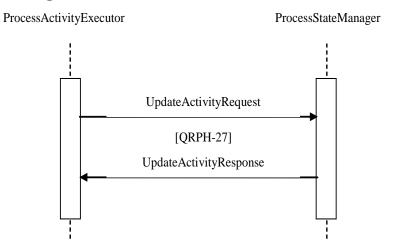
**Actor:** Process State Manager

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

#### 3.27.3 Referenced Standards

See Section 3.20.3.

#### 995 **3.27.4 Interaction Diagram**



#### 3.27.4.1 Update Activity Message

#### 3.27.4.1.1 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.

# 3.27.4.1.2 Message Semantics

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

1005

Table 3.27.4.1.2-1: Update Activity Request Parameters

Parameter Name	Optionality	Description	Value
activity	R	One or more process activities.	A complex XML element representing an activity within a process as specified per the activity Language attribute
activity Language	R	XMLattribute	Options: http://www.omg.org/spec/ BPMN/2.0.2/PDF/ (BPMN) PORT_RM100002UV (HL7 StudyDesign)
processIdentifier	R	Identifier for process instance	HL7 element of type InstanceIdentifier.
processState	R	State of the process	An XML element of type enumerated string.
assignedOrganizationIdentifier	О	Assigned identifier for organization.	HL7 element of type InstanceIdentifier.
patient	О	Provided if additional identifiers are assigned to the patient.	Simple patient definition, of type rpe:PatientType.

Section 3.27.6 describes the Web Services protocol requirements and the format of the message in full detail.

#### 1010 **3.27.4.1.3** 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.

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.

#### 3.27.4.2 Update Activity Response Message

#### 3.27.4.2.1 Trigger Events

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

#### 3.27.4.2.2 Message Semantics

A responseCode XML element of type string is returned which confirms successful update of the activity with a value of "ACTIVITY\_UPDATED".

#### 1025 **3.27.4.2.3** Expected Actions

The Process Activity Executor shall consume 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.

# 3.27.5 Security Considerations

1030 See Section QRPH TF-1:X.5

#### 3.27.6 Protocol Requirements

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

1035

Table 3.27.6-1: WSDL Namespace Definitions

ihe	urn:ihe:qrph:rpe:2009
soap 12	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 Update Activity transaction presented in the order in which they would appear in the WSDL definition:

- 1040
- The following types shall be imported (xds:import) in the /definitions/types section:
- namespace="urn:ihe:grph:rpe:2009", schema="RPE.xsd"
- The /definitions/message/part/@element attribute of the Update Activity request message shall be defined as: "ihe:Update ActivityRequest"
- The /definitions/message/part/@element attribute of the Update Activity response message shall be defined as: "ihe:UpdateActivityResponse"

40

- 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"

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 3.27.6.1 Sample SOAP Messages.

#### 3.27.6.1 Sample SOAP Messages

1050

1055

1060

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 3.27.5 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.

# 3.27.6.1.1 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.

```
<soap:Body>
          <rpe:UpdateActivityRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
1070
                <rpe:patient>
                    <rpe:candidateID root="" extension="" />
                    <rpe:name>
                        <hl7:given>John</hl7:given>
                        <h17:family>Smith</h17:family>
1075
                    </rpe:name>
                    <rpe:address />
                    <rpe:dob value="19990101 />
                 </rpe:patient>
                 <rpe:processIdentifier root="1.2.3.5" extension="1006-1" />
1080
                 <rpe:processDefinitionIdentifier root="1.2.3.4" extension="1006" />
                 <rpe:processState>SCREENING</rpe:processState>
                <rpe:assignedOrganizationIdentifier root="1.2.3.5" extension="CIS_CE_CB" />
                <rpe:activity activityLanguage="http://www.omg.org/spec/BPMN/2.0/">
                    <userTask xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL"</pre>
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"</pre>
                    codeSystemName="LOINC" displayName="BP Diastolic">
```

```
1095
                                            <originalText>Diastolic Blood Pressure/originalText>
                                        </code>
                                        <statusCode code="active"/>
                                        <value xsi:type="PQ" value="120" unit="mmHg"/>
                                   </hl7:observation>
1100
                                ] ] >
                                </from>
                                <to>ScreeningObservations</to>
                            </assignment>
                        </dataOutputAssociation>
1105
                    </userTask>
                </rpe:activity>
          </rpe:UpdateActivityRequest>
        </soap:Body>
1110
        <soap: Body>
          <rpe:UpdateActivityRequest xmlns:rpe="urn:ihe:qrph:rpe:2009" xmlns:hl7="urn:hl7-org:v3">
                <rpe:patient>
                    <rpe:candidateID root="" extension="" />
                    <rpe:name>
1115
                        <hl7:given>John</hl7:given>
                        <h17:family>Smith</h17:family>
                     </rpe:name>
                     <rpe:address />
                     <rpe:dob value="19990101 />
1120
                 </rpe:patient>
                 <rpe:processIdentifier root="1.2.3.5" extension="1006-1" />
                 <rpe:processDefinitionIdentifier root="1.2.3.4" extension="1006" />
                 <rpe:processState>SCREENING</rpe:processState>
                 <rpe:assignedOrganizationIdentifier root="1.2.3.5" extension="CIS_CE_CB" />
1125
                <rpe:activity activityLanguage="PORT_RM100001UV">
                    <hl7:study>
                     <hl7:instantiation>
                        <hl7:plannedStudy>
1130
                       </hl7:plannedStudy>
                     </hl7:instantiation>
                    </hl7:study>
                </rpe:activity>
          </rpe:UpdateActivityRequest >
1135
        </soap:Body>
```

### 3.27.6.1.2 Sample Update Activity 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.

# 3.28 Send Process State Alert [QRPH-28]

This section corresponds to transaction QRPH-28 of the IHE QRPH Transaction Framework. QRPH-28 is used by the Process State Manager and Process Activity Executor Actors.

# 3.28.1 Scope

1150 This transaction involves either:

\_\_\_\_\_

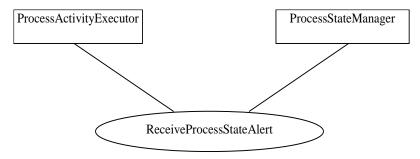
• a Process Activity Executor alerting a Process State Manager of a change that affects the state of a process it initiated,

#### 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.

In either case, the request passed by the actor supplies the current process context as per Table 3.25.4.2.2-1 and a process state value.

#### 3.28.2 Use Case Roles



1160

1155

**Actor:** Process Activity Executor

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

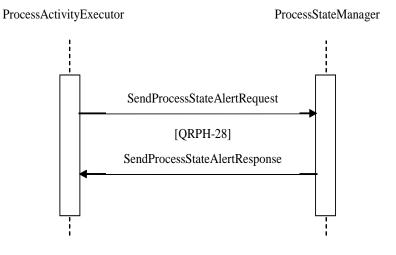
**Actor:** Process State Manager

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

## 1165 **3.28.3 Referenced Standards**

See Section 3.20.3.

#### 3.28.4 Interaction Diagram





ProcessActivityExecutor

SendProcessStateAlertRequest

[QRPH-28]

SendProcessStateAlertResponse

1170

#### 3.28.4.1 Send Process State Alert Message

# 3.28.4.1.1 Trigger Events

Either:

1175

• 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

1180

• 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.

# 3.28.4.1.2 Message Semantics

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

# Table 3.28.4.1.2-1: Send Process State Alert Request Parameters

Parameter Name	Option ality	Description	Value
patient	0	Basic demographics for the patient.	Simple patient definition, of type rpe:PatientType.
processDefinitionIdentifier	R	Identifier for the process definition to be initiated.	HL7 element of type InstanceIdentifier.
processIdentifier	R	Identifier for process instance	HL7 element of type InstanceIdentifier.

\_\_\_\_\_

processState	R	The process state change being alerted.	An XML element of type enumerated string.
assignedOrganizationIdentifier	0	Assigned identifier for organization.	HL7 element of type InstanceIdentifier.

Section 3.28.6 describes the Web Services protocol requirements and the format of the message in full detail.

#### 3.28.4.1.3 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 "ALERT\_RECEIVED".

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

# 3.28.4.2 Send Process State Alert Response Message

#### 3.28.4.2.1 Trigger Events

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

#### 3.28.4.2.2 Message Semantics

A responseCode XML element of type string is returned to confirm receipt of the alert with a value of "ALERT RECEIVED".

#### 3.28.4.2.3 Expected Actions

The Process Activity Executor or Process State Manager shall consume 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.

#### 3.28.5 Security Considerations

See QRPH TF-1:X.5.

#### 1210 **3.28.6 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-2x: Appendix V Web Services for IHE Transactions.

#### 1215

1220

1230

1235

1240

Table 3.28.6-1: 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 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"
- 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"
  - 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"

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 3.28.6.1 Sample SOAP Messages.

#### 3.28.6.1 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 3.28.5 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.

\_\_\_\_\_

# 3.28.6.1.1 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.

```
Process State Manager to Process Activity Executor (notification of patient enrollment):
1250
        <soap:Body>
          <rpe:SendProcessStateAlertRequest xmlns:rpe="urn:ihe:qrph:rpe:2009">
                <rpe:patient>
                    <rpe:candidateID root="" extension="" />
                    <rpe:name>
1255
                        <hl7:given>John</hl7:given>
                        <hl7:family>Smith</hl7:family>
                    </rpe:name>
                    <rpe:address />
                    <rpe:dob value="19990101 />
1260
                </rpe:patient>
                <rpe:processIdentifier root="1.2.3.5" extension="1006-1" />
                 <rpe:processDefinitionIdentifier root="1.2.3.4" extension="1006" />
                <rpe:processState>ENROLLED</rpe:processState>
                <rpe:assignedOrganizationIdentifier root="1.2.3.5" extension="CIS_CE_CB" />
1265
          </rpe:SendProcessStateAlertRequest>
        </soap:Body>
```

# 3.28.6.1.2 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.