Adverse Reaction (ADR) Form for Investigational Agents

Instructions: This form should be completed for all Adverse Reactions. It should be mailed according to the instructions of the Cooperative Group.

Patient's Initials: ___________________________ Protocol No.: ___________________________ Patient Sequence No.: ___________________________

Institution/Affiliate: ___________________________

Intergroup Protocol No.: ___________________________ Intergroup Patient Sequence No.: ___________________________

Name of treating physician: ___________________________ Diagnosis: ___________________________

Name of person completing this form: ___________________________ Phone No.: ___________________________

☐ Toxicity grading criteria used (01 - Common toxicity criteria, 02 - Other/specify)
☐ Toxicity category (01 -death, 02 -unusual, 03 -expected)
☐ Treatment arm code

I. DEMOGRAPHICS
☐ Date of birth (M, Y) ☐ Date of initial diagnosis (M, Y)
☐ Sex (01=male, 02=female) ☐ ECOG Performance Status, day 1 of Rx

Please record site(s) of metastatic disease if appropriate (01=no, 02=yes, -1=unknown/not applicable)
☐ Nodal Involvement ☐ Osseous Involvement ☐ Visceral Involvement/specify: ___________________________

☐ Was the patient taking non-protocol medications at the time of the ADR? (01=no, 02=yes, -1=unknown)
If yes, specify medications and any concurrent disease: ___________________________

II. ADVERSE REACTION
Specify agent(s) suspected of causing reaction. ☐ Date adverse reaction started (M, D, Y)

IF RELEVANT: ☐ Date adverse reaction ended (M, D, Y)

☐ Was any agent supplied by NCI? (01=no, 02=yes, -1=unknown)
If no, specify source: ___________________________

Specify toxicity type: ___________________________ (e.g., cardiac, infection, or note if disease progression)

☐ Date of Rx associated with the ADR (M, D, Y)

☐ Toxic grade of the ADR ☐ Date of death (if patient died) (M, D, Y)

III. PRIOR TREATMENT
Please list below any prior treatment for this malignancy (01=no, 02=yes, -1=unknown)

☐ Prior chemotherapy/immunotherapy Description Start Date Date End
And/or hormonotherapy ___________________________ ___________________________ ___________________________

☐ Prior radiotherapy ___________________________ ___________________________ ___________________________

☐ Prior surgery ___________________________ ___________________________ ___________________________

IV. CURRENT PROTOCOL TREATMENT (include all agents)

Agent Dose Schedule Route Relation to ADR* Action Taken** Total Dose to Date

* Options–unrelated, unlikely, possible, probable, definite, unknown/not applicable.
** Action Taken–dose reduced, dose withheld, dose discontinued.
**V. DOCUMENTATION OF REACTION**  
*Please complete Part A and/or Part B*

**Part A** – Complete this section if the patient had either a non-hematologic reaction OR an unexpected hematologic reaction.

1. Give a brief description of the reaction and its temporal relationship to the Rx administration.

2. Give a brief description of any relevant physical findings or laboratory data which documents the ADR.

<table>
<thead>
<tr>
<th>ADR Lab:</th>
<th>Baseline: Date/Value</th>
<th>Nadir: Date/Value</th>
<th>Recovery or Most Recent: Date/Value</th>
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3. Give a brief description of how the ADR was treated.

4. Please list any complications and sequelae (if death, was autopsy done? Please submit report).

5. Please describe any medical history of the patient, which might be relevant to this event.

6. If the suspected agent(s) was given again, please describe dose and reactions.

**Part B** – Complete this section if the patient had a hematologic reaction – expected OR unexpected.

1. Laboratory Data Documenting ADR

<table>
<thead>
<tr>
<th>ADR:</th>
<th>Baseline: Date/Value</th>
<th>Nadir: Date/Value</th>
<th>Recovery or Most Recent: Date/Value</th>
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<thead>
<tr>
<th>Platelets</th>
<th>Baseline: Date/Value</th>
<th>Nadir: Date/Value</th>
<th>Recovery or Most Recent: Date/Value</th>
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<thead>
<tr>
<th>HGB/HCT</th>
<th>Baseline: Date/Value</th>
<th>Nadir: Date/Value</th>
<th>Recovery or Most Recent: Date/Value</th>
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2. Please give a brief description of any complications, treatment, and sequelae if Part A HAS NOT already been completed.

   - [ ] [ ] [ ] Date telephoned Cooperative Group
   - [ ] [ ] [ ] Date telephoned NCI (301-230-2330)
   - [ ] [ ] [ ] Date telephoned pharmaceutical company
   - [ ] [ ] [ ] Report by

   - [ ] [ ] [ ] Date form sent to Cooperative Group
   - [ ] [ ] [ ] Date form sent to NCI
   - [ ] [ ] [ ] Date form sent to pharmaceutical company

   - [ ] [ ] [ ] 01=Institution
   - [ ] [ ] [ ] 02=Statistical center
   - [ ] [ ] [ ] 03=Study chairman
   - [ ] [ ] [ ] 04=Statistical center, but later documented as no report needed.

   **Signature of Responsible Physician**

   **M.D.**

   **Date**

**Investigator:** Keep a copy for your files and submit original form.