Minutes

**NAACCR Institutional Review Board Biannual Meeting**

**October 23, 2015**

**11:30 aM ET, 10:30 AM PM CT, 9:30 AM MT, 8:30 AM PT**

Call-In Info:

Toll free number: 1-877-953-0411

Passcode: 9206148

1. Welcome & Report from the Chair John Fulton

John Fulton took role, quorum was met (John Fulton, Cynthia O’Malley, Jack Finch, Ron Dewar, Iris Zachary, Annie MacMillan plus NAACCR representation: Recinda Sherman & Betsy Kohler)

Materials send to IRB members included call agenda, April 2015 meeting minutes, complete list of CINA projects, materials for NIH certification, and information about the proposed changes to the Common Rule.

1. Minutes from April 17, 2015 John Fulton

Cynthia motion Ron second minutes accepted of attendance

1. Status of Documentation of Required Trainings: John Fulton

A reminder a few members still need to provide documentation of Certification in Protecting Human Research Participants. They may send proof of certification from their institutional requirements (CITI for example) or get certified on the NIH site: <https://phrp.nihtraining.com/users/login.php>

This is a requirement for all IRB members and alternates. A pdf download of NIH Materials for Certification was sent to all members.

Status of certification by member below:

John Fulton—need documentation

Cynthia O’Malley (expires 8/29/17)

John Morgan—need documentation

Jack Finch (expires 7/29/17)

Nan Stroup (expires 8/14/16)

Ron Dewar (expires 4/20/18)

Vivien Chen (expires 2/2/18)

Iris Zachary (expires 4/10/17)

Martin Whiteside (expires 3/9/18)

Annie MacMillan—expiring 11-22-15

Joanne Hartnack—need documentation

Ann Marie Hill—need documentation

Recinda will follow up again with individuals who have not yet provided documentation.

1. Webpage Recinda Sherman

Any additional content needed?

<http://www.naaccr.org/Research/IRB.aspx>

Annie identified the Q8 & Q9 on application refer to page numbers for additional reference that do not exist. Recinda will correct and upload form on website.

1. Proposed New IRB Rules John Fulton

John has perused these rules and finds them interesting. The proposed changes are focused on the Common Rule. As drafted, they would have a significant effect on how we conduct the IRB. Currently, researcher who believes they are exempt in their research would have to submit an argument to one or more IRB for exemption. IRB reviews and accepts to sends to full IRB if not exempt. Under the proposed rule, the researcher will make this decision on their own and go ahead with research without going through IRB if the research is exempt. Therefore, our IRB would no longer review these cases. Because we rarely review nonexempt proposals, one potential implication for us is that our IRB may disband.

Cynthia was curious if there is data about how often researchers are wrong about exemption status.

John will ensure NAACCR responds with comments—due December 7, 2015 5 pm. After webinar, Recinda will send email to IRB members soliciting 3-5 key questions concerning the points of the changes which would impact us. This poll will result in a quorum opinion weighing in on the issues and will be the basis for the NAACCR response. The response will likely need to go to board for approval.

Annie—do we know target date for implementation? John does not know but believes there will likely be considerable time needed to implement—maybe 6 months.

Recinda will f/u with Vivian to see if SEER we can get SEER’s perspective on this as well.

Recinda will send an email reminding all IRB members to register/attend the webinar.

All members requested to attend the NAACCR webinar (this webinar was facilitated by Nan, who is not on the call)**:**

Webinar Oct 30, 2015 1pm EST (register here: <https://naaccrinc.webex.com> )

On September 2, 2015, the Department of Health and Human Services (DHHS) and fifteen other Federal Departments and Agencies announced that a Notice of Proposed Rule Making (NPRM) was put on public display and was published in the Federal Register on September 8, 2015.  This NPRM proposes changes to the Common Rule (45 CFR 46 Subpart A) with the goal of better protecting human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.  It also includes discussion of many of the comments received in relation to the Advance Notice of Proposed Rulemaking (ANPRM) that was released in July 2011.  Included within this 519-page NPRM are approximately 45 major proposals to the Common Rule and 88 questions to which DHHS is requesting comment.

Institutions involved in the conduct of human research should be aware that many of the proposals put forth in the NPRM, if implemented, would have profound and long lasting effects on the conduct and oversight of human research in the future with substantial implications for the workload of investigators, IRBs, and institutions.

This webinar will provide a summary of the key portions of the NPRM and provide an opportunity for audience questions, feedback and discussion.

**Presenters:**

**Tom Bechert, Director, Huron Consulting Group**

Tom has 11 years of experience working with research institutions to enhance compliance, maximize the efficiency of research operations, and improve the overall effectiveness of research operations within universities, academic medical centers, cancer centers, and community hospitals.

**Madeleine Williams, Senior Director, Huron Consulting Group**

Maddie has over 15 years of research experience and assists clients with and human research protection program evaluation and accreditation, institutional review board operational support, research biorepository design and development, and regulatory compliance evaluations.

1. Manuscript Reviews Recinda Sherman
   1. 13-05 Insurance status and cancer stage at diagnosis: recalibration of the association for the Affordable Care Act using national cancer registry data (Xuesong Han, NCI)

*Approved Oct 2015*

* 1. 12-04 Adaptive Robust Estimators to Handle Missing Values in Estimating Tumor Stage Distributions in Population-Based Cancer Registration (Qingzhao Yu, LA)

*Published Aug 5, 2015—did not go through scientific or IRB review*

* 1. 14-05 The epidemiology of pediatric brain cancers in Appalachia (Bin Huang, KY)

*Approved Aug 2015*

* 1. 12-01 Geographic Variation of Intrahepatic Cholangiocarcinoma, Extrahepatic Cholangiocarcinoma, and Hepatocellular Carcinoma in the United States (Sean Altekruse, NCI)

*Published April, 2015—did not go through scientific or IRB review*

* 1. 14-08 Demographic and regional/state variation in DCIS and early stage breast cancer incidence treatment (Elizabeth Ward, AC)

*Approved June 2015*

* 1. 14-04 Recent trends in incidence of testicular germ cell tumors in the US: rising rates among Hispanic men (Arman Ghazarian, NCI)

*Approved May 2015*

* 1. 13-09 2011 US burden of cancer by race and ethnicity (Joanie Tieulent, ACS)

*Approved April 2015*

* 1. 14-06 Variations in receipt of curative-intent surgery for early-stage non-small cell lung cancer (NSCLC) by state (Helmneh Sineshaw, ACS)

*Review pending*

* 1. Note: 3 additional manuscripts underwent scientific review since the last IRB meeting—however, they did not require IRB review

1. Projects requesting additional years of data Recinda Sherman

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| **IRB Application No.** | **Project Title (PI)** | **Notes** |
| 14-03 | Geographic clustering of invasive melanomas in the US (Gimotty, UPenn) | Additional year approved July 6, 2015 |
| 14-07 | Lymphoid malignancy statistics in the US (Jemal & Teras) | Additional year approved June 6, 2015 |
| 14-08 | Demographic and regional-state variations in DCIS & early stage breast cancer and treatment (Ward & Lin) | Additional year approved June 6, 2015 |

1. Expedited IRB Reviews since April 17, 2015

**Note: Applications 15-08 and 15-09 were not approved by the Research Application Review Committee and therefore never reviewed by IRB. Application 15-04 was withdrawn by PI and therefore also never reviewed by IRB**

15-04 was withdrawn because PI was on extremely tight timeline and decided to not do project.

15-08 & 15-09 were not approved because 1 had study validity issues and 1 because it requested only 1 registry’s data. Researchers must go to individual states/registries for their data alone. CINA is for national, US & Canada, or regional research.

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| **IRB Application No.** | **Project Title (PI)** | **Approval Date** |
| 15-01 | Recent trends in incidence of testicular germ cell tumors in the US | 5/4/15 |
| 15-03 | US CONCORD-2 Study: Incidence 1195-2009 | 6/11/15 |
| 15-05 | Testicular cancer incidence in men age 50 years and older | 6/22/15 |
| 15-06 | Assessing the relationship between rural-urban residence and cancer suing the NAACCR urban-rural indicator codes | 7/14/15 |

1. Review pending Expedited IRB Reviews:

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| **IRB Application No.** | **Project Title (PI)** | **Notes** | **Submission Date** |
| 15-02 | Maine Cancer Registry Annual Report and Routine Monitoring |  | Waiting for IRB forms from PI since 5/5/15 |
| 15-07 | Forecasting trends in testicular germ cell tumors in the US |  | 8/7/15-resend |
| 15-10 | Rates of childhood cancer in the US |  | 10/21/15 |
| 15-11 | The association between the incidence of Chronic Lymphocytic Leukemia among adults in the US and rural-urban residence |  | 10/20/15 |

1. Annual monitoring compliance since April 17, 2015

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| **IRB Application No.** | **Project Title (PI)** | **Original Review Date** | **Renewal Date** |
| 07-05 | Projecting estimates of cancer incidence for every US state both spatially and temporally | 6/3/03 | 10/22/15 |
| 08-05 | Hematopoietic cancers in the Hispanic population in the United States | 8/15/08 | Pending PI |
| 11-02 | Comparison of cancer incidence and mortality for rural vs urban counties in Pennsylvania and rural US | 4/1/11 | Study complete-- 6/15 |
| 12-02 | Assessing the relationship between poverty and cancer using the census tract poverty indicator | 8/12/12 | Pending PI |
| 12-03 | Analysis of ethnic disparities in colon cancer suggests a potential need for early colon screening in Asians living in USA | 8/21/12 | Pending PI--completed |
| 12-05 | Priorities for cervical cancer control based on disparities in race, social position, screening, vaccination, incidence, and mortality, 1995-2009 | 11/29/12 | 6/9/15 |
| 13-01 | Ovarian cancer mortality and survival trends in relation to changing patterns of menopause | 3/25/13 | 4/23/15 |
| 13-02 | Trends of hormone related-female cancer incidence in relation to changing patterns of menopausal hormone therapy in the US | 3/25/13 | 4/23/15 |
| 13-04 | Insurance coverage expansion and disparities in cervical, prostate, and lung cancer | 2/24/13 | 4/17/15 |
| 13-05 | Health insurance and cancer stage at diagnosis | 4/30/14 | 4/15/15 |
| 13-09 | The burden of cancer in the USA in 2012 by race/ethnicity | 1/10/14 | 4/29/15 |
| 14-02 | Comparison of latitude gradients for testicular cancer and remaining cancers in Australia and the US | 4/30/14 | 4/16/15 |
| 14-03 | Geographic clustering of invasive melanomas in the US | 6/26/14 | 6/18/15 |
| 14-04 | Recent trends in incidence of testicular germ cell tumors in the US | 8/7/14 | Study complete/10/15 |

1. Complete list of (active and terminated) CINA Projects (attached)

**Date truncated on the list. Recinda will send out again.**

1. Next call – tentative 2nd Friday in October 14th, 2016; 8:30 am PST,9:30 MST,10:30 CST; 11:30 EST

Ron moved to adjourn, Ann Marie—seconded. Meeting adjourned.