**COLON CANCER FAMILY REGISTRY (CCFR)**

**Amendment Form**

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| Principal Investigator | Application ID | Amendment # |
|  | | |
| Application Title | | |
| Amended study abstract: | | |

CCFR AMENDMENT INSTRUCTIONS: Please provide/respond to the following:

1. Please summarize proposed modifications and any information you wish to convey to the reviewing committee(s):

2. Are you proposing changes to an ongoing project that constitute new specific aims (Yes or No)?

*If Yes*, please list all original specific aims and the new, proposed specific aim(s).

3. Are you proposing modified and/or additional methodology (Yes or No)?

*If Yes*, please submit new protocols as an e-mail attachment.

5. Are you requesting additional study populations (Yes or No)?

*If Yes*, describe the new study population and how they will be used in your study.

6. Are you requesting additional data elements (Yes or No)?

*If Yes*, list:

7. Are you proposing to study additional genes (Yes or No)?

*If Yes*, are these genes are in a molecular pathway described in your approved application? Yes or No)?

*If Yes*, list the new genes:

*If No,* describe the new molecular pathway and list the genes:

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| **8. If requesting additional biospecimen material, complete table below.\*** | | | | | |
|  |  | ***Original Request*** | | ***Amended Request*** | |
| Description of Biospecimen | Type of Biospecimen | Number of Participants | Amount required/ participant | Number of Participants | Amount required/ participant |
| **Example** 1: Probands diagnosed < 35 yrs | Blood DNA | 25 | 10 ng | 50 | 20 ng |
| **Example** 2: MMR mutation carriers | PET tumor sections | 50 | 2 slides | 100 | 4 slides |
| **Example** 3: MYH mutation carriers | Plasma | 100 | 0.5 ml | 200 | 0.5 ml |
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| **IF YOU INTEND TO REQUEST CCFR BIOSPECIMENS**, please review the per-specimen and per-CCFR site/dispatch related costs pasted below and check the box immediately below.  I intend to request biospecimens and have reviewed and understand the associated costs. | | | | | |

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| **9. CFR Collaborators: Please specify in the table below the collaborators in your original application and proposed in this amendment (please include proposed new key personnel).** | | |
| **C-CFR Sites:** | ***Original*** Collaborators  (check box to select) | ***Proposed*** Collaborators  (check box to select) |
| ***Australasian Colorectal Cancer Family Study***  **Site PIs:**  Mark A. Jenkins, PhD and Daniel Buchanan, PhD |  |  |
| ***Cedars-Sinai Cancer Family Registry***  **Site PI:**  Jane C. Figueiredo, PhD |  |  |
| ***Cleveland Clinic Cancer Family Registry***  **Site PI:**  Stephanie L. Schmit, PhD, MPH |  |  |
| ***Hawaii Family Registry of Colon Cancer***  **Site PI:**  Loic Le Marchand, MD, PhD |  |  |
| ***Mayo Colorectal Cancer Family Registry***  **Site PI:** Risk K. Pai, MD, PhD |  |  |
| ***Ontario Familial Colorectal Cancer Registry***  **Site PI:** Steve Gallinger, MD |  |  |
| ***Seattle Familial Colon Cancer Registry***  Site PI: Amanda I. Phipps, PhD, MPH |  |  |
| ***UCSF Colon Cancer Family Registry***  Site PI: Iona Cheng, PhD, MPH |  |  |
| Other Collaborating Investigator(s) (including new key personnel) and Affiliation(s) | | |
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**Thank you. Please send the completed form by email to Allyson Templeton (**[**atemplet@fhcrc.org**](mailto:atemplet@fhcrc.org)**).**

**COLON CFR BIOSPECIMEN PRODUCT PRICING For Calendar Year: 2023\***

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| Each CCFR site’s biospecimens are stored and dispatched from their respective institution. The cost of acquisition and limited processing of C-CFR biospecimen collections were covered by CCFR grants at time of collection. Costs associated with dispatching biospecimens to researchers are not covered by CCFR grants and must be paid for by the requesting researcher and are calculated below. **Each CFR site providing biospecimens will require a Material Transfer Agreement and will prepare an invoice.** Payment may be requested before biospecimens are dispatched.  *\*The prices charged will correspond to the date the biospecimens are requested for delivery and all necessary assurance documentation (IRB/ethics, Data Use Agreements, Material Transfer Agreements, sample lists) have been received.*  Prices shown are U.S. dollars and are inflated 3% annually (and rounded up) and are subject to change without notice. | | | |
| **Administrative fees 1 (site specific)** | | | **$ SEE NOTE 1** |
|  | | | |
| **EDTA Blood Product** | **No. requested** | **Cost per specimen** | **Subtotal $** |
| DNA distribution 2 | N = \_\_\_\_\_\_\_\_ | $22.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Plasma distribution  NOTE: OFCCR collected plasma in ACD tubes, not EDTA | N = \_\_\_\_\_\_\_\_ | $27.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Guthrie (dried blood spot) distribution | N = \_\_\_\_\_\_\_\_ | $22.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA extraction from WBC Buffy Coat 3, 4 | N = \_\_\_\_\_\_\_\_ | $54.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| **EDTA Blood Subtotal** |  | | $ \_\_\_\_\_\_\_\_\_ |
|  | | | |
| **Buccal, Mouth Wash or Saliva** | **No. requested** | **Cost per specimen** | **Subtotal $** |
| DNA distribution 2 | N = \_\_\_\_\_\_\_\_ | $22.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA extraction from Buccal, Mouth Wash or Saliva 3, 4 | N = \_\_\_\_\_\_\_\_ | $54.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| **Buccal Wash or Saliva Subtotal** | | | $ \_\_\_\_\_\_\_\_\_ |
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| **Lymphoblast Cell Line (LCL) Product5** | **No. requested** | **Cost per specimen** | **Subtotal $** |
| DNA distribution from LCL 2 | N = \_\_\_\_\_\_\_\_ | $17.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA extraction from LCL 3 | N = \_\_\_\_\_\_\_\_ | $54.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Frozen LCL distribution *(****NOTE****: available if a LCL has been established and there are at least 2 LCL vials in storage). Otherwise a LCL must to be thawed and re-grown (see below)* | N = \_\_\_\_\_\_\_\_ | $23.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Re-growth to provide LCL for distribution *(****NOTE****: required if a LCL has been established but there are <2 vials of LCLs in storage)* | N = \_\_\_\_\_\_\_\_ | $151.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| EBV transformation and QC *(****NOTE****: required if a LCL has not already been established)* | N = \_\_\_\_\_\_\_\_ | $398.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Ficoll-separated cryopreserved lymphocytes *(****NOTE****: a limited number of aliquots were stored and may be available if specifically approved by each site PI(s))* | N = \_\_\_\_\_\_\_\_ | TBD | $ \_\_\_\_\_\_\_\_\_ |
| Lymphoblast Cell-Line Subtotal | | | $ \_\_\_\_\_\_\_\_\_ |

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| **DNA QUANTIFICATION 2, 4** | **No. requested** | **Cost per specimen** | **Subtotal $** |
| Fluorescent dye DNA quantification | N = \_\_\_\_\_\_\_\_ | $11.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Spectrophotometry DNA quantification | N = \_\_\_\_\_\_\_\_ | $7.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Re concentrating DNA to increase concentration | N = \_\_\_\_\_\_\_\_ | CFR center-specific | $ \_\_\_\_\_\_\_\_\_ |
| **DNA Quantification Subtotal** | | | **$ \_\_\_\_\_\_\_\_\_** |

**COLON CFR BIOSPECIMEN PRODUCT PRICING For Calendar Year: 2023\***

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| **Tumor Tissue Product** | **No. requested** | **Cost per specimen** | **Subtotal $** |
| Paraffin-embedded tissue (PET) slide distribution | N = \_\_\_\_\_\_\_\_ | $23.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Fresh frozen tissue5 distribution (excised piece) | N = \_\_\_\_\_\_\_\_ | $44.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| PET block sectioning *(NOTE: if all stored slides are exhausted and the block is in-house)* | N = \_\_\_\_\_\_\_\_ | $52.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| PET block sectioning *(NOTE: if all stored slides are exhausted and the block is not in-house and must be requested)* | N = \_\_\_\_\_\_\_\_ | $160.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Additional sections (after 1st) from PET blocks | N = \_\_\_\_\_\_\_\_ | $19.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Pathology review & H&E marking for microdissection 4 | N = \_\_\_\_\_\_\_\_ | $22.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Macrodissection for DNA extraction 4 | N = \_\_\_\_\_\_\_\_ | $24.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA distribution from tissue (PET or fresh frozen 5) 2, 4 | N = \_\_\_\_\_\_\_\_ | $22.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA extraction from PET tissue 3, 4 | N = \_\_\_\_\_\_\_\_ | $62.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| DNA extraction3 from fresh frozen tissue 5 | N = \_\_\_\_\_\_\_\_ | $62.00/specimen | $ \_\_\_\_\_\_\_\_\_ |
| Scanned image of H&E slide when one must be created | N = \_\_\_\_\_\_\_\_ | $25.00/image | $ \_\_\_\_\_\_\_\_\_ |
| **Tumor Tissue Subtotal** |  | | $ \_\_\_\_\_\_\_\_\_ |

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| **INVOICE TOTAL Biospecimen Subtotal** | **$ \_\_\_\_\_\_\_\_\_** |
| **Administration fees (site specific) SEE NOTE1** | **$ \_\_\_\_\_\_\_\_\_** |
| **Packing costs for shipment (e.g., containers, dry ice, etc.) SEE NOTE6** | **$ \_\_\_\_\_\_\_\_\_** |
| **Courier (if Applicant is not providing a courier account number) SEE NOTE6** | **$ \_\_\_\_\_\_\_\_\_** |
| **Institutional Indirect cost (site-specific) SEE NOTE7** | **$ \_\_\_\_\_\_\_\_\_** |
| **TOTAL (US$)** | **$ \_\_\_\_\_\_\_\_\_** |

PLEASE NOTE THESE IMPORTANT FOOTNOTES:

1 Administrative fees include local administrative and programming (non-laboratory) costs including IRB/ethics approval, MTA preparation, inventory management, sample selection and QC, dataset preparation, requests for data not available at the ISC and must be provided by individual centers, and special requests. Administrative fees are determined by each respective PI and typically range $1,000 - $2,000 per dispatching site and per dispatch request.

2 Stock DNA concentrations vary and change over time, sometimes requiring re-quantification for dispatching. Requests for concentrations requiring a dilution will be provided at the distribution cost. Requests for concentrations requiring re-concentration *may* be available for a per sample fee. When not available, the sample volume will be adjusted to meet the total DNA quantity.

3 All DNA extraction costs include quantification by spectrophotometry (e.g., Nanodrop) and Fluorescent dye (e.g., Picogreen, Qubit).

4 Sample processing for DNA extractions varied by site and over time. See the “CCFR Sample Processing for DNA Extraction by Center” table located at: <http://www.coloncfr.org/supplementary-information> for information.

5 Limited resource / availability.

6 Costs are estimates and will be determined at the time of shipment. Costs vary based on shipping distance, shipping container size and cost, amount of dry ice (if required), package weight, and courier service. Please note that shipping transit times from the Australia and Hawaii sites are typically longer than from the North American sites resulting in higher packing costs (e.g., shipment containers, dry ice quantity/weight, etc.) and courier fees relative to North American sites.

7 Total dispatch costs are subject to institutional indirect costs (F&A fees) for CCFR sites whose institutions withhold those costs from dispatch payments and are as follows: Cedars-Sinai (67%), Cleveland Clinic (61%), Fred Hutchinson (76%), Univ. of Hawaii (56.5%), Univ. of Melbourne (8%). Indirect (F&A) fees are not withheld by the Mayo and Ontario institutions so are not incurred. *We sincerely regret these costs but we have no recourse*.