Welcome to TOPAZ Technologies

Welcome to TOPAZ Technologies. TOPAZ provides clinical research software solutions for the medical research industry. With more than 30 years in the industry, TOPAZ is an established leader delivering software solutions for regulatory environments, such as pharmaceutical companies, educational institutions, and research laboratories. Known for its protocol research software, TOPAZ has clients in the United States and Europe.

TOPAZ offers software solutions for compliance management for institutional ethics committees such as Institutional Animal Care and Use Committees (IACUCs), Institutional Review Boards (IRBs), and the Institutional BioSafety Committees (IBCs).

TOPAZ develops and organizes its products into suites of software products , represented as Elements of the complete TOPAZ solution. Currently available products include:

Animal Protocols

BioSafety Protocols

Human Protocols

Conflict Disclosures

Cost Accounting

Animal Orders

Animal Census

Animal Billing

Staff Training

Veterinary Management

Reporter

All products share a data storage system and present a consistent graphical interface to ensure cross-application collaboration.

Your return on investment is streamlined operation, increased productivity, and high-quality information with no integration costs. Backed by a solid product road map and world-class professional services, TOPAZ Technologies software products provide an ideal end-to-end solution as you work to succeed in research. You can be confident that our products meet your needs for regulatory compliance and much more.

TOPAZ Elements 3.3

Human Protocols User Guide

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Resources and Support

Resources

For more information about TOPAZ Technologies applications refer to our built-in online help or contact Client Services at 512.249.8080.

Support

For all support issues your first line of defense should be your local facility resources, such as your facility's information technology (IT) department, administrators, core team members, and project managers. If the TOPAZ Elements software application issues persist, contact TOPAZ™ at support@topazti.com.

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Human Protocols – Introduction

The TOPAZ Elements Human Protocols application assists in the protocol creation and approval process, which is highly regulated. The application can be used by a variety of individuals responsible for studies involving human beings.

Human Protocols enables the following activities:

- **Create and manage forms** - A mechanism is provided to create forms for specific research protocols, reviews and meetings that take place during the submission and approval process.
- **Manage forms** - Forms can be activated, deactivated, and deleted as necessary.
- **Create and submit protocols** - As protocols are created and submitted, track which have been submitted and their status after submission.
- **Manage the review process** - Initiate internal and official reviews of protocols and amendments, and assign reviewers at the appropriate time.
- **Manage meetings** - Schedule meetings, track, invitees, and record minutes.
- **Generate reports** - Create reports on forms, protocols, reviews, and meetings.

Human Protocols is a powerful tool that can capture, and help you manage the entire protocol adoption process, critical to the pursuit of human research.

Human protocols – UI Overview

To access the application, click the **Human Protocols** link, located in the **Compliance** group on the TOPAZ Technologies home screen. This action displays the Main screen for Human protocols, including five icons: **Protocol Forms**,**Protocols**, **Reviews**, **Meetings**, and **Reports**. Placing the cursor over an icon displays available options for that feature.

Protocol Forms

The Protocol Forms feature enables the creation and management of protocol forms. This feature supports seven activities:

- **Create Original Form** - Create forms for the description of new protocols.
- **Create Amendment Form** - Create forms for the purpose of amending existing protocols.
- **Create Renewal Form** - Create forms for renewing existing protocols that are expired or about to expire.
- **Create Interim Review Form** - Create forms that enable an internal review before submission.
- **Create Meeting Form** - Create forms to schedule and manage meetings.
- **Open Active Forms** - Edit and manage forms currently in production.
- **Open Inactive Forms** - Edit and manage forms that have been withdrawn from production.

NOTE: Forms that have been associated with data can be deactivated but may not be deleted.

Protocols

After forms have been created, you can use them to create and mange protocols. The Protocols feature enables this effort.. This feature supports nine activities:

- **Create Original Protocols** - Use forms to create new protocols.
- **Create Amendment Protocol** - Use forms to amend existing protocols.
- **Create Renewal Protocol** - Prepare renewal requests for protocols.
- **Create Interim Review Protocol** - Prepare a protocol for an internal review.
- **Open Unsubmitted Protocols** - View and manage existing protocols that have not been submitted.
- **Open Submitted Protocols** - View and manage existing protocols that have been submitted.
- **Open Returned Protocols** - View and manage existing protocols that have been returned.
- **Open Approved Protocols** - View and manage existing protocols that have been approved.
- **Open Protocol Histories** - View the history of a protocol, such as the number of times they were returned for modifications and when they were approved or denied.

Reviews

As a protocol moves through the approval process, reviews are conducted. The Reviews feature enables tracking scheduled reviews and outcomes. This feature supports four activities:

- **Create Review Assignments** – Create a new review for a submitted protocol.
- **Open Unassigned Protocols** – Manage submitted protocols that have not been assigned a reviewer.
- **Open Assigned Protocols** – Manage submitted protocols that have been assigned a reviewer.
- **Open My Reviews** – Manage reviews that have been assigned to you.

Meetings

Meetings are a requirement of the protocol adoption process. The Meetings feature enables IRB meeting management. This feature supports six activities:

- **Create New Meeting** – Create and schedule IRB meetings.
- **Open Draft Meetings** – Open and modify existing meetings that have not been approved.
- **Open Scheduled Meetings** – Manage existing meetings that have been approved.
- **Open My Meetings** – Review meetings you are scheduled to attend.
- **Open Completed Meetings** – Review scheduled meetings that are complete.
- **Open Approved Meetings** – Manage meetings that have been approved, but not completed.

Reports

The Reports feature enables physical reports of IRB concerns such as protocols reviews and meetings. This feature supports five types of reports:

- **Print Form Reports** – Print copies of forms.
- **Print Protocol Reports** – Print any existing protocol.
- **Print Active & Current Reports** – Print protocols that have not been retired.
- **Print Review Reports** – Print reports on protocol reviews.
- **Print Meeting Reports** – Print reports on any meeting.

Human Protocols – Managing Forms

Form creation is often the first step in the workflow processes for many TOPAZ Elements applications. This topic deals with the various forms that are part of applications involving protocols. These forms can be accessed by placing the cursor over the Protocol Forms icon on the application main screen and selecting one of the form options listed.

TOPAZ Elements forms are used in the same way as any traditional form: to collect and record information. For most organizations, forms are created during the implementation phase. This application's form features are designed to provide you with the flexibility to create and manage either universal or specialized form types.

Forms can be created, edited, or deleted and, once created, may either be active or inactive. Active forms are those that are used in production and inactive forms are those that have been removed from production or are still being developed. Although you have the option of deleting unused forms, if they have ever been used to collect data they must instead be deactivated.

There are five types of protocol forms:

- **Original Forms** - Used by requesters when submitting a protocol request. These forms should capture information needed to ensure compliance and meet local needs for the protocol review process.
- **Amendment Forms** - Used by requesters when amending an existing protocol. They are based on an original form but they are independent from it. They typically contain additional questions specific to the amendment process.
- **Renewal Forms** - Used by requesters when renewing an existing protocol. They are based on an original form but they are independent from it. They typically contain additional questions specific to the renewal process.
- **Interim Review Forms** - Used by requesters when submitting protocol updates for interim reviews. Some organizations require annual reviews to monitor study activities.
- **Meeting Forms** - Used to set agendas and records meeting minutes.

These forms use a common interface that only varies with regard to the fields that are supported within each form type.

Note: Amendment, Renewal, and Interim Review forms are all based on original forms. They must contain the same sections and questions as the original form but contain one or more additional sections and associated questions needed to support actions specific to each form type.

What You See

When you open any of the form types for Human Protocols you see the following interface elements:

Toolbar buttons

- **Save** - Saves the form in its current state.
- **Activate** - Activates the current form and places it in a production mode.
- **Deactivate** - Changes the state of an active form to inactive. New forms are inactive by default.

- **Copy** - Replicates the current form, which can be modified and saved, to meet local needs.
- **Reports** - Generates a Blank Form Report.

Outline Panel

The outline panel, located in the upper left area of the screen, reflects sections and questions that have been placed in the form panel. This panel can be used to quickly navigate to items placed in the form panel. Outline elements can be filtered and can be expanded or condensed, as needed. This feature can be especially useful when dealing with large forms. It contains the following controls:

- **Required Questions** - Display only questions that are required for the requestor to answer. When you click this control it illuminates indicating it is active.
- **E-Signature Questions** - Display only questions that require an e-signature. When you click this control it illuminates indicating it is active.
- **Show Outline Numbers** - Displays the outline numbers of questions. Sections are numbered sequentially. Questions are numbered sequentially but include the section number in the following form: *x.y*, where *x* is the section number and *y* is the question number. Child questions take the following form: *x.y.z*, where *x* is the section number, *y* is the question number, and *z* is the child question number.
- **Expand/Collapse All Items** - Toggle between display sections and questions and display only sections.

Fields Panel

The Fields panel, located in the lower left area of the screen, contains the fields used to create questions in a form. Available fields vary depending on the form type involved.

Form Panel

The Form panel, located on the right side of the screen, contains the sections and questions that will comprise a form.

Form Structure and Usage

Forms consist of sections, which in turn contain questions. Sections are like chapters in a book and can be used to organize questions into appropriate categories. A form has a form title/name and a description.

Think of the Form as a container for one or more Sections, and think of Sections in turn as containers for one or more questions. When questions become the parent of additional child questions then they too become a container. A well-designed form, with its Sections and Questions, organizes and formats content in a manner that facilitates activities the form is intended to support.

When complete, a form becomes a source of information that can be used in a number of ways. Properly completed Forms can help answer reviewer questions, ensure regulatory compliance, record meeting minutes, and provide administrative data needed by the organization.

Sections

A Section is a container used to host one or more Questions. Each section contains pre-defined and/or user-defined questions related to the section's topic. For example, one form can contain a Section with Office Use Only questions, another section for personnel questions, and yet another section that includes details for a protocol.

Questions

It is important to understand how Questions function because the application uses them in different ways. Questions come in various types and are designed to capture needed information. Question types can include fill in the blank, multiple choice, true-false, drop-down menu selections, and others.

Questions can be used to collect and document information for regulatory compliance, and provide administrative data required by an organization.

The ability to control the placement of Questions provides great flexibility when building forms.

There are two types of Questions that can be added to sections:

1. **Pre-defined Questions** - Questions provided as part of the application to use as necessary. These questions often cover topics where the data involved is used elsewhere in the system. When adding a pre-defined question to a form, you can set it as a required question.
2. **User-defined (custom) Questions** - Questions that are created by the user. These can have different answer types including; rich text, plain text, single selection, multi-selection, date, table, numeric, and statement.

Section Buttons

- **Add/Allow Section Attachments** - Enables the requester and the form designer to add attachments and links. Click the paperclip link to display the Add Links and Attachments dialog box. The dialog presents three options:
  - A check box labeled **Allow Requester to Add Links and Attachments** - Check this box to allow the requestor to attach supplemental information.
  - A **Globe** - Allows the form designer to add a URL. Click the globe to display a line item in the panel below the check box. Click the line item below the label **File Name or URL**. Enter the URL.
  - A **Paperclip** - Allows the form designer to attach a file. Click the paperclip to display a line item in the panel below the check box that includes a folder. Click the folder and the system presents an explorer dialog from which you can attach an electronic file.
- **Make section as office use only** - Flag the section as being used for administrative purposes. The requestor should not complete anything in the section.
- **Hide section when Office use only** - Hide the section from anyone who doesn't have Edit Approved Office Use, Manage Reviews, or Review Protocol authority when it is flagged for office use only and they are in the Reviews section. This feature extends to reports as well. This button is inactive until the section is flagged for office use only.

- **Prevent Section from being Copied** - Prevent copying the section into a new or amended protocol. When creating a new protocol similar to an existing protocol, requestors sometimes copy the entire protocol and paste it into the new one. Likewise when a protocol is amended the existing information is copied into the amended version. If this flag is set, the section will not be copied into the new or amended protocol.
- **Remove** - To remove a question or a section, click the remove button. All questions are deleted when you delete a section. Likewise, deleting a question also deletes all child questions associated with it.

Question Buttons

- **Add** - Add a question related to the current question. In the case of Accounts, for example, you can use this button to add accounts. This feature is not applicable to all questions and therefore the application does not display the **Add** button on every question.
- **Make Answer Required** - Require the user to enter a response to a question.
- **Make E-Signature Required** - Require an e-signature for the question.
- **Add Attachments/Links** - Enables the requester and the form designer to add attachments and links. Click the paperclip link to display the Add Links and Attachments dialog box. The dialog presents three options:
  - A check box labeled **Allow Requester to Add Links and Attachments** - Check this box to allow the requestor to attach supplemental information.
  - A **Globe** - Allows the form designer to add a URL. Click the globe to display a line item in the panel below the check box. Click the line item below the label **File Name or URL**. Enter the URL.
  - A **Paperclip** - Allows the form designer to attach a file. Click the paperclip to display a line item in the panel below the check box that includes a folder. Click the folder and the system presents an explorer dialog from which you can attach an electronic file.
- **Add Question Help** - View annotations about a section or question. Click the link and enter supplemental information in the presented dialog.
- **Prevent printing on report** - Disallow the inclusion of the question in a report.
- **Edits Allowed after Approved** - Enable the editing the questions after the protocol is approved.
- **Remove** - To remove a question or a section, click the remove button. All questions are deleted when you delete a section. Likewise, deleting a question also deletes all child questions associated with it.

Field Types – Protocol Forms

The following field types to create questions for Human Protocols protocol forms. The field types are listed alphabetically, along with a description for each one.

Accounts - Select one or more accounts from an Items Selector grid. Accounts that appear are those approved for staff associated with the protocol being submitted.

Associate Selection - Select from among Associate names on protocols using the Select Staff grid.

Audit Trail - Provides protocol-by-protocol specification of whether audit trailing is applied to this protocol (after approved.)

Author - Change the Author designation for the protocol using the Select Staff grid. The author has certain access privileges, such as editing unsubmitted requests. By default this field displays the name of the person logged on when the request is first created.

Co-Author - Select and assign any active staff members to be co-authors on the protocol using the Select Staff grid. These individuals will be able to access the protocol as if they were the PI (edit the unsubmitted request, view the submitted request etc). They can also be set up as Email variable users. (See Protocol Associates.)

Created By - A read only field that captures the staff name of the individual who first created and saved this protocol request. The creator has certain access rights to the request, including the ability to edit the un-submitted request.

Date - Enter dates via a calendar selection tool. This control is available for all forms.

Department - Select one department from the Departments Master List. The value in this field will default to the protocol department.

Deputy Study Director - Designate one individual as the Deputy Study Director for the protocol using the Select Staff grid.

Emergency Phone - Enter an emergency phone number for the protocol.

Location Selection - Allows the requester to choose a single location where study activities will be conducted..

Multi Location Selection - Allows the requester to choose multiple locations where study activities will be conducted.

Multi Option - Choose one or more items from a list of options created at the time the form was created.

When you create or edit multi-option questions, it is important to set up Answers. These are the options the requester can choose from as they answer. For each answer option, it is possible to

- Provide the text of the answer.
- Define whether it is selected by default.
- Define an alert - this is a warning message that can be sent to the requester based on selecting that particular answer.
- Control the sequence in which the different answer options will appear on the form.

Multi-Select - Choose one or items from a pre-determined list created by the system administrator.

Numeric - Limits responses to numeric entry only.

Parent Protocol - Where a given protocol request has a “parent” (the request is an amendment, renewal or interim review) this field will show the Protocol number of the parent (e.g., an original or the preceding amendment). This field is non editable.

Plain Text - Limits responses to unformatted text.

Principal Investigator - The Principal Investigator has certain access privileges, such as editing unsubmitted requests. This is a required question on all protocol forms, and must be completed to activate and save the form.

Protocol Associates - Allows the requester to specify staff members who will be working on the protocol using the Select Staff grid. For each selected staff member the requester can specify if they are a Co-Investigator, etc. Co-Investigators have the same access privileges as the PI. Key associates can be set up to receive protocol related Email messages (as can Co-Investigators). If none of these are checked then the associate is an “other associate”. Other Associates are able to view the approved protocol only.

Protocol Number - A read-only field on the form that displays the protocol number for this protocol. The protocol number is typically assigned at approval, so this field will remain blank until the protocol is approved.

Protocol Type - A read-only field that displays the type of protocol (original, amendment, renewal, or interim review)

Reference Number - Allows the requester to enter a Reference Number, which is a way of uniquely identifying the protocol (since it will not get a Protocol Number until it is approved). It is also possible to set this Reference Number to be automatically generated, in which case this field is still required on the form, but becomes read-only. Note: this is a required question for all protocol forms, and must be completed to activate and save the form.

Related Protocols - Establish a link between two protocols within the application.

Rich Text - Use Rich Text formatting of content, insertion of images, and the creation of embedded hyperlinks. Note that requesters will be able to insert images on rich text fields using an icon at the top of the field; however, this does not appear within the forms designer.

Single Option - Choose a single item from a list of options created at the time the form was created.

When Creating or Editing single option questions, it is important that you set up “Answers.” These are the “options” the requester can choose from as they answer. For each answer option, it is possible to:

- Provide the text of the answer.
- Define whether it is selected by default.
- Define an alert - this is a “warning” message that can be sent to the requester based on selecting that particular answer.
- Control the sequence in which the different answer options will appear on the form.

Single Select - Choose a single item from a pre-determined list created by the system administrator.

Site - Indicate the Site where this protocol will be performed. This is selected from the Locations List Settings, and the options are limited to the top level from the 5-level hierarchy.

Source Protocol - Select one protocol from the Select Source Protocol grid. This field is typically used when a protocol is not directly linked to a parent but when it is still desirable to know the ID of the original protocol. An example would be when a protocol can be resubmitted after a fixed period of time (typically three years) but does not involve the Renewal process.

Staff Allowed to Copy - Give access to other users of the system to copy this protocol when creating a new request.

Staff Attendees - Authorize meeting administrators to choose a review committee for the meeting using the Select Review Committee grid. In addition, the administrator can add one or more additional staff attendees using the Select Staff dialog box and indicate a Role for each of these attendees. Following the meeting an authorized meeting administrator can indicate which attendees were present at the meeting. Selection of a review Committee is required to save the meeting.

Statement - Include text on the form that does not have an associated answer field. This field can be used a number of ways, including to provide regulations, guidelines, or SOP's.

Table - Include a simple table structure in a form. The table control enables the specification of the column headers that are then presented on the form. The requester then populates the column with fields such as plain text, custom lists, and questions.

Warning: The table structure cannot be altered after it has been added to the form. Labels and content text can be edited, but the table design is not editable.

Title - Enter a title for the protocol, which is displayed in ***selection grids***, ***filters***, and as an ***email variable***. (1300 character limit)

Unrestricted View - Protocols in the system have various controls in place restricting which individuals can access the protocol (e.g., PI, Co-Investigator, etc). This question allows requesters to bypass these controls and give all users access to the protocol. This might be the choice for a stock protocol, for instance.

User-Defined Repeater - Create a container of user-selected child controls that appear on the protocol form under a heading chosen by the user. When users complete the protocol form, they can create a variable number of answers that pertain to the protocol. Example: a series of controls under the heading *Surgeries*, the protocol could have multiple examples such as *Surgery Type A*, *Surgery Type B*, and *Sugery Type C*, each of which would then be answered by completing the selected control sets.

Field Types – Meeting Forms

The following field types to create questions for Human Protocols meeting forms. The field types are listed alphabetically, along with a description for each one.

Agenda Items - Allows an authorized meeting administrator to create and name one or more non-protocol agenda items for a meeting. Following the meeting this field will display meeting attendee and voting details, and will allow an authorized meeting administrator to record a final motion for the item. A quorum of more than 50 percent of eligible voting members must be present at the meeting for the protocol to be approved.

Agenda Protocols - Allows an authorized meeting administrator to select and add one or more protocols to a meeting agenda. Following the meeting this field will display meeting attendee and voting details, and will allow an authorized meeting administrator to record a final motion for the protocol. A quorum of more than 50 percent of eligible voting members must be present at the meeting for the protocol to be approved.

Date - Enter dates via a calendar selection tool. This control is available for all forms.

Date/Time - Allows an authorized meeting administrator to establish a set date and time for a meeting using Date, Start Time, and End Time selectors.

Guest Attendees - Allows an authorized meeting administrator to add one or more non-staff attendees to a meeting and to indicate a Last Name, First Name, Role, and E-mail address for each attendee. Following the meeting an authorized meeting administrator can indicate which attendees were present at the meeting.

Location - Allows an authorized meeting administrator to choose a location for the meeting using a Select Meeting Location dialog box.

Multi Option - Choose one or more items from a list of options created at the time the form was created.

When you create or edit multi-option questions, it is important to set up Answers. These are the options the requester can choose from as they answer. For each answer option, it is possible to

- Provide the text of the answer.
- Define whether it is selected by default.
- Define an alert - this is a warning message that can be sent to the requester based on selecting that particular answer.
- Control the sequence in which the different answer options will appear on the form.

Numeric - Limits responses to numeric entry only.

Plain Text - Limits responses to unformatted text.

Rich Text - Use Rich Text formatting of content, insertion of images, and the creation of embedded hyperlinks. Note that requesters will be able to insert images on rich text fields using an icon at the top of the field; however, this does not appear within the forms designer.

Single Option - Choose a single item from a list of options created at the time the form was created.

When Creating or Editing single option questions, it is important that you set up “Answers.” These are the “options” the requester can choose from as they answer. For each answer option, it is possible to:

- Provide the text of the answer.
- Define whether it is selected by default.
- Define an alert - this is a “warning” message that can be sent to the requester based on selecting that particular answer.
- Control the sequence in which the different answer options will appear on the form.
- Provide the text of the answer.
- Define whether it is selected by default.
- Define an alert - this is a “warning” message that can be sent to the requester based on selecting that particular answer.
- Control the sequence in which the different answer options will appear on the form.

Staff Attendees - Authorize meeting administrators to choose a review committee for the meeting using the Select Review Committee grid. In addition, the administrator can add one or more additional staff attendees using the Select Staff dialog box and indicate a Role for each of these attendees. Following the meeting an authorized meeting administrator can indicate which attendees were present at the meeting. Selection of a review Committee is required to save the meeting.

Statement - Include text on the form that does not have an associated answer field. This field can be used a number of ways, including to provide regulations, guidelines, or SOP's.

Table - Include a simple table structure in a form. The table control enables the specification of the column headers that are then presented on the form. The requestor then populates the column with fields such as plain text, custom lists, and questions.

Warning: The table structure cannot be altered after it has been added to the form. Labels and content text can be edited, but the table design is not editable.

Creating Forms

Forms are built using the Fields Panel and the Form Panel. The Fields Panel contains fields that essentially become questions when they are used to create a form. This is done by dragging them to the Form Panel. The Form Panel can be populated with sections, which can then be used to group questions into named categories.

A well designed form organizes information into tasks that can be described with increasing precision. This increases efficiency and accuracy by helping the requester think through various aspects of the protocol as they populate the form. When the form is completed it is a rich repository of information pertaining to an organization's requirements.

Prior to Creating Forms

Before creating a form, consider the following three recommendations, which should be part of your implementation process:

1. Review existing forms created outside of this software, or at least prepare a list of form requirements. Think about what is good, what is not good, and what minimal questions are needed to achieve compliance and other important requirements for the operation.
2. Consider any changes that might help improve the submission and review process.
3. Be sure settings in **Administration** are compatible with the form creation process being undertaken. Many of these settings influence how a requester must respond to questions placed in the form.

The Form Creation Process

The process for creating a form is the same, regardless of the form type. The primary differences are the available fields for a given form type.

1. Place your cursor over the Forms icon on the application main screen and choose one of the four form creation options. The chosen form opens. By default the Fields Panel displays the New tab, which contains all available fields for the form type selected. It is also possible to open and edit a previously created form by switching to the Existing tab and selecting an available form. If you choose the existing form option it will be necessary to rename the form in order to save it.
2. Type a unique name in the Form Name field in the Form Panel. At this point the **Save** button will become active and the form can be saved but not activated.
3. Type in details in the Form Description field, if needed.
4. Drag a Section field from the Fields Panel to the Form Panel. A form must contain at least one section before it can be activated. The section must also be given a name.
5. Drag needed fields to the section just added. Note that it is possible to add child fields as well.
6. Drag additional sections and fields to the Form panel as needed.
7. Confirm that required fields are present in the form and then click the **Save** button.

8. Click **Activate** and then **Save** to permit users to access the form. If the form is missing any require fields you will receive a Save Failed message.

Copying Forms

An open form can be copied using the **Copy** button in the toolbar. The new copy must be given a unique form name but is otherwise identical to the parent. Parent forms remain linked to child forms so that changes in the parent form are propagated to all child forms.

Using the Blank Form Report to Preview A Form

When you have completed and saved a form you can use the Blank Form Report option in the Print button in the toolbar for the form to generate a PDF copy. This can be a very useful tool for checking a form during the creation process, to ensure it will meet your needs.

Human Protocols - Managing Protocol Requests

Protocol request creation and submission is the first step in the workflow process for obtaining approval to conduct a study. This topic deals with the various protocol options that are part of the Human Protocols application. These protocol request options can be accessed by placing the cursor over the Protocols icon on the application main screen and selecting one of the options listed.

Protocol requests are submitted for review and approval using forms created by a system administrator.

TOPAZ Protocols supports four types of protocol request options:

- **Create Original Protocol** - Used by requesters to submit a new protocol request for the first time.
- **Create Amendment Protocol** - Used by requesters to amend an existing protocol. They are based on an original request but they are independent from it. They typically contain additional questions specific to the amendment process.
- **Create Renewal Protocol** - Used by requesters when renewing an existing protocol. They are based on an original request but they are independent from it. They typically contain additional questions specific to the renewal process.
- **Create Interim Review Protocol** - Often used to conduct annual reviews and to report progress for ongoing protocols.

The process for creating any of these request types is similar. In the case of original requests the process begins with choosing a form designed for original requests. Each of the other three request types are based on original requests so the first step is to choose an original request and then to choose the appropriate request form type. Those form types will open requests that contain all of the sections and questions contained in the original request plus one or more sections and associated questions that pertain to the request type to be submitted.

Additional options available in the Protocols icon include:

- Open Unsubmitted Protocols
- Open Submitted Protocols
- Open Returned Protocols
- Open Approved Protocols
- Open Protocol Histories

These options are used to open requests in different states, so they can be edited or compared to earlier versions.

Two additional options that appear when you click on the upper left drop-down button for any request type include:

- Print Protocol Reports
- Print Active & Current Protocol Reports

What You See

When you open any of the request types for Human Protocols you see the following interface elements:

Toolbar buttons

- **Save** - Saves the request in its current state.
- **Copy** - Copies answers from another protocol, replacing ALL matching answers.
- **Compare** - Compares the current protocol to a previously submitted version of the same protocol.
- **Presubmit** - Authorizes pre-submission review by choosing individuals in the Select Staff grid.
- **Submit** - Submits the request for formal review.
- **Signoff** - Prompts for an e-signature response from an assigned pre-submission reviewer. Only available if a system administrator has activated the Pre-Submission option in E-Signatures - Human Protocols.
- **Reports** - Generates a number of related reports.

Outline Panel

The outline panel, located on the left, displays the various sections and questions native to the form selected for the submission. Items in this panel can be filtered as needed. It is also possible to toggle outline number on and off and to expand or condense the outline. Clicking items in the outline can be used to quickly navigate to specific sections or questions in the form panel.

Form Panel

The form panel, located on the right, contains the sections and questions that will be used to submit the protocol for review.

Completing and Submitting Protocol Requests

Original Requests

The process for creating original protocol requests begins with the selection of an appropriate form. Some institutions will have only one form; others may choose to create multiple forms.

To create an original request, use the following procedure:

1. Place your cursor over the Protocols icon on the application main screen.
2. Click Create Original Protocol and the Select Form grid appears.
3. Click a form or select a check box next to a form and click the **OK** button. The form opens where you can see all the sections and questions on the form.
4. Complete the form by answering all questions. Consider whether to use the compare or pre-submission options prior to submitting the request.
5. Remember to **Save** often.
6. Click **Submit** to formally submit the protocol request.

Amendment, Renewal, and Interim Review Requests

The process for creating amendment, renewal, and interim review protocol requests is similar. The only difference is that these types of protocol requests will contain additional sections and questions that are unique to the form type that will be used for each of these request types.

To create these request types, use the following procedure:

1. Place your cursor over the Protocols icon on the application main screen.
2. Click appropriate request type. A selection grid appears listing available protocols.
3. Click a protocol or select a check box next to a protocol and click the **OK** button or use the Grid Filter documented in the next section, *The Protocol Selection Grid Filter*. Both actions open a form selection grid displaying available forms.
4. Click a form or select a check box next to a form and click the **OK** button. This opens the appropriate request form along with additional sections and questions associated with the request type.
5. Complete the form by answering all questions.
6. Click **Save**.

Consider whether to use the compare or pre-submission options prior to submitting the request.

The Protocol Selection Grid

The application displays the Protocols Selection Grid when you select one of the Open Protocols options. It contains a header and a grid listing the types of protocols you requested. The header contains the following elements:

- **Search Field** - Search protocols by attribute such as Protocol Number.
- **Report Button** - Produce the following reports:
    - Protocol Review Dates Report
    - Protocol List Usage Report
    - Protocol List Report
    - Protocol Detail Report
- **Export to Excel Button** - Export to Excel spreadsheet.
- **Export to PDF** - Export to PDF file.
- **Include Inactive Check Box** - Applies only to Open Approved Protocols. Include protocols that have been deactivated.
- **Grid Filter** - Filter the protocols to a target collection.

The Grid Filter

The Grid Filter enables filtering all protocols by specific field/value pairs such as Protocol Number. To activate the feature, click the funnel button in the upper right corner of the grid. The dialog box displays the filtering feature. The feature contains the following elements:

- A header containing the following buttons:
  - **Apply Filter** (blue left arrow)
  - **Save**
  - **Create New Filter** (funnel with sunburst)
  - **Add Conditions to Filter** (green plus)
  - **Delete Filter**
- The name field. Naming the filter is optional unless you want to save the filter.
- The Default check box. Check this box if you save the filter and want to set it as your default filter.

Use the following procedure to construct a filter:

1. Click the **Add Condition**s button. The application displays the **Fields** bar.
2. Click the down arrow on the **Fields** bar. The application displays the fields that can be filtered.
3. Click the field you want to filter. If the field can contain a value the application displays a **green plus** button beneath the field name, in which case proceed to step 3a. Otherwise proceed to step 4.
   a. Click the **green plus** button. The application displays the list of possible values.
   b. Click the value you want to filter.
4. Click the **NOT** check box if you want to exclude protocols containing the selected field.
5. Repeat steps 1 through 4 until all fields have been selected.

To remove a field, click the **red minus** button next to that field. To save the filter, click **Save**. To create a new filter, click the **Create New Filter** button.

Using the Copy Feature

The **Copy** button is used to copy ALL answers that have not been flagged as Do Not Copy from another protocol request to the one you are working on. This can be a useful feature when creating original requests as it allows you to avoid having to re-enter the same information.

Warning: This button should NOT be used when creating amendment, renewal, or interim review protocol requests as it may change answers that are important for those types of requests.

Use the following procedure to Copy a protocol:

1. Click the **Copy** button in the toolbar for an open new, unsubmitted or returned Original protocol. This will result in a warning message stating that copying answers from another protocol will replace all matching answers and asking if you want to continue.
2. Click OK to proceed. This opens a Select Protocol grid.
3. Choose a protocol in the grid by clicking it or by placing a mark in its check box and clicking **OK**.
4. Edit the protocol as needed.
5. Click **Save**.

Using the Compare Feature

The **Compare** button is used to compare the current version of a protocol request to any previous version of the same protocol. This can be a helpful feature when making changes to a protocol request.

To use the Compare feature:

1. Click the **Compare** button in the toolbar in an open protocol. This opens a Select Protocol grid.
2. Choose a protocol in the grid by clicking it or by placing a mark in its checkbox and clicking **OK**. This opens the protocol and a previous version in a side-by-side view. Any differences in the question answers are shown by outlining the field in red. For text and rich text questions the field includes a small flag icon that can be used to open a pop up that will show details of any additions or deletions to the text. Note that the outline will flag each question that has a different answer, and these questions can be filtered using the red flag icon at the top of the outline.
3. Review both protocols and use the comparison to made needed changes in the most recent version. You can close the previous version at any time.
4. Click **Save**.

Pre-Submission Review of Requests

The **Pre-Submit** and **Signoff** buttons are useful when it is desirable to request an internal review of a protocol request prior to formal submission. The process for using this process is as follows:

1. Click the **Presubmit** button in any open unsubmitted protocol request. This opens a Presubmission Review dialog box that allows you to add one or more reviewers who will be performing the review.
2. Click the green **Plus** button in this dialog box. This opens a Select Staff grid where you can choose one or more staff to add by clicking the OK button. Staff can also be removed by clicking the red **Minus** button next to each staff name. Authorized staff may then conduct a presubmission review of the request and indicate approval by clicking the **Signoff** button. This prompts an e-signature response indicating approval.

Note: The **Signoff** button will be active only if the Pre-Submission E-Signature option has been made active by a system administrator.

Resubmission of Returned Requests

When a request is returned to you for modifications you may, depending on system configuration, receive an email informing you of the return. The returned request can be found on your Dashboard, or under the Open Returned Protocols menu item.

Most of the detailed comments that the committee want you to address will be associated with the specific question to which they are related. To find these comments you can use the Outline to filter for *Questions with Comment Summaries.* The comments themselves will appear in-line with the protocol request, right underneath the related question. You can easily reference the comment, and even cut-and-paste if the committee has provided suggested language.

There may also be information of value in the Review Summary. This may have been included in the email that you received when the protocol was returned. Once all the requested updates have been made you can submit the updated request using the Submit button on the toolbar.

When you open a returned protocol you are able to make edits to your prior answers just as you did when first creating the request. You can also view comments that have been sent back to you from the committee. Depending on the comment, you can respond with a reply to any or all comments, and the system supports complete dialog threads between the PI or Co-author and anonymous commentators.

When you have completed modifications, resubmit the protocol.

Protocol Request Reports

These are reports available for individual protocols. They are only available by clicking the **Reports** button in the toolbar for an open protocol.

- **Protocol Detail Report** - Generates a PDF report displaying full details for the protocol chosen.
- **Protocol Detail Report Answered Questions Only** - Generates an abbreviated PDF report displaying answered questions only for the protocol chosen.
- **Protocol Comparison Report** - Generates a PDF report showing differences between two versions of a protocol. This report is only active when a “compare” has been performed in the application.
- **Protocol Review Detail Report** - Generates a PDF report displaying full details for the chosen protocol, including names of reviewers, etc. This report is only available to individuals approved for IACUC access to protocol information.
- **Protocol Review Comments Summary Report (Current)** - Generates a PDF report containing a summary of reviewer comments made for the current protocol chosen. It does not identify individual reviewers. This report provides the protocol PI with information that may be useful, especially if the protocol may need to be resubmitted.
- **Protocol Review Comments Summary Report (Previous)** - Generates a PDF report containing a summary of reviewer comments made for the previous version of the protocol chosen (eg. when working to resubmit a returned protocol, this will show the comments that were returned). It does not identify individual reviewers. This report provides the protocol PI with information that may be useful, especially if the protocol needs to be resubmitted.

Human Protocols – Managing Protocol Review Assignments

This topic deals with the process for managing protocol reviews during the assignment process. Key options for this process can be accessed by placing the cursor over the Reviews icon on the Human Protocols main screen and selecting one of the options listed. It is also possible to open assigned protocols using the Manage Reviews option in the Dashboard.

When a requester submits a protocol request for review it arrives on the Dashboard of the Protocol Administrator or Coordinator, the individual responsible for managing the review process. This individual assigns reviewers, manages feedback to the PI, sets up committee meetings, and guides the request through the review process.

While each protocol is unique, the following illustrates a typical protocol review process from submittal to finalized status:

1. The Administrator/Coordinator looks over the request to ensure it is complete, and that it complies with institutional requirements.
2. The Administrator/Coordinator creates one or more assignments for the request. Each assignment can include one or more reviewers. When more than one reviewer is assigned to a request assignment, each can be given different roles and responsibilities.
3. Reviewers access the request, record comments, and submit an opinion/vote on the request.
4. The Administrator/Coordinator moves the protocol through the review process, and coordinates the activities of reviewer groups and individual reviewers as necessary.
5. Once all reviewer comments are received, the findings are summarized and the protocol request is returned to the requester for modifications, if any are required. The request can even be approved at this point, or set to another status depending on the circumstances.
6. When a request is returned for modification, the requester can review the comment summaries online, make the required changes, and re-submit the protocol request.

Note: At any point in the process, the administrator/coordinator may add the request to a committee meeting agenda for further discussion or decision making.

Creating Review Assignments

The first step in the protocol review process following initial administrative review is the creation of one or more Assignments for a request. This is done by choosing the Create New Review Assignment option in the Reviews icon and selecting a protocol from the Select Protocol grid that open. This opens the protocol in the Manage Review Assignments screen, which contains three toolbar buttons and three horizontal panels dealing with protocol, assignments, and reviewer information.

What You See

Toolbar and Screen Buttons

- **Add Assignments** - A toolbar button used to add one or more assignments to the Assignments Panel.
- **Save** - A toolbar button that saves but does not close the review request.
- **Schedule Meeting** - A toolbar button used to schedule the review request for a meeting, should that be necessary.
- **Done** - A button located at the bottom right of the screen that saves and closes the review request.

Protocol Panel

The Protocol panel contains the following fields:

- **Reference Number** - A read only field that displays the reference number for the selected protocol request.
- **Protocol Number** - A read only field that displays the protocol number for the selected protocol request.
- **Protocol Title** - A read only field that displays the title for the selected protocol request.
- **Assigned Review Type** - A drop-down field that allows the user to select a review type from a list of options created by a system administrator to meet local needs. Examples might include full, convened review with PI, accelerated, designated, or sub-committee review.
- **Protocol Status** - A read only field that displays the current status for the selected protocol request.

Assignments Panel

The Assignments panel contains the following fields/buttons for each assignment created:

- **Name** field - Allows you to enter a name for each assignment created for the selected review request.
- **Due Date** field - Allows you to enter a date by which all reviewer feedback is due.
- **Add Reviewers** button - Allows you to add one or more reviewers to an assignment using the Select Staff grid.
- **Add Review Group** button - Allows you to add one or more reviewer groups to an assignment using the Select Reviewer Group grid.
- **Add Assignment Comments to Email** button - Allows you to include comments that will be added to emails sent to reviewers, but only if the Review Assignment Comments variable has been added to the Review Assignments email template in Administration.
- **Send Email to Reviewers** button - Allows you to send an email to a review requester notifying them that the request is scheduled for review.
- **Status** field - Allows you to select a status for the assignment. This will be Not Started for a new request but can be changed to Started or Completed as needed. Reviewers will only see and have access to review assignments in the Started status.
- **Completion Date** field - Displays a read only date when the assignment is set tp Completed.
- **Remove** button - Allows you to remove a selected assignment.

Reviewers Panel

The Reviewers panel lists all reviewers added to assignments highlighted in the Assignment panel and contains the following fields/buttons:

- **Name** field - Displays the names for each reviewer added to an assignment selected in the Assignments panel.
- **Role** field - Allows you to choose a role for the reviewer from a drop-down list created by a system administrator to meet local needs. Examples might include attending veterinarian, basic reviewer, committee chair, non-scientist, and scientist. Note that these roles can be set up to allow different capabilities to different reviewers.
- **Associated** field - Indicates (Yes/No) whether the reviewer is associated with the protocol or not. A yes response indicates a possible conflict of interest.
- **Commented** field - Indicates whether the reviewer has included comments on the request by populating this field with a date and time stamp.
- **Completed** field - Indicates whether the reviewer has completed their review assignment by populating this field with a date and time stamp.
- **Opinion/Vote** field - Displays the opinion/vote selection made by the reviewer for their assignment.
- **Remove Reviewer from Assignment** button - Allows you to remove a selected reviewer or group from the selected assignment.

Creating An Assignment and Adding Reviewers

Use the following procedure to create a review assignment:

1. Click the Create New Review Assignment option in the Reviews icon. This opens the Select Protocol grid.
2. Select a protocol to be reviewed by either clicking the protocol or by placing a mark in its checkbox and clicking **OK**. This opens the protocol in the Manage Review Assignments screen.
3. In the Protocol panel:
   a. Review the protocol information and confirm the protocol displayed is the correct one.
   b. Click the down arrow on the Assigned Review Type field and select an appropriate type.
4. In the toolbar:
   a. Click the **Add Assignments** button. This will add a new assignment to the Assignments panel.
5. In the Assignments panel:
   a. Enter a unique name in the Name field.
   b. Enter a date in the Due Date field.
   c. Add one or more reviewers and/or review groups using the appropriate buttons and selection grids.
   d. Click the Add Assignment Comments to Email button if you want to include comments or instructions to emails sent to reviewers. This opens the Add Comments dialog box. Enter desired comments and click the **OK** button. This option may or may not be available, depending on Administration settings.
   e. Click the Send Email to Reviewers button to initiate a message to reviewers selected for the assignment. This automatically sends the e-mail message created by a system administrator in Administration.

f. Leave the Status field as Not Started until all assignment and reviewer information for the review request is complete. This should be changed to Started when the request is ready to be viewed by reviewers.

6. In the Reviewers panel:
   a. Click the down arrow in the Role field and choose a role for each reviewer added to the assignment.
7. Change the Status drop-down field to Started when the assignment is complete and ready for reviewers. This will make the review request available to reviewers for that assignment.
8. Click the **Add Assignments** button in the toolbar and repeat steps 4 through 7 to add additional assignments and reviewers. In some cases it may be necessary to reopen a request to add additional assignments.

Note: Be sure to use the Save button often during the assignment process, to preserve changes in the event of a system problem.

Opening Unassigned and Assigned Protocols

These options, located in the Reviews icon, will allow you to open both types of protocols for further processing. Assigned protocols can also be opened using the Manage Reviews option in Dashboard. Unassigned protocols are those that have been submitted but that do not yet have assignments added. Protocols undergoing initial administrative review will often be in this state. Choosing either option opens a selection grid. Clicking a protocol or placing a mark in its checkbox and clicking **OK** opens the protocol in an Open Unassigned Protocols or Open Assigned Protocols screen. Clicking the **Manage** button in the toolbar on either screen opens the protocol in the Manage Review Assignments screen where you can continue to process the protocol.

Human Protocols – Performing Protocol Reviews

This topic deals with actions performed by reviewers during the protocol review process. Reviewers can access assigned protocols by clicking the Open My Reviews option in the Reviews icon on the Human Protocols main screen or by clicking the My Reviews option in Dashboard. Either method will open a selection grid displaying protocols for which the logged in user is an assigned reviewer.

Reviewers play an essential part in the protocol evaluation and approval process. To perform that function they must open assigned protocols and complete actions permitted by their assigned role.

Reviewer Roles and Permissions

Reviewer Roles and permissions are created and defined by a system administrator to meet local needs. Each reviewer assigned to a protocol is given an appropriate role to fulfill for the review.

Permissions that may be granted for a role include:

- Entering either comments or summary comments on individual sections and questions.
- Entering closing remarks.
- Calling for full committee review.
- Rendering an opinion or vote.
- Setting Status.

The list below includes some examples of possible reviewer roles you may want to consider as you set up your own review process. Role permissions are set by a system administrator to meet local needs.

- Committee Member
- Subcommittee Member
- Primary Reviewer
- Secondary Reviewer
- Expedited Reviewer
- Designated Reviewer
- Exempt Protocol Reviewer

What You See

When a reviewer clicks a protocol in the selection grid, the protocol opens in the Open My Reviews screen, which contains the following elements:

Toolbar buttons

- **Save** - Becomes active when a change is made to the protocol (creating a comment or other action) and allows you to save the protocol with those changes intact.
- **Manage** - Not generally available to reviewers.

- **Summarize** - Initially active. Depending on your role permissions, clicking this button lets you set closing remarks, call for full committee review, and render an opinion or vote.
- **Status** - May be available to some reviewers, depending on their role permissions.
- **Compare** - Available to all reviewers. Allows you to compare the current protocol to a previous version.
- **Reports** - Allows you to create various report for the current protocol.

Outline Panel

This panel contains an outline of the sections and questions for the current protocol. The outline can be expanded, contracted, and filtered to permit easy selection and display of specific sections and questions in the Protocol Panel. It is basically a navigation tool.

Protocol Panel

This panel displays all of the sections and questions specific to the protocol being reviewed. Depending on role permissions you will be able to enter either comments or summary comments for each section and question present using a button on the right side of each section/question.

Section and question comment buttons are plain. Comments made using these buttons are seen only by other reviewers and by administrators/coordinators authorized to manage the review process.

Section and question summary comment buttons are blue with a yellow figure in the center. Summary comments made using these buttons can be edited and made available to requesters when the protocol is approved or if it is returned to them for modification.

Reviewing a Protocol

Use the following procedure to perform a protocol review:

1. Perform an initial review of the protocol. Perform an initial review of the protocol. Either view sections and questions on screen or generate a Protocol Detail Report or Protocol Review Detail Report. Reports are available when you click the **Reports** button in the toolbar. Comments made by other reviewers can also be evaluated.
2. Enter comments or summary comments for sections and questions, as needed.
3. Click the **Compare** button in the toolbar and select a version from the selection grid that appears if you want to compare the protocol with a previous version.. The application will highlight changed areas of the form for quick comparison.
4. Click the **Summarize** button in the toolbar to open the Closing Remarks dialog box and enter your closing remarks. Comments entered here pertain to the protocol as a whole. If your role includes the ability to call for a full committee review of the protocol, that option will be displayed at the top of the Closing Remarks dialog box and you can make that determination. If your role includes the ability to render a vote or opinion, that option will be displayed at the top of the Closing Remarks dialog box and you will be able to select an appropriate option from the drip-down list that appears for that option.
5. Click the **Save** button and close the box.
6. Click the **Status** button in the toolbar if your role includes the ability to set status for the protocol and com-

plete that action.

7. Click **Save**.

Note: Be sure to click the **Save** button in the toolbar frequently, to preserve changes you have made in the event there is a system problem.

Human Protocols – Managing Protocol Review Status Changes

This topic deals with status changes made by the Protocol Administrator/Coordinator during the review process. Authorized reviewers may also be granted permission to change the status of a protocol.

Once a protocol is released to reviewers the role of the Protocol Administrator/Coordinator becomes that of managing the review process until a final status for the protocol is established. Feedback from reviewers comes in the form of comments and votes or opinions. When feedback is compete the Protocol Administrator/Coordinator opens the protocol and changes the status as needed. In some cases the decision may be to schedule the protocol for discussion at a committee meeting before a final status is determined. For protocols to be returned to the requester for modification, summary comments may be included.

Setting the Status for a Protocol

To set the status for a protocol it must first be opened. This is accomplished by placing the cursor over the Reviews icon on the Protocols main screen and selecting the Open Assigned Protocols option. Once the protocol is open, click the **Status** button in the protocol toolbar. This opens the Set Status dialog box. If a status has not been previously set, the system defaults to Status Not Selected.

Note: The Approved Pending Modification, Returned for Modification, and Tabled status settings behave much the same, but can be set up differently in Administration. This provides greater flexibility for managing the review process to meet local needs. Depending on Administration settings, Email Events and E-Signatures may be triggered for any of the status change actions.

To change a status, choose one of the following options:

Approved

This status allows authorized personnel to order animals. It may also trigger an e-mail notice to the Principal Investigator indicating the protocol is approved.

1. Click the Approved option. Fields and buttons specific to the Approved status appear to the right of the Set Status options.
2. Edit the prefix and suffix fields in the Protocol Number section, if needed. The protocol number field may or may not be editable, depending on whether it has been set to automatic or manual by the system administrator.
3. Enter Review Summary remarks, if needed. Also note that closing remarks made by reviewers, if any, will be displayed in the Reviewer's Closing Remarks area at the bottom of the screen. These remarks can be added to the Review Summary by clicking the **Summarize Closing Remarks** button located there. Once added, these remarks can be edited as needed to complete the review summary.
4. Edit any of the dates on the right (approval, effective, expiration, next review, or renewal) as needed. Some calendar fields default with the current date. Future date field defaults are based on periods set in the Protocol Settings page by an administrator. You may keep or change any of those dates.

5. Click the **Set Status** button to set the status to Approved. Once the approved status is selected it cannot be reverted to a previous status, but the protocol can be modified by submitting an amendment.

Approved Pending Modification

This status is used to return the protocol to the requester. It will include Review Summary comments and will require modification and resubmission.

1. Click the Approved Pending Modification option. Fields and buttons specific to the Approved Pending Modification status appear to the right of the Set Status options.
2. Click the triangle at the Select Re-Review Type option to display a drop-down menu. Single click a review type on the drop-down menu to select it.
3. Enter Review Summary remarks, if needed. Also note that closing remarks made by reviewers, if any, will be displayed in the Reviewer's Closing Remarks area at the bottom of the screen. These remarks can be added to the Review Summary by clicking the **Summarize Closing Remarks** button located there. Once added, these remarks can be edited as needed to complete the review summary.
4. Click the **Set Status** button to set the status to set the status to Approved Pending Modification. Once this status is set, it cannot be reversed until the request is resubmitted and approved.

Not Approved

This status puts the protocol in a Not Approved state. The requester is notified regarding the status but the protocol is not returned and is not eligible for resubmission.

1. Click the Not Approved option. Fields and buttons specific to the Not Approved status appear to the right of the Set Status options.
2. Enter Review Summary remarks, if needed. Also note that closing remarks made by reviewers, if any, will be displayed in the Reviewer's Closing Remarks area at the bottom of the screen. These remarks can be added to the Review Summary by clicking the **Summarize Closing Remarks** button located there. Once added, these remarks can be edited as needed to complete the review summary.
3. Click the **Set Status** button to set the status to set the status to Not Approved. Once this status is set, it can not be reversed unless an amendment, renewal, or interim review is submitted and approved.

Returned for Modification

This status returns the protocol to the staff member for modification. It will include Review Summary comments and will require modification and resubmission.

1. Click the Returned For Modification option. Fields and buttons specific to the Returned For Modification status appear to the right of the Set Status options.
2. Click the triangle at the Select Re-Review Type option to display a drop-down menu. Single click a review type on the drop-down menu to select it.

3. Enter Review Summary remarks, if needed. Also note that closing remarks made by reviewers, if any, will be displayed in the Reviewer's Closing Remarks area at the bottom of the screen. These remarks can be added to the Review Summary by clicking the **Summarize Closing Remarks** button located there. Once added, these remarks can be edited as needed to complete the review summary..
4. Click the **Set Status** button to set the status to set the status to Returned For Modification. Once this status is set, it cannot be reversed until the request is resubmitted and approved.

Tabled

This status places a protocol into a deferred state. It gets returned to the requester, but remains eligible for future resubmission and approval.

1. Click the Tabled option. Fields and buttons specific to the Tabled status appear to the right of the Set Status options.
2. Click the triangle at the Select Re-Review Type option to display a drop-down menu. Single click a review type on the drop-down menu to select it.
3. Enter Review Summary remarks, if needed. Also note that closing remarks made by reviewers, if any, will be displayed in the Reviewer's Closing Remarks area at the bottom of the screen. These remarks can be added to the Review Summary by clicking the **Summarize Closing Remarks** button located there. Once added, these remarks can be edited as needed to complete the review summary.
4. Click the **Set Status** button to set the status to set the status to Returned For Modification. Once this status is set, it can not be reversed unless an amendment, renewal, or interim review is submitted and approved.

Human Protocols – Protocol Review Reports

Several reports can be generated from within a protocol during the protocol review process. These report options can be accessed by clicking the **Reports** button in the toolbar for any open protocol.

Protocol Review Detail Report - Displays fields with comments, e-signatures, e-mails, review assignments, and summary comments. This report displays all of the protocol request content. All sections and questions are printed, irrespective of whether they have associated answers. This report can be used by submitters to review their own requests prior to submission.

Protocol Detail Report - Displays the entire protocol, which includes all questions and answers, however, this report excludes comments. Comments appear on the Protocol Review Detail Report.

Protocol Comparison Report - Displays the differences between two versions of a protocol. Users can view and compare an amendment and the parent original, or a resubmitted request compared to the version that was returned to the PI. This report is only available after selecting two protocols to compare. This report can be used by reviewers to verify that all changes in the protocol request have been made by the requester.

Protocol Review Comments Summary Report (Current) - Displays summaries of reviewer comments. This report is available to the PI or another staff member(s) not associated with the committee. The report displays comment summaries, but does not reveal the names of reviewers or other details, and the PI can request this report for a protocol that has been returned for modification.

Protocol Review Comments Summary Report (Previous) - Displays all comments. This report shows all of the details of a protocol submission review. For the selected protocol submission, the report displays review assignment information such as the name of the reviewer, comments, and opinions. Shows comments associated with the preceding version of the protocol.. If you have a returned protocol, this report will give you the comments on the returned version.

Human Protocols – Managing Protocol Meetings

Protocol meetings are managed by a protocol administrator/coordinator and are events where protocol or other issues can be discussed.

Meeting management options are accessed by clicking the Meetings icon in the Human Protocols main screen. Available options for that icon include:

- **Create New Meeting** - Opens a previously created meeting form using a Select Form grid.
- **Open Draft Meetings** - Opens an unscheduled meeting using a Select Meeting Draft Agenda grid.
- **Open Scheduled Meeting** - Opens a previously scheduled meeting using a Select Scheduled Meeting grid.
- **Open My Meetings** - Opens a meeting you are scheduled to attend using a Select My Meeting grid. The My Meetings option in Dashboard can also be used to perform this action.
- **Open Completed Meetings** - Opens a completed meeting using a Select Completed Meeting grid.
- **Open Approved Meetings** - Opens an approved meeting using a Select Approved Meeting grid.

The normal process for creating and managing meetings involves:

1. Creating a Draft meeting based on a previously created meeting form.
2. Changing the status of the draft to Scheduled. This action publishes the meeting for meeting attendees and may trigger an e-mail or call for an e-signature if those options are active in administration settings. This is equivalent to sending out the agenda for the meeting.
3. Changing the status of a Scheduled meeting to Completed. This action is used to indicate that a Scheduled meeting has taken place, minutes have been recorded, and the meeting is awaiting final approval. It may trigger an e-mail or call for an e-signature if those options are active in administration settings.
4. Changing the status of a Completed meeting to Approved. This action is used to indicated final approval of a completed meeting. It may trigger an e-mail or call for an e-signature if those options are active in administration settings.

What You See

Clicking any of the options in the Meetings icon opens a meeting formatted according to the meeting form chosen when the initial meeting was created. In the case of the Create New Meeting option the form is incomplete.

Toolbar Buttons

Three buttons are present in the toolbar for all agenda forms:

- **Save** - Saves the current meeting. It is a good idea to use this button frequently, to preserve changes you have made in the event there is a system problem.
- **Status** - Becomes available for previously saved meetings.
- **Reports** - Generates a Meeting Minutes Report.

Outline Panel

This panel contains an outline of the sections and questions for the current meeting agenda. The outline can be expanded, contracted, and filtered to permit easy selection and display of specific sections and questions in the Meeting Panel. It is basically a navigation tool.

Meeting Panel

This panel displays all of the sections and questions specific to the displayed meeting.

Creating A New Meeting

Use the following procedure to create meetings:

1. Click the Create New Meeting option. This opens the Select Form grid.
2. Select a meeting form by either clicking the form or by selecting the check box for the form and clicking the **OK** button. This opens the form in the Create New Meeting screen.
3. Complete questions for the meeting as needed.
4. Click the **Save** button to save the meeting. Note that a review committee and meeting location must be designated to save the meeting as a draft.
5. Click the **Status** button and set the status for a saved draft to Scheduled to save the meeting as a scheduled meeting. Once the status is set to Scheduled the **Status** button can be clicked again and the Status can be changed back to Draft, or it can be changed to Completed.

Opening and Editing A Draft Meeting

Use the following procedure to edit draft meetings:

1. Click the Open Draft Meetings option. This opens the Select Meeting Draft Agenda grid.
2. Select a meeting by either clicking the meeting or by selecting the check box for the meeting and clicking the **OK** button. This opens the meeting in the Open Draft Meetings screen.
3. Make needed changes to the meeting.
4. Click the **Save** button.
5. Click the **Status** button and set the status for a saved draft to Scheduled to save the meeting as a scheduled meeting. Once the status is set to Scheduled the **Status** button can be clicked again and the Status can be changed back to Draft, or it can be changed to Completed.

Opening and Editing A Scheduled Meeting

Use the following procedure to edit scheduled meetings:

1. Click the Open Scheduled Meetings option. This opens the Select Scheduled Meeting grid.
2. Select a meeting by either clicking the meeting or by selecting the check box for the meeting and clicking the **OK** button. This opens the meeting in the Open Scheduled Meetings screen.
3. Record meeting minutes as needed.
4. Click the **Save** button.
5. Click the **Status** button and set the status for a saved draft to Completed to save the meeting as a completed meeting, awaiting final approval. Once the status is set to Completed the **Status** button can be clicked again and the Status can be changed back to Scheduled, or it can be changed to Approved.

Opening and Editing A Completed Meeting

Use the following procedure to edit completed meetings:

1. Click the Open Completed Meetings option. This opens the Select Completed Meeting grid.
2. Select a meeting by either clicking the meeting or by selecting the check box for the meeting and clicking the **OK** button. This opens the meeting in the Open Completed Meetings screen.
3. Make needed changes to the meeting.
4. Click the **Save** button.
5. Click the **Status** button and set the status for a saved draft to Approved to save the meeting as an approved meeting. This indicates all changes are complete and final. Once the status is set to Approved the **Status** button can be clicked again and the Status can be changed back to Completed.

Opening and Editing An Approved Meeting

Use the following procedure to edit approved meetings:

1. Click the Approved Meetings option. This opens the Select Approved Meeting grid.
2. Select a meeting by either clicking the meeting or by selecting the check box for the meeting and clicking the **OK** button. This opens the meeting in the Open Approved Meetings screen.
3. Edit the meeting as needed. It is possible to edit a meeting save in the Approved status, but that may trigger an audit trail Enter Reason for Change dialog box, which must be completed to save changes to the meeting. Clicking the **Status** button will allow you to revert the meeting back to the Completed status.

Recording Meeting Minutes

The **Staff Attendees** question enables roll call for the meeting by providing Present check boxes next to attendees. The system later uses the attendance list to determine who can vote on each motion. Note that if some uninvited attendees turn up at the meeting, this fact can be recorded by adding new attendees at this time.

The **Agenda Protocols** field enables votes for each protocol on the agenda. For each protocol, select the Motion that is proposed. Often these motions are similar to the statuses for the protocols. If any of the voting members attending the meeting are flagged as having a Conflict of Interest (such as an associate on the protocol), this is indicated on the voting grid. The system may indicate that the Voting Quorum is not met. This occurs if the members eligible to vote on this protocol falls below 50% of the committee membership.

The **Agenda Items** question enables votes for each item during the conduction of a meeting. These can include things such as minutes, meeting planning, and whether to vote on a protocol.

To vote for agenda protocols or agenda items, click the Vote button near the top of the question. The question expands to display a list of committee voting members and four voting options for each member:

- For
- Against
- Abstain
- Conflict

Votes can be recorded for each eligible attendee for each agenda item listed. A voting agenda item can be added to a future meeting, if a vote is not conducted for the current meeting. To do this, click the Re-Schedule button, to the right of the Motion drop-down. Select a meeting on which to include the agenda item.

If, during a meeting, attendees have discussed a protocol request and have reached a decision, the protocol status can be set during the meeting by clicking the Set Status button for the agenda item. This makes it possible to approve a protocol as soon as the vote has occurred.

Meeting minutes can be edited after the meeting has finished. When the minutes have been reviewed and are accurate, the meeting status can be set to Approved. It is possible to edit an Approved meeting, but that will trigger an audit trail request asking for a reason for the change. A meeting status can also be changed from Approved back to Completed.

Meeting Minutes Reports

At any point in the meeting management process it is possible to generate a PDF Meeting Minutes Report by clicking the **Reports** button in a meeting toolbar. Being able to generate a hard copy of meeting minutes can be a handy option in some cases.

The report prints the meeting information regardless of the status of the meeting. It can also be used to print out an agenda to share with committee members.

This report can be generated in the following ways:

- From the Dashboard/My Meetings selection grid.
- From a meetings selection grid.
- Within an open meeting.

Human Protocols – Reports

Reports are accessed by placing your cursor over the Reports icon on the application main screen and clicking one of the available options.

Each of the Reports options opens a selection grid that lists available options for that grid (forms, protocols, reviews, or meetings). This topic focuses on print options present in the grid toolbars, which allow you to generate reports that include one or more items in the grid. This is in contrast to report options available once an item is opened, which are limited to the single item opened from the selection grid.

Available options include the following reports:

Print Form Reports

This option opens the Select Form To Print grid displaying currently available forms. Clicking one or more of the reports in the grid and then clicking one of the print options in the grid toolbar will generates a report that includes information pertaining to all of the forms selected in the grid.

Clicking the **Select Report** button in the grid toolbar is limited to generating a Blank Form Report. Clicking this option opens an Optional Comments dialog box that lets you add comments to the generated report and determine whether the output will be in PDF or RTF form. PDF is the default.

Clicking **Export Grid to Excel** or **Export Grid to PDF** generates a report that displays information in the grid for the forms selected.

Print Protocol Reports

This option opens the Select Protocol To Print grid displaying currently available protocols. Clicking one or more of the reports in the grid and then clicking one of the print options in the grid toolbar will generate a report that includes information pertaining to all of the protocols selected in the grid.

Clicking the **Select Report** button in the grid toolbar for this option displays the following report options:

- Protocol Review Dates Report
- Protocol List Usage Report
- Protocol List Report
- Protocol Detail Report
- Protocol Detail Report Answered Questions Only
- Protocol Review Comments Summary Report (Current)
- Protocol Review Comments Summary Report (Previous)

These are the same report options that are available in an opened protocol. The key difference is that clicking this button generates a report that includes all of the protocols selected in the grid, rather than one that only includes details for a single open protocol. Clicking any of these report options opens an Optional Comments dialog box that lets you add comments to the generated report and to determine whether the output will be in PDF or RTF form. PDF is the default.

Clicking **Export Grid to Excel** or **Export Grid to PDF** generates a report that displays information in the grid for the forms selected.

Print Active & Current Protocol Reports

This option opens the Select Active & Current Protocols To Print grid displaying currently available protocols. Clicking one or more of the reports in the grid and then clicking one of the print options in the grid toolbar will generate a report that includes information pertaining to all of the protocols selected in the grid.

Clicking the **Select Report** button in the grid toolbar for this option displays the following report options:

- Protocol Review Dates Report
- Protocol List Usage Report
- Protocol List Report
- Protocol Detail Report
- Protocol Detail Report Answered Questions Only
- Protocol Review Comments Summary Report (Current)
- Protocol Review Comments Summary Report (Previous)

Note that these are the same report options that are available in an opened protocol. The key difference is that clicking this button generates a report that includes all of the protocols selected in the grid, rather than one that only includes details for a single open protocol. Clicking any of these report options opens an Optional Comments dialog box that lets you add comments to the generated report and to determine whether the output will be in PDF or RTF form. PDF is the default.

Clicking **Export Grid to Excel** or **Export Grid to PDF** generates a report that display information in the grid for the forms selected.

Print Review Reports

This option opens the Select Protocol To Print grid displaying currently available protocols. Clicking one or more of the reports in the grid and then clicking one of the print options in the grid toolbar will generate a report that includes information pertaining to all of the reviews selected in the grid.

Clicking the **Select Report** button in the grid toolbar for this option displays the following report options:

- Protocol Review Detail Report
- Protocol Review Comments Summary Report (Current)
- Protocol Review Comments Summary Report (Previous)

These are the same report options that are available in an opened review, with the exception that an opened protocol also contains Protocol Detail Report and Protocol Comparison Report options.. The key difference is that clicking this button generates a report that includes all of the reviews selected in the grid, rather than one that only includes details for a single open review. Clicking any of these report options opens an Optional Comments dialog box that lets you add comments to the generated report and to determine whether the output will be in PDF or RTF form. PDF is the default.

Clicking **Export Grid to Excel** or **Export Grid to PDF** generates a report that displays information in the grid for the forms selected.

Print Meeting Reports

This option opens the Select Meeting To Print grid displaying currently available forms. Clicking one or more of the reports in the grid and then clicking one of the print options in the grid toolbar will generates a report that includes information pertaining to all of the forms selected in the grid.

Clicking the **Select Report** button in the grid toolbar is limited to generating a Meeting Minutes Report. Clicking this option opens an Optional Comments dialog box that lets you add comments to the generated report and to determine whether the output will be in PDF or RTF form. PDF is the default.

Clicking **Export Grid to Excel** or **Export Grid to PDF** generates a report that displays information in the grid for the forms selected.

Human Protocols – Administration

Human Protocol administration settings are typically used by an authorized system administrator during the implementation phase for an application.

Once added, settings can be inactivated but not removed.

Depending on system settings some actions may trigger an Audit Trail dialog box. If they do, enter a Reason for Change and click **Save**.

Toolbar

Elements Administration offers management features to assist with day-to-day administrative duties. The features are located in the toolbar on the Administration home page:

- **Save** - Use this button to save any changes to administrative features such as Lists and Email Events. Before performing changes, the **Save** button is disabled. When you perform a change, the system illuminates the **Save** button indicating it is now enabled. Click **Save** to save your changes.
- **Reports** - Use this button to print any of the following reports:
    - Audit Trail Reports
    - Custom Lists
    - Email Events
    - E-Signature Report
    - Invalid E-Signature Attempts
    - Invalid Logins Report
    - Master Lists

HUMAN PROTOCOL LIST SETTINGS

Human Protocol List Settings determine which automated recording options are available to users. Some list settings are pre-determined by the system. Others (custom settings) are user-determined and can be created to meet local needs. Any of these settings can be made Active or Inactive, as needed., thus allowing for great flexibility in controlling human protocol actions.

Authorized personnel can access Human Protocol List Settings by clicking the Administration Icon in the Places group on the TOPAZ Elements main screen or by clicking the Administration option in the Product Selector for any screen and then clicking the Human Protocol List Settings option in the Administration Settings screen that opens.

What You See

Choosing the **Human Protocols List Settings** option displays the Human Protocols List Settings panel, below the Administration Settings panel. This panel contains a collection of list settings. Click a setting to open a third panel below the Human Protocols List Settings panel, containing available options for the selected setting.

Click an option to open the properties panel for that option to the right. Properties vary depending on the nature of the option. Additional list settings and list setting options can be added as required.

Pre-Determined Human Protocol List Settings

The following settings are system determined. They can be distinguished from custom settings by the absence of fields in their respective properties panels. Each of their options can be made active or inactive, as needed, but they cannot be deleted.

Human Protocol List Setting Options With Pre-Determined Options.

Two of the pre-determined list settings also contain pre-determined options. These options can be renamed and can be made active or inactive in their respective properties panels, but it is not possible to remove them or to add custom options for these settings.

- **Form SubType** - Types of protocol forms that can be created.
  - Amendment
  - Interim Review
  - Original
  - Renewal
- **Protocol Status** - Status options available for human protocols.
  - Approved
  - Approved Pending Modification
  - Not Approved
  - Not Submitted
  - Returned For Modification
  - Submitted
  - Suspended
  - Tabled
  - Withdrawn

Human Protocol List Settings Without Pre-Determined Options

The following pre-determined list settings come without pre-determined options. Custom options for these settings can be added to meet local needs. Once added, these options can be renamed and can be made active or inactive, but they cannot be removed.

- **Review Committee** - Displays a list of review committees as well as members and roles for assigned staff.

- **Review Group** - Displays a list of review groups as well as members and roles for assigned staff.
- **Review Opinion** - Displays a list of options for reviewers authorized to render an opinion.
- **Review Type** - Displays a list of categorized review options that meet local needs.
- **Review Role** - Displays a list of established reviewer roles that meet local needs.
- **Vote Motion** - Displays a list of options for reviewers authorized to render a vote.

Adding User-Determined Human Protocol List Settings

Perform the following procedure to add additional settings the Human Protocols List Settings panel:

1. Click the green **New** button at the top right of the panel. This adds a New List item to the panel and opens a properties.
2. In the properties screen, select the appropriate checkboxes if you want the setting to be Available In Filters and Available In Email Variable.
3. Enter a name in the field below the check boxes.
4. Click the **Save** button in the toolbar.

Adding User-Determined Human Protocol List Settings Options

Use the following procedure to add List Setting options to pre-determined settings (if allowed) and to custom settings:

1. Click a list setting in the Human Protocols List Settings panel. If it is possible to add an option for the setting, the application displays a green **New** button at the top right corner of the right panel.
2. Click the **New** button in the options panel to add a New Item and display the properties panel.
3. Enter a name in the Name field.
4. Enter a description in the Description field.
5. Place a mark in the **Active** checkbox.
6. Click the **Save** button in the toolbar.

Editing Settings and Setting Options

Settings and their options can be renamed and can be made active or inactive as needed. When changes are complete, click the **Save** button in the toolbar.

HUMAN PROTOCOL SETTINGS

Authorized personnel can access Human Protocol Settings by clicking the Administration Icon in the Places group on the TOPAZ Elements main screen or by clicking the Administration option in the Product Selector for any screen and then clicking the Human Protocol Settings option in the Administration Settings screen that opens.

What You See

Choosing the Human Protocol Settings option opens the Human Protocol Settings panel at the bottom of the screen, which contains the following fields:

- **Assign Reference Numbers** - A drop-down selection field used to determine whether protocol reference numbers will be set automatically or manually. The default is automatic.
- **Assign Protocol Numbers** - A drop-down selection field used to determine whether protocol numbers will be set automatically or manually. The default is automatic.
- **Set Default Protocol Expiration Period** - A numeric field used to enter the number of months after approval at which point protocols automatically expire.
- **Set Default Protocol Renewal Period** - A numeric field used to enter the number of months after approval at which point protocols must be renewed.
- **Record Audit Trails** - A Yes checkbox that, if checked, activates the audit trail function for approved protocols. The default is checked.
- **Next Reference Number** - A numeric field used to enter a number that determines the next reference number for a protocol. The default is 100000.
- **Next Protocol Number** - A numeric field used to enter a number that determines the next protocol number for a protocol. The default is 100000.

Editing and Saving Protocol Settings

Edit available fields as needed. When changes are complete, click the **Save** button in the toolbar.

HUMAN PROTOCOL EMAIL EVENTS

The Email Events - Human Protocols feature allows authorized personnel to determine whether e-mail messages will be generated for given circumstances and to customize the content contained in those messages.

Authorized personnel can access human protocol email events by clicking the Administration Icon in the Places group on the TOPAZ Elements main screen or by clicking the Administration option in the Product Selector for any screen and then clicking the Email Events - Human Protocols option in the Administration Settings screen that opens.

What You See

Choosing the **Email Events - Human Protocols** option displays the Email Events - Human Protocols panel, below the Administration Settings panel. This panel contains three event types or categories:

- Human Protocols
- IRB Reviews
- IRB Meetings

Click the event type to open a third panel below the Email Events - Human Protocols panel containing available email events for the selected event type. Click the event you want to set. This action opens a properties panel for that event on the right.

Email Event Types

Email events are grouped into three types, which are displayed in the center panel.

- Human Protocols
- IRB Reviews
- IRB Meetings

All email event types and their associated events are pre-determined by the system. However, event properties can be edited.

Human Protocols E-Mail Events

- Expired Human Protocols Query
- Expiring Human Protocols Query
- Human Protocol Approved
- Human Protocol Approved Pending Modifications
- Human Protocol Inactivated
- Human Protocol Not Approved
- Human Protocol Pre-submission Review Request
- Human Protocol Returned For Modification
- Human Protocol Submitted For Approval
- Human Protocol Suspended
- Human Protocol Tabled
- Human Protocol Withdrawn
- Inactive Human Protocol Query
- Renewing Human Protocol Query

IRB Reviews E-Mail Events

- Human Protocol Closing Remarks
- Human Protocol Opinion Submitted
- Human Protocol Review Assignment Set
- Human Protocol Vote Submitted

IRB Meetings E-Mail Events

- Human Meeting Approved
- Human Meeting Completed
- Human Meeting Scheduled

Email Event Properties

The properties panel for email events, regardless of type, are very similar. The only change is in the variables, which may differ depending on the email type chosen.

Email Content Tab

The Email Content tab contains the following elements:

- **Active** - A checkbox used to make the event either active or inactive.
- **Allow Editing Subject and Message** - A checkbox used to permit editing an email prior to sending it. Selecting this checkbox makes the View Email Before Sending checkbox inactive.
- **View Email Before Sending** - A checkbox that lets senders view the message prior to sending it. This checkbox is inactive if the Allow Editing Subject and Message checkbox is selected.
- **Allow Editing of Recipients** - A checkbox that lets senders modify the list of recipients prior to sending a message.
- **Attach PDF: Browse for PDF Template** - A checkbox that automatically attaches a PDF template to the email. The checkbox remains inactive until a template is chosen.
- **Name** - A non-editable field that displays the name of the event chosen.
- **Subject** - A text box used to enter a subject for the e-mail message.
- **Message** - A text box used to compose the e-mail message. A message must be prepared for each event that will be used.
- **Email Variables** - A list of fields used to insert custom information into a message.

Email Recipients Tab

The Email Recipients tab contains the following elements:

- **Staff Recipients** - A field used to add one or more staff names who are to received messages for the event.
- **Role-Based Recipients** - A field used to add one or more message recipients based on their role.

It is possible to include both individual staff and role recipients to a message.

Creating An Email Message

Use the following procedure to create an email message:

1. Select an event type and event from their respective panels.This action displays the properties panel for the event.
2. Select the appropriate sending options, such as Active and View Email Before sending.
3. Edit the name as necessary. By default the Name field for the message will be populated with the name of the event.
4. Enter the subject in the Subject field. Variables are permitted in this field.
5. Enter the text of your message in the Message box. Variables are permitted in this box.can be added to both Subject and Message fields.

6. Click the Email Recipients tab and use the green **Plus** buttons to add staff and role-based recipients for the message.
7. When the message is complete and recipients have been selected, click the **Save** button in the toolbar.

HUMAN PROTOCOL E-SIGNATURES

The E-Signatures - Human Protocols feature allows authorized personnel to determine whether an e-signature will be required in order to complete an action for specific system-determined events.

Authorized personnel can access human protocol e-signature settings by clicking the Administration Icon in the Places group on the TOPAZ Elements main screen or by clicking the Administration option in the Product Selector for any screen and then clicking the E-Signatures - Human Protocols option in the Administration Settings screen that opens.

What You See

Choosing the E-Signatures - Human Protocols option opens an E-Signatures - Human Protocols panel, on the right. This panel contains a list of system-determined events that can be chosen to trigger the need for an e-signature. Clicking an event in that panel opens a properties panel for that event in the lower part of the screen.

Human Orders E-Signature Events

The system provides the following events, which will trigger the need for an e-signature if the properties for that event is set to Active.

- Human Meeting Approved
- Human Meeting Completed
- Human Meeting Scheduled
- Human Opinion Submitted
- Human Protocol Approved
- Human Protocol Approved Pending Modification
- Human Protocol Not Approved
- Human Protocol Pre-submission
- Human Protocol Question Answered
- Human Protocol Returned For Modification
- Human Protocol Submitted For Approval
- Human Protocol Suspended
- Human Protocol Tabled
- Human Protocol Withdrawn
- Human Review Assignment Set
- Human Vote Submitted

The Human Protocols E-Signature Properties Panel

This panel contains the following items:

- **Active** - A checkbox used to require an e-signature for the event if checked.
- **Item Name** - A non-editable field that displays the name of the event selected in the upper right panel.
- **Display Name** - A text field used to enter an alternative name to be displayed in the e-signature dialog box when it appears.
- **Description** - A text field used to enter comments that will appear in the e-signature dialog box when it appears.

Activating Human Protocols E-Signature Events

Perform the following procedure to activate an e-signature for an event:

1. Select an event in the E-Signatures - Human Protocols panel.
2. Select the **Active** checkbox.
3. Enter an alternative name in the Display Name field.
4. Enter comments in the Description field.
5. Click the **Save** button in the toolbar.

HUMAN PROTOCOLS SHARED LIST SETTINGS

Accessing Shared List Settings

In Administration Settings, click Shared List Settings. This opens a Shared List Settings panel on the right displaying both pre-determined and user-determined shared settings options.

Understanding Shared List Settings for Human Protocols

Clicking one of the items listed in the Shared List Settings panel opens a third panel, on the right, displaying various options associated with that shared list setting. Checking one of those options in turn displays a properties panel, below. What appears in the properties panel depends on the item chosen. For user-determined items that will typically include an Active checkbox, a Name field, and a Description field.

Pre-determined Shared List Settings Associated With Human Protocols

- Department
- Location

Department

The following fields and buttons are present in the Department properties panel:

- **Name** - A text field used to name the department/sub-department.
- **Type** - A non-editable field displaying the department level in the hierarchy.
- **Code** - A text field used to enter a custom code for the department/sub-department displayed.

- **Active** – A checkbox used to determine whether the department/sub-department is active or not.
- **Description** – A text field used to describe the department/sub-department.
- **Administration** – A field that allow you to add one or more staff as names administrators using a green **Plus** button. Names can be removed from the list by clicking their associate red **Minus** (Remove) button.

Adding Departments and Sub-departments

To add a department

1. Click Department in the Shared List Settings panel to display the Department panel.
2. Click the green Plus button on the Department to open the properties panel containing the new department.
3. Edit the Name field as needed and confirm the Type is appropriate.
4. Enter a code, if needed.
5. Enter a description, if needed.
6. Add one or more names to the Administration field, if needed, by clicking its green **Plus** button and choosing names from the Select Staff grid that appears. Names can be removed by clicking their red **Minus** button.
7. Click **Save**. The new department will appear in the hierarchy panel.

To add a sub-department, click a department and begin the procedure at step 2.

Editing Departments and Sub-departments

Individual Departments and Sub-departments can be edited by selecting them in the Department list, making needed changes in the associated properties screen, and clicking the **Save** button in the toolbar.

Location

Location Shared List Settings are user-determined and appear as a hierarchical list in the right panel when Location is selected in the Shared List Settings panel. Locations and child locations are added to the list by clicking the green **Plus** button and completing details in the properties panel that appears at the bottom of the screen.

Location and Child Location Properties

The following fields and buttons are present in the Location properties panel:

- **Location/Name** – A text field used to name a location/child location. Note that the label for this field changes depending on the location level (site, building, floor, room, ,sub-room).
- **Active** – A checkbox used to determine whether the location/child location is active or not.
- **Meeting Room** – A checkbox used to indicate whether the location/child location hosts meetings as part of its function.
- **Description** – A text field used to enter a description for the location/child location, if needed.

Adding Locations and Child Locations

Use the following procedure to add locations and child locations:

1. Highlight Locations in the Shared List Settings panel.
2. Select any location or child location in the right panel, or choose All Locations if none have been added.
3. Click the green **Plus** button in the right panel. The properties panel for the selected location or child location appears at the bottom of the screen.

4. Edit the Name field as needed and confirm the level is appropriate.
5. Select the Meeting Room checkbox if the location or child location is to be used for holding meetings.
6. Enter a description.
7. For human studies, ignore the fields dealing with Animal Housing Location, Hygienic Level, and Species.
8. Click the **Save**button in the toolbar.

Editing Locations and Child Locations

Individual locations/child locations can be edited by selecting them in the Location list, making needed changes in the associated properties screen, and clicking the **Save** button in the toolbar.