## Understanding Protocol Management

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
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<tbody>
<tr>
<td>1.</td>
<td>Protocol Management architecture is designed with two levels: header and version. The header level is a parent to the child version level. Header information remains static regardless of the many modifications, reviews, or renewals that the protocol may undergo in its full life cycle.</td>
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<td>2.</td>
<td>Version information may change frequently; therefore, copying functionality becomes necessary to avoid manual reentry of data into the next version to retain history. The distinction between these two levels enables maximum flexibility in copying versions and in tracking changes between versions, which is essential to protocol management.</td>
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<td>3.</td>
<td>The protocol undergoes a series of phases during its life. The system captures phases at the version level through the phase type. A protocol moves from one phase to the next by way of version creation. Only one version can govern at any one time and is considered the current version. By viewing the versions in relation to one another on the version grid you can determine the history and flow of the protocol life.</td>
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<td>4.</td>
<td>Phases and versions follow specific rules. The system creates the initial, new protocol header with a version of phase type New and status of Draft. You cannot add or copy versions at this stage.</td>
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<td>5.</td>
<td>When you submit the protocol version, the status changes to Pending. You cannot copy this version until the status changes to Approved or Returned. If the disposition is issued as approved, the status also changes to Approved. You can now copy the protocol version. If the disposition is issued as returned, the status also changes to Returned. You can now copy the protocol version.</td>
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<tr>
<td>6.</td>
<td>You can copy any protocol which is in any status. The status of the new copied protocol is always reset to Draft. You can copy a protocol version only when the status is Approved or Returned. There are restrictions for copying a Protocol Version. A Protocol is copied to a brand new protocol within the same Protocol type. Example, animal to animal and human to human.</td>
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### Step 7

The seven protocol management statuses are:

- **Draft**: The version is added or copied, but not submitted.
- **Pending**: The draft version is submitted (date/time stamped) for the review process.
- **Approved**: The pending version is reviewed and approved by the reviewing authority.
- **Denied**: The pending version is reviewed and denied by the reviewing authority. This status cannot be changed, as it captures indefinitely that this version was rejected. You can copy this protocol to a new protocol but are not permitted to act against it in any other way.
- **Returned**: The pending version is reviewed and returned for further modifications by the reviewing authority.
- **Expired**: The version is approved and has expired because the project end date has passed.
- **Inactive**: The version is submitted for the review process but no action was taken against it.

### Step 8

The version level status reflects the status for the entire protocol (for example, header) as this is the only status, and only one version governs at any given time. Carrying the status at the version level allows for maximum flexibility when you are creating the various phase type protocol versions.

### Step 9

The phase type enables the tracking of submissions and re-submissions of the various phases of the protocol. The reviewing committee must be able to track such changes to make their final approval as well as for ongoing reviews and reporting. A phase type, along with the status, helps identify which phase the protocol is in.

### Step 10

The phase types are:

- **New**: Indicates a brand new protocol version. It is at the first phase.
- **Modified**: Indicates changes or updates being made to: (1) An approved protocol version which is initiated by the Principal Investigator (for example, a minor amendment), or (2) A pending protocol version that was returned by the review committee (for example, a disposition requested clarification of methodology) so that a modified version is created to which the PI updates with appropriate changes and then resubmits for approval.

### Step 11

- **Continuing Review**: Indicates a scheduled review of how the protocol research is progressing. The PI is responsible for informing the review committee of the progress for their approval. The interval from review to review is typically no greater than a year. The Continuing Review interval is preestablished at setup time on the BU-Award Set Up page. The system automatically increments the next CR date, beginning at the start date, by the number of months that you have determined, and this date is displayed on the Version Info page. Also, this is the date by which workflow notifications are triggered.
- **Renewal**: Indicates updates to the approved protocol for the purpose of renewing (or extending) protocol research. In this case, the user would also update the expiration date. If after receiving a notification that protocol is approaching its end date and you want to renew it, you can copy to a new version and reenter a new start and end date for the process to begin again.

### Step 12

This concludes the Understanding Protocol Management topic.

**End of Procedure.**