Resource Request Application

***Commonly Used Abbreviations**: **ANBS**: Archived Neonatal Blood Spots; **BC**: Birth certificate; **CA**: California;; **CBP**: California Biobank Program; **CBT**: Childhood Brain Tumor; **CCLS**: California Childhood Leukemia Study; **CCR**: California Cancer Registry; **CDPH**: California Department of Public Health; **CHSI**: Center for Health Statistics and Informatics; **CL**: Childhood Leukemia; **co-I**: co-Investigator; **CPHS**: Committee for the Protection of Human Subjects; **DBS**: Dried blood spots; **DUMTA**: Data Use/Materials Transfer Agreement; **IRB**: the Institutional Review Board; **PI**: Principal Investigator.*

The Resource (i.e., data/materials) Request is intended as a mechanism for internal and external investigators to formally express their interest in an area of research, and to request DATA (e.g., interview data, disease classification) and/or MATERIALS (e.g., biospecimens, home samples). Please see Appendix A for an overview of procedures and a brief table of possible available* resources by each parent study or program.

Projects requesting data/materials must be within the scope of the Program's hypotheses and pose a research question of sufficiently high priority. Every effort will be made to fill requests for data/materials as quickly as possible, but the limits of staffing resources and competing requests may result in delays in data/materials being sent.

Instructions and a checklist for requesting DATA/MATERIALS are described below. (See Appendix A-2 for the full instructions and Standard Operating Procedures)

1. Prepare a Resource Request application and submit to icareadmin@berkeley.edu. Please see Appendix A-1 for a list of completed/ongoing studies* from which resources may be available.

2. In the process of preparing the project proposal, it may be necessary to meet with the Program Manager from the study to determine its feasibility (i.e., identify variables, sample size, biospecimen availability, etc).

3. Depending on the request, you may be requested to present the proposal in an ICARE monthly data meeting.

4. If necessary, the investigator will be requested to revise the project proposal in response to comments and suggestions. Please resubmit the application electronically to icareadmin@berkeley.edu.

5. The Principal Investigator (PI) and Lead Investigator(s) will review the final application, and will grant final approval for the request.

6. If approved, discuss with the PIs and/or Program Managers about your project timeline including funding/grant, IRBs, and DUMTAs.

7. If project is approved, resources are delivered to the investigator.

8. The investigators provide updates of the status of the project as relevant (including a list of publications, posters, presentations, manuscripts, etc.) as relevant but at least three times a year.

**While all resources requested require the permission of the Study PI for release, certain biospecimens (i.e., dried blood spots (DBS) and maternal sera during pregnancy) require additional separate approvals as they belong to the State of California (e.g. the California Department of Public Health (CDPH), the Genetic Disease Screening Program (GDSP), the California Committee for the Protection of Human Subjects (CPHS), and the California Biobank Program (CBP)) before release.*

Resource Request Application

Section 1 to be completed by requesting investigator (Guideline: 2-3 pages)

Which study(s) are you requesting resources from? *(Please mark)*

☐ CCLS ☐ CRECERE

Requesting Investigator:	
Date of Request:	
Project Title:	
Running/Working Title (50 characters):	

Names and institutions of the lead person and all collaborators of which at least one of which should be a Lead Investigator from the Study. *Please include the following: Name, Title, Institution (full address), Email address, and Phone number (e.g., Catherine Metayer, University of California, Berkeley, SPH-ICARE, 1995 University Avenue, Suite 460, Berkeley, CA 94704, cmetayer@berkeley.edu, (510) 643-1156 ph, (510) 643-1735 fax).*

Lead Investigator :	
All Co-Investigators:	
Co-Investigator 1:	
Co-Investigator 2:	
Co-Investigator 3:	
Co-Investigator 4:	

State whether this is a new project or an updated one:	
Is this project already funded, or is funding being sought?	

Which resources are you requesting?

- **If personal identifiers *(e.g., names, addresses, GIS coordinates, date of birth, date of diagnosis, etc.)* are requested, provide an explanation of why they are needed** (this summary will be used to write any Collaborative Research Agreement or Material Transfer Agreement, if needed):

Provide a short summary (10 sentences max.) of specific aims; including study population(s) and research hypothesis (this summary will be included in the IRB Protocols).

Provide background and significance.

Specify the study population information (selection criteria for the analysis subset, sample size, etc).

If appropriate, describe the laboratory methods to be used:

Describe the statistical analytic methods to be used (may include power calculation):

Describe the expected outcome(s).

Specify the timeline for accomplishing the IRB submission and analyses.

Explain how and where the data/materials will be stored, your data security plan, and how confidential DATA (if any) will be encrypted.

Are computing needs necessary for conducting the proposed research?

Describe other non-data/biospecimens resources needed to conduct the proposed research (e.g., personnel).

If requested, who will receive all the data/materials (name and address of all institutions including fee-for-service locations) and how will MATERIALS be delivered to the institution(s) where work will be conducted:

Initial next to <u>each</u> confirming you and your co-investigators have read the following document (see appendices):

Document in Appendices	**Initials**
Policies Governing Transfer of Data/Materials from UCB (CCLS/CRECERE) (see Appendix B-1)	

Please note: Other appendices may be applicable depending on the nature of your request. ICARE staff will review your application and if applicable, will advise you of any other needed document(s).

Recipient Investigator Acknowledgment: I have read and understood the policies and conditions outlined in this Resource Request Application, and I agree to abide by them in the receipt and use of the DATA/MATERIALS.

	[Signature]	[Date]
[Name of Recipient Scientist]		

Recipient Co-investigator Acknowledgment: I have read and understood the policies and conditions outlined in this Resource Request Application, and I agree to abide by them in the receipt and use of the DATA/MATERIALS. *(Copy & paste as needed for all key personnel (i.e. co-investigators))*

[Name of Co-Investigator]	[Signature]	[Date]

Approved by study PI(s):

[Name of Study PI]	[Signature]	[Date]

Section 2 (to be completed by Resource Sharing Committee or ICARE Administrator ONLY)

1. Date request submitted:		
2. Reviewed by *(first & last name; date)*:		
3. Is the project new research or updated research?		New or Updated/Amended?
4. Is there a copy of the CITI Human Subjects Training on file for the individual(s) requesting data?		Yes or no?
5. Does the receiving institution have an adequate security plan for requested Data/Materials?		Yes or no?
6. Is there a signed copy of the CCR agreement for Access to CCR Data (referred to as CCR Appendix 2)?		Yes or no or not applicable?
7. IRB Submission Plan? *(ex.: USC will submit state IRB/UCB will likely…/Yale will likely… etc.)*		
8. Request approved:	Yes or no? Date?	