

**NAACCR Data Evaluation & Publication Committee (DEPC)**  
**Town Meeting Conference Call Summary**  
**November 3, 2003 at 2:00 PM Eastern Time and 1:00 PM Central Time**

**DEPC members present:** John Fulton (Chair), Vivien Chen, Xiao-Cheng Wu, Dave Roney, Andy Lake, Holly Howe, Joellyn Hotes

**Representation from:** Texas, Connecticut, Rhode Island, California, American Cancer Society, NAACCR, Los Angeles, Louisiana, Anaheim, IMS, CDC, New York, Oregon, New Jersey, Alberta, North Dakota, New Jersey, Virginia, Tennessee, Illinois, Massachusetts, Alaska

**Welcome**

1. Dennis Deapen, NAACCR President, welcomed everyone to the meeting on behalf of NAACCR. He thanked John Fulton, the DEPC, and the NAACCR staff for organizing the Town Meeting.
2. Dennis is delighted that the demand for high quality population-based surveillance data has been growing to the level it has and expects it to continue to grow. NAACCR is taking the issues very seriously.

**CINA Deluxe File Definition and NAACCR IRB**

1. Holly L. Howe, NAACCR Executive Director, described the CINA Deluxe File Definition and the NAACCR IRB:
  - a. **Eligibility** - Registries maintain ownership and consent power of their data for every individual project using the NAACCR data. NAACCR tries to ensure the data file produced is of the highest quality. The data that are submitted is evaluated for accuracy and completeness. To be considered “high quality”, a registry must meet “silver” criteria at the time of submission for each year that would be included in the analytic file. Registries are asked during the Call for Data if they would like to be included on the analytic file. If they respond with a yes, they need to complete an informed consent form to be included for individual projects. If they respond no, they will not be included on any special project through the year. Some registries do not have data back to 1995, so the DEPC decided that any registry that has 3 consecutive years of high quality data can be included on the analytic file. Twice a year, NAACCR sends the consent forms with a brief description of the special projects so registries may choose whether they want to be included in the data file or not. If the project involves state-specific analysis, before the data are published, it is shared with the states that are included. If the state feels their data do not look accurate, they can ask to be removed from the study. If any data are removed from SEER\*Stat to be used in another software, the registry is asked to sign a consent form at that time also.
  - b. **NAACCR IRB** - The researchers who have access to the file have described in a proposal to the DEPC or the CINA Deluxe Advisory Group how the data will be used and protected. The researchers must sign assurances and the researcher agreement

upon approval and then complete the NAACCR IRB application. The NAACCR IRB reviews the proposal for assessment of the protection of confidentiality of human subjects. IRB approval is required before the researcher may proceed. The researcher agreement is sent to the registries as part of the Call for Data materials, so the registries can see what the researchers have agreed to. The NAACCR IRB is relatively new and its importance has increased greatly with confidentiality concerns. It is designed and implemented according to federal guidelines. The IRB spent the first year developing guidelines for the operation of the IRB. The guidelines and applications are available on the website. Every NAACCR project is submitted to the NAACCR IRB for review.

2. Questions about CINA Deluxe and the NAACCR IRB:
  - a. Paul Mills from California - What happens when a non-NAACCR researcher approaches NAACCR for the data? Holly explained the data are restricted to members only until there is a higher comfort level with the data. CINA Deluxe has been and will continue to undergo testing to improve it. The expectation is that over time there will be a growing and shared comfort with the file, so it can be used and interpreted correctly by those that are not as close to cancer registry data as we are.
  - b. Melanie Williams from Texas – Who are the members of the IRB? Holly explained the IRB meets federal guidelines by having members from different races, genders, and fields of expertise. A complete list of the NAACCR IRB members, who serve 3-year terms, is available on the website.

### **SEER\*Stat and Data File Access**

1. Dave Roney, IMS, explained that IMS is under contract to NAACCR to provide the data processing, data analysis and systems development services for NAACCR. They receive, process, store and analyze the information submitted by the individual cancer registries in response to NAACCR's Call for Data. The CINA publication is produced, along with the CINA Analytic File. A brief overview of practices regarding data security and access to the data include:
  - a. Security practices – IMS is very concerned about security and confidentiality and have a number of safeguarding practices in place.
    - Personnel - All personnel sign confidentiality agreements.
    - Physically - Access to all confidential data is restricted. Visitors are never allowed into the computer center.
    - Electronically - There is a firewall and all traffic is screened. Anyone connecting is authenticated through a username and password. Access is only allowed to the user and services they are authorized to use. Data coming through their network are encrypted and virus checks are done on everything to and from the Internet. Recovery plans are in effect and outside analysis helps maintain the security system for integrity and guard against any breaches.
  - b. Electronic access to data through SEER\*Stat – IMS is currently using a client-server environment for access, which allows IMS to have control over the data being accessed. Username and passwords are only given to researchers after approval from the IRB and permission from individual registries is obtained for each project. The

- username and password references a security file, which details which registries are approved for access by that username. IMS is creating one CINA Analytic file which NAACCR member researchers can access only those registry's data that consent to participate in their project.
- c. Capabilities within the electronic access – Since the creation of the NAACCR IRB, the case listing function was turned on to enhance researcher data. It allows users with proper authorization to view the individual data elements of a cancer registry.
  - d. Safeguards and risks – The main safeguard is that all data are available through the client-server, which keeps the data physically on IMS servers. The only time the data is let out of this environment is for a very specialized analytic need of a researcher. The risk within IMS is they are responsible for maintaining the security of the system. The risk outside of IMS is when letting the data out of their environment, but those researchers are bound by their researcher agreement.
2. Questions about SEER\*Stat and data file access:
    - a. Vivien Chen from Louisiana – Have the projects approved by the CINA Deluxe Advisory Group been given exempt or expedited reviews? Holly answered that each project has been and will be reviewed by the IRB on a case-by-case basis.
    - b. Vivien Chen from Louisiana – Will the researchers with IRB approval be given access to all the data variables that are submitted? Dave responded that with proper authorization, the researchers would be given access to all the data variables that are submitted, as well as the derived variables that IMS creates for analytic purposes.

### **Researcher Access to CINA Deluxe**

1. Holly Howe explained that only NAACCR members or employees of NAACCR members can get access to the CINA Deluxe Analytic File. They must be involved in a subcommittee or special research group of the DEPC or through CINA Deluxe. Through CINA Deluxe, an individual researcher can submit an application to the CINA Deluxe Advisory Group, who scores them. A researcher can receive up to \$10,000 to work on these projects. After the DEPC or CINA Deluxe Advisory Group approves a proposal, the NAACCR IRB must approve it. Then, Joellyn Hotes gets permission from the registries to be included in the study. Access to the analytic file is for 1 year unless the researcher is approved for an extension.
2. Questions about researcher access to CINA Deluxe:
  - a. Jim Martin from Virginia – What can the \$10,000 be used for? Holly responded that it is generally used for staff time, materials, and support time. There are restrictions listed on the application.

### **Current CINA Deluxe Projects**

1. Joellyn Hotes, NAACCR Program Manager of DEP, reported there are five projects in the analysis phase by NAACCR researchers, who currently have access to the file:
  - a. Dr. Will Athas of New Mexico – Quality Assessment and Use of CINA Deluxe Morphology Data, 1995-1999

- b. Dr. Holly Howe of NAACCR – Urban-rural Variation in the Incidence of Selected Cancer Sites, United States, 1995-1999
  - c. Dr. Frank Groves from South Carolina – Urban-rural Incidence Gradient in Childhood Leukemia, 1995-2000
  - d. Ms. Colleen McLaughlin of New York – Incidence of Non-cutaneous Melanomas in the United States, 1996-2000
  - e. Dr. Xiao Cheng Wu of Louisiana - Subsite-specific Colorectal cancer Incidence Rates and Stage Distributions in Asian/Pacific Islanders, Whites, and Blacks in the US, 1995-1999
2. In October 2003, consent forms were sent to registries for 8 proposed projects.

### **Open Discussion**

1. John Fulton opened the floor for discussion.
  - a. Jim Martin from Virginia – How is the access of data dealt with for a student using the data set for academic purposes? Holly Howe explained that the one case like that includes Dr. Frank Groves, who is an individual NAACCR member. The student is a co-investigator and is included on all the proposals and assurances.
  - b. ??? from Massachusetts – Are there deadlines for submitting projects? Holly Howe announced a deadline for CINA Deluxe on February 6, 2004. Joellyn Hotes would like proposals by early September and early March so they can be included when the consent forms are sent to the registries.

### **Adjournment**

1. John Fulton adjourned the meeting at 3:00pm Eastern.