**Colorectal Cancer**
**IDGN-CRC-AO2**

# I. INCLUSION AND EXCLUSION CRITERIA

## INCLUSION CRITERIA

| | Yes | No |
|---|---|---|
| 1. Subject is diagnosed with primary colorectal adenocarcinoma by histopathology. | ☐ | ☐ |
| 2. Age ≥ 18 years. | ☐ | ☐ |
| 3. Subject is of Ashkenazi Jewish origin, as declared by the subject. | ☐ | ☐ |
| 4. Subject or subject's legal representative has signed the informed consent form. | ☐ | ☐ |

## EXCLUSION CRITERIA

| 1. Subject is diagnosed with one of the following: | Yes | No |
|---|---|---|
| a. Metastatic adenocarcinoma **to** the colon or rectum; hereditable gastrointestinal polyposis syndromes (familial adenomatous polyposis, Gardner's syndrome, Turcot's syndrome, Peutz-Jeghers syndrome, juvenile polyposis); inflammatory bowel disease; carcinoid tumor; lymphoma; sarcoma; adenoacanthoma. | ☐ | ☐ |
| b. Patient underwent ureterosigmoidostomy. | ☐ | ☐ |
| c. Subject has a history of exposure to ionizing radiation in the abdominal region (e.g. gynecological carcinoma, lymphoma). | ☐ | ☐ |
| 2. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated. | ☐ | ☐ |
| 3. Subject's **current** white blood cell (WBC) count is less than 2000 cells/$mm^3$. | ☐ | ☐ |

**Subject is eligible for the study, if all INCLUSION criteria are YES and all EXCLUSION criteria are NO.**

## INVESTIGATOR'S STATEMENT

I have verified the data entered in the Case Report Form and have determined that it is complete, accurate and compatible with the source documents.

| Investigator's name (printed) | Investigator's signature | Day | Month | Year |
|---|---|---|---|---|
| _____ | _____ | ☐☐ / | ☐☐ / | ☐☐ |

Where appropriate mark like this ☒ (not like this √)

**SUBJECT BARCODE STICKER**

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## II. DEMOGRAPHICS

| | |
|---|---|
| **1. Sex:** ☐ **Male** ☐ **Female** | **3. Country of birth:** _____ |
| **2. Year of birth:** ☐☐☐☐ | **4. Year of immigration:** ☐☐☐☐ |

## III. FAMILY HISTORY

| **1. Maternal** | | | **2. Paternal** | | |
|---|---|---|---|---|---|
| | Country of birth | | | Country of birth | |
| 1.1 Mother: | _____ | | 2.1 Father: | _____ | |
| 1.2 Grandfather: | _____ | | 2.2 Grandfather: | _____ | |
| 1.3 Grandmother: | _____ | | 2.3 Grandmother: | _____ | |
| | Yes | No* | | Yes | No* |
| 1.4 Mother is alive | ☐ | ☐ | 2.4 Father is alive | ☐ | ☐ |
| *If not, specify age at death: | ☐☐ | | *If not, specify age at death: | ☐☐ | |

**3. Blood relatives:**

3.1 Specify number of siblings (including patient): ☐☐

3.2 **For close relatives suffering from malignancies**, mark appropriate boxes and specify approximate age at diagnosis:

| | **Colorectal cancer** | | **Other GI cancer** | | **Other** | |
|---|---|---|---|---|---|---|
| | Yes | Age | Yes | Age | Specify | Age |
| Mother | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |
| Father | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |
| Sib. 1 | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |
| Sib. 2 | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |
| Sib. 3 | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |
| Sib. 4 | ☐ | ☐☐ | ☐ | ☐☐ | _____ | ☐☐ |

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## IV. MEDICAL HISTORY

**1. Date of diagnosis (month / year):** ☐☐ / ☐☐☐☐

**2. Pathologic stage at diagnosis (choose one):**

a. Stage 0 (carcinoma in situ, Tis, N0M0) ☐

b. Stage I (TIN0M0 or T2N0M0, Dukes A) ☐

c. Stage II (T3N0M0, Dukes B) ☐

d. Stage III (any T N1-3M0 or T4N0M0, Dukes C) ☐

e. Stage IV (any T any N M1, Dukes D) – measurable disease ☐

f. Stage IV (any T any N M1, Dukes D) – non-measurable disease ☐

g. Stage IV (any T any N M1, Dukes D) – no evidence of disease ☐

**3. Tumor location:** Proximal (to splenic flexure) ☐ Distal ☐

| | Yes | No | Unknown |
|---|---|---|---|
| **4. Were multiple primary colonic neoplasms diagnosed simultaneously?** | ☐ | ☐ | ☐ |
| **5. Was there an elevated level of carcinoembryonic antigen (CEA)?** | ☐ | ☐ | ☐ |
| **6. Before the disease was diagnosed, was the patient taking aspirin (any dosage) or other NSAIDS[1] regularly (>2 tablets per week, for more than 6 months)?** | ☐ | ☐ | ☐ |

**7. Smoking history** – no. of years: ☐☐ no. of packs per day: ☐☐

**8. <u>For women</u>: Before the disease was diagnosed, was the patient treated with hormonal replacement therapy for at least 6 months?** ☐* ☐ ☐

**9. Did the disease recur?** yes ☐* no ☐ irrelevant ☐

***If yes, specify date (month / year):** ☐☐ / ☐☐☐☐

**10. Specify patient's other chronic diseases:** _____

_____

[1] NSAIDS – Non Steroidal Anti-inflammatory Drugs.

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# V. MEDICATIONS

| | Yes | No | Did not get adjuvant chemotherapy |
|---|---|---|---|
| **1. Was adjuvant chemotherapy (Fluorouracil (5-FU) based) stopped because of severe toxicity[1-4]?** | ☐ | ☐ | ☐ |

**2. If the patient was treated for <u>metastatic</u> disease, please fill the tables regarding drug efficacy and side effects:**

| **2.1 Efficacy:** | **First line** | | | | **Second line** | | | |
|---|---|---|---|---|---|---|---|---|
| | **Complete response** | **Partial response** | **Stable disease** | **Unknown** | **Complete response** | **Partial response** | **Stable disease** | **Unknown** |
| 5-FU-Leucovorin | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Cisplatinum | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Irinotecan | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Oxaliplatin | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Other, specify: _____ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**3. Side effects – if the patient was treated with chemotherapy, mark the appropriate boxes:**

| | **5 - FU Leucovarin** | **Cisplatin** | **Irinotecan** | **Oxaliplatin** |
|---|---|---|---|---|
| Never treated | ☐ | ☐ | ☐ | ☐ |
| Treated without significant adverse reactions | ☐ | ☐ | ☐ | ☐ |
| Grade 4 vomiting[1] | ☐ | ☐ | ☐ | ☐ |
| Grade 4 mucositis[2] | ☐ | ☐ | ☐ | ☐ |
| Grade 4 diarrhea[3] | ☐ | ☐ | ☐ | ☐ |
| Grade 3-4[4] neutropenia | ☐ | ☐ | ☐ | ☐ |
| Hand-foot syndrome[5] | ☐ | ☐ | ☐ | ☐ |
| Hypersensitivity reaction[6] | ☐ | ☐ | ☐ | ☐ |
| Peripheral neuropathy | ☐ | ☐ | ☐ | ☐ |

[1] National Cancer Institute (NCI) toxicity criteria grade 4 stomatitis is defined as requiring enteral or parenteral support. NCI toxicity criteria grade 4 gastritis is defined as life threatening bleeding requiring emergency surgery. NCI toxicity grade 4 colitis is defined as perforation or requiring surgery or toxic megacolon.

[2] NCI toxicity criteria grade 4 vomiting is defined as requiring parental nutrition, intensive care admission or hemodynamic collapse.

[3] NCI toxicity criteria grade 4 diarrhea is defined as an increase of greater than 10 stools daily, grossly bloody stools, or the need for parental fluid replacement therapy.

[4] NCI toxicity criteria grade 3 or 4 neutropenia is defined by a neutrophill count of less than 1000/microL.

[5] An erythematous, desquamative rash involving the hands and feet. The rash may be accompanied by tingling or painful hands and feet, swollen palms and soles, and phalangeal tenderness.

[6] Flushing, rush, hypotension, dyspnea, tachycardia, anaphylaxis.

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