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| --- | --- | --- |
| Principal Investigator: | | Application ID: |
| Application Title: | | |
| Please specify the  type of request: | Approved CCFR Project, **Date approved:** | |
| CCFR approved amendment for additional data and/or biospecimens | |
| Ad hoc CCFR request | |
| Study Abstract: | | |

**INTRODUCTION AND INSTRUCTIONS**

**PLEASE NOTE:** The information requested on this form will be used by collaborating CCFR sites: 1) to obtain local IRB approval, 2) initiate data and material use agreements, 3) query for data/biospecimens meeting your eligibility criteria, 4) dispatch and invoice for biospecimens, 5) prepare analytic datasets. This form (and your IRB documentation) is the first step in launching your study. **Be sure the information you provide is complete**. Contact Allyson ([atemplet@fredhutch.org](mailto:atemplet@fredhutch.org)) with any questions and return the completed form to her.

**All individual-level data will be DE-IDENTIFIED**: Personal health information (PHI) dates (dates of birth, death, diagnosis, procedure, etc.) will be truncated to the year and ages over 89 will be reported as 90 or more.

Before you start, here are some helpful links:

* Descriptions of variables can be found in on-line **data dictionaries** at: <http://www.coloncfr.org/data-dictionaries>
* CFR center **recruitment strategies** can be found at <http://www.coloncfr.org/supplementary-information>

Before work can begin on your data and/or biospecimen request:

1. **IRB**: Documentation of IRB review of the research involving CFR data must be provided to Allyson (above).
2. **DUA**: A Data Use Agreement (DUA) must be fully executed with the CCFR Informatics Center (IC) at the University of Melbourne. The IC will initiate this agreement. **You can find the template DUA here:** <https://www.coloncfr.org/images/CCFR_DUA_TEMPLATE_2018_FINAL.pdf>
3. **MTA**: If biospecimens are being requested, a Material Transfer Agreement (MTA) must be fully executed with **each** CCFR site providing biospecimens (CCFR sites will initiate these).

Data requests are assigned in order by the date the IC receives this DRF and confirms that all assurance documents have been provided/executed. Upon completion of the data request, the person identified **to receive the FileSender link to the downloadable data file(s)** (next page)will receive an e-mail from the CCFR IC Manager, Maggie Angelakos ([m.angelakos@unimelb.edu.au](mailto:m.angelakos@unimelb.edu.au)). Datasets will be delivered in CSV or Excel format (unless otherwise specified) and will be compressed and e-mailed from **AARNet FileSender** (secure file sharing link from the University of Melbourne).

**DATA SHARING:** After projects have been completed all investigators are expected to return study results (at the genotype level) to the IC within six months of their publication. In this way, the annotation of each CCFR subject grows over time. Please contact Maggie (above)for information on returning study results.

**Part A: Administrative Information**

**1: STUDY TEAM**

|  |  |
| --- | --- |
| **Principal Investigator:** | Name |
| Institution: |  |
| Address: |  |
| Address, cont. |  |
| Phone: | Email: |
| **IRB Number** |  |
| **Study Manager/primary team contact:** | Name: |
| Phone: | Email: |
| **Person completing this form** | Name: |
| Phone: | Email: |
| Date this form is submitted to the CCFR |  |
| **Person to receive the AARNet FileSender link to the downloadable data file(s)** | Name: |
| Phone: | Email: |
| **Is there a deadline for the data delivery?** | No  Yes, deadline date: |
| What is the reason for deadline? |  |

**2: INSTITUTION DATA/MATERIAL TRANSFER AGREEMENT CONTACT(S)**

|  |  |
| --- | --- |
| **Data Use Agreement (DUA) Contact Person** | Name: |
| Institution: |  |
| Phone: | Email: |
| **If Biospecimens are requested**: Check box if contact person is the same as above | |
| **Material Transfer Agreement Contact Person** | Name: |
| Institution: |  |
| Phone: | Email: |

**3: BIOSPECIMEN REQUEST & INVOICE CONTACT(S).** Complete if requesting biospecimens

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| Please check the CCFR sites PROVIDING biospecimens (if available) | | | | | | |
| Australia | Cleveland | Hawaii | Mayo | Ontario | Seattle | UCSF |
|  |  |  |  |  |  |  |
| **BIOSPECIMEN RECIPIENT Information** | | |  | | | |
| **Person to receive biospecimens:** | | | Name: | | | |
| **Fed Ex** Address (for biospecimen delivery) | | |  | | | |
| Address, cont. | | |  | | | |
| Fed Ex account no. (if available): | | |  | | | |
| Phone: | | | Email: | | | |
| **Is there a deadline for biospecimen receipt?** | | | No  Yes, deadline date: | | | |
| What is the reason for deadline? | | |  | | | |
| **BILLING information for biospecimens** | | |  | | | |
| **Person to receive the invoice:** | | | Name: | | | |
| Address: | | |  | | | |
| Address, cont. | | |  | | | |
| Phone: | | | Email: | | | |

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| **Part B. Eligibility Criteria:** Please check the criteria to be used to identify eligible persons/records/samples   |  |  | | --- | --- | | Does inclusion depend on membership within a family? | One person only from each family | | (check all that apply) | Probands | |  | Relatives | |  | Non-relatives e.g., spouses, population controls | | Does inclusion depend on cancer status? | Only subjects with cancer | |  | Only subjects without cancer | |  | Both | | Does inclusion depend on ascertainment source? | Population-based only | |  | Clinic-based only | |  | Both | | Does inclusion depend on recruitment site? | Australia/University of Melbourne | |  | Former USC Consortium | |  | Hawaii/University of Hawaii Cancer Center, HI | |  | Mayo Clinic, AZ | |  | Ontario/Sinai Health System, Canada | |  | Seattle/Fred Hutchinson Cancer Center, WA | |  | UCSF (formerly CPIC/NCCC), CA | |  | All |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **What criteria would you like to use to define colorectal cancer for your project?** Below are available site, behavior and histology codes that *can* be used to define colorectal cancer (CRC) and are available through the CCFR. Define your study criteria by checking the box next to the codes from each category.  **CRC Verification**: Do you wish to restrict CRC diagnoses based on source of information (select all that apply)?  Select only ‘verified’ sources (pathology review/report, clinical record, cancer registry, death certificate, etc.)  Allow diagnoses that were self-reported or 2nd hand reports (by relative or spouse), not otherwise verified.  **Site:** Please check which ICD-0 SITE codes to include:   |  |  |  | | --- | --- | --- | | Select all below | C18.5: Splenic flexure | C18.8: Overlapping lesion of colon | | C18.0: Cecum, ileocecal valve | C18.6: Descending colon | C18.9: Colon, unspecified | | C18.2: Ascending colon | C18.5: Splenic flexure | C19.9: Rectosigmoid junction | | C18.3: Hepatic flexure | C18.6: Descending colon | C20.9: Rectum | | C18.4: Transverse colon | C18.7: Sigmoid colon | Other, specify: | | **NOTE**: We do not consider the following sites part of the colon or rectum: C18.1 (appendix), C21.8 (anus and anal canal) and C26.0 (intestinal tract, NOS, which may include the small intestine), though there are small number of these in the CCFR. If you want to include these sites, please write the site codes in “Other” | | |   **Behavior:** Please check which behavior code(s) to include (ICD-0 BEHAVIOR codes):   |  | | --- | | Malignant (Behavior code = 3) | | In-situ (Behavior code = 2)*(NOTE: In-situ cases were most often excluded/not recorded*) |   **Histology group:** Please check which histology groups you wish to include (ICD-0 HISTOLOGY codes): | | | Adenocarcinoma, NOS (8140, 8211, 8220, 8221,8255, 8260,  8262, 8481) | Mucinous adenocarcinoma (8480) | | Signet ring cell carcinoma (8490) | | Adenocarcinoma in adenomatous polyp (8210, 8261, 8263) | Medullary carcinoma, NOS (8510, 8082) | | Carcinoma, NOS (8010) | Adenosquamous carcinoma (8560) | | Carcinoma, undifferentiated type, NOS (8020) | Other, specify: | |

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| **Please specify your CASE inclusion and exclusion criteria in as much detail as possible** |
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| **Does your study include matched CRC-unaffected CONTROLS?**  **Yes**  **No** |
| ***If yes***, detail your CONTROL inclusion and exclusion criteria and your matching criteria.   1. Define “unaffected with cancer”: can a control subject have an in-situ cancer or a non-melanoma skin cancer (quite common) or a malignant cancer after some time point (e.g., enrollment) and if so, what? 2. Define the type of subject that can serve as a control: population-based proband controls, spouse controls, unaffected family member, etc. 3. Detail matching criteria, e.g., CCFR site, sex, age (+/-5 years), etc. |

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| **Part C. Data Request: Please check all data categories to be included in your dataset.**  The CCFR data is stored centrally in a relational database where the tables have different fields (variables) defining unique records. Because of this, direct table merges will create record multiplicities that may later need to be undone as a part of the analysis. For example, if the Individual Table is merged to the Cancer Table, the resulting file will have multiple records per person, one record per person-tumor combination. |

Family History: <http://www.coloncfr.org/data-dictionaries/family-history>

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| Family membership information (ascertainment: cancer registry, clinic; proband type, funding phase) |
| Individual information (mother/father ID, vital status, **year** of birth/death, available data) |
| Cancer history (site, histology, behavior, age at diagnosis, etc.) |
| Cause of death |
| Amsterdam I/II, Type X family, triad member (yes/no) |
| Derived family history, **describe below** (e.g., # first-degree relatives with colorectal cancer, etc.) |
| *Describe*: |
| Derived race (race data from all sources are concatenated into a single set of values) |

Self-reported Epidemiologic/Risk Factors:

BL – baseline epi (data dictionary in 3 parts) <http://www.coloncfr.org/data-dictionaries/colon-epi>

FU – follow-up epi <https://www.coloncfr.org/data-dictionaries/colon-epi/colon-epi-followups>

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|  |  | Demographics/general (age at survey, income, education, marital status) (BL parts 1 and 3) |
|  |  | CRC Screening (BL part 1) |
|  |  | Polyps, polypectomies (BL part 1) |
|  |  | Surgeries (colon/rectum, gallbladder) (BL part 1) |
|  | na | Alcohol consumption, tobacco use (BL part 3) |
|  |  | Non-cancer medical history, medication use (BL part 1) |
|  |  | Female reproductive history, hormone use, surgeries (BL part 2) |
|  |  | Race, ethnicity, birthplace, type of Jewish ancestry (BL part 3) |
|  | na | Physical activity (BL part 2) |
|  | na | Diet (15 variables) (BL part 3) |
|  |  | Participation in research studies / genetic testing (BL part 3) |
| na |  | Behavioral (SF-12) |
| na |  | Non-core data (center- and phase-specific, see questionnaires at  <https://www.coloncfr.org/data-dictionaries/colon-epi/colon-epi-followups-non-core> |
| *Comment:* | | |

Diet: <http://www.coloncfr.org/data-dictionaries/hawaii-diet>

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| Self-reported Australasian Diet (collected at baseline in Phase I in Australasia) |
| Self-reported Hawaii Diet (collected at baseline in Phase I in Hawaii, USC, Ontario) |
| Calculated Hawaii Nutrient |
| *Comment*: |

Colorectal Pathology (abstracted from medical records): <http://www.coloncfr.org/data-dictionaries/colorectal-path>

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| Colorectal malignancy (resection or biopsy pathology report abstraction) |
| Polyps (reported at resection or biopsy in pathology report) |
| Clinical diagnosis and treatment (medical record abstraction) (limited availability) |
| *Comment*: |

Molecular: <http://www.coloncfr.org/data-dictionaries/molecular>

Germline (Genomic & MLPA)*:* Germline testing was done for the genes listed below based on testing schemes that can be found here: <http://www.coloncfr.org/supplementary-information>.

If you check the box, we will provide the results we have.

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| GENE | | SEVERITY | RESULT: Indicate what results to include: |
| MLH1 | PMS2 | Deleterious/Pathogenic | Positive, tested and change detected |
| MSH2 | EPCAM | Unclassified variant | Negative, tested and no change detected |
| MSH6 | MutYH | Polymorphism/neutral | All results, including equivocal, failures |

Somatic (tumor)

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| MSI (marker-level data): <http://www.coloncfr.org/data-dictionaries/molecular/msi> |
| IHC (protein-level data): <http://www.coloncfr.org/data-dictionaries/molecular/ihc> |
| BRAF\_KRAS: <http://www.coloncfr.org/data-dictionaries/molecular/braf-kras> |
| MLH1 methylation: (positive/negative/not tested) |
| CIMP: (positive/negative/not tested) |
| *Comment*: |

Derived molecular result

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| MSI (tumor-level): <http://www.coloncfr.org/data-dictionaries/molecular/derived-msi-ihc-primary-key-msi> |
| IHC (tumor-level): <http://www.coloncfr.org/data-dictionaries/molecular/derived-msi-ihc-pk-ihc> |
| MSI\_IHC (person-level): <http://www.coloncfr.org/data-dictionaries/molecular/derived-msi-ihc> |
| Germline MMR (person level): <http://www.coloncfr.org/data-dictionaries/molecular/derived-genomic> |
| *Comment*: |

Genome-wide Association studies

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| Harmonized dataset comprised of the following GWAS datasets:   * Illumina Human1M/ Human1M-Duo (non-Hispanic White population-based case/unrelated control) * Illumina Omni1 (non-Hispanic White population-based case/unrelated or family control * Affymetrix Axiom Array (non-Hispanic White case/control) * OncoArray (non-Hispanic White population-based case/unrelated or family control) |
| *Comment*: |
| Record any special data requests here. |

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| **Part D. Biospecimens:** | |
| Does your request include biospecimens? | YES (complete the rest of this form)  NO |
| Have you received the price sheet? | YES  NO (find at [www.coloncfr.org/collaboration](http://www.coloncfr.org/collaboration)) |
| Name of person who provided sample dispatch list: | |
| Do you anticipate more than one biospecimen request, e.g., a future request to follow up or validate initial findings? | YES  NO |
| Does your request here deviate at all from that which was approved in your application (e.g., participant type, number of samples, quantity, methodology, etc.)? | YES  NO |
| ***If YES***, describe here: | |
| Will biospecimens be shipped for each individual identified in the sample dispatch list or a subset? | ALL INDIVIDUALS  ONLY A SUBSET |
| ***If ONLY A SUBSET***, provide detailed subset criteria or instructions for dispatch staff here: | |
| Will biospecimens require internationally shipping by one or more CCFR site? | YES  NO |
| ***If YES,*** you will be responsible for providing all necessary customs paperwork that must accompany the shipment(s) to avoid delays clearing customs. | |

**Part D. Biospecimens,** *continued*

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| ***If requesting biospecimens, specify:*** | | Amount required if quantified by:  (provide amount for both methods) | | Concentration  (specify diluent below) |
| Spectrophotometry | Fluorescent dye |
| DNA1 from blood | | µg | µg | µg/ml |
| DNA1 from tumor tissue (paraffin embedded) | | µg | µg | µg/ml |
| DNA1 from normal tissue (paraffin embedded) | | µg | µg | µg/ml |
| DNA1 from tumor tissue (fresh frozen)4 | | µg | µg | µg/ml |
| DNA1 from normal tissue (fresh frozen)4 | | µg | µg | µg/ml |
| Plasma | | ml |  |  |
| Guthrie spot | | ml |  |  |
| Lymphoblast cell line (LCL)(growing culture)4, 5 | | vials |  |  |
| Tumor tissue from paraffin block (slide)2 | | Slide(s) |  |  |
| Normal tissue from paraffin block (slide)2 | | Slide(s) |  |  |
| Fresh frozen tumor tissue4 | | mg |  |  |
| Fresh frozen normal tissue4 | | mg |  |  |
| Other, specify | |  | | |
| 1 If requesting DNA, specify:   1. Specify sample format:  Tubes or  Microplates (list special requests (e.g., blank wells) below). 2. Specify diluent:  Water  TE  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_ 3. If blood DNA is not available, check if you can accept:  LCL cell-line DNA  buccal/saliva/mouthwash DNA 4. For DNA extracted from tumor PET, do you require a minimum threshold for tumor density?  NO  YES   ***If yes***, specify minimum: % neoplastic cellularity: \_\_\_\_\_\_\_\_\_ **and** minimum % tumor: \_\_\_\_\_\_\_\_\_   1. If DNA extractions would be required for one or more subjects (for example, if DNA has not been extracted, stored DNA is exhausted, or if PET tissue must be macrodissected for tumor DNA), will you:   **EXCLUDE** those samples or  **INCLUDE** and request extractions?6   1. DNA was quantitated by spectrophotometry. Do you require fluorescent dye quantification?6   NO  YES | | | | |
| 2 If requesting tissue slides from paraffin blocks, specify:   1. Type of slide:  Charged7  Uncharged  Either type 2. Tissue thickness (µm): 3. Number of slides per participant: 4. Do you require a scanned image (20x) of the H&E slide6?  NO  YES | | | | |
| 4 Available on a subset of subjects. | | | | |
| 5 LCL cells are available only if a cell-line has already been established and there are at least 2 vials in storage. If fewer than 2 vials in storage, cell-lines will need to be thawed and re-grown for dispatch.6 | | | | |
| 6 Additional costs apply.See CCFR Biospecimen Price List at <http://www.coloncfr.org/collaboration> | | | | |
| 7 A limited number of tissue sections were prepared on charged slides and generally are not available for dispatch. Some sites may be able to cut additional slides.6 | | | | |
| Record special requirements here.  NOTE: DNA will be shipped ambient unless shipment with a cold pack or dry ice is requested. |  | | | |

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| **Part E. Comments**  Any other information relevant to your request can be provided here. |
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| **Part F. Biospecimen dispatch file specifications**  Note to CCFR Dispatch staff: Include, at a minimum, the following variables in your dispatch list: |
| CENTER\_NO  Application PI Last Name  DISPATCH\_APPLICATION\_ID  PERSON\_ID  **And** those in the biospecimen group(s) checked below  **NOTE**: Provide the specimen CIDs transmitted to Informatics (instead of or in addition to local IDs) |

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| Blood product | LCL product | Tissue product | Fresh frozen tissue | Nucleic acid |
| BLOOD\_PROD\_CID  BLOOD\_PROD\_TYPE  VC\_TUBE\_TYPE  AMT\_VALUE | LCL\_CID  GENERATION  AMT\_UNIT  AMT\_VALUE | BLOCK\_SPEC\_CID  TUMOR\_NO  BLOCK\_SOURCE  (ICD-0 SITE)  BLOCK\_PROD\_TYPE  TISSUE\_TYPE  THICKNESS  EN\_NEO\_CELL\_PC or  Other, specify:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Digital image file name (if applicable) | FRESH\_SPEC\_CID  TUMOR\_NO  TISSUE\_TYPE  FRESH\_PROD\_TYPE  BLOCK\_SOURCE  AMT\_VALUE | NUC\_ACID\_CID  NUC\_ACID\_TYPE  NUC\_ACID\_SOURCE  AMT\_UNIT  AMT\_VALUE  QUANTITATION\_METHOD  CONCENTRATION  EN\_NEO\_CELL\_PC or  Other, specify:  Diluent (water, TE, or  other, specify:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other, specify | | | | |