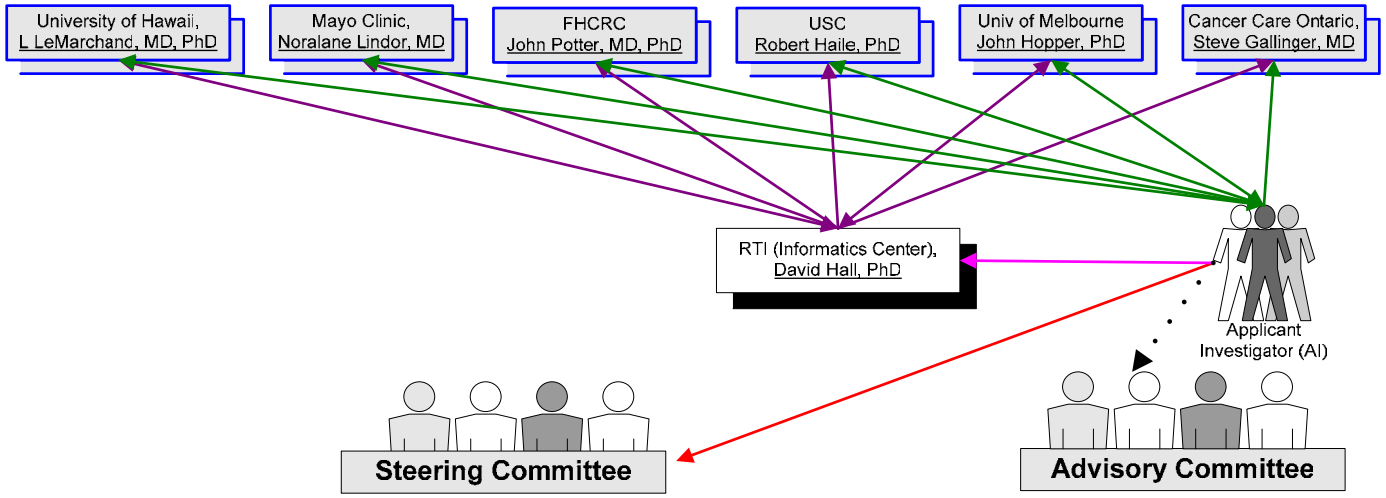
Colorectal Cancer Family Registry (C-CFR) Ethical, Legal and Access Policy Flow Diagram



I. Recruitment Centers (RC):
(1) Has *IRB approval*.
(2) Obtain Informed Consent for all Biospecimens
(3) Has been issued a *Certificate of Confidentiality*
(4) Acts as Gatekeeper to their biospecimens and institutes security to protect privacy

II. RC signs 1-time *Data Use Agreement* with RTI

III. AI submits application to CFR SC

IV. If applicable (requests biospecimens or participant recontact), AI submits application to the CFR AC

V. If approved:,
(1) Each collaborating RC signs *Collaboration Agreement* w/ AI
(2) AI obtains IRB approval
(3) CFR site obtains IRB approval/exemption
(4) CFR site initiates *MTA* (if applicable)
(5) AI signs:
  a. *Confidentiality Pledge* (if needed)
  b. *Biospecimen Request Form* and invoice
  c. *MTA*
(6) AI sends payment for biospecimens
(7) CFR site dispatches biospecimens

VI. For data requests:
(1) RTI initiates *Data Use Agreement* w/ AI
(2) AI signs and returns *DUA* to RTI
(3) RTI releases data to AI
(4) RTI notifies CFR PIs of data release via e-mail.

IRB Approval: Type of approval required will depend on proposal. Key issues include: 1) will the data released by identifiable or stricly anonymized (constitute a "limited data set")? 2) does the proposal involve a one-way exchange of data or a 2-way exchange (will CFR get data back?); 3) does the proposal involved the collection of study of data or the study of existing data?

Certificate of Confidentiality: A *Certificate of Confidentiality* is issued on behalf of the Secretary of the Department of Health and Human Services (DHHS) and protects Investigators against the involuntary release of information about participants collected during the course of study.

Data Use Agreement: This agreement must be executed with a covered entity in connection with obtaining a "limited data set". The covered entity may disclose a limited data set only if it also obtains specified assurances from the data recipient in the form of a DUA. RC each signed a one-time DUA with RTI. AI signs a project-specific DUA to obtain data files.

Collaboration Agreement: AI must obtain copies of this simple agreement showing that the RC has agreed to collaborate on approved project.

Material Transfer Agreement: Governs the transfer of one institution's proprietary materials to another organization for research purposes. MTAs are necessary when the site receives a request for research materials from an investigator outside the custodial institution. MTAs protect the site's ownership interest in the material that is being distributed to the other party by containing provisions regarding the use of the material.

Confidentiality Pledge serves to document: (1) IRB approval of the research involving access to repository data and/or specimens and (2) Confidentiality protections to be honored by the researcher and any study staff utilizing stored specimens and/or data. It is completed by each researcher and any study staff whose new research activity involves access to the repository's stored specimens and/or data.

Biospecimen Request Form: Confirms criteria, clarifies/tracks steps in collaboration, calculates biospecimen costs, serves an invoice.

NOTE: AI – Applicant Investigator; RC – Recruitment Center; SC – C-CFR Steering Committee; AC – C-CFR Advisory Committee; RTI – Research Triangle Institute; MTA – Material Transfer Agreement; DUA – Data Use Agreement