NAACCR Templated IRB and Registry Application:

For use with cancer registry linkages facilitated by the Virtual Pooled Registry

Background: NAACCR has developed this Templated IRB and Registry Application to be used in lieu of state-specific cancer registry and IRB applications, when agreed upon by the institution. It will also serve as the application for the NCI Central IRB. While a particular study may involve activities that are subject to full IRB review, this application is intended to focus on the cancer registry linkage aspect of studies where patient consent for linkage is in place or a waiver of consent for linkage has been granted. This Template is designed to fully meet IRB and registry requirements. It was developed for use by researchers applying for release of individual-level data on matched cancer cases identified through VPR minimal risk linkage studies; however, it can be adopted by state/local IRBs to use with all types of requests.

Online Instructions for Researchers: Please complete Sections I-VI of this Templated IRB and Registry Application and include the following documents with your application:

* Study Protocol (with section on registry linkages highlighted within the document)
* Copy of the Patient Consent Form that includes linkage with cancer registries and/or Waiver of Consent, if applicable Other survey/questionnaire materials relating to patient contact, if applicable
* Current IRB Approval from the researcher's affiliated institution
* CV or biographical sketch for PI/Co-PI (limit 5 pages each)
* Copy of Certificate of Human Subjects Training for PI/Co-PI (e.g. CITI, DHHS ethics training, etc.)
* List of requested variables

Section I: General Information

1. **Date of Submission:**
2. **Study Title:**
3. **Type of Submission:**

 [ ]  New [ ]  Renewal [ ]  Modification [ ]  Continuing Review Report

1. **List all PIs and Co-PIs Institutional/Organizational Information:**

**Name:**

**Title:**

**Degrees:**

**Organization:**

**Phone #:**

**Fax #:**

**Email:**

**Address:**

**Country:**

**State/ Province:**

**Zip:**

**Type of Organization:**

 [ ]  Public Agency [ ]  Private Nonprofit [ ]  For Profit [ ]  Other, please specify:

1. **Primary Contact’s Institutional/Organizational Information (if different from PI):**

**Name:**

**Title:**

**Degrees:**

**Organization**

**Phone #:**

**Fax #:**

**Email:**

**Address:**

**City:**

**State/ Province:**

**Zip:**

**Country:**

1. **Support Type (please include all sources of funding):**

**For each funding source selected, provide these items:**

1. **Funding Award Number:**
2. **Sponsoring or Funding Organization Address:**
3. **Period of Funding (start date – end date):**
4. **Amount of Funding:**

Federal Government

[ ] NIH/NCI Intramural

[ ] NIH/NCI Extramural

[ ] NIH/NIEHS

[ ] CDC

[ ] FDA

[ ] VA

[ ] DOD

[ ] OSHA
[ ] Other Federal Government, please specify:

State Government

[ ] State Government

Non-Profit Organization

[ ] American Cancer Society

[ ] Leukemia Society of America

[ ] Susan G. Komen Foundation

[ ] Livestrong Foundation

[ ] Central Brain Tumor Registry of the United States

[ ] Other Non-Profit Organization, please specify:

Industry

[ ] Pharmaceutical

[ ] Biotechnology

[ ] Health Insurer

[ ] Other Industry, please specify:

Individual Gifts and Bequests

[ ] Individual Gifts and Bequests

Other

[ ] Other Funding, please specify:

Section II. Study Proposal and Protocol

1. **Purpose of Study (Brief background, why it is being performed, and primary objectives):**
2. **Study Methodology (Brief description of study design, study population, source of data, and study duration) :**
3. **Analysis Plan (Brief description of your analysis plan, indicating specifically how data obtained from the Cancer Registry will be used, and the type of results to be presented (counts, rates, etc.):**
4. **Literature review of up to 5 key references and summary of research already accomplished with emphasis on any significant contributions and rationale for current study.**
5. **Describe the benefits of this study to society and/or academic knowledge:**
6. **How and to whom does the researcher intend to report findings (e.g., publication, grant application, presentation, etc.)?**
7. **Describe plans (if any) for sharing data (even de-identified) outside the originally proposed study**
8. **Describe the staffing and technical expertise that will be available for completing the project**

Section III: Patient Recruitment, Welfare, and Informed Consent

1. **Name of the institutional IRB:**
2. **IRB’s Multiple Project Assurance (MPA) number or Federalwide Assurance (FWA) number:**
3. **Date of current IRB approval:**
4. **Date of current IRB expiration:**
5. **Does the approved protocol include linkage with the cancer registries?**
6. **Does the proposed research involve any vulnerable populations?**

 [ ]  No

 [ ]  Yes (check all that apply):

 [ ]  Pregnant Women

 [ ] Fetuses

[ ]  Minors/Children

[ ]  Students

[ ]  Prisoners

[ ]  Individuals with mental disabilities or cognitive impairments

[ ]  Individuals with physical disabilities

[ ]  Elderly (65 & older)

[ ]  Other, please specify:

Provide justification for each item checked:

1. **Is Expedited or Exempt review being requested?**

[ ]  Expedited

[ ]  Exempt Human Subjects Research,

[ ]  Public health surveillance activity mandated by a public health authority

1. **Original method for recruiting prospective subjects and obtaining consent.**
2. **Does the study have written informed consent from persons in the study (that is, the individuals, their next-of-kin or legal representatives) to access information from their cancer registry records?**
3. **If the study involves minors or children, does the study have written assent from children capable of providing such assent (typically ages 7-17)? If no, please describe why.**
4. **Is the study requesting a Waiver of Informed Consent for linkage with and release of cancer registry records?**

**If yes, please check the box next to the criteria below that support how the proposal meets the requirements for waiver of informed consent.**

[ ]  **i. The research is to be conducted by or is subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine**

1. **public benefit or service programs;**
2. **procedures for obtaining benefits or services under those programs;**
3. **possible changes in methods or levels of payment for benefits or services under those programs, and**

**ii. The research could not practicably be carried out without the waiver or alteration.**

[ ]  **i. he research involves no more than minimal risk to the subjects;**

**ii. The research could not practicably be carried out without the requested waiver or alteration;**

**iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;**

**iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects, and**

**v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.**

 **Provide justification for the selection made above.**

1. **Is the study requesting a Waiver of Documentation of (Written) Consent?**

**If yes, please check the box next to the criteria below that support how the proposal meets the requirements for waiver of informed consent.**

[ ]  The only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting in breach of confidentiality, **or**

[ ]  The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

 Provide justification for the selection made above.

1. **Describe the subjects included in the study cohort (who, how many, how selected, age, gender, special qualifications, etc.).**
2. **Describe any exclusion criteria for subjects in study cohort.**
3. **Describe potential benefits of this linkage study to study subjects.**
4. **Describe potential risks or adverse consequences for study subjects, the probability of their occurrence, why study risks are reasonable in relation to the potential benefits, and how these risks will be monitored and minimized.**
5. **Does the study involve a new investigational drug (IND) or investigational devices exemption (IDE)?**

**If Yes, please list the IND/IDE numbers and names:**

1. **Does the study involve any active non-biological or biological data collection, including HIV testing?**

**If yes, please describe:**

1. **Does the study currently have ongoing contact with study participants?**

**If yes, please describe:**

1. **Will the information reported by the registry change the nature or type of contact with the study participant?**

**If yes, please describe:**

1. **Will the study seek additional information from individuals or institutions mentioned in a study participant’s cancer registry record (other than from the cancer registry or the study participant)?**

**If yes, please describe:**

1. **Will knowledge of an individual’s cancer diagnosis result in first-time recruitment into new research studies?**

**If yes, please describe:**

Section IV: Linkage and Data Release Information

1. **Will this be a recurring linkage?**

**If so, what is the frequency and timeframe for the additional linkages?**

1. **Please provide any inclusion criteria for the cancer registry records you are requesting**
	1. **Primary Site Group:**
	2. **If limited to more specific cancer sites, not covered by the SEER Site Recodes, please specify:**
	3. **Behavior type:**
	4. **Cancer registry diagnosis start year for linkage:**
	5. **Cancer registry diagnosis end year for linkage:**
	6. **Interest in most recent diagnosis year available:**
	7. **Sex:**
	8. **Age at Diagnosis:**
	9. **Race/Ethnicity:**
	10. **Other Specifications:**
2. **Will individual-level data from the cancer registries be linked to a study file that contains patient identifiers? (e.g. Name, DOB, SSN, etc.)?**
3. **Will the analytic study file include any patient identifiers?**
4. **Are there any proposed linkages between registry data and other data files?**

**If yes, please specify:**

1. **In some states, full dates are considered identifiable data and may not be able to be released or may require additional review. Are any full dates (e.g. diagnosis, treatment, etc.) being requested?**
2. **In some states, cause of death (COD) may not be able to be released or may require a separate application to the state vital statistics office. Is COD being requested?**

**Requested Data Items: Please complete and upload the list of Requested Data Items prior to submitting the TIRA.**

1. **Link to secure site where registries will submit file of matched records:**

Note: A secure website uses encryption and authentication standards to protect the confidentiality of web transactions.

1. **Individual to contact for password or assistance with secure site** (Name, Email, Phone):

**\***The NAACCR Data Dictionary Chapter X has descriptions of the NAACCR item numbers (use link below and enter item #): <http://datadictionary.naaccr.org/?c=10>

Section V: Data Security and Confidentiality

1. **Is access to records that identify individuals limited only to members of the research team?**

**If no, please explain:**

1. **Provide a list of other organizations who will have access to records identifying individuals and describe why access to the data is necessary**
2. **Provide a list of all individuals who will have access to either the raw registry files or the registry files linked to study data that identify individuals (Name, Title, Organization, Role, Level of Access)**
3. **Describe how confidentiality of data and privacy of study subjects will be maintained, how data will be stored, and how secure conditions, both physical and electronic, will be maintained.**

1. **Provide anticipated date when the project will be completed:**
2. **Describe when (month/year) and how Registry data will be destroyed. If the above date is unknown or more than 5 years, provide strong justification for why this is the case.**
3. **If Registry data will not be destroyed, describe how the de-identified data will be stored and used after the study ends.**

Section VI: Conflict of Interest

1. **Is the PI or Co-PI employed by, or affiliated with, any other organizations?**

**If yes, please list employer/affiliation.**

1. **Describe any conflicts of interest (financial or non-financial) that could be perceived to compromise the integrity of the project and how it will be managed.**