NAACCR, Inc. CALL FOR DATA ASSURANCES AGREEMENT

Agreement executed this _____ day of _____ , 20_____, by and between the **NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES, INC.** ("NAACCR, Inc."), a California corporation, and _____ ("REGISTRY") of _____, _____.
(Name) *(City)* *(State/Province)*

NAACCR, Inc. is engaged in an annual Call for Data to conduct data evaluation, aggregation, analysis and publication of cancer incidence, specifically described in Attachment A:

NAACCR, Inc. uses and analyzes certain cancer incidence data (the "Data"). NAACCR, Inc. agrees and acknowledges that patient confidentiality is of the utmost importance in the use of the Data and in the manner in which all research results are presented and/or published. Accordingly, in consideration of NAACCR's receipt of the Data from the Registry, NAACCR, Inc. assures REGISTRY as follows:

1. NAACCR, Inc. agrees to treat the Data received from Registry as private, non-public health information. The Data will be used solely for the specified analyses and research described in Attachment A and not for any other purpose. The Data will never be used as a basis for legal, administrative or other adverse actions that can directly affect any individual about whom personal and/or medical information is included in the Data.

2. NAACCR, Inc. understands and agrees that any and all Data which may lead to the identity of any patient, research subject, physician, other person, or reporting facility is strictly privileged and confidential and agrees to keep all Data strictly confidential at all times.

3. If, in the course of evaluation, analysis, and research, NAACCR, Inc. believes it necessary to provide access to the Data to any NAACCR, Inc. researcher, NAACCR, Inc. will not do so unless and until such individual has properly executed a Data Confidentiality Agreement for NAACCR Researchers which has been accepted, in writing, by NAACCR, Inc. NAACCR, Inc. agrees to notify Registry in writing within forty-eight (48) hours of becoming aware of any violation of this Assurances Agreement or any Assurances Agreement executed by any other individual, including full details of the violation and corrective actions to be taken by NAACCR, Inc.

4. NAACCR, Inc. further agrees that all data provided under the provisions of this Assurances Agreement may only be used for the purposes described in Attachment A. Requests for ad hoc uses will only be provided after obtaining consent from each registry for each use.

5. NAACCR, Inc. agrees that (i) any and all reports or analyses of the Data prepared by NAACCR, Inc. shall contain only aggregate data. NAACCR, Inc. further agrees that (ii) at no time will any individual names or other personally identifying information or information which could lead to the identification of any Data subject ever be published, (iii) no report of the Data containing statistical cells with less than six (6) subjects shall be released without the prior written authorization of REGISTRY, (iv) aggregate data that identify individual REGISTRY will not be published without approval from REGISTRY.

6. NAACCR, Inc. further agrees that all data provided under the provisions of this Assurances Agreement shall remain the sole property of REGISTRY and may not be copied or reproduced in any form or manner without REGISTRY's prior written consent. Notwithstanding the foregoing, a NAACCR researcher may copy and maintain the Data on personal computer as long as such computer is secure and accessible only to the NAACCR, Inc. researcher.

7. NAACCR, Inc. will not take any action that will provide any Data furnished by REGISTRY to any unauthorized individual or agency or any other third party without the prior written consent of REGISTRY.

8. NAACCR, Inc. will not disclose in any manner, to any unauthorized person, information that would lead to identification of individuals described in the Data furnished by REGISTRY. Also, NAACCR, Inc.

will not provide any computer password or file access codes which protect the Data to any unauthorized person.

9. Should NAACCR, Inc. become aware of any unauthorized access or disclosure of the Data to other persons, NAACCR, Inc. will report it immediately to REGISTRY.

10. In the event that any attempt is made to obtain from NAACCR, Inc. any or all of the Data provided to NAACCR, Inc. by subpoena or other legal means, NAACCR, Inc. will notify REGISTRY immediately. NAACCR, Inc. agrees that REGISTRY may employ attorneys of its own selection to appear and defend the claim or action on behalf of REGISTRY. REGISTRY, at its option, shall have the sole authority for the direction of the defense and shall be the sole judge of the acceptability of any compromise or settlement of any claims or action against REGISTRY.

11. NAACCR's obligations hereunder shall remain in full force and effect and survive the completion of NAACCR's Call for Data projects described in Attachment A.

12. The terms of this Assurances Agreement shall be binding upon NAACCR, Inc. his/her agents, assistants, and employees.

13. Notwithstanding any contrary language in this Assurances Agreement, NAACCR, Inc. acknowledges and agrees that NAACCR's access to the Data shall at all times be in the sole discretion of REGISTRY.

14. REGISTRY reserves the right to review any and all of NAACCR's reports prior to dissemination or NAACCR's manuscripts before submission for publication to ensure that confidentiality is not violated and the Data are used appropriately.

15. This Assurances Agreement shall be governed by and interpreted under the laws of the State of Illinois.

Dated this 30th day of August 2021.
North American Association of Central Cancer Registries, Inc.

By:
Betsy A Kohler

Its: Executive Director

Print Name: Betsy Kohler
North American Association of Central Cancer Registries, Inc.

Received and accepted this _____ day of _____, 20_____.

REGISTRY _____ ("Registry" Signature)

By: _____

Its: _____

Print Name: _____

Address: _____

_____

_____

E-mail address: _____

Please upload on the submission site. Contact Recinda Sherman with questions at: rsherman@naaccr.org

Attachment A
Uses of Registry Data Submitted to the NAACCR Call for Data

1 Summary of Primary and Secondary Data Uses

Central registry data submitted to NAACCR, Inc. in the Call for Data include data from 1995-2019, as of December 1, 2021 and 2020 as late as January 31, 2021. The NAACCR website describes how data releases are approved, with registry consent, and summarizes the variables available for each use; the data release procedure, and steps to ensure patient confidentiality: https://www.naaccr.org/cina-data-products-overview/ .

1.1 Cancer in North America Primary uses (registry data included in these activities for all registries provided with signed general DUA except where specific consent is noted)

1.1.1. Produce Cancer in North America (CiNA), 2015-2019 monographs (Vol 1: Combined Incidence; Vol 2: Registry-Specific Incidence, Vol 3: Registry-Specific Mortality, Vol 4: Survival, Vol 5: Prevalence, and associated appendices).

1.1.2. NAACCR evaluations of 1995-2020 data to determine fitness for use in cancer surveillance and research projects and make assessments available on the NAACCR website and to the NAACCR community, e.g. 12 month data assessment, completeness of variables.

1.1.3. Produce the Annual Report to the Nation on the Status of Cancer (high quality U.S. registries only) which will include a short report based on early assessment of the impact of covid-10 on our 2020 data.

1.1.4. Create surveillance information and respond to data requests using the NAACCR CiNA research files for requests of aggregate data of high quality U.S., Canadian, or North American data; state/provincial/territorial-specific data; or cancer site-specific data using a suppression rule for fewer than six cases for any requested rates and counts by state, province or territory.

1.1.5. Create aggregated measures by central registry for use in the NAACCR web-based public query systems available here https://www.naaccr.org/interactive-data-online/.

1.1.6. Development of datasets to create project-specific datasets for proposals approved by the NAACCR Research Application Review Workgroup (RApR) (consent from registries required prior to release).

1.1.7. Utilize data internally within NAACCR and by NAACCR committees to assess quality, fitness for use, and appropriate methodologic approaches.

1.1.8. Use of CiNA Research dataset to support the ranking by state and province based on cancer-related health indicators to support comprehensive cancer control.

1.1.9. Produce a non-confidential, public use research file with limited variables that will be available upon request after signing a data use agreement. Inclusion in this dataset will require registry consent as well as meeting data quality criteria. Consent for this specific project is included in this document.

1.1.1 Produce an historical dataset annually to create delay factors based on multiple submission datasets. Consent for this specific project is included in this document.

1.2 Cancer in North America Secondary Uses (consent requested for each specific project)

1.2.1 Create project-specific datasets from the 1995-2019 CiNA Datasets (e.g CiNA Research, CiNA Survival/Prevalence) and special analytic files for researchers--consent for inclusion will be sent to registries as projects are approved.
1.2.2 Produce CiNA Research dataset, with a county variable (derived from data items 90, 94, 95, 96, 97), for calculation of incidence projections by the American Cancer Society (ACS) for their annual *Cancer Facts and Figures* publications (Active Consent attached)
1.2.3 Provide aggregated data for medullary thyroid cancer verification (Active Consent attached)
1.2.4 Produce Synthetic dataset for training and testing purposes (Active Consent attached)
1.2.5 Produce current CiNA Public Use datasets in SEER*Stat for Public Use. Registry inclusion is dependent upon standard data quality criteria as well as individual registry consent (Passive Consent attached)
1.2.6 Produce American Lung Association dataset (Passive Consent attached)
1.2.7 Produce an historical dataset annually for NCI collaborators to conduct delay-adjusted incidence rates (Passive Consent attached)
1.2.8 Produce dataset for evaluation of stage at diagnosis and impact of the Affordable Care Act (Passive Consent attached)

1.3 Registry Certification Program

The latest year of cancer diagnoses will be used for Registry Certification. This involves an evaluation of a registry's data to determine whether they meet NAACCR's high quality standards for use in computing incidence statistics. The Certification Committee review results annually. NAACCR Executive Office conducts the evaluation.

2 Physical and Electronic Data Security

2.1 Certificate of Confidentiality

The use of CiNA data is covered by a Certificate of Confidentiality (Certificate) that protects the privacy of research participants enrolled in research. The Certificate prohibits disclosure in response to legal demands, such as a subpoena. Effective October 1, 2017, NIH no longer provides documentation that specific NIH-funded studies are covered by a Certificate but NIH funded research activities are automatically issued a certificate under the NIH Policy on Certificates of Confidentiality. This has been confirmed with a Human Subjects Protections Consultant from the NIH Office of Extramural Research. More information is available here: https://humansubjects.nih.gov/coc/faqs#definitions. If you have any questions, please contact NAACCR Program Manager of Data Use & Research (Recinda Sherman at rsherman@naaccr.org).

2.2 File Submissions

All files are submitted to the NAACCR Statistical Analytic Unit, Information Management Services, Inc. (IMS) through secure electronic channels. Annually, IMS provides an assessment of their Data Security processes using the NAACCR document, *Inventory of Best Practices Assurance of Confidentiality and Security*. The data submissions are accessible only by IMS staff under contract with NAACCR, Inc. to process the files and produce the primary analyses of data.

Files used for CiNA Products and other primary and secondary uses of data will be deleted 5 years after publication of research. However, historic data will be maintained to support the on-going production of reporting delay-factors.

2.2 Secondary Dataset Files

The NAACCR Executive Office provides permission for client server access to the CiNA Research, CiNA Survival/Prevalence, or CiNA special files to approved NAACCR researchers. Each file is the property of NAACCR, Inc. Data may be exported to other statistical software, such as SAS, for analysis. General information and variables lists for all file types are available on the NAACCR Website: https://www.naaccr.org/cina-data-products-overview/.

There are 2 types of CiNA datasets:

- The first file type is a dataset made available only to approved researchers who are NAACCR members, have a NAACCR approved protocol, and have signed a data confidentiality agreement. These include the standard CiNA Research dataset and CiNA Survival/Prevalence and NAACCR is investigating the development of a CiNA Geographic dataset. Datasets with county identifiers, single-years of age, special variables, new methodology, or sensitive research (e.g. HIV) require ACTIVE CONSENT (see section 5) from individual registries to be included in the researcher's specific CiNA dataset. Datasets with the standard 19 age-groups and no county identifiers with well understood methodology and no special variables or sensitive research require PASSIVE CONSENT from individual registries to be included in the researcher's dataset. PASSIVE CONSENT may also be used for some special variables such as "reside in Appalachian County (Y/N)" or recodes for breast cancer subtypes.
- The second type of CiNA file is a limited variable, non-confidential, Public Use dataset. The dataset is available upon request after signing a data assurance agreement. The dataset automatically suppresses cells less than 16 and variables are recoded to enable all users to use standard analysis. This dataset does not allow data to be exported outside of SEER*Stat. The Data Assurance Agreement and a list of included variables and recodes are on the NAACCR website: https://www.naaccr.org/cina-public-use-data-set/.

All CiNA datasets created for research will be deleted 1 year after the project is documented as closed or 5 years after known publication date.

3 Further Explanation of Secondary Uses of Data

A list of NAACCR IRB approved projects is available on the NAACCR Website: https://www.naaccr.org/irb-information-for-cina/. A bibliography is available upon request.

3.1 Individual CiNA Research Projects

Access to CiNA Research datasets requires a submission of a proposal for review and approval by the NAACCR Research Application Review Work Group (RApR). RApR reviews the applications for scientific merit and appropriateness of using CiNA data. Due to changes in the Common Rule, NAACCR IRB is no longer required. If RApR approves a project, the NAACCR IRB is notified and consent is requested from all registries eligible for participation in each study. A dataset is created for the Researcher that only includes data from registries that consent to include their data through the consent process.

After all approvals are in place, but before receiving access to the file, all recipients must sign a Data Confidentiality Agreement for NAACCR Researchers (See Attachment B). The NAACCR

IRB monitors all projects annually. Copies of the NAACCR IRB procedures, forms, and meeting minutes are located on the NAACCR Website https://www.naaccr.org/irb-information-for-cina/. CiNA datasets are password protected and may not be accessed by anyone other than approved researchers. All manuscripts for publication resulting from the individual CiNA Research Projects are requested to be reviewed and approved by the NAACCR Scientific Editorial Board before release. They are also reviewed by the IRB to ensure the researcher publishes the data in accordance data agreement and approved proposal. When the studies are completed, researcher access to the SEER*State file is terminated except for Public Use Files. Access to the Public Use Files are automatically terminated annually after the release of the latest CiNA Public Use file—users must sign a new data assurances agreement to gain access to the latest file. New in 2021, the NAACCR Data Request Tracking (DaRT) System will track all data requests, data release, and associated processes. Prior to release of DaRT, these details were tracked manual by the NAACCR Executive Office.

4 Assurances of Proper Use

NAACCR members approved for access to CiNA Research datasets must sign the Data Confidentiality Agreement for NAACCR Researchers, which specifies in writing the proper protection and use of the data. Limitations on secondary data analyses are stated in the NAACCR Call for Data Assurances Agreement that the recipient of the data must sign. Recipients of the Public Use Dataset must initial and sign a Data Assurance Agreement.

5 Registry Consenting

NAACCR employs two approaches to obtain registry consent for *ad hoc* CiNA projects, summarized below. Both approaches are now conducted through the NAACCR DaRT system with a consent request sent the individual designated as the CiNA Approver by the Registry, as well as any alternate registry designates.

Passive Consent: Registries have 14 days to respond. If no response is received, approval is assumed. Projects qualifying for Passive Consent do not request single-years of age, do not request County at Dx, are not unique applications of surveillance data, and do not request special variables that increase the potential for identification of individual patients.

Active Consent: Registries have 14 days to respond. If no response is received, data from the non-responding registry will be excluded from the project. Projects requiring Active Consent may contain single-years of age or County at Dx, or both. Active Consent is also used for projects that are either unique applications of cancer registry data or that request special variables that have the potential to identify specific patients or residential locations of patients. Over time, as registries become familiar with projects and there is wide-spread participation, some Active Consents move to Passive Consents. Two examples are the Delay Adjustment Project (now qualifies for Passive Consent) and the CiNA Survival Project (which no longer requires consent because it is now included in CiNA Primary Uses).

	Passive Consent Process	**Active Consent Process**
Variable list	Standard File; Standard +area-based socioeconomic variables--county or tract-based poverty or urban/rural data ***without*** County (requires specific researcher justification)	Customized Request (e.g. Single Year of Age, County Identifier, county or tract-based socioeconomic variables, such as poverty or urban/rural status, released along with a County)

Geographic Presentation	United States, Canada, North America, regional, state-level analysis.	County
Linked Special Geographic Variables	County-level collapsed data, i.e. Appalachian Region Y/N, CHSDA region Y/N), coded economic or other SES data at does not uniquely identify a county; data appended at the state-level is allowed	Any area-level data linking to continuous variables or coded data that could uniquely identify county

5.1 Rescinding Consent

For all primary uses of NAACCR submissions, a registry director has the opportunity to rescind consent up to the time that the files go into production to produce the various products. Thus, it is important that every registry be familiar with their data file before it is submitted.

With regard to special studies (secondary data uses), once the dataset has been produced and released to a researcher, consent **may still be rescinded**. However, a researcher may have already conducted analysis on the original file or presented/published data. If a registry rescinds consent, we immediately remove the registry's data from the SEER*Stat research file, instruct the researcher to destroy any exported data for that registry, and instruct the researchers to remove the registry's data from any pending or future presentations/publications.

Attachment B:

DATA CONFIDENTIALITY AGREEMENT FOR NAACCR RESEARCHERS

NOT INTENDED FOR COMPLETION BY REGISTRIES

Agreement executed this _____ Day of _____ 20 ___

By and between ("Researcher") _____ of

_____ _____ _____

Organization *City* *State/Province*

and **NORTH AMERICAN CENTRAL CANCER REGISTRIES, INC.** ("NAACCR"), a California corporation. Researcher is engaged in research into the causes, control, or prevention of cancer, specifically described as follows:

_____

_____

_____

NAACCR collects and maintains certain research data (the "Data") that will or may assist Researcher in this regard. Researcher agrees and acknowledges that patient confidentiality is of the utmost importance in the use of the Data and in the manner in which all research results are presented and/or published. Accordingly, in consideration of his/her receipt of the Data from NAACCR, Researcher agrees as follows:

1. Researcher agrees to treat the Data received from NAACCR as private, non-public health information. The Data will never be used as a basis for legal, administrative or other adverse actions that can directly affect any individual about whom personal and/or medical information is included in the Data.

2. Researcher further agrees that all data provided under the provisions of this Data Confidentiality Agreement may only be used for the purposes described hereinabove and that any other or additional use of the data may result in immediate termination of this Confidentiality Agreement by NAACCR.

3. Researcher understands and agrees that any and all Data which may lead to the identity of any patient, research subject, physician, other person, or reporting facility is strictly privileged and confidential and agrees to keep all Data strictly confidential at all times.

4. If, in the course of his/her research, Researcher believes it necessary to provide access to the Data to any other individual, Researcher will **NOT** do so unless and until such individual has properly executed a Data Confidentiality Agreement that has been accepted, in writing, by NAACCR. And, Researcher agrees to notify NAACCR in writing within forty-eight (48) hours of his/her becoming aware of any violation of this Confidentiality Agreement or any Confidentiality Agreement executed by any other individual, including full details of the violation and corrective actions to be taken by Researcher.

5. Researcher agrees that (i) any and all reports or analyses of the Data prepared by Researcher shall contain only aggregate data. Researcher further agrees that (ii) at no time will he/she ever publish any individual names or other personally identifying information or information which could lead to the identification of any Data subject, and (iii) no report of the Data containing statistical cells with less than six (6) subjects shall be released without the prior written authorization of NAACCR's Executive Director, who has received written authorization from contributing registries.

6. Researcher agrees that linkage to another database is allowed, but not for the purpose of identifying an individual on the file and only as described and specified in the NAACCR IRB approved proposal.

7. Researcher further agrees that all data provided under the provisions of this Confidentiality Agreement shall remain the sole property of NAACCR and may not be copied or reproduced in any form or manner without NAACCR's prior written consent.

8. Researcher shall indemnify NAACCR from any and all liability, loss, or damage (including attorneys' fees) suffered as a result of claims, demands, costs or judgments arising out of the failure of Researcher or those acting in connection with Researcher to conform to and obey the provisions of this Data Confidentiality Agreement. In the event a claim should be brought or an action filed against NAACCR in connection with any such failure, Researcher agrees that NAACCR may employ attorneys of its own selection to appear and defend the claim or action on behalf of NAACCR, at the expense of Researcher. NAACCR, at its option, shall have the sole authority for the direction of the defense and shall be the sole judge of the acceptability of any compromise or settlement of any claims or action against NAACCR.

9. Researcher will not take any action that will provide any Data furnished by NAACCR to any unauthorized individual or agency without the prior written consent of NAACCR.

10. Researcher will not discuss in any manner, with any unauthorized person, information that would lead to identification of individuals described in the Data furnished by NAACCR. Also, Researcher will not provide to any unauthorized person any computer password or file access codes that protect the Data.

11. Should Researcher become aware of any unauthorized access or disclosure of the Data to other persons, Researcher will report it immediately to NAACCR's Executive Director. Researcher understands that failure to report violations of confidentiality by others shall be considered as Researcher's own violation and may result in civil or criminal penalties and termination of current and future access to confidential data.

12. In the event that any attempt is made to obtain from Researcher any or all of the Data provided to Researcher by NAACCR by subpoena or other legal means, Researcher will notify NAACCR immediately. Researcher agrees that NAACCR may employ attorneys of its own selection to appear and defend the claim or action on behalf of NAACCR. NAACCR, at its option, shall have the sole authority for the direction of the defense and shall be the sole judge of the acceptability of any compromise or settlement of any claims or action against NAACCR.

13. Researcher's obligations hereunder shall remain in full force and effect and survive the completion of Researcher's research project described hereinabove.

14. The terms of this Confidentiality Agreement shall be binding upon Researcher, his/her agents, assistants and employees.

15. Notwithstanding any contrary language in this Confidentiality Agreement, Researcher acknowledges and agrees that Researcher's access to the Data maintained by NAACCR shall at all times be in the sole discretion of NAACCR.

16. NAACCR reserves the right to review any and all of Researcher's reports prior to dissemination or Researcher's manuscripts before submission for publication to ensure that confidentiality is not violated and the Data are used appropriately.

17. Researcher understands that access to the Data will be terminated when the report is submitted to the NAACCR Scientific Editorial Board or if no annual progress report is filed with the NAACCR Institutional Review Board. It will also be terminated upon report to the NAACCR IRB that the project is complete.

18. If Researcher is required by any other party or parties, including the state or province or any state or provincial agency, to execute any additional confidentiality agreement(s) as a condition of access to the Data, in the event of a conflict between the provisions of such agreement and this Agreement, Researcher agrees that the most restrictive agreement shall prevail.

19. This Confidentiality Agreement shall be governed by and interpreted under the laws of the State of Illinois.

Dated this _____ day of _____, 20__.
Researcher _____ ("Researcher" Signature)
_____(Print Name)
Address: _____
_____
_____
E-mail address:_____
Phone: ( ) ext. _____

Received and accepted this _____ day of _____, 20__.
North American Association of Central Cancer Registries, Inc.
By:_____
Its_____

Active Consent Form for ACS Facts & Figures

NAACCR requests permission from the (enter registry name):

_____

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. A response must be received by this date for your data to be included in the project.

Project Title:	**ACS Facts and Figures [US ONLY]**
Principal Investigator:	**Rebecca Siegel, MPH, Surveillance & Health Services Research Program (SHSRP), ACS**
Project Description:	A custom version CiNA Research with a county variable (data items 90, 94-97 as appropriate) is produced for ACS and IMS to calculate incidence projections for the ACS's signature annual, biannual, & triennial Facts & Figures publications: Cancer Facts and Figures (CFF), Cancer Facts and Figures for African Americans, Cancer Facts and Figures for Hispanics/Latinos, Breast Cancer Facts & Figures, Colorectal Cancer Facts & Figures, Cancer Treatment & Survivorship Facts & Figures, and the accompanying statistics articles published in the CA- A Cancer Journal for Clinicians. For the projection, the file is released to appropriate staff of IMS who prepare the file(s) and conduct the first steps in the methodology. IMS also adjusts incidence counts in the file using NAACCR registry-specific delay factors as available to provide the most accurate cancer burden. The output is released to one researcher at ACS who completes the final steps to generate the national and state-level projections published in the reports. This is a standing use of the NAACCR data submissions. Since a county identifier is required for linkage to Census data to compute the projections, active consent is requested. Importantly, however, no county-level information will be published and use of the county-level data is confined exclusively to the calculation of the estimated cases in the current year nationally and by state. The CiNA Research file is also used to disseminate cancer incidence rates nationally (stratified by state and/or race), as well as various other statistics (e.g., age distribution) for the most common cancer types. ACS, NAACCR, and NCI also plan to use the CiNA observed cases to check model predictions, by comparing with the estimated cases published in historical CFF for the corresponding years, and assist in the development of improved projection methods. A new case projection method was adopted beginning with the 2021 F&F (the projection method used since 2007 was updated in 2012).

CiNA Data

- A county identifier will be released in order to conduct the state-specific cancer case projections.
- Registry-specific data will be presented. County-specific data will NOT be presented.

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Custom ACS F&F File
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Active Consent Form for Medullary Thyroid Project

NAACCR requests permission from the (enter registry name):

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. A response must be received by this date for your data to be included in the project.

Project Title:	**Medullary Thyroid Cancer Verification**
Principal Investigators:	Annette Stemhagen, DrPH, FISPE SVP, Chief Scientific Officer, SERRM (Safety, Epidemiology, Registries & Risk Management) at United BioSource, LLC
Project Description:	As required by the FDA, United BioSource (UBC) is conducting post-marketing surveillance on behalf of the MTC Registry Consortium (currently consisting of the following members: Novo Nordisk Inc., AstraZeneca Pharmaceuticals LP , GlaxoSmithKline LLC and Eli Lilly and Company) as the sponsor of the study for GLP-1 medications to monitor any increase in medullary thyroid carcinoma which may be associated with its use. UBC has entered into surveillance agreements with many statewide registries on behalf of the Sponsors and needs to verify that there are a) no missing MTC cases in the participating states, and b) monitor the incidence of MTC in the remaining states. NAACCR will release tabular aggregate data to UBC to assist in this important study. Since this is such a rare cancer, many cells may be smaller than 6 on a state level. We are requesting to release tabular data with counts less than 6. These data are for internal use by UBC only and will not be published or presented. The following variables are reported for adults: Counts by State by Year, Counts by Sex (M/F) by Year (US), Counts by Age by Year (US)—includes 0-17 age category, single ages for adults, Stage by Year (US), Counts & Rates by Age-group by Year by Sex (M/F) US, Counts & Rates by Year (US), Counts & Rates by Sex by Year, and Counts & Rates by Age-group and Year. **Note**: This consent is to cover the national data shared. States actively participating in the MTC Registry will have a separate consent and/or state agreement for the data shared specifically for the registry.

CiNA Data

- Registry-specific data will be presented. County-specific data will NOT be presented.

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Research Custom File **without** County Identifier
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Active Consent Form for CiNA Synthetic Dataset

NAACCR requests permission from the (enter registry name):

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. A response must be received by this date for your data to be included in the project.

Project Title: **CiNA Synthetic Dataset**

Principal Investigators: PI: David Stinchcomb, Chair, NAACCR Synthetic Dataset Task Force

Goal: The goal is to create a synthetic dataset with realistic & complete cancer information that can be used for diverse purposes, including training & demos, software testing, & analysis. The CiNA Synthetic Dataset will be about 500,000 cases total, in the current NAACCR layout, will pass edits, & contain a diverse set of sites, stages, & ages with fictitious demographics & place but reflect legitimate diagnostic & treatment possibilities.
Background: The NAACCR Synthetic Dataset Task Force has developed a process for creating an annual synthetic dataset. The annual synthetic dataset will include all the current call for data fields populated with synthetic data derived from real CiNA data. An initial version of the CiNA Synthetic Dataset was created based on the December 2017 submission thanks to the active participation of over 40 registries. The dataset has been successfully used in a number of applications including the first NAACCR Hackathon in June. Participants were very impressed with the synthetic dataset and remarked on how realistic it was. Their main request was to have a larger dataset to work with. For this reason, we plan to increase the size from 10,000 records to 500,000 records with this new version. We hope you will continue to or join in the support of this project.
Methods: Deidentified tumor data will be combined with synthetic demographic and geographic information. The state in the synthetic person record assigned to each tumor record will be different than the state of the tumor record's originating registry. Sets of dates in the tumor data will be randomly altered within diagnosis year & age group to maintain internal consistency & duration. Combinations of primary site category, stage group, age group, & sex that are rare will be NOT be included in the synthetic dataset. The process also analyzes uniqueness characteristics & removes any records that pose significant risks of identification. Additionally, there is often the need for a Type C (confidential) synthetic dataset (e.g. geocoding training). In this case, fictitious names & non-residential addresses will be added.

CiNA Data

- This consent is for the task force to refine the methodology and create an annual CiNA Synthetic Dataset. Applications to use the CiNA Synthetic Dataset for training or other purposes will be reviewed and approved by the NAACCR Program Manager of Data Use and Research.

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Custom Synthetic File
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Passive Consent Form for CiNA Public Use Dataset

NAACCR requests permission from the (enter registry name):

_____

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. If a response is not received by this date, it will be assumed that consent is given and your data will be included in the project.

Project Title:	**CiNA Public Use Dataset—Case Listing (Exporting from SEER*Stat) NOT Allowed**
Contact Person:	**Recinda Sherman, PhD MPH CTR, NAACCR**
Project Description:	Cancer registry data is designed to be used at both local and national levels to improve our understanding of cancer pathology, clinical progression, etiology, and to describe populations at risk. Our cancer surveillance system is consider the "gold standard" for public health disease surveillance, and our data allow for the systematic analysis of cancer data to identify burdens, trends, and to generate hypotheses about cancer risk and etiology To this end, we produce the CiNA Public Use file to be made available for research. The CiNA Public Use File is a non-confidential, limited, public use research file from 1995 forward for U.S. and Canada. It will be available to all researchers upon request after signing a Data Use Agreement, similar to the procedures currently used to access SEER data. The purpose of the dataset is to provide non-confidential data to both NAACCR and outside researchers, whose studies require more variables than currently provided in our on-line query systems, but do not need the full CiNA Research file, in a timely manner. The dataset includes 6 demographic variables, 12 cancer characteristics variables, and 5 derived variables. No treatment data are included. Many of the variables are recoded to reduce uniqueness and standardize analysis. The CINA Public Dataset allows a user to generate counts, rates, and trends within the SEER*Stat system, and includes age in the 19 age group categories. CiNA Public Dataset DOES NOT allow the user to export the data as a case-listing to support regression or other analysis in standard, statistical programs. **Output is automatically suppressed at <16.**

CiNA Data

- The list of variables and recodes as well as the Data Use Agreement is available here: https://www.naaccr.org/cina-public-use-data-set/

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Public Use File; no case listing allowed
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Passive Consent Form for American Lung Association

NAACCR requests permission from the (enter registry name):

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. If a response is not received by this date, it will be assumed that consent is given and your data will be included in the project.

Project Title:	**State-level lung cancer burden**
Principal Investigators:	PI: Zack Jump, American Lung Association Dataset Task Force
	The goal of this project is to describe each state's lung cancer burden in a consumer-friendly online report using visual graphics and simple text explanations. Burden will be represented by lung cancer incidence rate, percent of cases diagnosed by stage, percent of cases first treated with surgical resection, radiology, or untreated (if available), five-year survival rate (if available), and by race/ethnicity as available. Survival by race/ethnicity, stage at diagnosis, and treatment will also be examined at the national level if data is of sufficient quality. All results will be based on five years of aggregated data. This project will be updated annually. More information can be found on NAACCReview https://www.naaccr.org/2018-state-lung-cancer-report/. The survival statistics will be pulled from the CiNA Monograph not a research file.

CiNA Data

- Registry/state-specific data WILL be presented.
- County-specific data are NOT requested. Single-years of age NOT requested.

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Research File **without** County Identifier
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Passive Consent Form for Delay Adjustment

NAACCR requests permission from the (enter registry name):

To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. If a response is not received by this date, it will be assumed that consent is given and your data will be included in the project.

Project Title:	**Delay Adjustment**
Principal Investigator:	**Huann-Sheng Chen, NCI, Rocky Feuer, NCI**
Project Description:	NCI statisticians in collaboration with IMS will use the NACCR CiNA files to estimate delay adjustments needed in trend data for the US and Canada. Delay adjustment has been demonstrated to be an important and significant correction in the analysis of cancer incidence trends. This project will enhance trend analyses in all cancer incidence data, including NPCR, SEER, and Canadian registry data. All registries will be included in the analysis in order to create more robust estimates. The earliest data used in the model will be diagnosis year 2008 from the 2010 submission, but earlier years of data will be included in the database. Delay factors may be estimated based on groups of registries, or individual registries and delay adjusted rates can be produced for the US, Canada, and North America, individual registries, or any selected registry group. Observed and delay adjusted counts and rates are available for each registry that meets the data quality criteria by race, sex, for all sites combined and the five most common cancer sites. **ACS:** ACS uses delay factors as part of the methodology to produce projections of cancer incidence counts for Cancer Facts and Figures. IMS staff compiles delay adjusted incidence counts prior to passing them to ACS for them to run the projections models. Since these delay factors are applied at IMS, ACS staff do not see or have access to the delay factors. **NAACCR:** NAACCR uses delay factors to present national-level, delay adjusted rates—in the CiNA monographs for US and Canada, Annual Report to the Nation, and will incorporate into CiNA Explorer in 2022. Registry-level delay adjusted factors are only released back to the reporting registry (when requested via the NAACCR Data Request Tracking (DaRT) System). **NPCR:** NPCR uses delay factors to create delay rates for the US Cancer Statistics and other publications. IMS provides the delay factors to NPCR. NPCR creates an internal database each year with the combined NPCR and SEER registries with delay factors that account for cancer site, registry, age, race, ethnicity, and diagnosis year, and are used to estimate delay-adjusted counts and rates. Access to this database is strictly limited and accessed on a case-by-case review by an internal data workgroup. Additional information on CDC NPCR's use of the delay adjustment factors can be found in the NPCR-CSS Data Release Policy. **SEER**: Registry-level, delay adjustment factors are available in for SEER Registries according to an agreement with NCI/SEER. NCI does release a registry-specific delay database to any user with "Research Plus" access, which requires additional user authentication over the Research Data (https://seer.cancer.gov/data/access.html). Users accessing delay databases get a warning in SEER*Stat that indicates that users should have a full understanding of the use of delay factors and provides a link to cautions and a guide to their proper use (especially the use of registry-level factors).

CiNA Data

- Upon request, all registries may have access to their individual delay-adjustment factors in a SEER*Stat database via NAACCR DaRT.
- Registry-specific identifiers, for SEER registries only, will be released in a specialized database available from SEER in accordance with the SEER Data Use Agreement.
- Registry-specific identifiers, for NPCR & SEER registries, will be released in a specialized database available from NPCR in accordance with the NPCR-CSS Data Release Policy.

Please mark yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Custom Delay Adjustment Dataset
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

Passive Consent Form for The Affordable Care Act and cancer stage at diagnosis

NAACCR requests permission from the (enter registry name):

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To be included in the project described below, please confirm via the on-line submission, upload a signed copy on the submission site, or email to Recinda Sherman at rsherman@naaccr.org or 217.698.0188 by December 1, 2021. If a response is not received by this date, it will be assumed that consent is given and your data will be included in the project.

Project Title: **The Affordable Care Act and cancer stage at diagnosis**

Principal Investigators: PI: Xuesong Han, American Cancer Society

Lack of adequate health insurance has shown to be a significant factor contributing to advanced stage at cancer diagnosis. The Affordable Care Act vastly increased health insurance coverage in the US, but the impact of ACS on cancer care and outcomes is still unknown. We aim to examine the impacts of ACA on insurance coverage and cancer stage at diagnosis, cancer treatment and survival. The following data analysis steps will be conducted:

- Monthly insurance rates for cancer patients at the time of cancer diagnosis will be calculated and graphed from 2007 through the most recent year, nationally and by state.
- Using patients from non-Medicaid-expansion states as a control group, the changes in Medicaid coverage among the patients from Medicaid-expansion states will be evaluated and adjusted by sociodemographic factors.
- Calculate risk ratios of an early stage diagnosis, standard care, and treatment within 30 days pre and post ACA for all cancer patients and those with common cancers and adjusted for sociodemographic factors.
- Survival analysis for the deadly cancers will be conducted by diagnosis period and Medicaid expansion status and adjusted for sociodemographic factors.

A sensitivity analysis replacing county-level-poverty with census-tract-level-poverty will be conducted for the patients whose census-tract-level-poverty information is available.

CiNA Data

- Registry/state-specific data WILL be presented.
- County-specific data are NOT requested.
- Single-years of age NOT requested but to 2 additional categories (15-17; 18-19) will be provided
- Project is requesting poverty codes (at both the county and tract-level; but county will NOT be released and tract is NOT available in CiNA data).
- Project is requesting data for survival but Cause of Death is NOT requested.

Please indicate yes or no to indicate your consent for this project:

Yes	No	1995-2019 CiNA Research & CiNA Survival Custom File **without** County Identifier
		If no, why not?

If you have any questions regarding this project or data uses, please contact Recinda Sherman at rsherman@naaccr.org or 217.698.0800.

Print Name: Signature:

Title: Date:

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