

1.3 Advanced Disease On-Study Form

1.3.1. Special notes about this form:

This form must be submitted within 14 days of starting therapy.

1.3.2. Accessing the form:

To select this form for data entry, from the Data Entry Main Menu, highlight the appropriate patient, click on the form name to highlight, and then click the [Select] button.

1.3.3. Adding the form:

Click the [Add Record] button to continue.

1.3.4. Modifying the form:

From the Data Entry Main Menu, click on the form name to highlight then click the [Select] button. The previously entered On study Form will be listed under **Existing Records**. To modify the form, click the [Update] button.

1.3.5. Instructions – Data Entry – Adding new record:

Date Informed Consent Signed - Enter the date the subject signed the protocol consent form in MM/DD/YYYY format.

1.3.6. Colorectal: Current Disease Description

Note: The questions that follow refer to current sites of disease. Previously resected sites with no evidence of disease should be coded as No.

- ? Is the Primary Site or tumor bed involved? - Select 'Yes' or 'No'.
- ? Regional Lymph Nodes? - Select 'Yes' or 'No'.
- ? Distant Lymph Nodes? - Select 'Yes' or 'No'.
- ? Lung? - Select 'Yes' or 'No'.
- ? Liver? - Select 'Yes' or 'No'.
- ? Other Abdominal? - Select 'Yes' or 'No'.
- ? Bone? - Select 'Yes' or 'No'.
- ? Brain? - Select 'Yes' or 'No'.
- ? Distant Skin/Subcutaneous Tissue? - Select 'Yes' or 'No'.
- ? Other? - Select 'Yes' or 'No'. If there are other sites involved that were not listed above then 'Yes' should be checked. If there are no additional sites then check 'No'.
 - ? If Yes, Specify Other Site(s) - Record the other involved site(s).
- ? Advanced Disease Status at Registration - Check either '1-Initial Diagnosis' or '2-Recurrence'.

1.3.7. Colorectal: Prior Treatment

Note: The following questions relate to prior surgery for colorectal cancer.

- ? Prior Surgery? - Select 'Yes' or 'No'.
- ? Prior Radiation Therapy? - Select 'Yes' or 'No'.
- ? Prior Adjuvant Chemotherapy? - Select 'Yes' or 'No'.

? Prior Adjuvant Immunotherapy? - Select 'Yes' or 'No'.

Record any additional notations with regards to data collected for this form in the **Comments** section.

Click [**Save**] to ensure that data are written to the database.