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COLON CFR POLICY ON PUBLICATIONS

I. INTRODUCTION

The Colon Cancer Family Registry (CCFR) was established by the National Cancer Institute (NCI) in 1996 to facilitate interdisciplinary studies in the genetic epidemiology of colorectal cancer (CRC) and to provide a flexible, comprehensive, and collaborative research infrastructure. At inception, the CCFR was made up of six recruitment centers and an external central Informatics Center (IC) each funded separately. Since 2013, the CCFR sites and informatics center has been funded collectively through a single NCI CEC grant. CCFR data and biospecimens are available to the scientific community at large through an internal peer review process predicated on the establishment of collaborative studies (www.coloncfr.org/collaboration). One of the most important goals of the CCFR program is timely publications of scientific findings resulting from the generous contributions of their study participants, the CCFR, its procedures and data bases.

I. PURPOSE

Peer reviewed publications are the main vehicle for disseminating findings to scientists and the public and are critical to the continued ability of the CCFR to compete for funding and continue to advance research on colorectal cancer. Recognizing that many scientists will be involved in the collection and use of the data, the following guidelines for publication and authorship have been developed. The purposes of this policy are:

A. To document a Policy for CCFR Publications, defined as publications reporting on the scientific findings resulting from the use of NCI-funded CCFR data and/or activities and/or biospecimens, and/or that describe CCFR policies, coordination, procedures, etc.
B. To state guidelines and procedures that are recommended for use in developing CCFR publications that are consistent with CCFR principles for data sharing and collaboration.
C. To provide practical and fair guidance for assigning authorship and acknowledgement that credit those who design, analyze and substantially participate in a study and the preparation of a publication or presentation;
D. To ensure accurate reporting of the design, conduct, and analysis of studies, most of which will be collaborative and multi-disciplinary;
E. To protect the confidentiality of medical and personal information in accordance with the Privacy Act and requirement for the protection of human subjects.

II. GUIDING PRINCIPLES

The CCFR Publication Policy is designed to advance and incorporate the following principles:

A. Maintain an inclusive stance on publications and acknowledge that CCFR is a large collaborative collection of projects involving a substantial number of researchers.
B. Provide a process for developing publications that are consistent with CCFR's initiatives, objectives, and priorities.
C. Provide a process that informs CFR investigators of planned manuscripts and gives them opportunities to contribute and earn authorship.
D. Require that all contributors to a work intended for publication that are consistent with the Vancouver Authorship Guidelines receive authorship credit.
E. Foster the careers of junior investigators and wherever possible, encourage them to take a lead in CCFR manuscript development and to earn lead authorship.
F. Require a central administrative review process for all publications that will be acknowledged as CCFR publications to ensure consistency and quality.

III. OWNERSHIP OF TOPICS

In any scientific collaboration a process is needed to determine who will take the lead to develop a topic or "own" it for the purpose of analyzing and publishing information. All research and methodological publications or presentations utilizing the CCFR should fall into one of the following categories:

OWNERSHIP OF TOPICS	CFR Investigators [a]	Institutional Collaborators [b]	External Collaborators [c]
Pilot Project [d]	☒	☐	☐
Core Project [e]	☒	☐	☐
New (investigator-initiated) Project [f]	☒	☒	☒
Methods/Protocol Development Project [g]	☒	☒	☒

[a] CFR investigators are supported by a CFR award.
[b] Institutional collaborators are within a CFR-awarded Institution but not supported by a CFR award.
[c] External Collaborators are not supported by the CFR award and not within the CFR Institution.
[d] Pilot projects may arise from core, supplemental, or non-CFR funds. Ownership is given to the CFR investigator initiating the project.
[e] Core projects arise from CFR grant applications (original or competitive renewal). Ownership resides with the CFR PIs and are assigned per majority vote by the SC.
[f] New projects are investigator-initiated using solely or in part CFR data. Ownership of new projects resides with the group that received approval from site PIs to undertake the analysis. These require that at least one CCFR investigator collaborates on the project and shares ownership of the manuscript.
[g] Resource-inspired projects may be related to methods or procedures, such as development of statistical, epidemiologic, or lab methods, pathology insights, etc.

IV. CCFR MANUSCRIPT APPROVAL PROCESS

The CCFR manuscript approval process has two steps: registration and final review.

A. Manuscript Registration

The first step of the CCFR manuscript approval process is the registration of the manuscript with the CCFR. The purpose of this step is to inform the site Investigators that a manuscript is being developed and give them the opportunity to contact the lead author and contribute to the manuscript. To register a manuscript, the lead author submits to the CCFR Program Manager (PM) a Manuscript Registration Form (MRF) (http://www.coloncfr.org/ publications) containing the concept for the paper, the CFR sites contributing data, potential for contributing to the paper. The registration form is then circulated to CFR investigators. Anyone interested in contributing to the manuscript must contact the lead author within two weeks from the date the form was distributed. The lead author will maintain a list of interested potential authors and send them teleconference agendas, minutes, list of covariates, tables, drafts of the manuscript, correspondence with journal, and any related materials for their input (see Section VII).

A Manuscript Registration Form…	
Needs to be submitted for:	Does not need to be submitted for:
1. Manuscripts 2. Abstracts submitted to meetings for which a subsequent manuscript is planned 3. Letters for peer-reviewed publication	1. Abstracts submitted to meetings for which a subsequent manuscript is not planned 2. Letters in the form of opinion pieces or in response to another article that will not be peer-reviewed 3. Posters and Presentations

B. Review Requirements

This policy pertains to all manuscripts to be submitted for publication.

1. Manuscripts

Once a manuscript is ready for submission and has been approved by all named CCFR co-authors, the manuscript will be submitted to the Program Manager (PM) along with a Colon CFR Manuscript Review Checklist (http://www.coloncfr.org/publications) with Section I completed for administrative review. The PM will complete Section II, ensuring that CFR protocols and data descriptions present and adequate, and that NCI and CCFR funding are accurately acknowledged. This review will be completed within two weeks.

2. Abstracts, letters, posters and presentations

Abstracts may be submitted for publication without prior review. A copy of the abstract should be sent to the PM upon submission. If the abstract is to be developed into a manuscript, a Manuscript Registration Form should be submitted along with the abstract. Letters for peer review should be handled like a manuscript. Opinion pieces or responses to other articles are exempt from CCFR Publication Policy.

C. Publication Requirements

Upon publication, published manuscripts should be submitted to the PM, who will distribute them to the CCFR SC and NCI Program Officer. The PM is also responsible for adding all published manuscripts to the tracking database and periodically searching PMC for compliance with the NIH Public Access Policy.

V. DETERMINATION OF AUTHORSHIP

A. Manuscripts

All persons designated as authors must "qualify" for authorship by having participated sufficiently in the work and taken responsibility for the content. Modified from the Uniform Requirements for Manuscripts as submitted to Biomedical Journals by the International Committee of Medical Journal Editors (Ann Intern Med, 1988; 108:258-304), authorship credit should be based on substantial contributions to:

1. Conception and design, acquisition of data or analysis and interpretation of data; and
2. Drafting the article or one of the following two:
    a. If the work is provided early with outline of text and draft tables of results, revising the draft critically for important intellectual content; or
    b. If the first communication is a polished draft of the complete article, reviewing it critically and suggesting revisions (major, minor, or none) to lead author, as appropriate; and
3. Final approval of the version to be published.

All three conditions must be met while taking into consideration what contributions were afforded the potential co-authors. The collection of data and scientific status may also be considered in determining authorship listing. If the participation is solely in the acquisition of funding or the collection of data and is deemed not to justify authorship, those contributions should receive an acknowledgement in the paper (*see* Acknowledgements, below).

B. The procedural steps for determining final authorship of CFR publications

1. The lead author submits an MRF (available at http://www.coloncfr.org/ publications) to the PM.
2. The PM circulates the MRF to all CCFR Investigators and the NCI Program Officer and one reminder one week later.
3. Investigators interested in earning authorship contact the lead author within 2 weeks and arrange ways to contribute intellectually. CFR Investigators may notify others of the registration in the spirit of being inclusive at this step.
4. The lead author maintains a list of interested authors and involves them in the manuscript development (e.g., shares tables, figures, list of covariates, drafts of the manuscript, etc.).
5. At the end of the analytic and writing process the lead author asks each potential author if they feel they have earned co-authorship per the guidelines above and based on an academic honor system.

The lead author has the right to question a claim for authorship and will determine the final authorship and author order.

6. The lead author distributes the final draft for review, comment and approval to submit, providing at least two weeks review time (non-response can be assumed as assent to submit).
7. Prior to submitting the manuscript to a journal, the lead author sends the CCFR-approved manuscript and CCFR Manuscript Checklist (www.coloncfr.org/publication) with Section I completed to the PM for administrative review and incorporates required revisions from that review.
8. The lead author circulates to co-authors the edited galley proofs and substantive correspondence with the journal and collects co-author signatures.

C. Authorship for abstracts

The CCFR does not have a formal policy for abstracts submitted to meetings. We support and encourage their submission and recognize that the timeline is often tight and does not always allow for review by all potential authors. Thus, we do not require a CCFR administrative review as we do for manuscripts. Our preference is that authorship on abstracts be appropriately representative, but also that only individuals who have reviewed the abstract be listed as a co-author. If the author list is too long, **and** at least one CCFR author has reviewed the abstract, the "Colon Cancer Family Registry" can be listed as an author in lieu of multiple CCFR authors. On the other hand, the Colon CFR should ***not*** be listed as an author or referenced in the abstract if the abstract has not been reviewed by at least one CFR investigator (or the CCFR Consortium Program Manager). If the abstract is selected for poster presentation or platform presentation, then acknowledgement of the CCFR funding should be included in the presentations as described in E. Financial acknowledgements for abstracts, posters and presentations using CFR resources, below.

VI. ACKNOWLEDGEMENTS

A. Non-funding acknowledgements

As appropriate and at the required place in the manuscript (title-page foot note or appendix; see the journal's requirement), abstract, poster or presentation, one or more statements should specify:

1. Scientific or other contributions that need acknowledging but do not justify authorship;
   NOTE: We ask investigators who make use of any CCFR samples derived from fresh frozen or paraffin-embedded tissue or pathology related variables to acknowledge as the source of your samples/data: *"The Jeremy Jass Memorial Pathology Bank".*
2. Acknowledgements for technical help;
3. Acknowledgements of financial and material support, specifying the nature of the support;
4. Contributions of study participants and/or study staff;
5. Financial relationships that may pose a conflict of interest.

B. Financial acknowledgements for manuscripts using CCFR resources

All manuscripts shall acknowledge the federal funding of the CCFR as follows:

[CCFR MULTI-SITE: Include 1 and 3, and 2 if GWAS data were used.]

[1-CCFR funding acknowledgment] *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).*

[2-If CCFR GWAS datasets were used, add respective acknowledgement(s)]:

- [OFCCR ARCTIC]: *Additional funding for the OFCCR/ARCTIC was through award GL201-043 from the Ontario Research Fund (to BWZ), award 112746 from the Canadian Institutes of Health Research (to TJH), through a Cancer Risk Evaluation (CaRE) Program grant from the Canadian Cancer Society (to SG), and through generous support from the Ontario Ministry of Research and Innovation.*
- [SFCCR (Illumina HumanCytoSNP (300k)): *The SFCCR Illumina HumanCytoSNP array was supported in part through NCI/NIH awards U01/U24 CA074794 and R01 CA076366 (to PAN).*
- [CCFR Set-1 and/or Set-2 scan (Illumina Human 1M, 1M-Duo, and/or Omni1-Quad)]: *The CCFR Set-1 (Illumina 1M/1M-Duo) and Set-2 (Illumina Omni1-Quad) scans were supported by NIH awards U01 CA122839 and R01 CA143247 (to GC).*
- [CCFR Set-3 scan (Affymetrix Axiom CORECT Set array)]: *The CCFR Set-3 (Affymetrix Axiom CORECT Set array) was supported by NIH award U19 CA148107 and R01 CA81488 (to SBG).*
- [CCFR Set-4 scan (Illumina OncoArray 600K SNP array)]: *The CCFR Set-4 (Illumina OncoArray 600K SNP array) was supported by NIH award U19 CA148107 (to SBG) and by the Center for Inherited Disease Research (CIDR), which is funded by the NIH to the Johns Hopkins University, contract number HHSN268201200008I.*

[3-Acknowledgement & disclaimer] *The Colon CFR graciously thanks the generous contributions of their 42,505 study participants, dedication of study staff, and the financial support from the U.S. National Cancer Institute, without which this important registry would not exist. The content of this manuscript does not necessarily reflect the views or policies of the NIH or any of the collaborating centers in the CCFR, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government, any cancer registry, or the CCFR.*

[**FYI**: CCFR CENTER_NO (case ascertainment source): 11-Ontario (Ontario Cancer Registry (Canada)), 12-USC/Cedars (the following U.S. state cancer registries: AZ, CO, MN, NC, NH), 13-Australasia (Victorian Cancer Registry, Australia), 14-Hawaii (SEER), 15-Mayo (Minnesota state cancer registry), 16-Seattle (SEER).

C. [STANDALONE Funding acknowledgement for OFCCR/ARCTIC]

The Ontario (OFCCR) site of the Colon CFR Cohort (www.coloncfr.org) is supported in part by the National Cancer Institute (NCI) of the National Institutes of Health (NIH) (Award U01 CA167551). Support for OFCCR/ARCTIC was through NCI/NIH awards U01/U24 CA074783 (to SG). Additional funding for the genetic analyses of OFCCR/ARCTIC was through award GL201-043 from the Ontario Research Fund (to BWZ), award 112746 from the Canadian Institutes of Health Research (to TJH), through a Cancer Risk Evaluation (CaRE) Program grant from the Canadian Cancer Society, and through generous support from the Ontario Ministry of Research and Innovation.

The content of this manuscript does not necessarily reflect the views or policies of the NIH or the OFCCR, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government, the Ontario Cancer Registry, or the CCFR.

D. [STANDALONE Funding acknowledgement for [SFCCR, PMH, SFCCR Illumina CytoSNP]

The Seattle (SFCCR) site of the Colon CFR Cohort (www.coloncfr.org), is supported in part by the National Cancer Institute (NCI) of the National Institutes of Health (NIH) Award U01 CA167551. Additional support for the SFCCR, Postmenopausal Hormones and Colon Cancer (PMH) study and the SFCCR Illumina HumanCytoSNP array were through NCI/NIH awards U01 CA074794 (to JDP) and U24 CA074794 and R01 CA076366 (to PAN). Support for case ascertainment was provided from the Surveillance, Epidemiology and End Results (SEER) Program of the NCI.

The SFCCR and the PMH study graciously thanks the generous contributions of their study participants, dedication of study staff, and the financial support from the National Cancer Institute, without which this important research was not possible. The content of this manuscript does not necessarily reflect the views or policies of the NIH or SFCCR, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government, the SEER Program, or the CCFR.

E. Financial acknowledgements for abstracts, posters and presentations

All abstracts, posters and presentations shall acknowledge the NIH funding of the CFR as:
[Include 1 and 3, and 2 if GWAS data were used.]

[1-CCFR] *The research reported in this* [abstract/poster/presentation] *was supported in part by the NCI of NIH under Award(s) U01 CA167551*.

[2-GWAS funding acknowledgment, if applicable]

- [OFCCR ARCTIC]: *NCI award U01 CA074783, ORF award GL201-043 and CIHR award 112746.*
- [SFCCR (Illumina HumanCytoSNP (300k)): *NCI awards U01 CA074794 and R01 CA076366.*
- [CCFR Set-1 and/or Set-2 scan (Illumina 1M, 1M-Duo, and/or Omni1-Quad)]: *NCI awards U01 CA122839 and R01 CA143237.*
- [CCFR Set-3 scan (Affymetrix Axiom CORECT Set array)]: *NCI award U19 CA148107* and R01 CA81488.
- [CCFR Set-4 scan (Illumina OncoArray)]: *NCI award U19 CA148107 and NIH contract number HHSN268201200008I*.

[3-Disclaimer] *The content does not necessarily reflect the views or policies of the NCI 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*.

VII. PROCEDURES & RESPONSIBILITIES

It is the intent of the PWG that these guidelines provide streamlined procedures that ensure that credit is provided for those who design, analyze, and are major participants in a study or publication; that all publications utilizing CFR data are reviewed for accuracy; that all publications are tracked and catalogued; and that the responsibilities to accomplish these objectives are clearly delineated.

A. CFR Steering Committee Responsibilities

1. Set priorities for CFR publications;
2. Resolve conflicts as necessary.

B. Lead Author Responsibilities

The first author is usually the person who has performed the central analysis of the project and is often the person who has prepared the first draft of the manuscript. The lead author is ultimately responsible for ensuring that all other authors meet the requirements for authorship as well as ensuring the integrity of the work itself.

1. Assume a leadership role in identifying co-authors, writing the paper, responding to reviewers' comments, corresponding with journal editors, and communicating with CCFR PM;
2. Submit a Manuscript Registration Form to the PM and maintain a list of interested authors;
3. Assign tasks, set deadlines, and assure that the tasks are completed on schedule;
4. Distribute the final manuscript to all CCFR co-authors to review and approve;

5. Complete and submit Section I of the Manuscript Review Checklist along with a copy of the manuscript, tables, figures, and supplementary files to the CCFR PM for administrative review and resubmit revised draft to the PM if required;
6. Determine the authorship order for the paper in consultation with the other authors and obtain written permission from all persons acknowledged by name, if required;
7. Submit the manuscript to the journal, correspond with journal editors, respond to reviewers' comments, circulate substantive correspondence with journal to CCFR co-authors, prepare journal revisions, and circulate edited galley proofs to the authors;
8. Send a copy of published document to the PM and NCI Program Officer;
9. Ensure all peer-review manuscripts arising from NIH funding are compliant with the NIH Public Access Policy and deposited in PMC. NOTE: ALL MANUSCRIPTS ACKNOWLEDGING NIH FUNDING MUST BE DEPOSITED IN PUB MED CENTRAL (PMC) AND THAT IS THE RESPONSIBILITY OF THE LEAD AUTHOR.
10. Return newly acquired data to the Informatics Center within 6 months of publication.

C. CCFR Collaborating Author Responsibilities

1. Contact the lead author within 2 weeks of the date the Registration Form is distributed to discuss interest in contributing to the manuscript and earning authorship;
2. Complete tasks assigned by the lead author in the timeframe provided;
3. Earn authorship as described above;
4. Review manuscripts and provide feedback to the lead author within 2 weeks.

D. Colon CFR Consortium Program Manager Responsibilities

1. Act as CCFR liaison to the author, unless otherwise assigned;
2. Provide CCFR Publication Policy and forms to authors upon request;
3. Upon receipt of a Manuscript Registration Form, assign a manuscript ID number, enter it into the CCFR Publications tracking database, and distribute to the PWG list serve and send 1 reminder 1 week later;
4. Track the publication, contacting the primary author after 6 months, if necessary;
5. Within 14 days of receiving a Manuscript Review Checklist and manuscript for review, complete Section II of the Checklist and send a copy of the Checklist to the author.
6. Upon learning of a published manuscript, update the CFR publication list with final citation, PubMed ID, and CFR project number. Update publication list on the website biannually.
7. Search PubMed routinely for PMCIDs. Follow-up with lead author as necessary to ensure applicable publications are compliant NIH Public Access Policy.

VIII. CONFLICTS & DISPUTES

A. Authorship: The principal author ultimately is in the position to make decisions regarding authorship. When a publication involves collaboration with multiple CFR sites, authorship and acknowledgement will be agreed upon by the collaborators. If there is still disagreement, the parties involved may seek help resolving such disputes with the help of the PWG and/or CFR SC, by providing a description of their role in the study and manuscript preparation.

B. Acknowledgement: The PWG Chairperson, on a case-by-case basis, will review disputes regarding acknowledgement of investigators or other personnel and institutions that made key contributions to the development of the publication.

C. Review process: The PWG Chairperson will resolve disputes with respect to the manuscript review process.

IX. PUBLICATION WORKING GROUP

The Publication Working Group (PWG), comprised of at least one investigator and one alternate from each CFR site and the NCI Program Officer and one designee, with additional members appointed by the Steering Committee (SC), develop and maintain these guidelines, and oversee all issues associated with publications. This working group proposes recommendations to the SC for full committee vote as necessary, but otherwise represents the SC in matters dealing with publications.

X. CONTACTS

CCFR Program Manager:	Allyson Templeton, MS	atemplet@fredhutch.org
CCFR Principal Investigators:		
Australasia (& Admin/Contact PI):	Mark A. Jenkins, PhD	m.jenkins@unimelb.edu.au
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USC/Cedars-Sinai	Jane A. Figueiredo, PhD	Jane.Figueiredo@cshs.org
USC/Cleveland Clinic	James M Church, MD	churchj@ccf.org

www.coloncfr.org

APPENDIX A: MANUSCRIPT REGISTRATION FORM

FFICE USE ONLY)	
Manuscript Number	
Date registration form submitted	

1. RESPONSIBLE AUTHOR: Who is responsible for the manuscript?

NAME	EMAIL ADDRESS	OTHER CONTACT INFORMATION (optional)

2. MANUSCRIPT WORKING TITLE:

3. CFR PROJECT ID & TITLE: What CFR project is associated with this manuscript?

CCFR Project ID	Project Title
C-	

4. QUESTION: What question is the manuscript addressing?

5. DESIGN: What type(s) of design(s) is(are) being used?

6. DATA:
   a. Which CFR centers' data will be used in this manuscript (**please check your analytic dataset and check the appropriate box(es)**) (NN = CENTER_ID)

11-Ontario	12-CedarsSinai	13-Australia	14-Hawaii	15-Mayo	16-Seattle	17-UCSF
☐	☐	☐	☐	☐	☐	☐

Cedars-Sinai is the former USC consortium center; UCSF is the former CPIC center.

   b. What data will be used (check box(es))?

☐ Family history/cancer	☐ Baseline diet	☐ Germline molecular
☐ Baseline epi/risk factors	☐ CRC pathology	☐ Somatic molecular
☐ Follow-up epi/risk factors	☐ Clinical/treatment	☐ GWAS
☐ Self-derived data from tested CCFR biospecimens, describe:		

   c. Which GWAS data set(s) will be used, if any ☐ None ☐ Individual level ☐ Summary level

CCFR GWAS PI:	G Casey	G Casey	S Gruber	S Gruber	G Casey
Data set	Set-1	Set-2	Set-3	Set-4	Set-5
Platform	Illumina 1M/1M-Duo	Illumina Omni1	Affymetrix Axiom	Illumina OncoArray	Infinium OncoArray
CFR Centers*	A, O, S	All but UCSF	A, C, M, O, S	ALL but UCSF	ALL
Check box(es)	☐	☐	☐	☐	☐

*A-Australia; C-Cedars-Sinai/USC; H-Hawaii; M-Mayo; O-Ontario; S-Seattle; U-UCSF/CPIC

d. What data will be generated, if any?

7. SUBJECTS: Which subjects are involved (if any)?

8. ANALYSIS: What statistical method(s) is(are) being used?

9. POTENTIAL AUTHORSHIP: Who from the CCFR has already contributed to the manuscript and earned authorship according to the Vancouver Guidelines?

10. POTENTIAL CONTRIBUTION: What contributions to earn authorship will be available to individuals responding to this registration form? (Check box(e))

☐	Study concept and design
☐	Analysis and interpretation of the data (statistical analysis, biostatistics, computational analysis
☐	Development of methodology
☐	Drafting of the manuscript
☐	Critical revision of the manuscript for important intellectual content
☐	Review and approval of final manuscript
☐	Administrative, technical, material support (organizing data, constructing databases)
☐	Other, specify:

11. PROJECTED DATE FINAL MANUSCRIPT will be submitted to CCFR for final review**

Thank you! Please send the completed form to Allyson Templeton (atemplet@fredhutch.org).

**Once your manuscript is ready for submission to a journal and has been reviewed by all CCFR co-authors, please submit a copy of it and a CCFR Manuscript Checklist with Section I completed to Allyson Templeton (atemplet@fredhutch.org).

The CCFR Policy on Publications and CCFR Manuscript Checklist can be found at www.coloncfr.org/publications.

COLON CFR POLICY ON PUBLICATIONS

APPENDIX B: MANUSCRIPT REVIEW CHECKLIST

Section I: To be Completed by the Corresponding Author

1. Name of manuscript: _____

2. Related CFR Application ID: _____

3. Related CFR Application Title: _____

4. Intended journal: _____

5. First and senior authors

	Name	Email
First author		
Senior author		

6. Which CCFR centers' data were used in the manuscript (check all that apply)

11-Ontario	12-CedarsSinai	13-Australia	14-Hawaii	15-Mayo	16-Seattle	17-UCSF
☐	☐	☐	☐	☐	☐	☐

Cedars-Sinai Consortium is the former USC Consortium center; UCSF is the former CPIC center.

7. Which GWAS data set(s) will be used, if any ☐ None ☐ Individual level ☐ Summary level only

PI	G Casey	G Casey	S Gruber	S Gruber	G Casey
Data set	Set-1	Set-2	Set-3	Set-4	Set-5
Platform	Illumina 1M/1M-Duo	Illumina Omni1-Quad	Affymetrix Axiom	Illumina OncoArray	Infinium OncoArray
CFR Centers*	A, O, S	All but H, U	A, C, M, O, S	ALL but U	ALL
Check box(es)	☐	☐	☐	☐	☐

*A-Australia; C-Cedars-Sinai (formerly USC); H-Hawaii; M-Mayo; O-Ontario; S-Seattle; U-UCSF (formerly the CPIC)

8. Authorship:

Colon CFR Site	CCFR investigators who requested authorship
Australasian	
Hawaii	
Mayo Clinic	
Ontario	
Seattle	
Cedars-Sinai & Cleveland Clinic (formerly USC)	
UCSF (formerly CPIC)	

9. Author review checklist:

If you check "no" to any item please comment below	No	Yes	NA
a. Have you submitted a Manuscript Registration Form to the CCFR?	☐	☐	☐
b. Are the NCI/CFR acknowledgement(s) & respective grant number(s) present? (See CCFR Policy for Publications at www.coloncfr.org/publications)	☐	☐	☐
c. Have all CCFR authors approved this manuscript for journal submission?	☐	☐	☐

Continued

Comments:	

Section I continued [To be completed by the corresponding author]

10. Publication Requirements: Check boxes indicating your agreement to meet these requirements.

☐ I will circulate all substantive correspondence with journal to the CCFR co-authors.

☐ Upon notification of acceptance by a journal, I will circulate journal proofs to the authors.

☐ Upon publication, I will send a copy of published manuscript, tables and figures to the CCFR Coordinator.

☐ Following publication, I will ensure the manuscript is compliant with the NIH Public Access Policy and is submitted to the PubMed Central (PMC) if: 1) it is a peer-reviewed journal manuscript AND 2) it is accepted for publication in a journal.

Information about the NIH Pubic Access Policy can be found at: http://publicaccess.nih.gov/.

A list of journals that automatically deposit published manuscripts to PMC can be found at: http://publicaccess.nih.gov/submit_process_journals.htm.

Instructions for manually depositing manuscripts submitted to journals that do not automatically submit to PMC can be found at: http://publicaccess.nih.gov/select_deposit_publishers.htm

☐ [If applicable] I will return all genotyping data generated from CCFR biospecimens to the CCFR Informatics Center within 6 months of publication.

Name of person completing this form _____ Date submitted _____

Author: Forward this form with Section I completed along with a copy of the manuscript to the Colon CFR Program Manager, Allyson Templeton (atemplet@fredhutch.org).

COLON CFR POLICY ON PUBLICATIONS

Section II: To be Completed by the CFR Program Manager or assigned reviewer:

11. CCFR MS Number: MS Submission Date: _____ /_____ /_____

12. Project category for manuscript under review (see Policy)

	CFR Investigators	Institutional Collaborators	External Collaborators
Pilot Project	☐	☐	☐
Core Project	☐	☐	☐
New Project New (investigator-initiated) Project	☐	☐	☐
Methods/Protocol Development Project	☐	☐	☐

13. CFR administrative review checklist:

	No	Yes	NA
a. Are NCI and the Colon CFR funding appropriately acknowledged?	☐	☐	☐
b. Are the CFR protocols and data descriptions present and adequate?	☐	☐	☐

Comments:	

14. Are modifications required?

☐ No, manuscript is acceptable as is.

☐ Yes, modifications are required (see above); a subsequent review by the PWG is not required.

☐ Yes, modifications are required (see above); a subsequent review by the PWG is required.

Reviewer: _____ Date completed _____ /_____ /_____

☐ Forward a copy of the completed Colon CFR Publications Review Checklist to the author.

☐ Forward completed form with manuscript to Colon CFR PWG Chair.

APPENDIX C: Study description of CCFR, OFCCR, and SFCCR for consortia papers

Colon Cancer Family Registry (CCFR, www.coloncfr.org). CCFR is a National Cancer Institute–supported consortium consisting of 6 centers dedicated to the establishment of a comprehensive collaborative infrastructure for interdisciplinary studies in the genetic epidemiology of colorectal cancer (CRC) [Newcomb et al., CEBP 2007 and Jenkins et al., Int J Epidemiol 2018]. The CCFR includes data from approximately 42,500 subjects (10,500 probands and 26,800 unaffected and affected relatives, 4,280 unrelated population-based controls and 920 spouse controls). CRC cases and unaffected controls, aged 20 to 74 years, were recruited at the 6 participating centers between 1998 and 2013. All participants completed a standardized questionnaire that asked about established and suspected risk factors for colorectal cancer, including questions on medical history and medication use, reproductive history (for female participants), family history, physical activity, demographics, alcohol and tobacco use, and dietary factors. Participants (excluding unrelated controls) are actively followed up every 5 years for updates on their personal and family history of cancer as well as history of surgery, cancer screening and some risk factors. New cancers and deaths are ascertained through linkages with cancer registries and death indices. All CRC cases and a subset of unrelated control participants are tested for *MUTYH* mutations. All CRC tumors are tested for MMR proficiency via microsatellite instability and/or immunohistochemistry analysis. Germline MMR testing is conducted on all CRC cases exhibiting tumor deficiency and relatives are subsequently tested for familial deleterious variants. Colorectal cancer tumor DNA is tested for the *BRAF* V600E somatic point mutation and for somatic mutations in *KRAS* codons 12 and 13. To date, 13,500 CCFR participants (7,640 population-based case probands, 2,830 unrelated population-based control probands, 470 clinic-based probands, and 25,600 proband relatives) have been genotyped on one or more GWAS platform. The **CCFR Set-1 scan** (Illumina Human 1M or 1M-Duo) included population-based case and unrelated control probands from three Colon CFR sites: Seattle Familial Colon Cancer Registry (SFCCR) at Fred Hutchinson Cancer Research Center, Ontario Familial Colorectal Cancer Registry (OFCCR) at Mount Sinai Hospital (previously at Cancer Care Ontario), and the Australasian Colorectal Cancer Family Registry (ACCFR) at the University of Melbourne. Case probands were genetically enriched by oversampling those with a young age at CRC onset or a positive family history of CRC. Control probands were matched to case probands on age and sex [Figueiredo J, et al., Cancer Res 2011]. The **CCFR Set-2 scan** (Illumina Omni-1Quad) included population-based case probands and matched controls from all 6 Colon CFR sites: SFCCR, OFCCR, ACCFR, the Mayo Colorectal Cancer Family Registry at Mayo Clinic, the Hawaii Colorectal Cancer Family Registry at the University of Hawaii, and the University of Southern California Consortium (USCC, now at Cedars-Sinai Medical Center). As with CCFR Set-1, case probands were enriched genetically by oversampling those with a young age at CRC onset or with a positive family history of CRC. Controls in Set-2 were unaffected same-generation family members (siblings or cousins) of case probands [Peters U, et al. Gastroenterology 2013]. The **CCFR Set-3 scan** (Affymetrix Axiom CORECT Set array) included CRC-affected population-based case probands, CRC-affected and unaffected clinic-based probands and matched controls from 5 Colon CFR centers (excluding Hawaii). Controls in Set-3 were related unaffected family members of case probands or unrelated population-based control probands [Schumacher FR, et al. Nat Commun. 2015]. The **CCFR Set-4 scan** (Illumina OncoArray) included CRC-affected population-based case probands from all 6 population-based centers and unrelated population-based control probands from SFCCR, OFCCR and ACCFR. All participants selected for CCFR Set-1, -2, -3, and -4 were non-Hispanic White or of European ancestral heritage, which was confirmed with genotype data [Schmit SL, et al. J Natl Cancer Inst. 2018]. The **CCFR Set-5 scan** (Infinium OncoArray 500K BeadChip) included population-based CRC cases (including incident CRC cases) and unrelated population-based controls not previously genotyped, regardless of race and ethnicity.

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Ontario Familial Colorectal Cancer Registry (OFCCR). Details of the case-control study and the OFCCR [Cotterchio M, et al, Cancer Causes Control 2005, Cotterchio M, et al., Chronic Dis Can 2000, see also Colon CFR], as well as the Assessment of Risk in Colorectal Tumours in Canada (ARCTIC) GWAS results [Zanke BW, et al., Nat Genet 2007] have previously been reported. In brief, cases were confirmed incident colorectal cancer (CRC) cases aged 20 to 74 years, residents of Ontario identified through comprehensive registry and diagnosed between July 1997 and June 2000. Population-based controls were randomly selected among Ontario residents (random-digit-dialing and listing of all Ontario residents) and matched by sex and 5-year age groups. The OFCCR has used several genotyping platforms over its existence, including the Illumina 1536 GoldenGate assay (Illumina, Inc, San Diego, CA), the Affymetrix GeneChip® Human Mapping 100K and 500K Array Set (Affymetrix, Inc, Santa Clara, CA), and a 10K non-synonymous SNP chip. Analysis was based on a set of unrelated subjects who were non-Hispanic, White by self-report or by investigation of genetic ancestry. Further exclusions were made for sample swaps, missing epidemiologic questionnaire data, appendiceal tumors, or if a subject overlapped with other datasets in the Colon Cancer Family Registry. For this GECCO analysis…[describe which data were used].

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Seattle Familial Colon Cancer Registry (SFCCR) [Newcomb et al., CEBP 2007] and ***Postmenopausal Hormones and Colon Cancer (PMH)*** Newcomb et al., Cancer Res 2007]. Eligible cases included all female residents, aged 50 to 74 years, residing in the 13 counties in Washington State reporting to the Cancer Surveillance SEER program, who were newly diagnosed with invasive colorectal adenocarcinoma (ICD-O C18.0, C18.2-.9, C19.9, C20.0-.9) between October 1998 and February 2002. Eligibility for all individuals was limited to those who were English-speaking with available telephone numbers, in which they could be contacted. Unrelated population-based controls were randomly selected according to age distribution (in 5-year age intervals) of the eligible cases by using lists of licensed drivers from the Washington State Department of Licensing for

individuals, aged 50 to 64 years, and rosters from the Health Care Financing Administration (now the Centers for Medicare and Medicaid) for individuals older than 64 years. Study participants residing in King, Pierce or Snohomish counties with available DNA who were not included in CCFR GWAS Set-1, -2, -3, or -4 (see Colon CFR below) were genotyped using Illumina HumanCytoSNP (300k) [Peters et al., 2013].

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