Targeted at individual studies and study consortia, OBiBa software stack (Opal, Mica etc.) provides a software solution for epidemiological data management, analysis and publication. While Opal, the core data warehouse application, provides all the necessary tools to import, transform and describe data, Mica provides everything needed to build personalized web data portals and publish content of research activities of both studies and consortia and Agate, the OBiBa’s central authentication server, provides services for user profile management.

Onyx is a web-based application that manages participant baseline interviews at assessment centres or clinics. An interview in Onyx is represented as a set of interdependent stages that participants have to go through in order to complete their visit (consent form signature, health questionnaire, biosample collection, and so on). Onyx stores the data collected during the stages centrally and makes it available to all workstations.

Warning: Onyx documentation is in the process of being rewritten. See also the Onyx Documentation Archive
CHAPTER 1

Introduction

1.1 Version of Onyx Covered by this Guide

This version of the Onyx User Guide describes Onyx 1.8.0, in particular, version 1.8.0 of Onyx.

1.2 How this Guide is Organized

Since most Onyx users are data collectors, most of this guide explains how to use Onyx to collect participant data. This guide also includes chapters for Participant Managers, Questionnaire Editors, and for System Administrators. This guide consists of the following chapters:

• **Introduction.** Presents Onyx. Includes key concepts that will help you understand Onyx’s approach to baseline interviews. For new Onyx users.

• **ADMINISTRATOR GUIDE.** Explains certain tasks that only system administrators can do such as Installing and deploying Onyx, managing Onyx users, and exporting and purging data. Of most interest to system administrators.

• **USER GUIDE.** Explains users common usage such as:
  – **Viewing Participants.** Presents the Participants page and key concepts related to viewing participants. Explains the ways you can search for a participant in Onyx. For new Onyx users.
  – **Viewing Managing an Interview.** Presents the Interview page and key concepts related to navigating through an interview. Covers various ways to access and exit the stages of an interview: starting, stopping, pausing, resuming, and so on. Of most interest to Onyx data collectors and participant managers.
  – **Obtaining Participant Consent.** Presents Onyx’s way of handling participant consent. Covers electronic consent forms and registering paper consent. Of most interest to Onyx data collectors and participant managers.
  – **Completing Questionnaires.** Presents key concepts related to the way questionnaires are handled in Onyx such as assisted versus self-administered questionnaires. Since each study designs its custom questionnaires, the chapter explains the types of questions and answers users will see, rather than how to
answer the particular questions in your study’s questionnaires. Of most interest to Onyx data collectors and participant managers.

– Collecting Physical Measurements. Presents key concepts related to physical measurement stages. Since each study determines the physical measurements it requires, the chapter explains the general workflow of a physical measurement stage and demonstrates the workflow with an example stage. Of most interest to Onyx data collectors and participant managers.

– Collecting Biospecimens. Presents key concepts related to stages used to record the collection of biospecimens. Since each study determines the biospecimens it requires, the chapter provides an example biospecimen collection stage. Of most interest to Onyx data collectors and participant managers.

– Managing Your Onyx User Profile. Explains how to do a few tasks that customize Onyx for you: changing your password and changing the language of the Onyx user interface (English or French are currently available). For all Onyx users.

– Managing an Onyx Workstation. Presents the Workstation page and key concepts related to storing data about a workstation. Explains how to register and calibrate instruments used for physical measurements, and how to maintain logs of experimental conditions. Of most interest to Onyx users who will register and calibrate instruments, and log experimental conditions.

– Creating and Editing Questionnaires. Explains how to create and edit questionnaires that can be included as stages of an Onyx interview. This work is typically done by researchers involved in design of the study. Of interest to users with the role of questionnaire editor.

– Topics for Participant Managers. Explains certain tasks that only participant managers can do such as receiving and enrolling participants. Of most interest to participant managers.

• DEVELOPER GUIDE. Explains developers common usage
A system administrator has all the permissions of the other two user roles (data collector (page 4) and participant manager (page 4)), as well as a few additional permissions. This section covers those additional permissions. In particular, it covers:

- **Key concepts** of interest to system administrators
- **Installation**
- **Server configuration**
- **Workstation configuration**
- **Procedures** *(in the Onyx user interface)* that can only be done by system administrators:
  - Adding an Onyx user (page 140)
  - Editing the profile of an Onyx user (page 140) (including password reset)
  - Activating and deactivating Onyx users (page 141)
  - Deleting an Onyx user (page 141)
  - Exporting data (page 142) (participant data, as well as data about instruments and experimental conditions)
  - Purging data (participant data only)
3.1 User Roles

These are the roles that are possible for Onyx users: * Data collector - has basic permissions * Participant manager - has data collector permissions plus a few more * System administrator - has permissions of participant manager plus a few more

For details about what each user role can do, see *Who Uses Onyx*.

3.2 User Status

Onyx users have one of these statuses: * Active: The user can log in. By default, when a user is created, their status is active. * Inactive: The user will not be able to log in. For example, you may want to deactivate a user who is away on leave.

The word that appears in the Status column in the User administration page is the user’s current status. Only system administrators can change the status of an Onyx user. See *Activating and Deactivating Onyx Users*.

3.3 Data Export

Exporting data from Onyx means reading data from the Onyx database and writing it to one or more export destinations. Here are some points worth noting about the Onyx export function:

- Exporting does not delete any data from the Onyx database. Deleting data from the database is done by the purge function. See *Data Purge* (page 139).
- An export destination is a compressed zip file. The name given to an export destination may indicate the location into which the data will be imported—for example, a data repository like Opal.
- Participant data and experimental conditions data can be exported. See *Participant Data* and *Experimental Condition Data*. 
• Configuration of data export is done entirely in configuration files, not through the Onyx user interface. Some things that can be configured:

  – Which data is selected for export
  – Directory to which export files are written
  – How many export destinations are defined

For detailed information about how the export function is configured, see the OBiBa Wiki Onyx+1.6.0+Upgrade. Only system administrators can execute a data export from the Onyx user interface. See Exporting data.

### 3.4 Data Purge

In Onyx, purging data means deleting data from the Onyx database. Only participant data can be purged—not experimental conditions data. Configuration of data purging is done entirely in configuration files, not through the Onyx user interface. For detailed information about how the purge function is configured, see the OBiBa Wiki Onyx+1.6.0+Upgrade. Only system administrators can execute a purge from the Onyx user interface. See Purging data.

### 3.5 Participant Data

Participant data includes personal information (such as the participant’s name and address), as well the data from all stages of the interview (consent, questionnaires, physical measurements, and information about the biospecimens collected). Participant data can be exported (see Exporting Data) and purged (see Purging Data).

### 3.6 Experimental Conditions Data

Each study can define experimental conditions that it would like to track on a regular basis. This information is stored in one or more experimental condition logs. The Workstation page of the Onyx user interface allows users to make entries in these logs. As a system administrator, you will export this data, so you should be familiar with the experimental condition logs that were defined for the study. The user interface for experimental condition logs is in the lower half of the Workstation page. Instrument data is a special case of experimental conditions data. See Instrument Data. Experimental conditions data can be exported (see Data Export), but it cannot be purged (see Data Purge). This data is not purged because it is needed for the log history, and because no privacy issues are involved with this kind of data.

### 3.7 Instrument Data

Instruments are part of the experimental setup, so data about instruments is a special case of experimental conditions data. As a system administrator, you will export this instrument data, so you should be familiar with the instrument calibrations that are done for the study. The user interface for instrument calibration is in the the top half of the Workstation page. Like other experimental condition data, instrument data can be exported but not purged.
Onyx is a web application that runs on a server. Users access it on client workstations via a browser over a local network. This guide is for whoever will set up Onyx in an assessment centre—typically, a system administrator. The guide covers hardware and software requirements and includes procedures for deploying Onyx on a server and setting up the client workstations.

4.1 What You Need from Your Organization

Your organization should provide you with the following:

- war file (custom-onyx .war) that contains a version of Onyx customized to your organization’s requirements.
- An appointment list (may be an Excel or XML file)

Note:

The war file is actually a zip file. You will need some information from two files in the war file before they are extracted during installation:

- onyx-config.properties.
- export-destinations.xml.
4.2 Requirements

4.2.1 Server Hardware Requirements

<table>
<thead>
<tr>
<th>Component</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPU</td>
<td>Recent server-grade or high-end consumer-grade processor</td>
</tr>
<tr>
<td>Memory (RAM)</td>
<td>Minimum: 2 GB</td>
</tr>
<tr>
<td>Disk space</td>
<td>Minimum: 160 GB Rule of thumb calculation: 10 GB for operating system + ((8 GB/2000 participants) * (expected number of participants))</td>
</tr>
</tbody>
</table>

4.2.2 Server Software Requirements

<table>
<thead>
<tr>
<th>Software</th>
<th>Suggested version</th>
<th>Download link</th>
<th>Usage</th>
<th>Installation/Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomcat</td>
<td>6.0.x</td>
<td><a href="http://tomcat.apache.org/download-60.cgi">http://tomcat.apache.org/download-60.cgi</a></td>
<td>Servlet container - needed to run Onyx</td>
<td>Fine-tuning Tomcat</td>
</tr>
</tbody>
</table>
5.1 Fine-tuning Tomcat

For general tips related to Tomcat, see http://tomcat.apache.org.

**Note:** The following tips assume that you are using Sun’s Java Virtual Machine

5.1.1 General Comments about Tomcat Memory Settings

On most default Tomcat installations, the memory allocated to the service is insufficient. You must increase the memory allocated to Tomcat by tweaking two memory settings.

- Xmx
- XX:MaxPermSize

In the OS-specific procedures below (see Allocating Memory on Ubuntu and Allocating Memory on Windows), we assume that your server has 2GB of RAM. We set -Xmx to 1024 and -XX:MaxPermSize to 256m.

- If your server has more than 2GB of RAM, you can increase the -Xmx setting. It is not necessary to increase the -XX:MaxPermSize setting.
- If your server has less than 2GB of RAM, you can decrease the -Xmx and the -XX:MaxPermSize settings. Try to keep the same ratio (4:1). **Do not** allocate less than 128m to -XX:MaxPermSize.

5.1.2 Using Tomcat on Ubuntu

Two issues need to be addressed when running Tomcat on Ubuntu: insufficient memory and the security manager.
To allocate memory on Ubuntu

To allocate memory to Tomcat, you need to create an environment variable. If Tomcat was installed using apt, you must edit the `/etc/default/tomcat6` file as shown below:

```bash
#/etc/default/tomcat6
JAVA_OPTS="-Xmx1024M -XX:MaxPermSize=256M
```

To disable the security manager on Ubuntu

Comment out the `#TOMCAT6_SECURITY=yes` and add the `TOMCAT6_SECURITY=no` line as shown below.

```bash
#/etc/default/tomcat6
# Use the Java security manager? (yes/no, default: yes)
# WARNING: Do not disable the security manager unless you understand
# the consequences!
#TOMCAT6_SECURITY=yes
TOMCAT6_SECURITY=no
```

5.1.3 Using Tomcat as a Windows Service

Two issues need to be addressed when running Tomcat as a service on Windows: insufficient memory and making the printer available to Tomcat.

To allocate memory on Windows

1. Open the Apache Tomcat Properties dialog in either of these ways:
   - If you have a Tomcat icon on your taskbar, right-click it and select Configure.
   - From the Start menu, select All Programs > Apache Tomcat 6.0 > Configure Tomcat.
2. Select the Java tab. See screenshot below.
3. Add this line in the Java Options field: `-XX:MaxPermSize=256M`.
4. In the Maximum memory pool field, enter the value 1024

Note: The Maximum memory pool setting is equivalent to passing the `-Xmx` argument to Java.
To enable printing from Tomcat

When running Tomcat as a Windows Service, make sure that the user running the Tomcat service can use the printer. This is not the case by default. Permissions must be given to the tomcat user in order for Onyx to see the printer you wish to use.

5.2 Configuring MySQL

5.2.1 To check the database connection settings

The default Onyx connection to the MySQL server uses the settings shown in the table below. They are defined in the onyx-config.properties file, which is Onyx’s main configuration file.

<table>
<thead>
<tr>
<th>Settings</th>
<th>value</th>
</tr>
</thead>
<tbody>
<tr>
<td>hostname:port</td>
<td>localhost:3306</td>
</tr>
<tr>
<td>username</td>
<td>Onyx</td>
</tr>
<tr>
<td>password</td>
<td>onyx-demo</td>
</tr>
</tbody>
</table>

Your organization may have already changed the defaults. You can check the values in the onyx-config.properties file (What You Need from Your organization). If the settings are different from the defaults shown in the table, note them so you can use them when Creating a Database for Onyx in MySQL.

#WEB-INF/config/onyx-config.properties
# Database configuration (if applicable)
# MySQL

```
# MySQL
org.obiba.onyx.datasource.driver=com.mysql.jdbc.Driver
org.obiba.onyx.datasource.url=jdbc:mysql://localhost:3306/onyx
org.obiba.onyx.datasource.username=onyx
org.obiba.onyx.datasource.password=onyx-demo
org.obiba.onyx.datasource.dialect=org.hibernate.dialect.MySQL5InnoDBDialect
org.obiba.onyx.datasource.validationQuery=SELECT 1;
org.obiba.onyx.datasource.testOnBorrow=true
```

## 5.2.2 To create a database for Onyx in MySQL

You must create a database for Onyx in MySQL, and you must also set up a user that has all privileges on that database. When Onyx starts for the first time, it will automatically create its schema in this database.

In a MySQL client:

1. Execute the command: 
   ```
   create database onyx
   ```
   (or whatever name that defined at the end of this line in onyx-config.properties: org.obiba.onyx.datasource.url=jdbc:mysql://localhost:3306/onyx)

2. Ensure that the MySQL users (onyx in this case) granted all privileges on that database instance (CREATE TABLE, ALTER, and so on)

Alternatively, in the MySQL Administrator application:

1. Select Catalogs.

2. Right-click in the field that lists the existing schemata, and select Create New Schema.

3. When prompted for a name for the new schema, enter onyx or whatever name was defined at the end of this line in onyx-config.properties: org.obiba.onyx.datasource.url=jdbc:mysql://localhost:3306/onyx).

4. Add a new user (with the name onyx or whatever value is defined in this line of onyx-config.properties: org.obiba.onyx.datasource.username=onyx).

5. Assign all privileges on the new database to the new user.

## 5.3 Setting Up an SSL Connection

To set up Onyx to run over a secured connection on the local network, you must do two tasks on the Onyx server: create a keystore and configure Tomcat to use an SSL connection.

**Note:** The procedures in this section use the following shortcuts to refer to certain directories: JAVA_HOME = the directory where java is installed CATALINA_BASE = the directory where Tomcat is installed

### 5.3.1 To create a keystore for the SSL connection

1. From the JAVA_HOME directory, execute this command:

   ```
   ./bin/keytool -genkey -alias tomcat -keyalg RSA -keystore CATALINA_BASE/keystore/onyx.keySTORE
   ```

2. When prompted, enter the requested information for the certificate and a new password.
3. Export the certificate to a file. You will import this file on each of the client workstations. See Setting Up the SSL Connection to Onyx.

### 5.3.2 To configure Tomcat to use an SSL connection

Edit the file `CATALINA_BASE...confserver.xml` as follows:

1. Comment out this section:

```
<!-- Define a non-SSL HTTP/1.1 Connector on port 8080 -->
<Connector
    port="8080" maxHttpHeaderSize="8192"
    maxThreads="150" minSpareThreads="25" maxSpareThreads="75"
    enableLookups="false" redirectPort="8443" acceptCount="100"
    connectionTimeout="20000" disableUploadTimeout="true" />
```

2. Remove comments from this section:

```
<!-- Define a SSL HTTP/1.1 Connector on port 8443 -->
<Connector
    port="8443" maxHttpHeaderSize="8192"
    maxThreads="150" minSpareThreads="25" maxSpareThreads="75"
    enableLookups="false" disableUploadTimeout="true"
    acceptCount="100" scheme="https" secure="true"
    clientAuth="false" sslProtocol="TLS" />
```

3. In the `<Connector>` element, add the following attributes:

```
keystoreFile="keystore\onyx.jks" keystorePass="password"
```

where “keystoreonyx.jks” and “password” are the values you entered when Creating a keystore for the SSL connection.

### 5.4 Generating a Key and Certificate for Data Export

Onyx can export data to one or more export destinations (see Configuring Data Export and Purge). If your organization has decided to encrypt participant data upon export to a particular destination, you must generate a key and certificate for that destination. You can check whether or not data is supposed to be encrypted on export, look in the file `export-destinations.xml` which is in your custom `-onyx.war` file (What You Need from Your organization). If any of the destinations include an `<encrypt>` element, the data will be encrypted on export. You will need the key and certificate when you carry out the procedure for Deploying Onyx. You can use a utility (like openSSL) to generate keys and certificates. For a Windows program that uses openSSL to generate keys and certificates, see Shining Light Productions.

### 5.5 Fine-tuning the Onyx Configuration

The global configuration settings for Onyx are contained in the file `onyx-config.properties`. See What You Need from Your organization.

As a minimum, you should check the configuration settings listed in this section. If you think other settings need to be fine-tuned, see Customizing the Global Configuration in the Onyx Customization & Configuration Guide.
5.5.1 To check the application mode

Onyx should be configured to run in deployment mode. This is very important since it improve the overall performance of the application. Check that the following property onyx-config.properties is set to deployment in :

```properties
# WEB-INF/config/onyx-config.properties
# Onyx Web application mode: deployment or development
org.obiba.onyx.webapp.configurationType=deployment
```

5.5.2 To set the printer

On startup, Onyx decides which printer to use. Onyx will try to find a printer with a particular name. If that printer does not exist, or does not support PostScript printing, then Onyx will fall back to using the system’s default printer. If that printer does not support PostScript printing, Onyx will not be able to print reports. You can change the printer that Onyx should look for at startup by editing this line in onyx-config.properties.

```properties
# WEB-INF/config/onyx-config.properties
# Name of printer for PDF printing.
org.obiba.onyx.pdfPrinterName=ONYX PDF Printer
```

5.5.3 To set up the appointment list

1. Check the input and output directories for the appointment list file. The output directory is optional. The default paths are shown below. They may have been changed in your version of Onyx.

```properties
# WEB-INF/config/onyx-config.properties
# Appointment management
# Directory that contains the appointment list files to process dropped by external process
org.obiba.onyx.appointments.inputDirectory=WEB-INF/appointments/in
# Optional directory that contains the successfully processed files
org.obiba.onyx.appointments.outputDirectory=WEB-INF/appointments/out
# Schedule for automatic appointment list updates (4am every day)
org.obiba.onyx.appointments.schedule=0 0 4 * * ?
```

2. Create the input and output directories on the Onyx server.

3. If your organization gave you an appointment list file, put it in the input directory.

5.5.4 To set up the data export directory

1. Check the export directory setting in onyx-config.properties. The default export directory is target in Onyx’s current working directory (usually the Tomcat home directory). It may been changed in your version of Onyx.

```properties
# WEB-INF/config/onyx-config.properties
# System path where to export Onyx Data
org.obiba.onyx.export.path=target
```

2. Create the export directory on the Onyx server.
5.5.5 To set up the keystore for data export

1. Check where the keystore file should be written to. The default path and filename are shown below. They may have been changed in your version of Onyx.

```properties
# WEB-INF/config/onyx-config.properties
# Keystore
org.obiba.onyx.keystore.file=file:${java.io.tmpdir}/onyxKeyStore.jks
org.obiba.onyx.keystore.password=youshouldchangethispassword
```

2. Change the password for the keystore and save onyx-config.properties.

3. Create the keystore directory on the Onyx server.

5.6 Deploying Onyx

To deploy Onyx, you need a war file (custom-onyx.war) containing a customized version of Onyx. If you do not already have it, see here

**Note:** You must enter the custom-onyx part of the war filename when you access Onyx in a browser in the procedure below.

1. Copy the war file to the webapps directory in the Tomcat installation directory `$TOMCAT_HOME/webapps`.
2. If Tomcat is already running, it should deploy Onyx automatically. To check if Tomcat is running on Windows:
   1. Select Control Panel > Administrative Tools > Services > Apache Tomcat
   2. Click Start if Tomcat is not running. Onyx will be deployed when Tomcat starts.
3. Check that you can access Onyx by opening a browser and pointing it to: `http://localhost:8080/custom-onyx`. If you cannot access Onyx, try restarting Tomcat. If you still have trouble, see *Troubleshooting*.
4. When you access Onyx for the first time, you must complete the Onyx setup page (see the screenshot below) as follows:
   1. Enter details about the Onyx instance (study name, site name and site id).
   2. If you configured Onyx to Generate Participant Identifiers Automatically, you will have to specify the Identifier Prefix and the First Indentifier (starting point for generating the identifiers).
      See *Configuring Participant ID Generator* for more details about generating identifiers.
   3. Set up an account for the Onyx Administrator.
   4. Set the Session Timeout (minutes) to at least 45 or 60 (which should be enough for any physical measurements that must be performed).
   5. If your organization will encrypt participant data upon export, copy and paste the certificate you generated for this purpose into the field provided.
      If you did not generate a certificate yet, see *Generating a Key and Certificate for Data Export*. 

Note: Take note of these values for future reference:

- Administrator’s user name and password. You will always need them to log in to Onyx.
- Collection Site Id. This value will be used in the appointment list file. If your organization has or will have several sites (each with its own Onyx server), each site should have a unique Id. The value can be alphanumeric, but should not contain spaces.

5.6.1 Checking the Deployment

Here are a few items to check after you have deployed Onyx:

- If your data will be encrypted upon export (see *Generating a Key and Certificate for Data Export*), check that the file `onyxKeyStore.jks` was created at the location defined by the property `org.obiba.onyx.keystore.file` in `onyx-config.properties`.
- If you put an appointment list file in the input directory (see *Setting up the appointment list*), check that you can update the appointment list from the Participants tab of the Onyx user interface.

5.6.2 Troubleshooting

The first place to look is Tomcat’s console output which is written in the log directory. Under windows, the file is called `stdout_XXX.log` on Debian/Ubuntu, this file is called `catalina.out`. 
### 5.7 Miscellaneous

#### 5.7.1 Consent Form Submission Problems

You may encounter an error when attempting to submit a consent form, especially a large multi-page consent form written in a double-byte character set. This error occurs because the consent form is too large to be stored in the database. To get around this, you must modify the MySql database settings to allow storage of larger amounts of data. The configuration file that you must edit is `my.ini` on Windows and `my.cnf` on Linux. This is the line you need to change:

```
max_allowed_packet=3M
```

To start, try a value of 3M (for 3 megabytes). If it still doesn’t work, increase the value. You will need to restart the MySql database server after making the change.
Workstation Configuration

6.1 Setting Up Touchscreens (if applicable)

If touchscreen monitors are being used with any of the client workstations, the monitors should be put in “Click on contact” mode. You should avoid any kind of “mouse emulation” mode, since it will complicate use of the touchscreen.

6.2 Registering Instruments

An instrument must be registered on the workstation(s) with which it will be used. An instrument can be reserved for one workstation or it can be shared by several workstations. This is done on the Workstation page of the Onyx user interface, as explained in the Onyx User Guide.

6.3 Installing Proprietary Software for Instruments

If your organization has chosen to use any of these electronic instruments (except those manufactured by Tanita), you must install the instrument’s proprietary software on the workstation with which the instrument will be used.

6.4 General Troubleshooting for Instruments

6.4.1 BadFieldException when Starting an Instrument

This exception is caused by a bug in the version of Java installed on the workstation. To fix this issue, ensure that the JRE installed on the Onyx server is at least 1.6.0_02.
6.4.2 Unable to Save Instrument Data Due to Timeout of Onyx Session

After an instrument’s software is launched, the user’s Onyx session may timeout because the user is no longer interacting with Onyx. If the Onyx timeout is set too low (for example, 5 minutes) and the physical measurement takes longer than the timeout, the Onyx session will timeout and the measurement data will not be saved. The user will need to log in to Onyx again after the test is over, and repeat the measurement or enter the measurements in Onyx manually, if Onyx is configured to accept manual measurements. The timeout is set when you access Onyx for the first time (see Installing Onyx on the Server). The timeout setting is stored in the Onyx database. It cannot be changed in a configuration file or in the Onyx user interface. When accessing Onyx for the first time, be sure to set the Session Timeout to at least 45 or 60 (minutes). This should be enough to complete physical measurements. See Setting Up the Server.

6.4.3 Tanita Scales and Bioimpedance Instruments

If your organization is using instruments manufactured by Tanita, read this section when you are setting up the instrument(s) for use with an Onyx workstation.

Cable for the Tanita scale

If the cable provided has a serial 9 pin connector, the Port Settings for Flow control must be set to Hardware.

Configuring the Port Settings on Windows

1. Open the Control Panel in classic view.
2. Select System > Hardware (tab) > Device Manager > Expand Ports.
3. Double-click the port that needs to be changed (usually COM1).
4. Select the Port Settings tab.
5. Set Flow Control to Hardware.

6.4.4 Achilles Express

Achilles Express software (version 5.11 and earlier versions) produces erroneous data. Specifically, the SOS and BUA parameters are not calculated properly. However, the Stiffness Index is correct. Version 5.12 fixes this issue.

6.4.5 TOPCON TRC-nw8

If SQL Server uses windows authentication to connect to the database, “ntmlauth.dll” library must be added in lib java folder. This library is provided by jtds driver located at http://jtds.sourceforge.net/. Once zip archive downloaded (jtds-1.2.x-dist.zip), DLL library is in {x86, x64, IA64}/SSO/ntmlauth.dll (Platform Dependant).
Procedures (in the Onyx user interface) that can only be done by system administrators

7.1 Adding an Onyx user
7.2 Editing the profile of an Onyx user (including password reset)
7.3 Activating and deactivating Onyx users
7.4 Deleting an Onyx user
7.5 Exporting data
7.6 Purging data (participant data only)
Chapter 7. Procedures (in the Onyx user interface) that can only be done by system administrators
If you are new to Onyx and would like a gentle introduction, this chapter is for you. If you are already familiar with Onyx and need specific information about how to do something, skip this chapter and find the topic you need by scanning the table of contents or by searching for some key words that describe what you are looking for.

This chapter covers these topics:

8.1 What Onyx is?

Onyx is a web-based application used to manage participant baseline interviews by assessment centres and clinics that are collecting data for research. Typically, the data is being collected for Biobanks or large-scale population studies. This figure shows the typical assessment centre activities that Onyx supports. As shown in the figure, Onyx is installed on a server in the assessment centre and can be accessed from workstations via the assessment centre’s intranet. An assessment centre may have one or more workstations dedicated to collecting data using Onyx.

8.1.1 A Highly Customizable Software Solution

Onyx is modular as shown in this figure. The Onyx engine is a backbone into which independent data collection components are inserted. Onyx is configurable which means certain stages may or may not be included in your version of Onyx. For example, your study may not accept volunteer participants. And if a stage is included, it can be fine-tuned to meet the requirements of your study. For example, for your study Onyx may be configured to only accept electronic signatures for consent forms, whereas for another study Onyx may accept electronic or handwritten signatures. Onyx is also customizable which means certain stages are tailor-made for each research study. For example, each study develops its own questionnaires, and each study defines which physical measurements will be collected and in which order.
Fig. 1: Onyx facilitates the typical activities of the staff at an assessment centre.

Fig. 2: Onyx treats an interview as a set of interdependent stages.
8.2 Key concepts related to the way Onyx works

8.2.1 Participant

A participant is a person who has come to the assessment centre in order to participate in the research study. Assessment centre staff collect data from participants by asking questions, collecting biospecimens, and taking physical measurements. Each research study determines how they will recruit participants. Typically, participants are either invited or volunteers. Onyx can be customized to accept volunteer participants or not. Whether or not this functionality appears in Onyx at your assessment centre depends on how Onyx was configured for your study. See Receiving vs. Enrolling Participants

8.2.2 Invited Participant

A participant who was selected by the study and given an appointment time for their interview.

8.2.3 Volunteer Participant

A volunteer participant (also known as a “walk-in” Walk-in participants) arrives at the assessment centre without an appointment. They heard about the study in some way and decided that they would like to participate.

8.2.4 Interview

Onyx treats an interview as a set of interdependent stages that a participant goes through in order to complete their visit to the assessment centre. See this figure. An interview starts when a staff member receives the participant and enters registration information for the participant in Onyx. The participant then passes through some or all the stages that have been defined for the study. The interview ends when a staff member clicks the Close interview button in Onyx.

8.2.5 Interview Stages

An interview stage is one of the interdependent parts of an interview during which a particular type of data is collected from the participant. Each research study defines the stages it requires to obtain the necessary data, as well as the sequence in which the stages appear in Onyx. Typical interview stages include:

- Signing a consent form
- Questionnaires (one or more)
- Physical measurements (one or more)
- Collection of biospecimens (one or more)
• Conclusion of the interview (may include printing a report for the participant that includes information considered appropriate by the research study)

Each research study defines its own stages, creates its own questionnaires, and decides which physical measurements and biospecimens must be collected. Onyx stores the data collected during the stages centrally and makes it available to all workstations.

8.3 Who Uses Onyx?

Onyx is used by the staff of an assessment center or a clinic that is collecting data from participants in a biobank study. Onyx supports four roles for users. An individual user can be assigned one or several of these roles:

• Data Collectors
• Participant Managers
• Receptionists
• Questionnaire Editors
• System Administrators

8.3.1 Data Collectors

These Onyx users are responsible for one or more of these tasks:

• interviewing participants
• collecting biospecimens
• taking physical measurements

Onyx data collectors are typically nurses and technologists.

8.3.2 Participant Managers

These Onyx users coordinate the activities of Data Collectors. Participant managers can do the tasks of a data collector, and in addition, they can do these tasks:

• receiving participants
• enrolling volunteer participants (if your study permits this)
• updating the appointment list
• unlocking a locked interview

8.3.3 Receptionists

These Onyx users can do the following tasks:

• receiving participants
• enrolling volunteer participants (if your study permits this)
• updating the appointment list
8.3.4 Questionnaire Editors

These Onyx users create and edit the questionnaires that form part of an Onyx interview. Typically, they would be researchers involved in the design of the study, but not in interviewing participants. This role only gives a user the permission to create and edit questionnaires.

8.3.5 System Administrators

These Onyx users are typically Information Technology Managers (IT Managers) who handle the technical tasks required to set up and maintain Onyx. This role gives a user the permission to manage users and data.

8.4 What Onyx does?

Onyx facilitates the work of the staff members by allowing them to collect data electronically:

- obtain participant consent with the help of an electronic signature pad
  (if your assessment centre does not have a signature pad or the pad is not available, you record the fact that the patient signed a printed consent form in Onyx)
- complete onscreen questionnaires with participants
- set up participants to answer self-administered questionnaires on a touchscreen or a workstation
- record the collection of biospecimens (using a barcode scanner to identify the sample or entering a sample number manually)
- register physical measurements such as height, weight, bone density, and any other measurements that the study may require

Onyx provides researchers with tools that allow them to optimize the workflow of baseline interviews:

- control stage availability and dependencies between stages (some examples: require that consent was obtained before an interview can proceed; prevent staff from taking measurements or samples that are contraindicated; ensure that dependent measurements are done in the correct order)
- capture administrative parameters such as start and end times of each stage
- automate the calibration of electronic instruments used to take physical measurements
- produce personalized reports for participants
- export encrypted data to multiple destinations

8.4.1 Some things Onyx does not do

While Onyx includes many features and functions that an assessment centre needs, it does not include the following functionality:

- Onyx does not allow you to schedule participant appointments. The appointment list must be imported into Onyx.
- Onyx does not arbitrarily decide when and whether you can proceed with a certain stage of an interview.

Onyx is highly configurable and customizable. Each research study defines its own questionnaires, the physical measurements and biospecimens to be collected, the order of interview stages, and the conditions for passing from one stage to another.

Based on how your research study configured Onyx, Onyx may inform you that a stage is contraindicated or prompt you about what to do during a certain stage.
For example because of the participant’s answers to certain questions, Onyx might prompt you about how to measure the participant’s blood pressure: **Use the participant’s right arm to take blood pressure**

- Onyx does not allow you to analyze the data collected from participants. It can export the data to other destinations where the analysis can be done.
- Onyx is not a Laboratory Information Management System (LIMS). It does not track processing of biospecimens.

### 8.5 Who makes Onyx?

Onyx is developed by OBiBa, a collaborative international project whose mission is to build high-quality open source software for biobanks. To learn more about OBiBa, please have a look at our website.

### 8.6 Onyx user support

- You can reach Onyx customer support by email at: support@obiba.org
- You can join the OBiBa users group. New releases of Onyx are announced through this group. You can use this forum to make comments, to ask questions, and to share ideas with other users of OBiBa software.
- You can visit the OBiBa website where you will find:
  - News stories and presentations about Onyx and other OBiBa products
  - JIRA, an issue-tracking system that allows you to enter bug reports, request new features, and suggest ways to improve Onyx

### 8.7 Attachments:

OnyxUserGuide_1-8.pdf (application/pdf)
This chapter is your starting point for jumping in and starting to use Onyx. Sit down in front of an Onyx workstation and try the things described in this chapter. This chapter covers these topics:

- How to log in
- Onyx home page and the features it shares with other pages of Onyx
- How to start an interview
Onyx stores information about participants in its database on a server computer located in the assessment centre. All Onyx workstations can access the database. The Participants page allows you to view a list of the participants in the database and to find individual participants so that you can view or edit their registration information, and work on their interviews. This chapter includes these topics related to viewing participants in the Participants page:

- The Participants page and its important features
- Key concepts related to viewing participants
- Procedures related to viewing participants
  - Displaying a List of All Participants
  - Displaying a List of Today’s Interviews
  - Displaying a List of Participants Currently Being Interviewed
  - Finding a Participant
  - Viewing a Participant’s Registration Information
  - Determining Who Has a Lock on an Interview

## 10.1 The Participants Page

When you select the Participants tab, the Participants page is displayed. This page gives you access to all the participants in the Onyx database. The Home page gives you one way of finding a participant. The Participants page lets you find a participant in a number of ways. *this figure* shows the Participants page and points out some of its more important features.

Here is an overview of the important features of the Participants page:

- The Participants Search panel — includes three buttons that give you easy access to participants that you often need to view
  - the All Participants button - displays a list of all the participants in the Onyx database
Fig. 1: The Participants page
– the **Appointments of the day** button - displays a list of all the participants who have appointments on today’s date
– the **Interview in progress** button - displays a list of all the participants whose interviews have the status In progress

- The Participant Search field and button - allow you to search for a particular patient by name or ID
- The Participants list occupies the lower part of the page. Initially, it is empty, but after you do a search, it is filled with a list of participants.
- The Actions column contains one or more action links beside each participant. These are the actions you can do for the participant—for example: View their registration information and Interview them.
- The Page selection links ( ). If the Participants list contains many participants, they are displayed on several pages. These links allow you to view the different pages.
- A Locked interview (indicated by a small icon) means that some user is interviewing the participant. See Locked status.

### 10.2 Key concepts

This section contains key concepts related to viewing participants.

#### 10.2.1 🗓 Participants List

A list of participants stored in the Onyx database. When you are in the **Participants** page, you can choose to see some or all of the participants in the Onyx database by filtering the participants list in various ways: by name, enrollment ID, or participant ID. You can view all participants with appointments today or those currently being interviewed.

#### 10.2.2 🗓 Appointment List

A list of appointments stored in a file or created in a programme other than Onyx. Since Onyx does not allow you to schedule appointments for participants, it imports an appointment list from a file or another programme. Onyx users of the type participant manager can update the appointment list. As a minimum, the appointment list contains the following information for each participant:

- participant name
- appointment date and time
- enrollment ID

The appointment list may contain other information depending on how Onyx was configured for your study.

#### 10.2.3 🗓 Enrollment ID

A unique identifier for a participant that is imported into Onyx from the appointment list. Enrollment IDs are either assigned automatically by the programme that schedules appointments, or they are defined in the file containing the appointment list. After the participant has been received, the Enrollment ID is not used very much in Onyx. Instead, the Participant ID is used to identify the participant during the interview. However, you can search for a participant by their Enrollment ID. You may notice that some participants do not have an Enrollment ID. This is probably because your study accepts Volunteer Participants. Volunteers do not have an enrollment ID since they were never on an appointment list.
10.2.4 Participant ID

A unique identifier for a participant that must be entered in Onyx when the participant arrives at the assessment centre and at various times during the interview. Each study or assessment centre decides how it will assign Participant IDs and the format of its Participant IDs (the pattern of numbers and letters in the ID). Some studies use barcodes that can be scanned and displayed automatically in Onyx. Other studies will require you to enter the Participant ID manually.

10.2.5 Participant Barcode

A barcode that is used for the Participant ID. Some studies use a barcode as the source of Participant IDs. The barcodes may be on a blood collection tube, an ID bracelet, or a label of some sort. If your study uses barcodes, a barcode scanner will be connected to your Onyx workstation so that you can easily obtain the Participant ID.

10.2.6 Interview Status

The current state of a participant’s interview. See also Stage Status. The status of a participant’s interview appears in the Status column of the Participants list. Before a participant has been received, nothing appears in the status column for that participant. After a participant has been received, their interview can have one of these statuses:

- **In Progress** — This status means that the participant has been received and that their interview has been started. Even if the participant leaves the room for some reason (and a stage of their interview has been paused), the status of their interview remains In Progress. See Displaying a list of In Progress interviews.

- **Locked** — The lock icon means another staff member is interviewing the participant. If you suspect that there is a problem or if you need to work on the interview, contact your participant manager who can remove the lock, if necessary. See Unlocking an Interview.

- **Completed** — This status means that the interview was completed and that all stages were completed successfully and the interview was concluded correctly by a staff member.

- **Closed** — This status means that the interview was closed without all the stages being completed. An interview can be closed at any stage, if necessary. A closed interview cannot be restarted. The data collected cannot be changed in any way. Depending on how your study configured Onyx, it may or may not be possible to export the data. See Closing an Interview.

- **Cancelled** — This status means that the participant was withdrawn from the study. A staff member cancelled the interview. A cancelled interview cannot be restarted. See Cancelling an Interview.

Your study customized what Onyx does when an interview is cancelled or closed. It may delete the participant or may keep some or all of the data so it can be exported.

10.3 Procedures

10.3.1 Displaying a List of All Participants

You can view a list of all the participants in the Onyx database: past and future participants, as well as those whose interviews are scheduled for the current date—today. The list does not include participants that have been purged from the Onyx database. See Data Purge.
Procedure

1. If the Participants page is not displayed, click the Participants tab.

2. Click the All Participants button. The Participants page is updated to show all participants in the Onyx database.

![Fig. 2: The Participants page](image)

10.3.2 Displaying a List of Today's Interviews

You can view a list of all the participants whose interviews are scheduled for the current date—today.

Procedure

1. If the Participants page is not displayed, click the Participants tab.
2. Click the **Appointments of the day** button. The **Participants** list is updated to show all participants who have interviews today.

![Fig. 3: The Participants page](image)

### 10.3.3 Displaying a List of Participants Currently Being Interviewed

You can view a list of all the participants whose interviews have the status **In Progress**. This status does not necessarily mean that the participant is seated with a staff member and that data is being collected from the participant. **In Progress** simply means that the participant’s interview was started and that it is not finished yet.

**Procedure**

1. If the **Participants** page is not displayed, click the **Participants** tab.
2. Click the **Interviews in progress** button.

   - The **Participants** list is updated to show all participants whose interviews have the status **In Progress**.
Fig. 4: The Participants page
If you see a 🗝 icon at the end of the row for the participant, this indicates that an Onyx user has a lock on the interview. See *Determining who has a lock on a participant*.

### 10.3.4 Finding a Participant

Onyx gives you several ways to find participants. This table summarizes the techniques you can use to search for participants.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scan participant’s barcode (or enter participant ID manually) in the Home page and click <strong>Go to interview</strong></td>
<td>The participant’s Interview page opens.</td>
</tr>
<tr>
<td>Scan participant barcode (or enter participant ID in the search field) in the Participants page and click</td>
<td>The Participants list is updated and will include only one participant—the one with the scanned barcode</td>
</tr>
<tr>
<td>Enter participant ID or enrollment ID in search field on the Participants page and click</td>
<td>The Participants list will be updated and will include only one participant—the one with the ID that you entered.</td>
</tr>
<tr>
<td>Enter all or part of participant’s name in search field in the Participants page and click</td>
<td>The Participants list is updated—it contains one or more participants, depending on what you entered and the names of the participants in the database.</td>
</tr>
<tr>
<td>Sort the Participants list by clicking on the heading of a column. You can sort on:</td>
<td>The Participants list will be reordered according to the column you selected. Examples:</td>
</tr>
<tr>
<td>• Enrollment ID</td>
<td>• If you click on First Name, the list will be displayed in alphabetical order by participants’ first names.</td>
</tr>
<tr>
<td>• Participant ID</td>
<td>• If you click on Enrollment ID, the list will be displayed in numerical order of enrollment IDs.</td>
</tr>
<tr>
<td>• Last Name</td>
<td></td>
</tr>
<tr>
<td>• First Name</td>
<td></td>
</tr>
<tr>
<td>• Appointment</td>
<td></td>
</tr>
</tbody>
</table>

If you cannot find a particular person who has arrived for an interview, a couple of explanations are possible:

- The appointment list may not be up-to-date.
- The person does not actually have an interview.

In either case, contact your participant manager who can update the appointment list or enroll a volunteer if your study accepts them.

### 10.3.5 Viewing a Participant’s Registration Information

After a participant has been added to the Onyx database (either through an update of the appointment list or when they were enrolled as a volunteer), you can view their registration information.

**Procedure**

1. If the Participants page is not displayed, click the Participants tab.
2. Find the participant whose information you want to view. If you need help finding the participant, see *Finding a Participant*. When the Participants list is displayed, a View link appears (in the Actions column) for the participant.
Fig. 5: To view a participant’s registration information, click their View link.
3. Select the View link for the participant. The Participant dialog is displayed. Each study defines the information that is stored for its participants. You may not see the same fields as those shown in this figure.

4. When you have finished viewing the information, select the Close button. The Participant dialog closes.

10.3.6 ✉ Determining Who Has a Lock on an Interview

If a lock icon 🗝️ is displayed at the right end of the row for a participant in the Participants list, an Onyx user has a lock on the interview, they are probably in the middle of an interview stage. You might even have a lock on the interview yourself, if you logged in on another workstation and worked on the interview from there. You can find out who has a lock on the interview as follows:

1. Move the mouse until the arrow cursor is on the lock icon and do not move the mouse for a few seconds. ✉ A small popup message will show the name of the person who has the lock on the interview. See this figure.

   To see who has a lock on an interview, position the mouse cursor on the lock icon and do not move the mouse.

If necessary, your participant manager can unlock the interview. See Unlocking an interview.
Fig. 6: Participant dialog each study defines the information that is stored for participants

<table>
<thead>
<tr>
<th>Participant</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment ID</td>
<td><strong>100080</strong></td>
</tr>
<tr>
<td>Participant ID</td>
<td><strong>234234</strong></td>
</tr>
<tr>
<td>Name</td>
<td><strong>John Baker</strong></td>
</tr>
<tr>
<td>Gender</td>
<td><strong>M</strong></td>
</tr>
<tr>
<td>Birth Date</td>
<td><strong>1970-06-06</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Street</td>
<td><strong>799 Lakeshore Rd</strong></td>
</tr>
<tr>
<td>City</td>
<td><strong>Pointe-claire</strong></td>
</tr>
<tr>
<td>Province</td>
<td><strong>QC</strong></td>
</tr>
<tr>
<td>Country</td>
<td><strong>CA</strong></td>
</tr>
<tr>
<td>Postal Code</td>
<td><strong>H8R 2W3</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>514-343-9898 ext 9573</strong></td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>Actions</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------</td>
</tr>
<tr>
<td>In Progress</td>
<td>View Interview</td>
</tr>
<tr>
<td></td>
<td>Edit</td>
</tr>
<tr>
<td>In Progress</td>
<td>View Interview</td>
</tr>
<tr>
<td>Dana Thomas</td>
<td>has a lock on</td>
</tr>
<tr>
<td></td>
<td>this interview</td>
</tr>
<tr>
<td>In Progress</td>
<td>View Interview</td>
</tr>
<tr>
<td>In Progress</td>
<td>View Interview</td>
</tr>
<tr>
<td>In Progress</td>
<td>View Interview</td>
</tr>
</tbody>
</table>
CHAPTER 11

Participant Managers

This section covers topics of interest to Onyx users of type participant manager, including:

- **Key concepts** related to viewing participants
- Procedures that can only be done by participant managers:
  - Receiving a participant;
  - Enrolling a volunteer participant (customizable)
  - Enrolling a Participant from an External System
  - Editing a participant’s registration information
  - Updating the appointment list
  - Unlocking an interview

11.1 Key concepts

This section contains concepts of interest to participant managers.

11.1.1 Receiving vs. Enrolling a Participant

Some studies invite people to participate in the study and set up appointments to interview them. These participants are added to the Onyx database when the appointment list is updated (see *Updating the Appointment List*). When a participant arrives at the centre for their interview, a participant manager receives them. Receiving a participant involves finding the participant in Onyx, assigning a Participant ID, and checking some information about the participant that Onyx already obtained from the appointment list. See *Receiving a Participant*. Some studies accept volunteer or walk-in participants. When a volunteer participant arrives at an assessment centre, a participant manager must enroll them. Enrolling a participant involves assigning a Participant ID and entering some information about the participant. See *Enrolling a Participant*. 
Enrolling volunteer participants is a customizable feature of Onyx. If your study accepts volunteers, participant managers will see the Enroll volunteer button in the upper right corner of the Participants page. See this figure.

**Fig. 1: If your study accepts volunteers, participant managers will see an Enroll Volunteer button in the Participants page**

### 11.2 Receiving a participant

When a participant (who has been invited to participate in the study) arrives at the site for their interview, a participant manager must receive them as explained in this section. You will have to assign a Participant ID number, the number that will be used to track the participant during the interview and, will probably be used to track their data for the duration of the study. It is important to review the list of participants carefully when registering a new participant and assigning them a Participant ID.

#### 11.2.1 Prerequisites

- You must be an Onyx user of type participant manager
- The appointment list should have been updated recently to ensure that the participant is in the Onyx database. See *Updating the Appointment List.*
- You must be prepared to assign a new Participant ID to the participant.

Each study determines how it will assign Participant IDs: either by scanning a barcode or by manually entering a number in a certain format and from a certain series of numbers.
11.2.2 Procedure

1. If the Participants page is not displayed, select the Participants tab to display it. (see this figure)

![Fig. 2: The Participants page as it appears to participant managers](image)

2. Search for the participant in any of the ways described in Finding a Participant. After you find the participant, their name is displayed in Participants list and Receive appears in the Actions column for the participant. See this figure.

3. Select the Receive link for the participant that you want to receive. The Participant Reception page is displayed. See this figure.

   If Onyx has been configured to generate participant identifiers, the Participant ID field will have a Generate ID button next to it. Click on this button to automatically generate an ID for the participant being received. See this figure

4. If your study requires that you check a photo ID of the participant, now would be a convenient time to do so.

5. Check the information in the Participant Registration page with the participant and correct it, if necessary. Ensure that all required fields (marked with asterisks) are filled in. Fill in optional fields if the participant is willing to provide the information.
   The fields you see were defined by your study and may be different from those shown in this figure.
Fig. 3: Finding the participant that you want to receive
To receive a participant, you need to check the information here... ...and scan a barcode or manually enter a Participant ID here... ...and select Save here

Fig. 4: Example of the Participant Reception page the fields are defined by the study page

Fig. 5: Participant ID field with Generate ID button

11.2. Receiving a participant
Some fields are already completed with information that is in the appointment list. Certain key information (such as Enrollment ID in this figure) cannot be edited.

6. Assign a participant ID by scanning a new barcode or by entering a value manually in the Participant ID field.

7. If you decide not to proceed with receiving the participant, select the Cancel button. The Participant Reception page closes and the Participants page is redisplayed unchanged.

8. If you want to go ahead with receiving the participant, select the Save button. The Participant Reception page closes and the Participants page is redisplayed.

The Status of the participant’s interview has been updated to In Progress and Interview has been added in the Actions column for the participant. See this figure.

Fig. 6: After you receive a participant, the Participants page is updated

9. If there are several pages of participants in the list, you can step through the pages in the list or search for the participant in order to confirm the change in their status or start the interview.

The participant can now be interviewed. See The Simplest Way to Start an Interview or Entering the Interview page.
11.3 Enrolling a volunteer participant (customizable)

If your study accepts volunteer participants, a participant manager can enroll them as explained in this section. You will have to assign a Participant ID number, the number that will be used to track the participant during the interview and, will probably be used to track their data for the duration of the study. It is important to review the list of participants carefully when registering a new participant and assigning them a Participant ID.

11.3.1 Prerequisites

- You must be an Onyx user of type participant manager
- Your study accepts volunteer participants. The Enroll volunteer button is displayed in the Participants page as shown in this figure.
- You must be prepared to assign a new Participant ID to the participant.

Each study determines how it will assign Participant IDs: either by scanning a barcode, by manually entering a number in a certain format and from a certain series of numbers, or by automatically generating an ID.

11.3.2 Procedure

1. If the Participants page is not displayed, select the Participants tab to display it. The Enroll volunteer button is displayed in the upper right corner.(see this figure).
2. Select the Enroll volunteer button. The Volunteer Registration page is displayed. See this figure.
   The fields you see were defined by your study and may differ from those shown in this figure.
3. If your study requires that you check a photo ID of the participant, now would be a convenient time to do so.
4. Complete the fields. Required fields are indicated with an asterisk. You can scan a barcode to obtain a participant ID or enter a value manually.
5. If you decide not to enroll the participant, select the Cancel button. The Volunteer Registration page closes and the Participants page is redisplayed unchanged.
6. If you want to go ahead with enrolling the participant, select the Save button. The Volunteer Registration page closes and the Participants page is redisplayed.
   The participant’s status updated to In Progress and Interview has been added in the Actions column for the participant. See this figure.

11.4 Enrolling a Participant from an External System

If Onyx has been configured to look up participant information stored in an external system (a “participant registry”), the enrollment procedure is slightly different. You will first search for the participant in that system, using whatever unique identifier that system requires. After that, you will assign to that participant a Participant ID.

11.4.1 Prerequisites

The prerequisites are the same as in “regular” enrollment.
Fig. 7: Example of the Volunteer Registration page the fields are defined by the study
After you enroll a volunteer, the status of their interview is set to In Progress here...

...and Interview is added to the list of available Actions here.

Fig. 8: After you enroll a volunteer, the Participants page is updated
11.4.2 Procedure

1. The Participant Registry button is displayed in the upper right corner of the Participants page. See this figure.

![Participant Registry button]

Fig. 9: Participant Registry button

2. Select the Participant Registry button. The Participant Registry Lookup pop-up window is displayed. See this figure.

   The fields you see were defined by your study and may differ from those shown in this figure.

3. Enter the participant’s unique identifier and select Lookup. Upon a successful lookup, the participant fields will be filled in with the retrieved information.

4. To enroll the participant, select Receive. The Volunteer Registration page will be displayed. Now proceed the same way as with “regular” enrollment.

5. If you decide not to enroll the participant, select the Cancel button. The Participant Registry Lookup pop-up window closes and the Participants page is redisplayed unchanged.

11.5 Editing a participant’s registration information

After a participant has been received or enrolled, a participant manager can edit their registration information. It is potentially dangerous to change a participant’s registration information after their interview has been started. For example, changing the participant’s gender could cause a problem since some physical measurements and questionnaires depend on it. Onyx does not prevent you from creating this kind of problem. Each study defines the registration information that is stored for a participant. Certain key information (such as the participant’s name and ID numbers) cannot be changed after the participant was received or enrolled. Other information can be modified.

11.5.1 Prerequisites

You must be an Onyx user of type participant manager

11.5.2 Procedure

1. If the Participants page is not displayed, click the Participants tab.

2. Find the participant whose information you want to edit. If you need help finding the participant, see Finding a Participant.

   When the Participants list is displayed, an Edit link appears (in the Actions column) for the participant. See edit-a-participant-s-registration-information
Fig. 10: Example of the Participant Registry Lookup pop-up. The fields are defined by the study.
Fig. 11: To edit a participant’s registration information, click their Edit link.
3. Select the **Edit** link for the participant. The **Edit Participant** dialog is displayed. See *this figure.*

Each study defines the information that is stored for its participants. You may not see the same fields as those shown in *this figure.*

4. Make the necessary changes. Certain key information (such as the participant’s name and ID numbers) cannot be edited.

5. If you decide not to store the changes, select the **Cancel** button.

6. If you want to proceed with changing the information, select the **Save** button. The **Edit Participant** dialog closes. Your changes have been stored in the Onyx database.

### 11.6 Updating the appointment list

Onyx does not schedule appointments for participants. Instead it imports an appointment list from a file. The appointment list is updated automatically. If necessary, Onyx users of type participant manager can also update the appointment list manually as explained in this section. Your study customized how often the appointment list is updated. Contact your system administrator if you want to know how often the list is updated or have any other questions about the list.

#### 11.6.1 Prerequisite

- You are an Onyx user of type participant manager.
- If you want to select an appointment list file, you must know the name and location of such files. Appointment files usually have an XML or XLSL extension.

Each study customizes its appointment list. Your study defined the file type, name, and location, as well as the information stored for each participant. Contact your system administrator to know more about appointment list files for your study.

#### 11.6.2 Procedure

1. If the **Participants** page is not displayed, select the **Participants** tab to display it. The **Update appointment list button** is displayed in the upper right corner. See *this figure.*

2. Select the Update appointment list button. The Update Appointments dialog is displayed. See *this figure.*

3. If you want to use the appointment file from the default location, select the first option button (**Update appointments with the latest appointment file available**).

4. If you want to search for an appointment list file to use for the update, select the second option button (**Update appointments with an alternative appointment file**). If you need help locating a file, contact your system administrator.

5. If you decide not to update the list, select the **Cancel** button. The **Update Appointments** dialog is closed and the Participants page is visible again.

6. If you want to proceed with updating the list, select the Update Appointments button. During the update, a progress bar is displayed in the dialog. When the update is complete, the dialog displays a report about the update. See this figure.

7. Select the **Details** button if you want to read more about how the update went. A **Log** dialog is displayed. If any errors were reported in the log, contact your system administrator.

When you have finished viewing the log, select the **Close** button of the dialog.
Fig. 12: Edit Participant dialog each study defines which information is stored for its participants.
Fig. 13: Participant managers see the Update appointment list button in the Participants page

11.6. Updating the appointment list
Fig. 14: The Update Appointments dialog

Fig. 15: The Update Appointments dialog displays a report when the update is complete
8. When you have finished viewing the report in the Update Appointments dialog, select its Close button. The dialog is closed and the Participants page is visible again. The list of participants is now up-to-date.

11.7 Unlocking an interview

When a staff member is in the middle of an interview stage with a participant, that staff member has a lock on the interview. This prevents conflicts in storing data. Occasionally, you may need to unlock an interview. For example, a technical problem may be preventing the interview from being released, or the staff member who has a lock on the interview is not able to continue the interview. A participant manager can unlock the interview as explained in this section.

11.7.1 Prerequisite

You are an Onyx user of type participant manager.

11.7.2 Procedure

1. If the Participants page is not displayed, select the Participants tab to display it.
2. Locate the participant whose interview is locked. See this figure.
3. Select the Interview link for the participant whose interview you want to unlock. A message is displayed asking you to confirm that you want to unlock the interview.
4. If you decide not to unlock the interview, select the No or Cancel button. The Participants page is visible displayed. The interview is still locked.
5. To unlock the interview, select the Yes button. The Interview page for the participant is displayed.
6. To allow another Onyx user to work on the interview, select the Exit X button. The Interview page closes. The Participants page is visible displayed. The interview is unlocked.
Fig. 16: A participant manager can unlock an interview in the Participants page.

A lock icon means the interview is locked.

To unlock it, click the Interview link.
11.7. Unlocking an interview

Fig. 17: A message asks you to confirm that you want to unlock the interview
Interviewing a participant in Onyx is a multiple stage process. You enter and control the interview from one place, the Interview page, which gives you access to all the stages of the interview for a particular participant. Interview stages include everything from signing a consent form to concluding the interview. Most stages are questionnaires, collection of biospecimens, and physical measurements. Due to Onyx’s high degree of customizability, this chapter cannot cover the actual stages defined by your study. Instead, this chapter covers the features and procedures that allow you to start an interview, to work your way through the stages of the interview, and to end an interview a safe way in various circumstances. By safe, we mean, so that you do not lose any data that you have collected. This chapter covers these topics:

- The Interview page and its important features
- Key concepts related to the interview workflow
- The interview workflow broken down into steps
- Routine procedures at the interview level
- Routine procedures at the stage level
- Procedures for unusual situations

12.1 Interview page

When you find a participant and click their Interview link, the Interview page is displayed. This page gives you an overview of a participant’s interview and shows the status of each interview stage. It is from this page that you start working on each stage of an interview and to which you are returned after a stage is complete. This figure shows the Interview page and points out some of its more important features.

Here are the important features of the Interview page:

- Interview Exit buttons. The Exit X and the Exit this interview button both close the Interview page properly. They release the lock that was put on the interview when you entered the Interview page. See Obtaining a Lock on an Interview.

You can select either Exit button when you need to leave the Interview page before the interview is complete.
Fig. 1: The Interview page
They can be used at any time and do not affect the status of the interview. Some examples of when you would exit an interview (using either of these buttons):

- After you complete a stage and need to take a break
- After you view the state of the participant’s interview for information purposes
- When you have finished the stages for which you are responsible and are ready to pass the participant over to another staff member

The two Exit buttons function in exactly the same way—there are two of them for convenience sake.

- After you complete a stage and need to take a break
- After you complete a stage and need to take a break
- After you complete a stage and need to take a break

• The **Onyx Exit button** (the X in the upper right corner of the Onyx window—see this figure) is not the same as the **Interview Exit** buttons.

  If you select the **Onyx Exit button** while in the **Interview** page, Onyx will close immediately without releasing your lock on the interview.

  The next time anyone (including you) looks for the participant in the **Participants** list, a lock will be displayed on the interview.

  A participant manager will have to unlock the interview. See Unlocking an interview.

• **Close button** — You select this button if you need to end the interview early (before all stages are complete), but do not need to withdraw the participant from the study.

  **CAUTION**: If you select **Close**, you will not be able to resume the interview.

  Each study defines what will be done with the data acquired to the point of stopping an interview in this way.

• **Print Reports** button — Each study can define one or more reports that can be printed and given to the participant.

  You can select this button after any stage of an interview. It allows you to print reports as you go along rather than waiting until all stages are complete.

• **Cancel** — You select this button if you need to cancel the interview and withdraw the participant from the study.

  **CAUTION**: If you select **Cancel**, you will not be able to resume the interview.

  Each study defines what will be done with the data acquired to the point of cancelling the interview.

• **Log panel** (in the Interview section of the page) — You use the buttons in this panel to view system messages and user comments for all the stages of the interview.

  You can also enter general comments about the interview.

• **Log column** (in the Stages section of the page) — You click the icons in this column to view logs (system messages and user comments) about particular stages of the interview.

  You can also view a list of user comments only for a particular stage.

• ![View button] — The **Interview** page contains several of these buttons: one for the interview in general, one for each interview stage that has been started.

  When you want to view a particular log, click its ![View button].

• ![Comments button] — Onyx users can add comments about the interview in general and about individual interview stages.

  The **Interview** page contains one or more of these buttons: one for the interview in general and one for each interview stage that has user comments.

  When you want to view user comments, click the appropriate ![Comments button].
• **Status** column (in the Stages section of the page) indicates the status of each stage of the interview. See Stage Status.

• **Actions** column (in the Stages section of the page) indicates the actions that are available for each stage of the interview. See Stage Actions.

### 12.2 Key concepts

This section contains key concepts related to working your way through the stages of an interview.

#### 12.2.1 🛠 Obtaining a Lock on an Interview

When you enter the **Interview** page of a participant, you obtain a lock on the interview. No other user can access the participant’s Interview page until you exit the **Interview** page properly (by selecting an Interview Exit button—see **Interview Exit buttons**). If Onyx crashes or if you exit the Interview page improperly (by selecting the Onyx Exit button—see this figure), a participant manager will have to unlock the interview. See **Unlocking an Interview**.

#### 12.2.2 🛠 Stage Status

An interview stage passes through various statuses from “ready” to “completed”. Each type of stage (consent, questionnaire, physical measurement, specimen collection, interview conclusion) follows a particular path through the statuses. The **Actions** that are available depend on the **Status** of the stage Each study defines the conditions that are required for a stage’s status to change. A study can customize the names of the statuses that appear in the **Interview** page.

#### 12.2.3 🛠 Stage Actions

The **Actions** column lists the actions that are available to you for a particular stage of the interview. The **Actions** depend on the **status** of the stage. Each study defines the actions that are available when a stage has a certain status. A study can also customize the names of the actions that appear in the **Interview** page. Despite all the customization that Onyx allows, only five stage actions are possible: By default, the actions have the names indicated in this list.

- **Start** — You select this action to start a stage.
- **Skip** — You select this action to skip a stage. Some examples of why you might need to skip a stage: the stage is **Not ready**; it is more convenient to do the stage later; another staff member is responsible for the stage.
- **Reinstate** — You select this action to redo a stage that was skipped.
- **Cancel** — You can cancel a stage that is contraindicated or not applicable for some reason.
- **Review** — You can review a stage that was contraindicated in order to determine if the contraindication is appropriate or, if the answers that caused it should be corrected so that the contraindication will be removed.

#### 12.2.4 🛠 Closing vs. Cancelling an Interview

Closing an interview means ending the interview early before all stages have been completed (or skipped, if your study permits). The participant is not withdrawn from the study. Cancelling an interview means withdrawing the participant from the study. The decision to withdraw a participant may come from the participant or a staff member. **CAUTION:** If you select the **Close** or **Cancel button** in the **Interview** page, you will not be able to continue the interview with...
the participant later. If you want to leave the Interview page temporarily and continue the interview later, you need to exit the Interview page. Each study defines what will be done with the data acquired to the point of closing or cancelling an interview.

12.2.5 Reviewing vs. Reinstating a Stage

You can review a stage if its status is **Contraindicated**. If you review the stage and change the condition (for example, the answer to a particular question) that caused the stage to be contraindicated, you can actually change the status of the stage from **Contraindicated** to **Ready**. You can reinstate a stage that was skipped. When you reinstate a stage, its status will change to **Ready** and it will be possible to **Start** the stage again.

12.2.6 Action Windows

Depending on how your study customized Onyx, Onyx may display an action window when you select an **Action** in the Interview page. These windows usually require you to enter your password and the Participant ID (you can scan the barcode or enter it manually). An action window may contain other fields depending on the action that you selected and how your study customized the window. The purpose of action windows is to ensure the integrity of the data being collected. When you enter your password, you confirm that it was actually you who carried out the action. When you enter the Participant ID, you confirm that the data is indeed being collected for the correct participant.

---

12.2.7 Stage Navigation Buttons: Previous, Next, Finish

When you are in a stage, you will see various buttons at the bottom of the page. These buttons allow you to move back and forth through the pages of the stage and to finish the stage. See this figure. By default, the buttons are named as shown in See this figure. Your study may have changed the names on the buttons.

You use the buttons as follows:

- **Next** button — Select it to display the next page in the stage.
- **Previous** button — Select it to display the previous page in the stage if you need to check or change something in that page.
- **Finish** button — This is only displayed when you are on the last page of a stage. You select it when you are ready to complete the stage.
- You can also use hot keys to navigate through the pages. See Hot Keys Hot Keys.

12.2.8 Administration Button and Administration Dialog

The **Administration** button is always displayed at the bottom of the page during an interview stage. When you select the **Administration** button, the **Administration** dialog is displayed. See this figure. You access this dialog when you need to pause or cancel the stage. For a questionnaire stage, the dialog includes **First** and **Last** buttons. These buttons allow you to jump directly to the first and last pages that need your input. If no pages require your input, they jump to the first page or last page of the questionnaire.
Fig. 2: Example of the action windows that may be displayed during an interview

Fig. 3: The buttons that allow you to move through and finish the pages of an interview stage
12.2.9 📝 Hot Keys

To make the task of completing long questionnaires easier, Onyx allows you to use certain keyboard keys in a special way. When you are working in a stage, you can use these hot keys instead of having to use the mouse to select buttons. This figure lists the hot keys available during interview stages.

<table>
<thead>
<tr>
<th>Onscreen Button</th>
<th>Hot Key</th>
<th>Effect</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next</td>
<td>The + key on your keyboard</td>
<td>Displays next page of the stage</td>
<td>Don’t press Shift. Works for all kinds of stages, but not on the last page of a stage.</td>
</tr>
<tr>
<td>Previous</td>
<td>The — key on your keyboard</td>
<td>Displays previous page of the stage</td>
<td>Don’t press Shift. Works for all kinds of stages</td>
</tr>
<tr>
<td>Finish</td>
<td>The F key on your keyboard</td>
<td>Finishes the stage. The stage closes and you are returned to the Interview page.</td>
<td>Don’t press Shift. Works for all kinds of stages, but only on the last page of a stage.</td>
</tr>
<tr>
<td>Administration</td>
<td>The A key on your keyboard</td>
<td>Displays the Administration dialog.</td>
<td>Don’t press Shift. If a text field is selected (the focus is on the text field), this hot key will not work. This is so you will be able to enter the letter “a” in the text field.</td>
</tr>
<tr>
<td>First</td>
<td>The Home key on your keyboard</td>
<td>Jumps to the first page that needs your input. If no page requires your input, it jumps to the first page of the questionnaire.</td>
<td>Only works in questionnaire stages</td>
</tr>
<tr>
<td>Last</td>
<td>The End key on your keyboard</td>
<td>Jumps to the last page that needs your input. If no page requires your input, it jumps to the last page of the questionnaire.</td>
<td>Only works in questionnaire stages</td>
</tr>
<tr>
<td>The X button in the corner of a dialog</td>
<td>The Esc key on your keyboard</td>
<td>Closes any dialog or small window that is displayed on top of a stage page.</td>
<td>Does not work on stage pages</td>
</tr>
</tbody>
</table>
12.2.10 Log

In the Interview page, a log contains a list of system messages and user comments. A log can either be about the interview as a whole, or about a particular stage of the interview. The list is in chronological order—the oldest entry is at the top, and the most recent entry is at the top bottom.

12.2.11 Comment

In the Interview page, a comment list only contains comments added by users. Depending on which button you select, the list of comments will either be about the interview as a whole, or about a particular stage of the interview. The list is in chronological order—the oldest entry is at the top, and the most recent entry is at the top bottom.

12.3 The interview workflow broken down into steps

Due to Onyx’s highly customizable nature, we cannot tell you which stages you will see when you enter the Interview page or the exact names of the stage statuses and stage actions that you will see, but we can tell you–more or less–what you will do each time you enter the Interview page.

12.3.1 Basic Workflow

The basic workflow of an interview is as follows:

1. **Enter the Interview page.** You enter the Interview page. You look at the list of stages and determine the next stage that must be done.
   Consent is usually the first stage. If it hasn’t been obtained, you must obtain it.
2. **Start a Stage.** You start a stage. You would usually do the next stage that is “ready” and has a “start” action available for it.
   Depending on how your study customized Onyx, an action window may be displayed when you select a stage action (start, pause, resume, and so on).
   If an action window is displayed, you must complete it to confirm your identity and the identity of the participant, and, in some cases, to enter a comment explaining why the action was necessary.
3. **Work your Way through the Stage.** When you are inside a stage, you follow the directions displayed onscreen to collect the data required for the stage.
   You step through the pages of the stage by selecting the Next and Previous buttons. If you need to pause or cancel the stage, you select the Administration button.
4. **Finish the Stage.** When you have completed all the pages of a stage, the Finish button is displayed. You select the Finish button.
   Depending on how your study customized Onyx, you may have to complete an Action dialog.
   After that, you can start working on another stage or you can exit the Interview page (for example, you may need to take a break or pass the interview over to another staff member).
5. **Do all data-collecting stages.** You would repeat B, C, and D for each stage.
6. **Conclude the Interview.** Studies usually define a conclusion stage. If your study defined a conclusion stage, you would do it after all data-collecting stages have been completed (or skipped if your study allows this for certain stages).
   You complete a conclusion stage in the usual fashion: start, next, next, next, finish. After, this all the stages will have the status “completed” (or “skipped”).

Chapter 12. Managing an Interview
The interview is closed. You cannot make any changes to the data.

7. **Exit the Interview.** You exit the Interview page in the usual way, by selecting either of the Interview Exit buttons.

### 12.3.2 Common Alternative Steps

Here are some alternative steps that you will probably use fairly often:

- **Pause the Stage.** If you need to pause a stage, you select the Administration button and then the Pause button in the Administration dialog.
  
  You will have to fill out an Action dialog again to confirm your identity and the participant’s identity. After that, you can exit the Interview page.
  
  Later, when you or another Onyx user wants to continue working on that stage, you re-enter the Interview page, and you will be able to resume the stage.

- **Exit the Interview.** If you leave a stage by pausing or finishing it. You can exit the Interview page, if necessary, by selecting either of the Interview Exit buttons.
  
  You will be able to re-enter the stage later, if you need to complete it or modify it.

- **Re-enter the Interview page of a participant.** You can always re-enter the Interview page of a participant immediately or afterward, by selecting the Interview action for the participant in the Participants page.
  
  You might want to do this in order to modify the data collected during a stage or to check how the interview went: were all stages completed, what were the user comments and system messages, how long a stage took, and so on.

### 12.3.3 Occasional Alternative Steps

Here are a few alternative steps that you may use occasionally:

- **Skip a Stage.** If you need to skip a stage (usually because of a technical problem like an instrument not being available for a physical measurement), you can select “skip” in the Actions column of the Interview page.
  
  You may or may not be able to complete the interview if it has skipped stages—it depends on how your study defined the conditions for completing the study.

- **Modify a Stage.** Occasionally, you may need to change a participant’s answer to a question, or some other data collected during a stage.
  
  To do this, you modify the stage which opens the stage again. You can step through the pages of the stage and make the necessary changes.

- **Delete a Stage.** Occasionally, you may want to get rid of the data collected during a stage and start the stage over again.
  
  To do this, you delete the stage. Then you will be able to start it again.

### 12.3.4 Rare Alternative Steps

These are alternative steps that you will use rarely:

- **Cancel the Interview.** If the participant decides they don’t want to be part of the study, you can withdraw them by cancelling the interview.
  
  In this case, you select the Cancel button in the Interview page. You will have to complete an Action dialog as usual.
  
  Your study will have decided what it wants to do with the data acquired up to the point of cancelling an interview. Follow the onscreen directions.
• **Close the Interview.** If the participant has done part of the interview, but must leave early for some reason, you can end the interview early, without actually withdrawing the participant. In this case, you select the Close button in the Interview page. You will to complete an Action dialog. Your study will have decided whether it will keep or delete the data acquired up to this point. Follow the onscreen directions.

• **Reinstate the Interview.** If by mistake you cancel or close the interview, you can restore the interview to its earlier state by selecting the Reinstate button in the Interview page. See *this figure*

![Reinstate](image)

*Fig. 5: To reinstate a cancelled or closed interview, select Reinstate in the Interview page*
12.4 Routine procedures at the interview level

12.5 Routine procedures at the stage level

12.6 Procedures for unusual situations
Onyx can be customized to meet the needs of any organization that is collecting data from participants for a medical research study. Customizing Onyx involves creating custom questionnaires and configuring Onyx to collect the physical measurements and biosamples required by the study.

13.1 Planning Your Customization

Note: To the Organization that is Customizing Onyx

We recommend that you plan your customization of Onyx using this spreadsheet. The completed spreadsheet will serve as a guideline for the programmer who will carry out the customization of Onyx for your organization.
<table>
<thead>
<tr>
<th>Item</th>
<th>Explanation</th>
<th>What you need to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment mode</td>
<td>Onyx can manage participants with appointments or walk-in participants or both.</td>
<td>Decide which enrollment mode(s) you will use.</td>
</tr>
<tr>
<td>Participant information</td>
<td>Before the consent stage, Onyx can capture some identification information about the participant. This information is either provided with the appointment list or obtained when the participant is received. Mandatory fields are: participant ID, name, and DOB. Other fields are configurable. Onyx does not assign participant IDs. The study does. We need to know the format of your participant IDs so Onyx can validate them when participants are received. Participant IDs can be on barcode labels.</td>
<td>Define a list of participant information fields. For each field, define: • name (to be displayed onscreen) • variable name • type (date, list, and so on) • validation rule</td>
</tr>
<tr>
<td>fields</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage ordering</td>
<td>Onyx stages (consent, questionnaires, physical measurements, biosample collection) can be listed onscreen in any order that is convenient for the study.</td>
<td>Define a list of the stages in an interview; in the order that you want them to appear onscreen. For each stage, define: • name of the stage as it should appear onscreen • any stages that must be completed before the current stage can be started (and any data that the current stage must receive from those stage(s)) • any stages that could be contraindicated after the current stage is completed (and any data that the current stage must send to the dependent stage) • whether or not the stage can be skipped</td>
</tr>
<tr>
<td>Consent form</td>
<td>The participant’s signature can be obtained in various ways: Manual, electronic, or both.</td>
<td>Decide which signature modes will you use. If you will accept consent electronically, prepare the</td>
</tr>
</tbody>
</table>
13.2 Who should read this Guide

This guide is mainly for Onyx customizers. By a customizer we mean a programmer who has been asked by an organization to customize Onyx to meet the requirements of their research study. Ideally, this person is somewhat or very familiar with Java and how Java implements web applications. The result of the customizer’s work will be a war file that will be used to install the custom version of Onyx on a server at the site where Onyx will be used.

This guide may also be used by Onyx installers to tweak the Onyx configuration immediately after installation or later. By an installer, we mean the person who will set up the Onyx server and workstations at the site where Onyx will be used. An installer may be a system administrator, an IT person, or even the customizer.
14.1 Introduction

Onyx can be customized to meet the needs of any organization that is collecting data from participants for a medical research study. Customizing Onyx mainly involves creating custom questionnaires and configuring Onyx to collect the physical measurements and biosamples required by the study.
Partners and Funders

The development of this application was made possible thanks to the support of our partners and funders:
Support

Please visit OBiBa support page.