Integrating the Healthcare Enterprise

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IHE IT Infrastructure

Technical Framework Supplement

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Retrieve Form for Data Capture (RFD)

Trial Implementation

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework 8.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

25 This supplement is submitted for Trial Implementation as of August 19, 2011 and will 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 IT Infrastructure Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/iti/iticomments.cfm or by email to iti@ihe.net.

30 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 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
35 relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

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

40 Information about the IHE IT Infrastructure 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:
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:
45 http://www.ihe.net/Technical_Framework/index.cfm

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Introduction

The Retrieve Form for Data Capture (RFD) profile provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

This profile is published again for public comment, and subsequently for Trial Implementation in 2009, based upon the experiences of the past two IHE North America Connectathon events and HIMSS Interoperability Showcases. Vendors from both the Form Filler and the Form Manager/Form Receiver community submitted change proposals that substantially changed some of the existing profile transactions. These changes will be found in both Volumes 1 and 2b. Of note are:

- Profile Options supporting multiple formats for forms
- Changes to the information supplied with the Retrieve Form and Retrieve Clarifications transactions
- Addition of an optional form instance id to both the Retrieve Form request and response.
- Removal of the HTTP Get and HTTP Post options from the Retrieve Form and Retrieve Clarifications transactions.
- Update to the protocol requirements and support materials.

Open Issues and Questions

1. CLOSED – see 10 below. This profile is using W3C XForms 1.1. While XForms 1.1 is in *Last Call for Comments* status, this profile will remain in Trial Implementation.

2. At what point does the investigator verify /sign off on the data?

3. Digital signatures seem like they might be applicable, but it is not clear what risk they mitigate, and more importantly how they are accomplished within the constraints of the profile.

4. Are there use cases requiring the use of simple HTTP Get for the Retrieve Form transaction?

5. Are there use cases requiring the archival of the prepopData used in the Retrieve Form transaction? If so, are there requirements that the archiving transaction come directly from the Form Filler?

6. CLOSED – see 14 below. Should the Named Options for the formats reflect the details of the standards used to constrain those formats? Should we name the option XHTML 1.0 instead of HTML? Likewise, XForms 1.1 instead of XForms?

7. What are the requirements for supporting case workers in the field that might have no or only intermittent connectivity?

Closed Issues

1. Should the Form Manager be broken into two actors: one for supplying and a second for consuming forms? Yes: Form Manager and Form Receiver.

2. If one application supports Form Manager and Form Receiver, does there need to be an IHE transaction between the two to handle the case of partially completed forms? No: the Form Manager and Form Receiver may be grouped for communication purposes but these communications are internal and are not IHE Transactions.

3. Should the XForm instance element be allowed to use the src attribute? Yes, this is allowed; this is a change from the public comment version of this document.

4. Should there be other constraints on the XForms that comply with this profile? Yes, see Volume 2, 3.a.4.3.1 XForm Instance Data Constraints and 3.a.4.3.2 XForms supporting the Archive Capability for the existing constraints.

5. Should the Archive Form transaction be a separate transaction? Yes.

6. Need a way to summarize the x-forms submission for the audit log, there is no way to identify the transaction.
    - Require Form Manager assign an id for each xform transaction.
    - Require Form Manager assign a description for each xform transaction
    - Audit log includes both in the audit log

7. The Security Analysis of Assets, Risks, Threats removed this from the open issues.

8. How are data queries/ data corrections documented? Functionality now included within the profile.

9. The Domain Use Cases and appendix examples will be removed and placed in another location when this document transitions to Trial Implementation. – it was decided that the Domain Use Case text should remain in place.

10. This profile is using W3C XForms 1.1. While XForms 1.1 is in *Last Call for Comments* status, this profile will remain in Trial Implementation…..closed since the use of XForms has become one of several named options.

11. Should there be a parameter on the Retrieve Form and Retrieve Clarifications transaction to request one of the named format options? No. After much discussion it was decided that the formID, and consequently the orgID, both of which are assigned as a part of configuration and set up outside of the profile, would convey this information. A form in multiple formats would have multiple formID values.

12. Is there a standard version of PDF that could be used as an additional named option for available formats? What constraints would be needed for this format? Discussed and decided that there is no known way to constrain the ability for executing objects; this is considered to be a security risk that the committee found not acceptable.

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13. Removal of the HTTP Get and HTTP Post options from the Retrieve Form and Retrieve Clarifications transactions. The use of HTTP Get from a standalone browser, operating outside of an EHR System, was no longer necessary. HTTP Post was
180   replaced with use of Web Services and SOAP.

14. Should the Named Options for the formats reflect the details of the standards used to constrain those formats? Should we name the option XHTML 1.0 instead of HTML? Yes.

15. Are there any limitations to the syntax of the formID? Is there a reason to profile the
185   format of formID? No. There is no reason to profile this, as per discussions from July 2009 public comments.

Profile Abstract

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The Retrieve Form for Data Capture (RFD) profile provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

GLOSSARY

form – An area with editable fields into which users and applications insert data

CDISC – Clinical Data Interchange Standards Consortium

195 *eCRF* – Electronic Case Report Form

EDC – Electronic Data Capture

ICSR – HL7's Individual Case Safety Record

ODM – CDISC's Operational Data Model

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Changes to Sections 1 – 1.X

1.7 History of Annual Changes

Add the following bullet to the end of the bullet list in Section 1.7

Retrieve Form for Data Capture (RFD) - provides a means for the retrieval and submission of forms data between physicians/investigators and electronic data capture systems or other data

205 collection agencies.

Add the following row to Table 2-1 Integration Profiles Dependencies

Retrieve Form for Data Capture (RFD)	None	None	-

Add the following new section to Section 2.2

210 **2.2.17 Retrieve Form for Data Capture (RFD)**

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

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Add the following new Section 17

17 Retrieve Form for Data Capture (RFD) Profile

The Retrieve Form for Data Capture (RFD) profile provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the
220   retrieval of a form from a form source, the display and completion of the form, and the return of instance data from the display application to a receiving application. In addition, RFD provides a mechanism to amend data that was previously captured.

Consider the case where a healthcare provider site uses an Electronic Health Record (EHR) to document patient care. In this case, the EHR acts as the local home application for the
225   provider's personnel. Suppose an external agency, through some contractual arrangement, requires data from the provider, some of which reside in the EHR's database, the rest requiring data entry by the EHR's users. RFD enables the EHR user to retrieve a data capture form from the external agency, to fill out the form, and to return the data to the external agency without leaving the provider's local home application, the EHR. The profile also permits the external
230   agency to indicate that there is a need to clarify points about the data so captured and provides the mechanisms to allow the data to be modified.

Many potential uses of RFD want the form to dynamically pre-populate forms from the host application's database, that is have the form delivered with host application database values filled in to appropriate fields of a form. RFD permits automatic form population and provides a
235   generic mechanism by which this can be accomplished. However, the profile does not speak to the issue of content, remaining silent on normative vocabularies and other enablers of semantic interoperability. Specific domain groups – clinical trials, drug safety, bio-surveillance – will build on RFD by contributing content specifications or by evaluating and recommending existing content standards that will operate within RFD. When RFD, as an infrastructure profile,
240   integrates with domain-specific content standards, a much greater level of interoperability will result.

The RFD profile provides a generic polling mechanism to allow an external agency to indicate issues with data that have been captured and enable the healthcare provider to correct the data. The profile does not dictate the mechanism employed or content required to achieve such
245   corrections.

In this profile, the external agency provides data capture forms in a schema appropriate to its domain. The profile intends to minimize the work that the displaying application should do, and to bring over fully functional forms that carry with them the instruction necessary to complete the form. The RFD Profile uses XForms technology to support negotiation between the form
250   display and form provider systems, so that iterative exchanges can deal with issues like form selection, completion of a series of forms, partial completion of forms, returning to forms partially filled out in earlier sessions. RFD also supports archiving a copy of the completed form.

RFD offers the capability to leverage industry standards that address both the structure and
255   content of forms used for data capture. HL7's Individual Case Safety Record (ICSR) and CDISC's Operational Data Model (ODM) provide examples.

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The infrastructure provided by the RFD profile can be utilized by many domain groups and the following domain-specific use cases illustrate the wide variety of uses to which RFD can be made.

17.1 Use Cases

The following use cases indicate how this profile might be used by various disciplines. The RFD profile enables all of these use cases. It does not implement any of them. Actual discipline specific profiles that specify both the use of RFD and the rules for data objects are expected in future domain-specific IHE profiles.

17.1.1 Investigational New Drug Clinical Trial Use Case

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, Holbin Medical Group, is a multi-site physician practice, employing over 100 physicians in a variety of specialties. Holbin's CEO encourages the physicians to participate as site investigators for pharmaceutical-sponsored clinical trials; Holbin 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. Holbin Medical Group uses an Electronic Health Record (EHR) and a number of sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial activities. (For our purposes, an EHR is any application which is the primary site for documenting patient care, and retrieving patient care information. Thus we include in our span of interest many systems installed today that are not quite EHRs in the strictest sense, but which would still benefit from this approach.)

Holbin's involvement in a clinical study begins when the Research Department receives a request for proposal from a study sponsor. A Study Coordinator, Patricia Zone, RN, evaluates the RFP for business viability and clinical appropriateness, and provides the requested documentation back to the sponsor. After being selected as a site for the trial, identified as #1234, and providing the required regulatory documentation to the sponsor, the physician identified as the Principal Investigator and other study personnel receive protocol-specific training from the sponsor. During the trial set-up period, Patricia ensures that the appropriate system security is in place for this protocol, recruits patients to participate as subjects according to inclusion and exclusion criteria described in the study protocol, schedules patient visits, manages data capture and data entry, and performs all the attendant financial tasks.

Patricia contacts Corey Jones, a patient at Holbin, about participating in the trial, and Corey agrees to participate as a subject. Patricia registers Corey in the EHR as a subject in trial #1234, using the EHR's patient index. She schedules Corey's study visits using the EHR scheduling module, and flags the visits as pertaining to the trial #1234. After the set-up stage, the site initiates clinical trial care and trial-specific documentation.

The use case continues with current state and desired state scenarios, which describe data capture utilizing EDC technology during a patient clinical trial visit before and after the RFD implementation.

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17.1.1.1 Current State

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Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone for a face-to-face interview. Patricia logs into the EHR and documents the visit with a terse entry: 'Mrs. Jones comes in for a clinical trial visit associated with study #1234.' Patricia interviews Mrs. Jones, makes some observations, and records her observation on a source paper document. She looks up recent lab results in the EHR and records them in the Case Report Form (CRF). The EHR provides only a portion of the data required to complete the form, the rest comes from the interview and observations. (Estimates on the percentage of data required for a clinical trial that would be available in an EHR vary from 5% to 40%. Even in the best case, the EHR typically captures only a subset of the data required by a study protocol.)

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The completed source document is forwarded to Bob, the data entry person. Bob identifies the CRF as belonging to trial #1234, and selects the trial #1234 EDC system, which may be housed on a dedicated laptop provided by the sponsor or may be accessible via a browser session connected to the Sponsor's EDC system via the Internet. He takes a three ring binder off the shelf and refers to his 'crib sheet' to get the instructions for how to use this particular system. He logs into the EDC application, using a user name and password unique to this system, and enters the data into the correct electronic case report form (eCRF) for that trial visit. Once the source document has been processed, Bob files it in a 'banker's box'[1] as part of the permanent source record of the trial (in order to meet the requirements of the Federal Code of Regulations 21CFR 312:62).

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In addition to trial #1234, Bob performs data entry on eight additional EDC systems, five on dedicated laptops and three that are web-based. The web-based EDC systems save on table space, but still require entries in the three ring binders where Bob puts his 'crib sheets'. It is a chore to make sure that data from a particular trial gets entered into the corresponding laptop with its unique login ritual and data capture form, so Bob experiences much frustration in dealing with this unwieldy set of systems. Bob is a conscientious employee, and stays current in his work. But in many other sites the data entry person holds the CRF for a period of time before entering the data, perhaps entering data twice a month, or entering the data the week before the monitor visit occurs.

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17.1.1.2 Desired State

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Mrs. Jones arrives for a visit and Patricia logs into the EHR, pulls up Mrs. Jones's record, and identifies the scheduled clinical trial visit. Because of the patient identification and scheduling steps that took place in the set-up stage, the EHR recognizes Mrs. Jones as a subject in Trial 1234, and requests an electronic case report form from trial #1234's EDC system, using RFD. If the trial is sufficiently complex, the retrieved form may contain a list of relevant forms from the EDC system for Patricia to choose from. When the correct context is established between the EHR and the EDC, Patricia selects the clinical research tab within the EHR application to reveal the appropriate form. The EHR checks Patricia's credentials, confirms that she is empowered to

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[1] See the definition: http://www.archivists.org/glossary/term_details.asp?DefinitionKey=1193

view the form, and displays the form. The data capture form is essentially the same form that the
335   EDC system would offer for this visit, and its presentation may take on some of the look and feel
of the EHR's user interface. The use of a crib sheet may still be necessary, although
sophisticated forms should carry with them information on how to fill out the form.

Patricia interviews Mrs. Jones and enters data into the clinical trial form. Data from the EHR
database may be pre-populated into the proper data fields (which have built-in edit checks).
340   Upon completing the form, Patricia hits the submit button, and the EHR returns the complete
form to the EDC system, using RFD. A copy of the document is archived in the site clinical trial
document vault as part of the permanent source record of the trial.

17.1.2 Public Health Reporting Use Cases

17.1.2.1 Public Health Scenario 1

345   ### 17.1.2.1.1 Current State

Mrs. Smith presents to the Emergency Department of the Community Hospital with digestive
complaints. The health care provider sends samples to the lab. The laboratory identifies
cryptosporidium. The laboratory personnel query the laboratory database for weekly required
public health reporting. Cases are identified, and information from the laboratory information
350   system is copied to the public health form, printed, and sent to the public health authority. The
public health officials review the reports submitted from the health care providers in the
jurisdiction and identify that multiple cases of cryptosporidium have been presenting to area
hospitals. Notification of the event is communicated to health care providers in the area to notify
them to watch for additional cases. Water supplies servicing the affected areas are tested and
355   treated accordingly. However, with the delay in the detection process caused by the paper-based
process, numerous additional cases of cryptosporidium infection present for care.

17.1.2.1.2 Desired State

Mrs. Smith presents to the Emergency Department of the Community Hospital with digestive
complaints. The health care provider sends samples to the lab. The laboratory identifies
360   cryptosporidium. The laboratory system identifies this test result as a required public health
report and sends it to the state DOH using PHIN standards as soon as the result is verified in the
laboratory system. In addition or alternatively, a form is retrieved using the RFD profile from the
Biowatch public health system. The case reporting form is presented to the provider, pre-
populated with EHR mapped data. The healthcare provider fills out the remaining supplemental
365   information and submits this data electronically to the public health authority. The public health
authority receives numerous electronic reports from laboratories and health care providers in the
jurisdiction. Notification is sent to area health care providers and laboratories in the area to notify
them to watch for additional cases. Water supplies servicing the area are tested and treated
accordingly. With the early detection through process automation, further illness in the
370   community is minimized.

17.1.2.1.3 Anthrax and Avian Influenza Scenarios: Disease Monitoring Based on Presumptive Diagnoses and/or Patient 'Problems'

Anthrax: Patient presents at ED with rapidly progressive respiratory symptoms. Gram stain of sputum reveals gram positive rods, chest X-ray reveals a widened mediastinum, and patient's condition rapidly deteriorates. Culture of sputum in laboratory is suspicious for Bacillus anthracis. State DOH contacted and specimens sent for confirmation. Once confirmed, the state DOH notifies appropriate local, regional, state, and federal officials (e.g., CDC, FBI, USAMRID), and notifies local hospitals, providers, and media. (This involves a bioterrorist scenario on the back end after ID confirmation – the influenza scenario below does not, but probably invokes the same pathways.)

Once notified of the potential for additional cases, the ED performs STAT Gram stains on sputa and PA/Lateral Chest Xrays for all patients presenting with rapidly progressive respiratory symptoms. Presence of Gram positive rods in sputum is entered directly into the lab system OR by designated ER staff into a specific ADT field on the patient ADT screen in the CIS for internal / external surveillance reporting. Rapid reading of Chest Xray with mediastinal widening is entered in a specific ADT field by designated staff (e.g., Radiology technician) on behalf of physician. Entry of information in these fields creates a transaction of the information to the local public health department biosurveillance system (BIS) as presumptively diagnosed inhalational anthrax. The BIS aggregates information received from multiple sites to present the location, origin and extent of presumptive and defined case presentation.

 Influenza: Physicians around hospital and hospital ED get rapidly increasing number of patients with respiratory symptoms suggestive of a viral infection, but no increased prevalence of similar symptoms in surrounding hospitals. Rapid test for influenza A/B is positive in many of the patients and epidemic influenza is circulating in the community. Respiratory culture is negative for bacterial pathogen at 24 hr., but viral culture is positive for influenza A. AH5N1 is suspected due to association of patients with each other and "dead chickens". All specimens are sent to state DOH ASAP for ID. State lab identifies AH5N1. Follow-up similar to #1 above. The follow-up once notification is disseminated from health department(s) to local providers, is similar to the presumptive diagnosis information transmission to public health BIS. A more robust method for collection of presumptive diagnoses in either scenario (but not near-term) is to use standardized "problem" terms (using SNOMED) for selection of presumptive problems as part of routine operations of a CIS for physician order entry and for physician and nursing documentation.

The difference in these two scenarios is that the Anthrax case involves syndromic surveillance (severe respiratory symptoms and a widened mediastinum on X-ray: need radiology surveillance and cross-correlation to ED and Lab – much more complex.)

17.1.3 Pharmaco-vigilance Scenario

A community-based physician, Dr. Cramp, sees a patient in an outpatient clinic and accesses the patient's electronic health record which reveals that the patient is on one of the new statin drugs. The physical examination turns up muscle weakness in the patient's calves, which the physician

recognizes as a possible adverse reaction to the statin. He orders a total creatinine kinase lab test to help in diagnosing the problem.

17.1.3.1 Current State

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Dr. Cramp exits the EHR and, using a web browser, goes to http://www.fda.gov/medwatch/. He brings up form FDA 3500, for 'voluntary reporting of adverse events noted spontaneously in the course of clinical care'. He navigates through several screens of routing and instructions to arrive at the first screen of the actual form, which requests patient identifier, age at time of event or date of birth, sex, and weight; the second screen requests seven entries: a classification of the event, classification of outcome, event date, report date, description, relevant tests (he notes that

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a test has been ordered), and other relevant history (the last three fields are text entry); the third and fourth screens ask for details about the product ; and so forth. In actuality, the current state is that this form is seldom completed.

17.1.3.2 Desired State

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Dr. Cramp sees the patient and accesses the EHR as above. Upon finding the potential problem, he clicks on an 'Adverse Event Reporting' button which brings up FDA form 3500, using the EHR user interface. The form is presented with the demographics already completed. The product name is part of the working context of the EHR session, and is automatically loaded into the appropriate field. Dr. Cramp completes the empty fields of the form and submits directly to the FDA Medwatch site.

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RFD takes care of retrieving the form from MedWatch, displaying it, and returning the form to FDA. Note that the profile does not address whether or not the EHR stores a copy of the form or preloads it with EHR data. Simply using the EHR to display, complete, and submit the form is sufficient. The EHR and the site might decide to capture and store the form in the EHR database, which would be a permitted extension of the profile, but not necessary.

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17.1.4 Cardiology Research Use Cases

17.1.4.1 Cardiology Use Case 1 - Submission to National, State and Regional Data Registries

Several jurisdictions have mandatory requirements for submission of data for particular cardiac procedures, (e.g., New York State for angioplasty and cardiac surgery, or the US for

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implantation of cardioverter defibrillators in Medicare patients). Additionally, many institutions participate in voluntary regional or national data registries, notably the NCDR™ National Cardiovascular Data Registry.

A single cardiac patient's data may be submitted to multiple registries. It is therefore useful for data collections for multiple submissions to be done simultaneously, so that the nurse preparing

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the data can review the patient medical record once and extract relevant data to each of the submission forms. Additionally, the patient's "medical record" is in fact spread across several

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electronic and paper-based systems, so that repeated access in the preparation of multiple submissions must be minimized.

450 Most of the cardiac registry submissions require data from several encounters. E.g., the NCDR gathers data on patients who undergo diagnostic cardiac catheterization followed by a percutaneous coronary intervention (PCI). If the patient had presented to the Emergency Department with an ST-elevation infarction, only a small portion of the NCDR-required data is gathered in association with the catheterization procedure. The following information is needed to complete the NCDR data set: Date of previous CABG, date of previous PCI, time of arrival in 455 the ER, baseline laboratory data (BUN, creatinine), information from the patient's history (family history of CAD, history of stroke, pulmonary and renal disease, etc.), measured cardiac ejection fraction prior to PCI, QCA findings, inventory of the devices used (including bar codes), and medications administered.

Thus, the preparation of the submission must be done incrementally at each encounter, and/or 460 retrospectively at a time that all the information can be determined. Incremental preparation is problematic, since at the initial encounters it is not known what procedures the patient will undergo, and hence what registries' data forms need to be filled in. Purely retrospective data collection is similarly problematic, as it is better to obtain the data when it is produced, rather than needing to search through the record for it.

465 Carl Cardiac, a patient, presents at the ED with chest pain, and based on ECG and history is whisked to the cath lab for a diagnostic and interventional procedure. During the PCI, while things are slow during the angioplasty balloon inflation, Ted Tech, the cath lab technologist, calls up the (empty) state and national angioplasty registry forms from the forms repository onto the cath lab logging system, and begins filling in relevant information from the case. During 470 post-procedure clean-up, he completes as much information as he knows, and stores the partially filled-in forms back to the forms repository.

At the end of the month, Nancy Nurse is assigned the task of completing the registry data collection for that month's cath patients. She retrieves a list of cath patients, and for each one pulls up partially completed forms. When she gets to Carl's name, she pulls up the forms as 475 partially completed by Ted, and accesses Carl's lab results, cath procedure report, nursing notes from the CCU, and discharge summary report. She fills in the remainder of the registry forms, and stores the completed forms back to the repository.

At the end of the quarter, Adele Admin uses a specialized application to retrieve all the completed forms for the national registry for the quarter from the repository, and to prepare the 480 submission. She does a similar task with an application that processes the state registry forms.

17.1.4.2 Cardiology Use Case 2 – Performance Measures

A major issue in cardiology is improving the quality of care by monitoring select performance measures. There is a strong collaborative arrangement between the ACC, AHA, CMS, JCAHO, and AHRQ on the development and use of performance measures, such as the new ACC/AHA 485 Clinical Performance Measures for Adults With ST-Elevation and Non–ST-Elevation Myocardial Infarction.

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These performance measures require data collection, similar to the collection of data for submission to registries. However, after collection of data for a particular time period, further analysis on the total patient population must be applied to obtain an appropriate denominator for the reported measures (i.e., certain patients must be retrospectively excluded from the population data set).

17.1.5 Radiology Use Case – Clinical Impact Registry

As part of the effort to assess the impact of PET imaging on cancer patient management, the Centers for Medicare and Medicaid Services have predicated reimbursement, for a number of otherwise non-reimbursed procedures, on the submission of study data to a National Oncologic PET Registry (NOPR) operated by the American College of Radiology at www.cancerpetregistry.org.

This use case involves a sequence of forms which must be submitted for a given patient study and includes overlaps with the billing process.

PET Facilities are required to register their site with NOPR. Because access to NOPR is limited to registered facilities and because the facility depends on complete submission to get the reimbursement, the PET Facility has the primary responsibility and direct access for submitting all data. The referring physician does not have access to NOPR.

Paul Positron, a patient, presents with indications of stomach cancer (or other indication covered only by participation in the NOPR). His physician, Dr. Jones, refers him to PET-Pros, a participating PET facility. PET-Pros obtains basic demographic information from Dr. Jones and submits this information to NOPR via a Web form, at which time a Registry case number is assigned by NOPR.

Once a Registry case number is created, NOPR emails Dr. Jones the Pre-PET Form that must be completed with case specific clinical details and forwarded to PET-Pros for entry into the NOPR database by midnight of the day of the PET scan.

At some time before the PET study, or when Paul arrives for the PET scan, PET-Pros provides Paul with the ACR IRB-approved standard NOPR Patient Information Sheet. Paul can contact the NOPR directly for more information, if necessary. Paul indicates his NOPR consent verbally to staff at the PET facility, either on the day of the PET study or within two working days after the PET study is completed. Written consent is not required. PET-Pros notes in the PET Report Form, if the patient gave or withheld consent for use of his data in future NOPR research.

Once the PET scan has been performed and reported, PET-Pros submits a study completion form and a report form (including the report provided to Dr. Jones) to NOPR.

NOPR emails Dr. Jones the Post-PET Form for completion. This form collects information relating to the impact of the scan. It also includes an ACR IRB-approved Referring Physician Information Sheet and indication whether physician consent for use of the response data in future NOPR research has been given or withheld. The Post-PET form must be completed, forwarded to PET-Pros and entered into the NOPR database within 30 days of the PET scan.

525   The NOPR database notifies PET-Pros when all case data have been entered so that the facility can bill CMS for the study. PET-Pros can check on the case status of their patients at any time using the PET Facility Reporting Tools available on the NOPR Web site.

17.1.6 Data Clarification

There is a need for a clarification process that enables a sponsor organization to highlight data
530   that needs to be examined and potentially corrected. These are detected by sponsor-initiated checks (edit checks) that result in sponsor data queries for clarification, correction, or verification relating to previously submitted data. These queries about previously submitted data are provided to the EHR system upon request. Note that there is no automated notification to the EHR that these queries for clarification / correction / verification exist. It is up to the EHR to
535   periodically make requests when working with a sponsor that performs these edit checks. Performing these longitudinal edit checks on submitted data does not apply to all use cases.

17.1.6.1 Current State - query process

Edit checks built in to eCRFs can facilitate accurate and complete data capture; however, it is probable that during the course of a trial, some data elements will need to be reviewed by the site
540   for clarification, correction, or verification. As data managers review the data (through manual and/or system-supported validation processes), they identify missing, incomplete, or potentially discrepant data (e.g. a site reports a patient was prescribed penicillin for a headache). Data queries are generated through an EDC system and sent back to the site for clarification/ correction/ verification by the research coordinator. For each data query, the coordinator must
545   reference the source record where the data element was originally documented and compare the queried data element to the source. On occasions, the site may need to contact the patient if the source is incomplete (e.g., a stop date on a medication). Clarifications to the data are documented by the coordinator in the source and if it is determined that the source record is in error, corrections are clearly documented in the source per GCP guidelines. The coordinator
550   then responds to the query in the EDC system providing a reason for any updates to the original record which the system captures in the audit trail. The data manager can then review the updates and the response and close the query if no further information is required.

17.1.6.2 Future State - query process

Edit checks built into trial-specific XForms and eCRFs in the EHR system can facilitate accurate
555   and complete data capture; however, it is probable that during the course of a trial, some data elements will need to be reviewed by the site for clarification, correction, or verification.

As data managers review the data (through manual and/or system-supported validation processes), they identify missing, incomplete, or potentially discrepant data (e.g. a site reports a patient was prescribed penicillin for a headache). Data queries are generated through the sponsor
560   system and prepared to the site for clarification/ correction/ verification by the research coordinator. The EHR study coordinator accesses and reviews each data query through the EHR system referencing the EHR data in order to respond to the query. On occasions, the site may need to contact the patient if the EHR data is incomplete (e.g., a stop date on a medication). The

coordinator documents clarifications to the data in the EHR system if needed and submits a
query response as well as any data updates to the sponsor system and to the investigator site
archive. The query response includes a reason for any changes made which is included as part of
the audit trail in the EHR system, sponsor system, and the investigator's site archive. The data
manager of the sponsor can then review the response and the updates in the sponsor system and
close the query if no further information is required.

17.2 Actors/ Transactions

Figure 17.2-1 shows the actors directly involved in the Retrieve Form for Data Capture
Integration Profile and the relevant transactions between them. Actors that may be indirectly
involved due to their participation in other profiles are not shown.
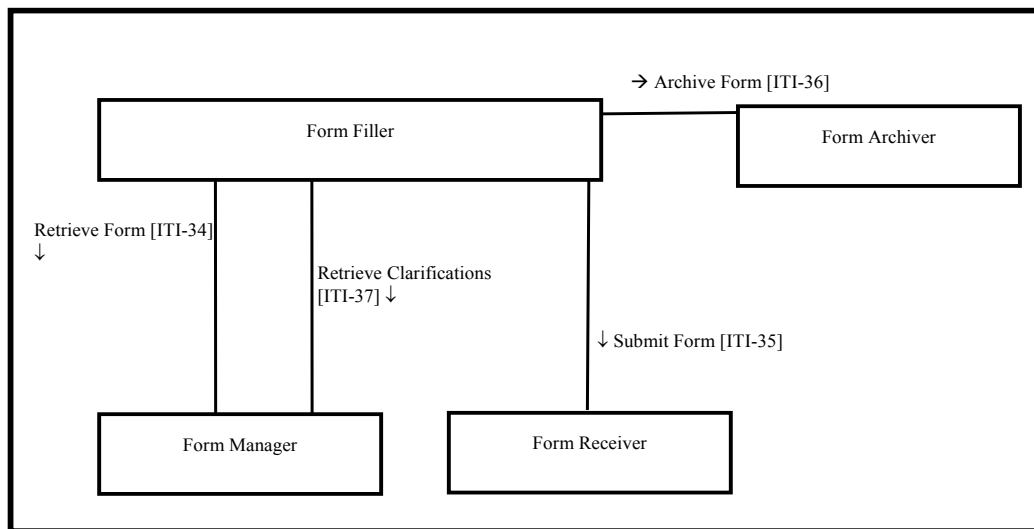
Figure 17.2-1 Retrieve Form for Data Capture Actor Diagram

Table 17.2-1 lists the transactions for each actor directly involved in the Retrieve Form for Data
Capture 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 that the implementations may choose
to support is listed in Section 17.3.

**Table 17.2-1 Retrieve Form for Data Capture Integration Profile - Actors and
Transactions**

Actors	Transactions	Optionality	Section in Vol. 2
Form Filler	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Submit Form [ITI-35]	R	ITI TF-2b: 3.35

Actors	Transactions	Optionality	Section in Vol. 2
	Archive Form [ITI-36]	O	ITI TF-2b: 3.36
	Retrieve Clarifications [ITI-37]	O	ITI TF-2b: 3.37
Form Manager	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Retrieve Clarifications [ITI-37]	R	ITI TF-2b: 3.37
Form Receiver	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Archiver	Archive Form [ITI-36]	R	ITI TF-2b: 3.36

585 ## 17.2.1 Actors

17.2.1.1 Form Manager

The Form Manager supplies forms to Form Fillers based upon form retrieval requests. In some cases, the Form Manager may simply return a form from a store of forms, whereas in other cases the returned form may be selected or even constructed based upon context information supplied
590 in the form retrieval request. Additionally, forms from a store may be modified based upon whether or not the Form Filler supplies additional information about a Form Archiver. A Form Manager may return a form instance id along with a form in response to a request to retrieve a form.

17.2.1.2 Form Filler

595 The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide EHR context information by providing pre-population xml data in the request for use by the Form Manager, as well as workflow data that may be used to facilitate form selection. A form instance id may be provided to identify use of previously submitted data.

600 The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

17.2.1.3 Form Receiver

The Form Receiver actor receives and processes completed or partially completed forms instance data from a Form Filler. Form Receiver processing is out of the scope of the profile.

605 ### 17.2.1.4 Form Archiver

The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes.

21

17.2.2 Transactions

17.2.2.1 Retrieve Form

610   The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction allows a Form Filler to optionally specify a Form Archiver actor. Additional data containing context information as well as workflow information may be supplied with the request to facilitate the selection and pre-population of the requested form. The value of the assigned form identifier determines the format of the form. Assignment of form identifiers is not
615   profiled and is assumed to take place as a part of the setup configuration process necessary between Form Fillers and Form Managers.

17.2.2.2 Submit Form

The Submit Form transaction allows a Form Filler to submit form instance data to a Form Receiver actor.

620   ### 17.2.2.3 Archive Form

The Archive Form transaction allows a Form Filler to submit form instance data to a Form Archiver actor.

17.2.2.4 Retrieve Clarifications

The Retrieve Clarifications transaction allows a Form Filler to request the set of clarifications for
625   a given organization from a Form Manager. The value of the assigned organization identifier determines the named option format of the clarifications form. Assignment of organization identifiers is not profiled and is assumed to take place as a part of the setup configuration process between Form Fillers and Form Managers.

17.3 Retrieve Form for Data Capture Integration Profile Options

630   Options that may be selected for this Integration Profile are listed in Table 17.3-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 17.3-1 Actors and Options

Actor	Options	Vol & Section
Form Filler	Archive Form	ITI TF-2b: 3.36
	Data Clarifications	ITI TF-2b: 3.37
	XForms (Note 1)	ITI TF-1: 17.3.3
	XHTML (Note 1)	ITI TF-1: 17.3.4
Form Manager	XForms (Note 1)	ITI TF-1: 17.3.3
	XHTML (Note 1)	ITI TF-1: 17.3.4

22

635 Note 1: At least one of these options is required for each Actor. In order to enable better interoperability, it is highly recommended that the actors support both the XForms and XHTML options.

17.3.1 Archive Form Option

The Archive Form option allows a Form Filler to submit, for archival purposes, the form instance data to a Form Archiver.

17.3.2 Data Clarifications Option

640 The Data Clarifications option allows a Form Filler to retrieve clarifications from a Form Manager and submit updates to a Form Receiver for data that have been previously submitted.

17.3.3 XForms Option

The XForms option allows Form Fillers and Form Managers to exchange forms in XForms format. See ITI TF-2b: 3.34.4.1 for constraints that apply to this option.

645 ### 17.3.4 XHTML Option

The XHTML option allows Form Fillers and Form Managers to exchange forms in XHTML format. See ITI TF-2b: 3.34.4.1 for constraints that apply to this option.

17.4 Retrieve Forms for Data Capture Process Flow

This section describes the process and information flow when a form is retrieved for data capture 650 and subsequently submitted upon partial or full completion. The criteria for determining whether or not the form is "complete" is outside the scope of this profile.

 Five cases are distinguished.

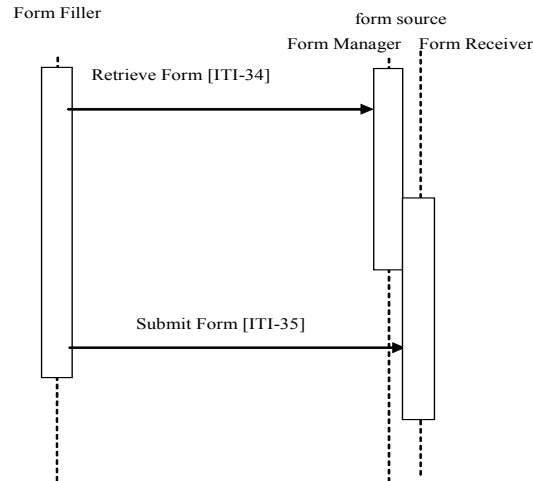- **Case 1:** This case illustrates a simple, Retrieve Form using a known formID.

655 The identifier of a form, the formID, is known to the Form Filler, such as may happen during the registration process for participation in a Clinical Trial. formID values could also be communicated by publication of form directories or by personal communications. The method of acquisition of the formID is outside the scope of this profile and is a precondition for the Retrieve Form request.

660

The Form Manager and Form Receiver are grouped on the same system functioning as the form source.

The Form Filler makes a Retrieve Form request to a Form Manager. The Form Manager either returns the requested form, or an error indicating no form is available. When a 665 form is returned, the Form Filler will subsequently submit the form instance data to a Form Receiver using the Submit Form transaction. Since the Form Manager and Form Receiver are grouped, there may be communications between the Form Receiver and the

23

Form Manager, as would be necessary to support partially completed forms, but these communications are internal and are not IHE transactions.

670

Figure 17.4-1 Case 1: Retrieve Form and Submit Form; Form Manager grouped with Form Receiver

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675 • **Case 2**: This case illustrates that a Form Receiver may be standalone (i.e., not grouped with a Form Manager).

In this illustration there are two Form Receivers: 1) the intermediate Form Receiver, is grouped with the Form Filler; 2) the final, ungrouped Form Receiver.

680 The identifier of a form, the formID, is known to the Form Filler; there is a grouped Form Manager and Form Receiver on one system supporting intermediate form storage, and a separate Form Receiver on a different system for final storage of form data.

The Form Filler makes a Retrieve Form request to a Form Manager. The Form Manager either returns the requested form or an error indicating no form is available. When a 685 form is returned, the Form Filler submits partially complete forms to the intermediate Form Receiver. This partially completed form can be retrieved with another Retrieve Form request to the Form Manager, and final completed form data can be submitted to the final storage, standalone, Form Receiver, such as a national data registry. The action upon submit is controlled by the form, hence the Form Manager is responsible for 690 defining the post-submit action by selection of, or generation of, the desired action during the Retrieve Form transaction processing.
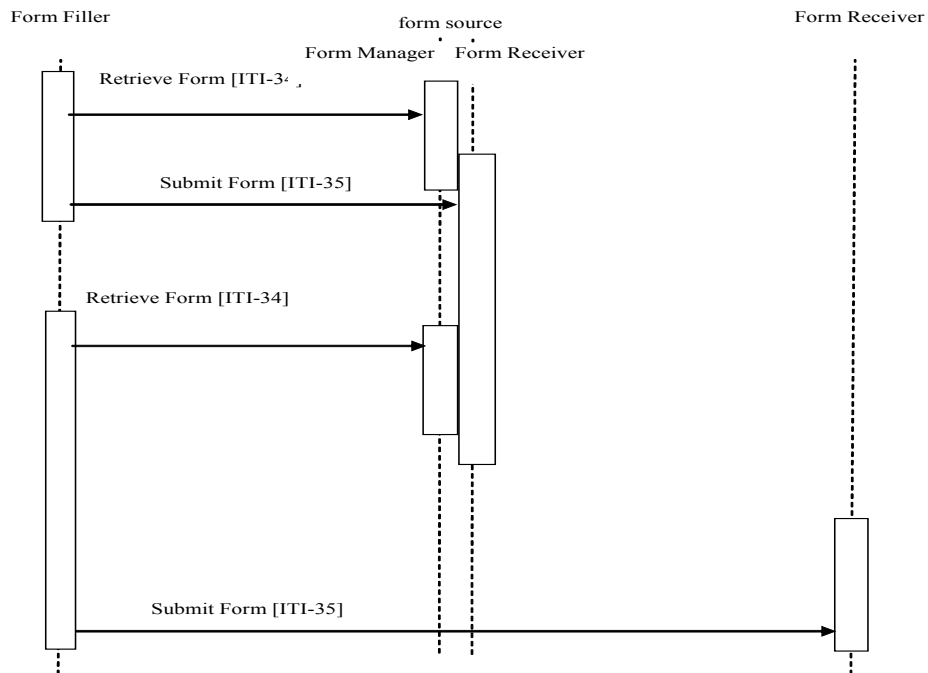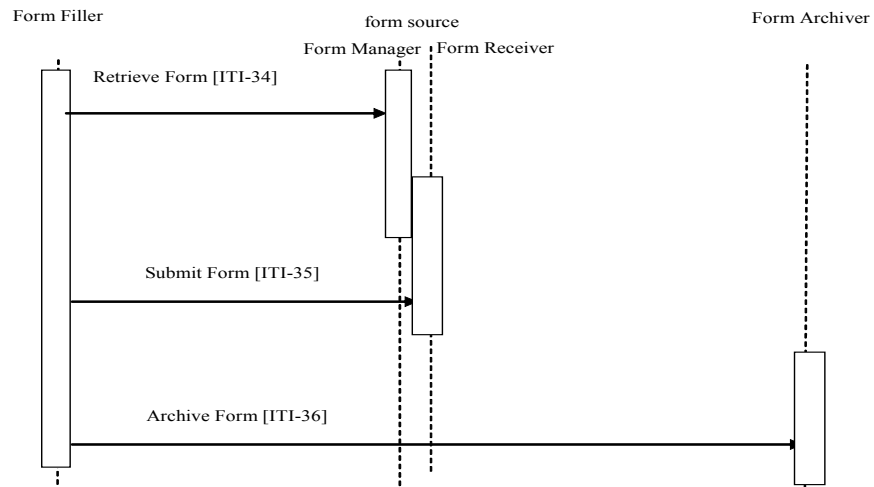

Figure 17.4-2 Case 2: Retrieve Form, Submit Form;
695 **Form Manager separate from Form Receiver**

- **Case 3**: In this case the Form Filler uses the Archive option.

  700

  The Form Filler makes a Retrieve Form request to a Form Manager, specifying that archival is necessary to a specific Form Archiver. The Form Manager either returns the requested form or an error indicating no form is available. The Form Manager constructs the form to perform an archive transaction to the Form Archiver specified in the Form Filler's Retrieve Form request. When the form is returned and subsequently submitted, form instance data is submitted to the Form Receiver and also to the Form Archiver.

705

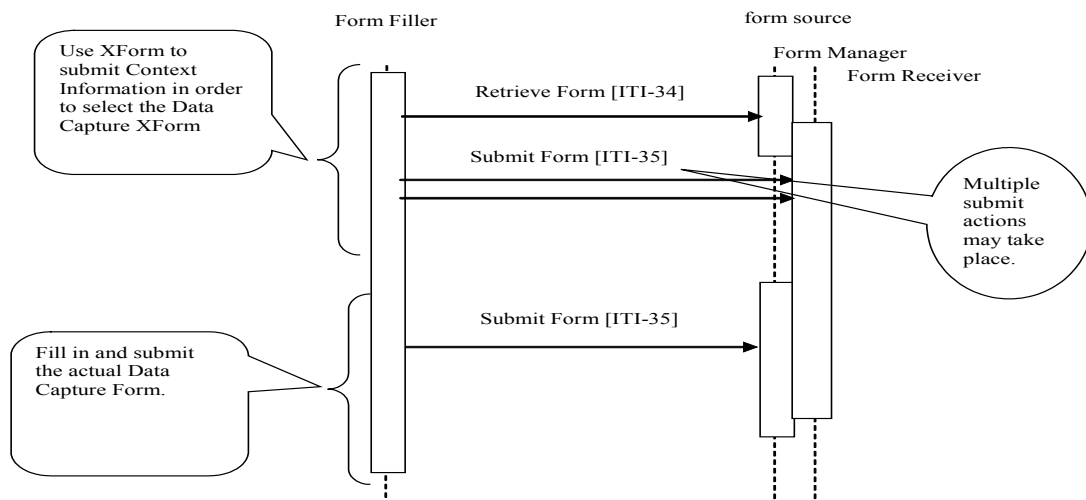**Figure 17.4-3 Case 3: Retrieve Form, Submit Form, Archive Form**

- **Case 4**: This case illustrates one way to use Form design to solve the issue where a formID is not known in advance.
  The identifier of a form, the formID, is not known to the Form Filler, but a set of context value (name, value) pairs is known. A context form where these values could be entered would have a formID. Information collected by the instance of a context form would be used by the Form Manager to determine the appropriate data capture form to return to the Form Filler.

710

  The Form Filler has enough information to request a context form that collects information that can help the Form Manager determine the actual data capture form. The Form Filler completes the context form, submits this to the Form Receiver which returns either new instance data, or a new form.

715

Figure 17.4-4 Case 4: Retrieve Form using an XForm; Submit Form

720

- **Case 5**: In this case the Form Filler supports the Data Clarifications option.

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  The Form Filler makes a Retrieve Clarifications request to a Form Manager. The interactions of Form Receiver and Form Manager are outside of the scope of this profile. An example of a solution for providing clarification information to a Form Manager is to group the Form Manager with the Form Receiver, as shown in Figures 17.4-5 and 17.4-6. The request made by the Form Filler contains an organization identifier allowing the Form Manager to return only the set of clarifications relevant to the organization making the request. The Form Manager returns a form containing the necessary information to allow the site or organization making the request to amend the data as required. These Retrieve Clarifications requests must be periodically executed by the Form Filler. The frequency of request is likely based upon some duration as defined or agreed upon by the Form Manager / Form Receiver.

730

  The Form Manager can return either a form containing the data to be modified or a form containing a list of references to other forms. In the second case, the references are used

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27

735   to obtain the individual forms using the Retrieve Form transaction. In both cases the data
       are then modified and submitted to the Form Receiver using the Submit Form transaction.
       Submitted data may then be evaluated by the data manager of the sponsor for proper
       handling.

740   The profile does not distinguish between the two responses, the content returned within
       the form allows the user of the Form Filler to process the form returned in the appropriate
       manner.
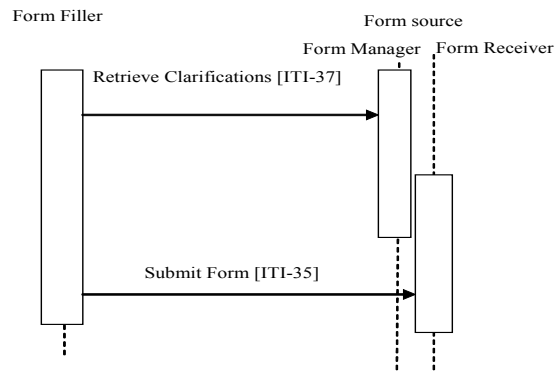
Figure 17.4-5 Case 5: Form Filler supporting Data Clarifications Option
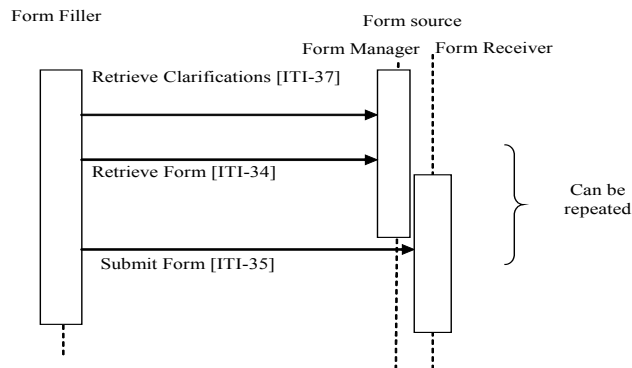
745

Figure 17.4-6 Case 5: Form Filler supporting Data Clarifications Option

17.5 Security Considerations

17.5.1 RFD Risk analysis Risk Assessment

The risk analysis for RFD enumerates assets, threats, and mitigations. The complete risk data is
750   stored and available from IHE[2].

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[2] The risk analysis data may be found at: ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr5-2007-
2008/Technical_Cmte/Profile_Work/RFD/ RFD%20Risk%20Analysis%202007-05-15.xls

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The purpose of this risk assessment is to notify vendors of some of the risks that they are advised to consider when implementing RFD 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.

17.5.2 Recommendations

The high impact risks include: accuracy errors, mismatch between data and schema, disclosure of trade secrets. This profile includes the mitigations:

M1. If the user notices that the wrong form has been retrieved they will discard the form. Since Form Retrieval is stateless, a discard of the form shall cause no problems.

M2. When using the XForm option, the XForms model provides for schema validation of the data model. The XForms plugins responsible for processing and displaying XForms, which are outside of this profile, are required to validate forms.

M3. TLS may be implemented, so that those affinity domains and enterprises that need privacy protection and site authentication can use it. (Implementations must provide the TLS, but the decision to activate it is up to the affinity domain and enterprises.)

M4. Form validations will prevent submission of forms with missing data.

M5. The RFD Archive Form Transaction for saving source data to a trusted third party is an option that it is available to enterprises.

These mitigations are transferred to Vendors and Clients.

T1. IHE recommends that providers evaluate and review forms as presented before entering data and submitting. Provider review is an essential part of the forms retrieval and submission process to ensure data is entered into the correct form and for the correct patient. Vendors are cautioned not to use RFD for unmediated treatment or diagnosis. A doctor must always intervene prior to treatment or diagnosis to ensure that errors that may occur in transit are checked by a human prior to engaging in any treatment or diagnosis of a patient.

T2. The supported format options allow for basic data validity checks within the form. It is the responsibility of the forms designers/implementers to take advantage of this to protect against entry errors, etc.

T3. The need for partially filled forms identifies this as a workflow issue within the organization(s) supplying the data.

T4. Forms and workflow designers should break forms into sequential step forms if possible.

T5. Forms Design should facilitate evaluation of workflow and gaps.

T6. Access control and security at the client site are important mitigating factors to potential disclosures.

T7. Policy controls are recommended to determine which systems may be used to perform the Form Filler actor.

T8. Policy controls are recommended to determine which users may fill out forms.

790 **T9**. This profile does not require audit logging. An enterprise audit logging process is recommended to reduce errors and track malicious behavior.

T10. An application feature to support roll back of forms data may be needed.

T11. Notification of the need to clarify data.

T13. Form Managers, Receivers, Archivers must be on well protected systems.

795 **T14**. Network and Infrastructure and Systems robustness must be considered, especially for forms applications that are to be used during disasters, epidemics, and other situations where the local infrastructure may be significantly disrupted.

T15. Forms should be designed for high latency, low bandwidth links if they are for applications that are to be used during disasters, epidemics, and other situations where the local infrastructure 800 may be significantly disrupted.

T16. Form Fillers should be robust in the face of user error, network failure, and underlying hardware failures.

T17. Workflow must be addressed in the requirements gathering phase. Vendors are advised to discuss investigator workflow with clients.

805 **T18**. Vendors are advised to consider the implications of their logging and audit repository implementation.

Appendix A Actor Summary Definitions

Add the following Actor Descriptions in Appendix A

Form Filler: the actor responsible for retrieving a form from a Form Manager, and for 810 submitting form instance data to a Form Receiver. The Form Filler may optionally be responsible for retrieving clarifications information from a Form Manager.

Form Manager: the actor that supplies a form based upon a request that supplies a form identification. The Form Manager also supplies clarification information.

Form Receiver: the actor that receives form instance data.

815 **Form Archiver:** the actor responsible for receiving form instance data for archival purposes.

Appendix B Transaction Summary Definitions

Add the following Transaction Descriptions in Appendix B

Retrieve Form: This transaction retrieves the requested form from a Form Manager.

Submit Form: This transaction submits form instance data, in XML format, to a Form Receiver.

820 **Archive Form:** This transaction supplies the form instance data, in XML format, to a Form Archiver.

Retrieve Clarifications: This transaction retrieves a set of clarifications from a Form Manager.

Volume 2b - Transactions

3 IHE Transactions

825 **3.34 Retrieve Form**

This section corresponds to Transaction ITI-34 of the IHE IT Infrastructure Technical Framework. Transaction ITI-34 is used by the Form Filler and Form Manager actors.

3.34.1 Scope

This transaction involves a Form Filler requesting a form from a Form Manager. The Form Filler
830 has a formID, and possibly additional workflow information, obtained by a means that is outside the scope of this profile. The Form Filler may also provide a form instance id to reference a previously submitted form. The Form Manager will return a form or URL corresponding to the given formID, and optionally a form instance id, or else it returns an error response. Forms are defined and constrained below by the format options.

835

3.34.2 Use Case Roles
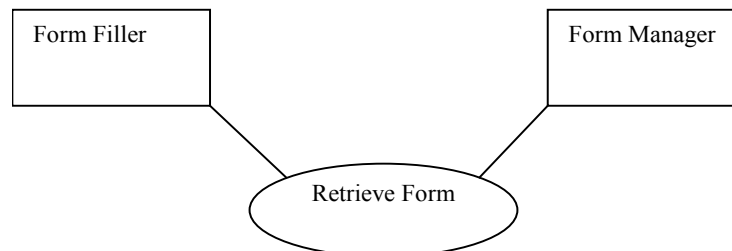
Actor: Form Filler

Role: A forms display and editing system capable of allowing form fields to be completed.

840 **Actor:** Form Manager

Role: A system that provides forms based upon requests that provide specific formIDs, and optionally additional work flow data.

3.34.3 Referenced Standards

Implementors of this transaction shall comply with all requirements described in ITI TF-2x:
845 Appendix V: Web Services for IHE Transactions.

IETF RFC1738, Uniform Resource Locators (URL), December 1994,
http://www.faqs.org/rfcs/rfc1738.html

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

850 Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml.

ITI TF-2x: Appendix V Web Services for IHE Transactions

XForms 1.1, W3C Working Draft. http://www.w3.org/TR/2004/WD-xforms11-20041115/
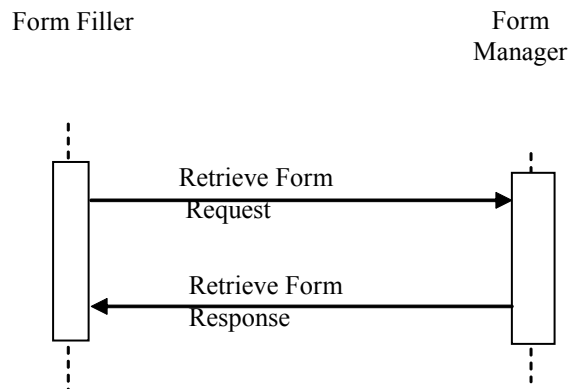
XHTML™ 1.0 The Extensible HyperText Markup Language (Second Edition).A Reformulation of HTML 4 in XML 1.0. W3C Recommendation 26 January 2000, revised 1 August 2002.
855 http://www.w3.org/TR/xhtml1.

XHTML™ Basic. W3C Recommendation 19 December 2000. http://www.w3.org/TR/xhtm-basic.

http://www.w3.org/TR/xhtml-basic

860 **3.34.4 Interaction Diagram**

3.34.4.1 Retrieve Form Request

Retrieve Form involves a Form Filler requesting a form from a Form Manager. The Form Filler shall supply workflow data and prepopulation data. The Form Filler may also supply a form
865 instance id.

The Retrieve Form Request shall provide an archiveURL value, as a nill value or as a URL pointing to a Form Archiver actor. See ITI TF-2b: 3.34.4.1.2 for details.

The Form Filler requests that Form Filler use context information in the selection and/or creation of the returned form by supplying the prepopData argument with well-formed xml representing
870 the Form Filler context. Specification of the prepopData schema is left to content profiles. This value may be nill.

33

The Form Filler supplies any additional workflow information to be used in the selection and/or creation of the form using the context element of the workflowData parameter. Specification of this context element is left to content profiles.

875 The response to a Retrieve Form Request returns the form, or reference to a form, and may return a form instance id.

3.34.4.1.1 Trigger Events

The Form Filler, based upon human decision or application of a rule for automatic operation, requests a form hosted by a Form Manager.

880 **3.34.4.1.2 Message Semantics**

Implementors of this transaction shall comply with all requirements described in ITI TF-2x: Appendix V: Web Services for IHE Transactions. The following parameters are specified for this transaction.

Parameter Name	REQ	Description	Value
prepopData	R	The xml context information supplied by a Form Filler for use in pre-populating XForm fields	This value shall be nill or a well-formed xml document.
workflowData	R	The xml representation of workflow specific values.	This value is a well-formed xml document.as defined below.
formID	R	The identifier of a form.	A string identifying the form
encodedResponse	R	Tells the Form Manager whether or not to return an encoded response	{true,false}
archiveURL	R	Tells the Form Manager whether or not the Form Filler is exercising the Archive Option	the URL of any Form Filler identified Form Archiver or the null string
context	R	The xml specifics of workflow context	Defined by content profiles; may be nill
instanceID	R	An id value of a previously submitted instance of data.	A string identifying an instance of previously submitted data; may be nill.

885 The contents of the prepopData parameter is defined in a prepopData schema specified by IHE content profiles. When there is no prepopData the attribute xsi:nill shall be set to "true" (see the support materials).

The content of workflowData parameter shall minimally be:

890
```
<workflowData>
      <formID>a String identifying the form</formID>
      <encodedResponse>false</encodedResponse>
      <archiveURL />
      <context/>
```

34

895
```
        <instanceID/>
</workflowData>
```

See the schema provided with the support materials (ftp://ftp.ihe.net/TF_Implementation_Material/ITI/). The workflowData may be extended by IHE content profiles with further definition of the <context> element.

900 **3.34.4.1.3 Expected Actions**

Upon receipt of the Retrieve Form request, the Form Manager shall parse the request and shall return the requested response in the RetrieveFormResponse element, or errors with SOAP Faults. The Form Manager shall return the form or URL based on the values of: a) the encodedResponse; b) the formID; c) any additional workflowData; d) the optionally supplied
905 instanceID.

If encodedResponse is 'true', then the response from the Form Manager shall be either a Structured(XML) or Unstructured (non-XML) element. When the encodedResponse parameter is 'true', all anchor addresses that are not fragment identifiers shall be composed of absolute URIs.

If encodedResponse is 'false', then the response from the Form Manager shall be a URL element
910 that can be used directly by a web browser for retrieval and operation of the form.

The Form Manager may assign and return a value for a form instanceID.

When the Form Filler provides a valid URL in the archiveURL parameter of the request, the Form Manager shall return a form that shall perform an Archive Form transaction upon form submission, in addition to any predefined actions associated with the form submission. As shown
915 in ITI TF-2b: 3.36 Archive Form, this additional archival transaction is between Form Filler and Form Archiver actors.

When the Form Filler supplies data in the prepopData parameter, the Form Manager may use this information to determine the form to be returned and to pre-populate the fields of the form. The exact use of the prepopData, and the structure, is deferred to the publication of an IHE content
920 profile.

The Form Manager shall use the values within the workflowData parameter, as well as the optionally supplied instanceID, to determine the form to be returned and to pre-populate the fields of the form.

The value of the formID has been previously assigned by the Form Manager to identify a form to
925 be returned to the Form Filler using one of the named format options. A Form Manager may support multiple named options, but for each formID there is only one named option that is supported.

The Form Manager shall use the SOAP Faults defined in Table 3.34.4.1.3-1 when appropriate.
930 Form Fillers shall be capable of accepting other values beyond the ones specified here.

35

Table 3.34.4.1.3-1

Description of error	Code	Reason Text
There is missing information, such as no formID	Sender	Required Information Missing
No form is available	Sender	Unknown formID

An example of a SOAP Fault is:

```
<env:Envelope xmlns:env="http://www.w3.org/2003/05/soap-envelope"
              xmlns:xml="http://www.w3.org/XML/1998/namespace">
  <env:Body>
    <env:Fault>
      <env:Code>
        <env:Value>env:Sender</env:Value>
      </env:Code>
      <env:Reason>
        <env:Text xml:lang="en">Required Information Missing</env:Text>
      </env:Reason>
    </env:Fault>
  </env:Body>
</env:Envelope>
```

3.34.4.1.4 Security Considerations

As noted in the mitigations section of ITI TF-1: 17.5 Security Considerations, endpoints are free to implement TLS as needed for additional privacy and protection. Content Profiles, based upon the nature of the data, may need to require use of ATNA.

3.34.4.2 Retrieve Form Response

3.34.4.2.1 Trigger Events

This message is triggered by a Form Manager actor responding to a Retrieve Form request.

3.34.4.2.2 Message Semantics

The form or URL is returned.

3.34.4.2.3 Expected Actions

The Form Filler shall retrieve from the URLvalue returned if the Retrieve Form encodedResponse value was false.

Regardless of the Retrieve Form encodedResponse value, the Form Filler may fill any form fields needed for form submission, and may display the form for user interaction.

3.34.4.2.3.1 XForm Option

A Form Manager that supports the XForms option shall return a form, whether returned as the response or referenced by a returned URL, that conforms to XForms 1.1 The host language for the XForm shall be XHTML Basic according to the W3C HTML Compatibility Guidelines

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965   provided in the Appendix C of the W3C XHTML 1.0 Recommendation. The returned form shall support the Submit and all required Archive transactions.

3.34.4.2.3.2 XHTML Option

A Form Manager that supports the XHTML option shall return a form, whether returned as the response or referenced by a returned URL, formatted as HTML using XHTML Basic and W3C
970   HTML Compatibility Guidelines provided in the Appendix C of the W3C XHTML 1.0 Recommendation. The returned form shall support the Submit and all required Archive transactions.

3.34.5 Protocol Requirements

The Retrieve Form request and response shall be transmitted using Synchronous Web Services
975   Exchange, according to the requirements specified in ITI TF-2x: Appendix V.

The Retrieve Form transaction shall use SOAP 12.

WSDL Namespace Definitions

ihe	urn:ihe:iti:rfd:2007
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 Form transaction presented in the order in which they would appear in the WSDL definition:

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

   • Namespace="urn:ihe:iti:rfd:2007", schema="RFD.xsd"

   • The /definitions/message/part/@element attribute of the Retrieve Form Request message shall be defined as: "ihe:RetrieveFormRequest"

   • The /definitions/message/part/@element attribute of the Retrieve Form Response message
985   shall be defined as: "ihe:RetrieveFormResponse"

   • The /definitions/portType/operation/input/@wsaw:Action attribute for the Retrieve Form Request message shall be defined as "urn:ihe:iti:2007:RetrieveForm"

   • The /definitions/portType/operation/output/@wsaw:Action attribute for the Retrieve Form Response message shall be defined as: "urn:ihe:iti:2007:RetrieveFormResponse"

990   • The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:iti:2007:RetrieveForm"

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 ITI TF-2b: 3.34.5.1 Sample SOAP Messages.

995   For informative WSDL for the Form Manager see ITI TF-2x: Appendix W. A full XML Schema
Document for the RFD types is available online on the IHE FTP site
(ftp://ftp.ihe.net/TF_Implementation_Material/ITI/).

3.34.5.1 Sample SOAP Messages

The samples in the following two sections show a typical SOAP request and its relative SOAP
1000   response. The sample messages also show the WS-Addressing headers <Action/>,

<MessageID/>, .; these WS-Addressing headers are populated according to the

ITI TF-2x: Appendix V: Web Services for IHE Transactions. Some of the body of the SOAP
message is omitted for brevity.

3.34.5.1.1 Sample Retrieve Form SOAP Request

1005
*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:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
    <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>
     <wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
     <wsa:Action soap:mustUnderstand="1">urn:ihe:iti:
2007:RetrieveForm</wsa:Action>
  </soap:Header>
  <soap:Body>
   <RetrieveFormRequest xmlns="urn:ihe:iti:rfd:2007">
     <prepopData>...some xml content...</prepopdata>
     <workflowData>
      <formID>1</formID>
      <encodedResponse>false</encodedResponse>
      <archiveURL />
      <context />
      <instanceID />
     </workflowData>
   </RetrieveFormRequest>
  </soap:Body>
</soap:Envelope>
```

1030   ### 3.34.5.1.2 Sample Retrieve Form 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.*

1035
```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
```

```
            <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>

<wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
            <wsa:Action soap:mustUnderstand="1">urn:ihe:iti:
2007:RetrieveFormResponse</wsa:Action>
  </soap:Header>
  <soap:Body>
    <RetrieveFormResponse xmlns="urn:ihe:iti:rfd:2007">
      <form>
        <URL>http://somehost/xxx/services/someForm</URL>
        <instanceID>1.2.3.4.5</instanceID>
      </form>
      <contentType />
      <responseCode />
    </RetrieveFormResponse>
  </soap:Body>
</soap:Envelope>
```
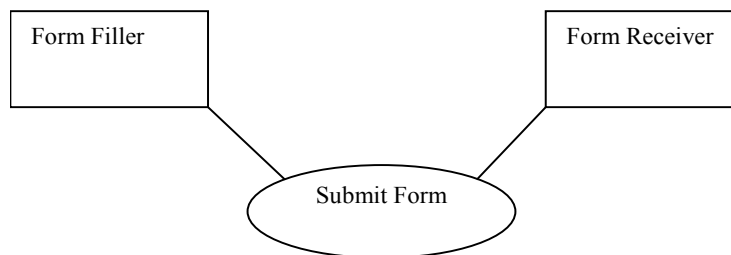
3.35 Submit Form

This section corresponds to Transaction ITI-35 of the IHE IT Infrastructure Technical Framework. Transaction ITI-35 is used by the Form Filler and Form Receiver actors.

3.35.1 Scope

This transaction involves a Form Filler submitting a form to a Form Receiver.

3.35.2 Use Case Roles

Actor: Form Filler

**Role:** A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Receiver

Role: A system that receives submitted forms.

3.35.3 Referenced Standards

1070 IETF RFC1738, Uniform Resource Locators (URL), December 1994, http://www.faqs.org/rfcs/rfc1738.html

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml.

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3.35.4 Interaction Diagram
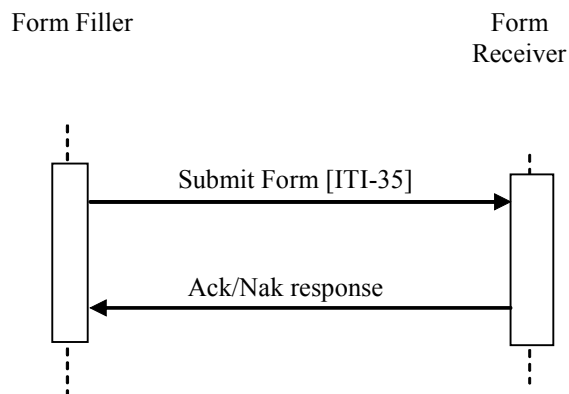
3.35.4.1 Submit Form

1080

This transaction is initiated by a Form Filler submitting form instance data, using XML as a format, to a Form Receiver.

3.35.4.1.1 Trigger Events

The Submit Form transaction is triggered by the submission action from within the form.

3.35.4.1.2 Message Semantics

1085

The Submit Form transaction is performed by invocation of a Web Service call using SOAP, by the Form Filler, submitting the form instance data (XML) to a Form Receiver. See section 11.19 Integration with SOAP (http://www.w3.org/TR/2006/WD-xforms11-20061212/#submit) for submitting from within XForms.

1090 **3.35.4.1.3 Expected Actions**

The Form Receiver shall return the HTTP response code 200 – OK to indicate success. If the Form Receiver cannot recognize the posted data, then the Form Receiver shall return the HTTP response code 400 – Bad Request.

The Form Filler may display the results of the response from the Form Receiver.
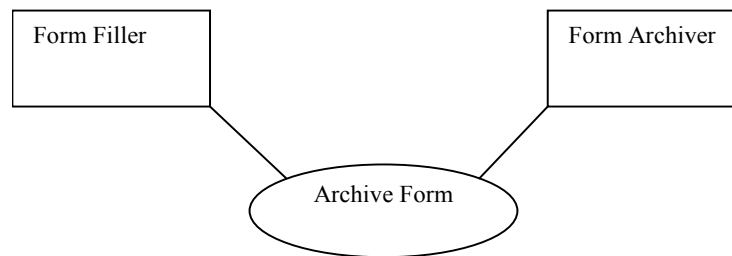
1095 # 3.36 Archive Form

This section corresponds to Transaction ITI-36 of the IHE IT Infrastructure Technical Framework. Transaction ITI-36 is used by the Form Filler and Form Archiver actors.

3.36.1 Scope

This transaction involves a Form Filler submitting form instance data to a Form Archiver.

1100

3.36.2 Use Case Roles

1105 **Actor:** Form Filler

Role: A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Archiver

Role: A system that receives submitted forms for archival purposes.

3.36.3 Referenced Standards

1110 IETF RFC1738, Uniform Resource Locators (URL), December 1994, http://www.faqs.org/rfcs/rfc1738.html

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. http://www.w3.org/TR/REC-xml.

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3.36.4 Interaction Diagram

Form Filler   Form Archiver

Archive Form [ITI-36]

Ack/Nak response
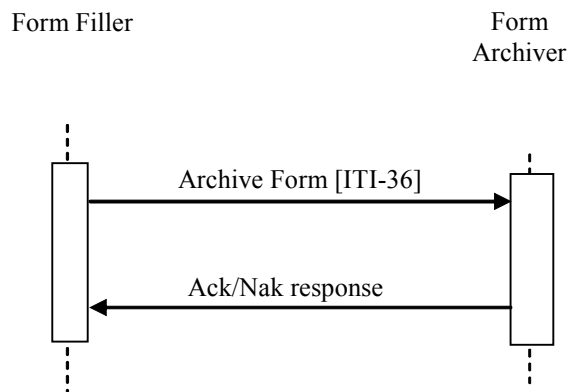
3.36.4.1 Archive Form

1120   This transaction is initiated by a Form Filler submitting a data to a Form Archiver for archival purposes.

3.36.4.1.1 Trigger Events

The Form Filler shall use this transaction to submit data to a Form Archiver for archival purposes. The Archive Form transaction may be initiated by a Form Filler, or it may be triggered 1125   as a secondary submission action from within a form.

3.36.4.1.2 Message Semantics

The Archive Form transaction is performed by invocation of a Web Service call using SOAP, by the Form Filler, submitting the form instance data (XML) to a Form Archiver. See section 11.19 Integration with SOAP (http://www.w3.org/TR/2006/WD-xforms11-20061212/#submit) for 1130   submitting from within XForms.

3.36.4.1.3 Expected Actions

The Form Archiver shall return the HTTP response code 200 – OK to indicate success.

The transaction data shall be saved by the Form Archiver.

If the Form Archiver fails to save the data then the Form Archiver shall return the HTTP 1135   response code 500 – Internal Server Error.

If the Form Archiver cannot recognize the request, then the Form Archiver shall return the HTTP response code 400 – Bad Request.

The Form Filler may display the response from the Form Archiver.

3.37 Retrieve Clarifications

1140 This section corresponds to Transaction ITI-37 of the IHE IT Infrastructure Technical Framework. Transaction ITI-37 is used by the Form Filler and Form Manager actors.

3.37.1 Scope

This transaction involves a Form Filler requesting a set of clarifications from a Form Manager. A Form Filler supporting the Retrieve Clarifications option shall perform this request periodically,
1145 based upon a duration defined by or agreed upon with the Form Manager / Form Receiver. Note that not all use cases will need to support this option.

The Form Filler has an orgID, obtained by a means that is outside the scope of this profile, and the Form Manager will either return a form that contains either the data to be clarified or a set of links to other forms that can be retrieved using the Retrieve Form transaction. All updates /
1150 clarifications / new data are submitted to the Form Receiver using the Submit Form transaction.

3.37.2 Use Case Roles
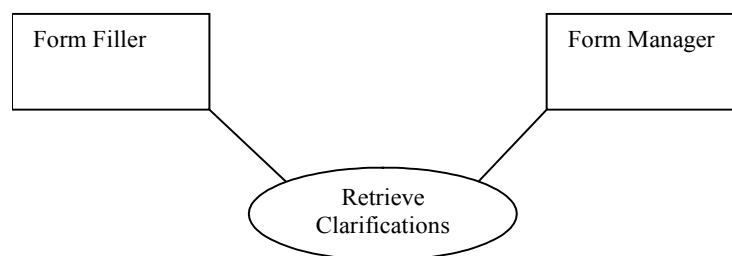
1155 **Actor:** Form Filler

Role: A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Manager

Role: A system that provides clarification information based upon requests that provide specific orgIDs.

1160 **3.37.3 Referenced Standards**

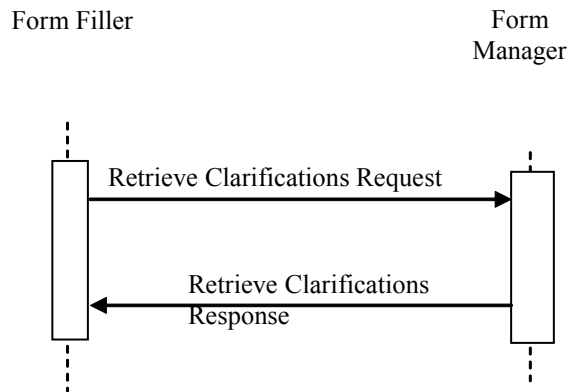IETF RFC1738, Uniform Resource Locators (URL), December 1994, http://www.faqs.org/rfcs/rfc1738.html

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October
1165 2000. http://www.w3.org/TR/REC-xml.

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43

XForms 1.1, W3C Working Draft. http://www.w3.org/TR/2004/WD-xforms11-20041115/

3.37.4 Interaction Diagram

Form Filler   Form Manager

Retrieve Clarifications Request

Retrieve Clarifications Response

1170

3.37.4.1 Retrieve Clarifications Request

This transaction is initiated whenever a Form Filler which supports the Retrieve Clarifications option needs to obtain clarification information relevant to the organization or site.

1175 **3.37.4.1.1 Trigger Events**

The Retrieve Clarification event is triggered by the need for information on current clarifications to be made available within an EHR system. The profile does not specify when the Retrieve Clarification happens, only that this transaction is available when information regarding clarifications is needed from a Form Manager. It is the responsibility of the Form Filler that
1180 supports this option to periodically execute this transaction.

3.37.4.1.2 Message Semantics

Implementors of this transaction shall comply with all requirements described in ITI TF-2x: Appendix V: Web Services for IHE Transactions.

The following parameters are specified for this transaction.

1185

Parameter Name	REQ	Description	Value
clarificationData	R	The xml representation of clarification specific values.	This value is a well-formed xml document.as defined below.

Parameter Name	REQ	Description	Value
orgID	R		A string identifying the organization
encodedResponse	R	Tells the Form Manager whether or not to return an encoded response	{true,false}
archiveURL	R	Tells the Form Manager whether or not the Form Filler is exercising the Archive Option	the URL of any Form Filler identified Form Archiver; may be nill
context	R	The xml specifics of workflow context	Defined by content profiles; may be nill

The clarificationData may be extended by IHE content profiles with further definition of the <context> element. The content of clarificationData shall minimally be:

```
<clarificationData>
      <orgID>a String identifying the form</orgID>
      <encodedResponse>false</encodedResponse>
      <archiveURL />
      <context/>
</clarificationData>
```

3.37.4.1.3 Expected Actions

Upon receipt of the Retrieve Clarifications request, the Form Manager shall parse the request and shall return the requested response in the RetrieveClarificationsResponse element, or errors with SOAP Faults.

The Form Manager shall return the form or URL based on the values of: a) the encodedResponse; b) the orgID; c) any additional clarificationData.

If no clarification information is available, this is shall be indicated by a form indicating that no clarification information is available.

If encodedResponse is 'true', then the response from the Form Manager shall be either a Structured(XML) or Unstructured (non-XML) element, based upon the formatOption. When the encodedResponse parameter is 'true' all anchor addresses that are not fragment identifiers shall be composed of absolute URIs.

If encodedResponse is 'false', then the response from the Form Manager shall be a URL element that can be used directly by a web browser for retrieval and operation of the form.

The value of the orgID has been previously assigned by the Form Manager and identifies use one of the named format options. A Form Manager may support multiple named options, but for each orgID there is only one named option that is supported.

The Form Manager shall use the SOAP Faults defined in Table 3.37.4.1.3-1 when appropriate. Form Fillers shall be capable of accepting other values beyond the ones specified here.

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Table 3.37.4.1.3-1

Description of error	Code	Reason Text
There is missing information, such as no orgID	Sender	Required Information Missing
No form is available	Sender	Unknown orgID

An example of a SOAP Fault is:

```
<env:Envelope xmlns:env="http://www.w3.org/2003/05/soap-envelope"
              xmlns:xml="http://www.w3.org/XML/1998/namespace">
  <env:Body>
    <env:Fault>
      <env:Code>
        <env:Value>env:Sender</env:Value>
      </env:Code>
      <env:Reason>
        <env:Text xml:lang="en">Unknown orgID</env:Text>
      </env:Reason>
    </env:Fault>
  </env:Body>
</env:Envelope>
```

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The orgID has been assigned by the Form Manager use one of the named format options. A Form Manager may support multiple named options, but for each orgID there is only one named option that is supported.

1235 **3.37.4.1.4 Security Considerations**

The security considerations for the Retrieve Clarifications request message are no different than those of the Retrieve Form request message. See ITI TF-2b: 3.34.4.1.4.

3.37.4.2 Retrieve Clarifications Response

3.37.4.2.1 Trigger Events

1240 The Delivery of a Form is triggered by a Form Manager actor providing a form based upon the orgID supplied with the Retrieve Clarifications transaction.

3.37.4.2.2 Message Semantics

The form or URL is returned in response to the Retrieve Clarifications.

3.37.4.2.3 Expected Actions

1245 The Form Filler may display the form or navigate to the returned URL to retrieve the form.

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3.37.4.2.3.1 XForm Option

A Form Manager that supports the XForms option shall return a form, whether returned as the response or referenced by a returned URL, that conforms to XForms 1.1 The host language for the XForm shall be XHTML Basic according to the W3C HTML Compatibility Guidelines provided in the Appendix C of the W3C XHTML 1.0 Recommendation. The returned form shall support the Submit and all required Archive transactions.

3.37.4.2.3.2 XHTML Option

A Form Manager that supports the XHTML option shall return a form, whether returned as the response or referenced by a returned URL, formatted as HTML using XHTML Basic and W3C HTML Compatibility Guidelines provided in the Appendix C of the W3C XHTML 1.0 Recommendation. The returned form shall support the Submit and all required Archive transactions.

3.37.5 Protocol Requirements

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

The Retrieve Clarifications transaction shall use SOAP 12.

WSDL Namespace Definitions

ihe	urn:ihe:iti:rfd:2007
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 Clarifications 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:iti:rfd:2007", schema="RFD.xsd"
- The /definitions/message/part/@element attribute of the Retrieve Clarifications Request message shall be defined as: "ihe:RetrieveClarificationsRequest"
- The /definitions/message/part/@element attribute of the Retrieve Clarifications Response message shall be defined as: "ihe:RetrieveClarificationsResponse"
- The /definitions/portType/operation/input/@wsaw:Action attribute for the Retrieve Clarifications Request message shall be defined as "urn:ihe:iti:2007:RetrieveClarifications"
- The /definitions/portType/operation/output/@wsaw:Action attribute for the Retrieve Clarifications Response message shall be defined as: "urn:ihe:iti:2007:RetrieveClarificationsResponse"

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- The /definitions/binding/operation/soap12:operation/@soapAction attribute shall be defined as "urn:ihe:iti:2007:RetrieveClarifications"

1280 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 ITI TF-2b: 3.34.5.1 Sample SOAP Messages.

For informative WSDL for the Form Manager see ITI TF-2x: Appendix W. A full XML Schema Document for the RFD types is available online on the IHE FTP site (ftp://ftp.ihe.net/TF_Implementation_Material/ITI/).

1285 **3.37.5.1 Sample SOAP Messages**

The samples in the following two sections show a typical SOAP request and its relative SOAP response. The sample messages also show the WS-Addressing headers <Action/>, <MessageID/>, …; these WS-Addressing headers are populated according to the IHE Appendix V: Web Services for IHE Transactions.

1290 **3.37.5.1.1 Sample Retrieve Clarifications 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.*

```
<?xml version="1.0" encoding="utf-8"?>
1295
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
        <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>
1300
<wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
        <wsa:Action soap:mustUnderstand="1">urn:ihe:iti:
2007:RetrieveClarifications</wsa:Action>
  </soap:Header>
1305  <soap:Body>
    <RetrieveClarificationsRequest xmlns="urn:ihe:iti:rfd:2007">
     <clarificationData>
       <orgID>123</formID>
       <encodedResponse>false</encodedResponse>
1310       <archiveURL />
       <context />
     </clarificationData>
    </RetrieveClarificationsRequest>
  </soap:Body>
1315 </soap:Envelope>
```

3.37.5.1.2 Sample Retrieve Clarifications 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.*

1320
1325
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```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
        <wsa:To>http://localhost:4040/axis2/services/someservice</wsa:To>

<wsa:MessageID>urn:uuid:76A2C3D9BCD3AECFF31217932910053</wsa:MessageID>
        <wsa:Action soap:mustUnderstand="1">urn:ihe:iti:
2007:RetrieveClarificationsResponse</wsa:Action>
  </soap:Header>
  <soap:Body>
    <RetrieveClarificationsResponse xmlns="urn:ihe:iti:rfd:2007">
      <form>
        <URL>http://somehost/xxx/services/someForm</URL>
      </form>
      <contentType />
      <responseCode />
    </RetrieveClarificationsResponse>
  </soap:Body>
</soap:Envelope>
```