**APPLICATION FOR COLLABORATION WITH THE**

COLON CANCER FAMILY REGISTRY (COLON CFR, CCFR)

The Colon Cancer Family Registry (CCFR) is an international research infrastructure comprised of multidisciplinary team of investigators with a central goal of facilitating laboratory, clinical and prevention research for the benefit of registry participants and the general public. The resources collected by the C-CFR are available to the scientific and medical community for collaborative research on the etiology, risk, prevention, and prognosis of colorectal cancer.

Before you begin, you may find the following helpful:

* The Colon CFR overview manuscript: <https://pubmed.ncbi.nlm.nih.gov/17982118>
* Summary data can be found at <https://www.coloncfr.org/summary-data>
* Descriptions of variables can be found in our data dictionaries at: <http://www.coloncfr.org/data-dictionaries>
* Center questionnaires and abstraction forms can be found at <http://www.coloncfr.org/questionnaires>
* Information pertaining to collaborations with the CCFR can be found <https://www.coloncfr.org/collaboration>.

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| --- | --- |
| **TITLE OF PROJECT:** |  |

# INVESTIGATOR AND GENERAL INFORMATION

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| --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator: | | | | Job Title: | | |
| Institution: | | | | Department: | | |
| Email address: | | | | Phone Number: | | |
| Address: | | | | | | |
| City: | | | | State: | | |
| Zip: | | | | Country: | | |
| Will a 2nd institution require access to CCFR data/biospecimens be involved in your study? | | | | | | No  Yes |
| If yes, access to what? | Data only  Biospecimens only  Both data and biospecimens | | | | | |
| Investigator: | | | | Job Title: | | |
| Institution: | | | | Department: | | |
| If requesting CCFR biospecimens, will they be used for product commercialization? | | | | | | No  Yes |
| Is there a deadline for the receipt of data? | | | No  Yes, provide deadline date: | | | |
| Is there a deadline for the receipt of biospecimens? | | | No  Yes, provide deadline date: | | | |
| The National Cancer Institute (our funding institute) requires us to report on the following metrics: | | | | | | |
| Are you an early-career Investigator? | | | | | No  Yes | |
| What is your source of funding support for this study (from all sources)? | | | | | Internal  External  None | |
| Granting Institution | | Grant Number | | | Period of Support | |
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| Will this study provide any training (including student projects) to the following groups? (check all that apply) | | | | | | |
| Early career investigator(s)  Post doctorates  Doctoral student(s)  Master level student(s)  Undergraduate student(s)  Co-authorship on a peer-reviewed manuscript | | | | | | |

# CCFR COLLABORATORS

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| Center No | *CCFR Site* and Site Principal Investigator | | Check which apply (if known) |
| **13** | ***Australasian Colorectal Cancer Family Study,* Site PI:** Mark A. Jenkins, PhD | |  |
| **12 (02)** | ***Cedars-Sinai Colorectal Cancer Family Registry,* Site PI: **Jane Figueiredo, PhD**** | |  |
| **12 (05)** | ***Cleveland Clinic Cancer Family Registry,* Site PI: **Stephanie Schmit, PhD, MPH**** | |  |
| **14** | ***Hawaii Family Registry of Colon Cancer,* Site PI:** Loic Le Marchand, MD, PhD | |  |
| **15** | ***Mayo Colorectal Cancer Family Registry,* Site PI:** Rish Pai, MD, PhD | |  |
| **11** | ***Ontario Familial Colorectal Cancer Registry,* Site PI:** Steve Gallinger, MD | |  |
| 16 | Seattle Familial Colorectal Cancer Registry, Site PI: Amanda Phipps, PhD, MPH | |  |
| 17 | UCSF Colon Cancer Family Registry (previously CPIC), Site PI: Iona Cheng, PhD, MPH | |  |
| Other Collaborating Investigator(s) | | Affiliation | |
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# DESCRIPION OF PROPOSED COLLABORATIVE STUDY

## STUDY DESIGN (1-2 pages): Provide a brief description of the proposed research to use data/biospecimens from the Colon CFR.

### Abstract:

### Specific Aims:

### Background and Significance: State the purpose and rationale of the research including why the resources of the Colon CFR are needed for the study

### Preliminary Data: Provide evidence of experience in analyzing data and/or biospecimens requested.

### Study Design: Describe the design you will be using and the data that you will be requesting from the Colon CFR including justification of sample numbers with power calculations if applicable.

### Selection Criteria: Describe selection inclusion/exclusion criteria.

## SPECIMEN AND DATA CRITERIA: The tables below describe in basic terms the data and biospecimens that are available. Use this information to complete DATA AND SPECIMEN CRITERIA table, below.

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| **BIOSPECIMENS** (**see biospecimen pricing sheet below**) |  | **DATA** |
| DNA from blood |  | Family history of cancer data |
| DNA from lymphoblast cell-lines\*1 |  | Baseline epi/risk factor questionnaire data |
| DNA from buccal or saliva cells |  | Follow-up epi/risk factor questionnaire data |
| DNA from paraffin-embedded tumor tissue |  | Baseline diet questionnaire data\*4 |
| DNA from paraffin-embedded normal tissue |  | Colorectal pathology data |
| DNA from fresh frozen tumor tissue\*2 |  | Clinical / treatment data\*5 |
| DNA from fresh frozen normal tissue\*2 |  | Molecular data |
| Plasma |  | Other, describe: |
| Dried blood “Guthrie spot” |  | Other, describe: |
| Tumor tissue from paraffin blocks |  |  |
| Normal tissue from paraffin blocks |  |  |
| Fresh frozen tumor tissue\*2 |  |  |
| Fresh frozen normal tissue\*2 |  |  |
| Lymphoblast cell line (LCL)(growing culture) \*1 |  |  |
| Ficoll-separated cryo-preserved lymphocytes \*2,3 |  |  |
| Digital image of the H&E slide |  |  |
| \*1Limited primarily to Phase I high-risk probands |  | \*4Limited to Phase I, no data for centers 15, 16 |
| \*2Very limited availability |  | \*5Limited to Phase I probands, no data for centers 12 and 17 |
| \*3Access to these will require approval by each site PI |  |

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| **DATA AND SPECIMEN CRITERIA: C**omplete this table to describe your selection criteria, the type of data and biospecimens, and preferred number of subjects/samples needed (see examples below). | | |
| Selection Criteria | Type of data/biospecimen  **Include amount of biospecimen to be requested** | Number of Participants/  Samples |
| ***Example 1***: Colorectal cancer cases diagnosed under the age of 35 yrs from population-based ascertainment | Family history of cancer and lymphocyte DNA **(200 ng)** | 50 |
| ***Example 2***: Female MMR mutation carriers with no previous diagnosis of any cancer. | Baseline epi questionnaire data | 100 |
| ***Example 3***: MYH mutation carriers with a diagnosis of colorectal cancer at any age. | Molecular and pathology data  **Two 5um FFPE slides/tumor** | 200 |
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| Please note: The CCFR operates under a cost recovery system. CCFR-wide and site-specific costs for CCFR biospecimens can be found at [www.coloncfr.org/collaboration](http://www.coloncfr.org/collaboration). Prices inflate 3% at the beginning of each year and are allocated at the time the data and/or biospecimens are requested for dispatch and all necessary assurance documentation (IRB/ethics, MTAs) have been established. | | |

# AGREEMENT for use of epidemiologic, pathologic and outcome data and for biomaterials provided from the Colon Cancer Family Registry

# I agree to form a collaboration with the Colon CFR (CCFR). I agree to assume all risks and responsibilities in connection with the receipt, handling, storage and use of data/biomaterials. I agree that the data/biomaterials to be provided by the NCI CCFR will be used only for the purposes specified in the approved proposal. I will provide documentation of IRB/ethics committee review that will include my IRB file number and IRB review date. I agree not to distribute data or biomaterials to third parties without the approval of the CCFR Principal Investigators and then only with fully executed data-use agreement and/or material transfer agreement.

# I agree to make study-generated results available to the scientific community by transferring them to the central CCFR Informatics Center within 6 months of their publication and to submit progress reports upon request (at most annually) until the project is completed.

# I agree to adhere to the CCFR Policy on Publications and notify the CCFR of planned publications that make use of CCFR data and/or biospecimens and to: 1) register publications with the CCFR early in the planning process; 2) submit publications to the CFR for administrative review prior to submission to a journal; and, 3) acknowledge the contributions (financial and otherwise) of the NCI and CCFR. The CCFR Policy on Publications, Manuscript Registration Form and Review Checklist can be downloaded at [www.coloncfr.org](http://www.coloncfr.org)/publications.

# I understand that the Colon CFR has been funded entirely by the NCI of the U.S. NIH, and that all applicable publications arising from the use of Colon CFR resources must comply with the NIH Public Access Policy by ensuring they are submitted to the PubMed Central (PMC) upon acceptance for publication (see: <https://www.nlm.nih.gov/bsd/public_access/resources.html>).

**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.

# [Recommended funding acknowledgement] *"The Colon Cancer Family Registry (CCFR, www.coloncfr.org) is supported in part by funding from the National Cancer Institute (NCI), National Institutes of Health (NIH) (award U01 CA167551). Support for case ascertainment was provided in part from the Surveillance, Epidemiology, and End Results (SEER) Program and the following U.S. state cancer registries: AZ, CO, MN, NC, NH; and by the Victoria Cancer Registry (Australia) and Ontario Cancer Registry (Canada). The content of this manuscript does not necessarily reflect the views or policies of the NIH or any of the collaborating centers in the Colon Cancer Family Registry (CCFR), nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government or the CCFR.”* [Additional funding acknowledgement for the manuscripts utilizing CCFR GWAS data can be found in our Policy for Publications [www.coloncfr.org](http://www.coloncfr.org)/publications.]

This document formalizes the agreement between the applicant and site(s) to collaborate.

# BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN AGREEMENTS IV.

|  |  |
| --- | --- |
|  | |
| Signature of Applicant | |
|  |  |
| Typed Name of Above | Date |

Thank you! Please send the completed, signed form to Allyson Templeton ([atemplet@fredhutch.org](mailto:atemplet@fredhutch.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** | | | $ \_\_\_\_\_\_\_\_\_ |
|  | | | |
| **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*.