Tribal Review Boards

August 16, 2013

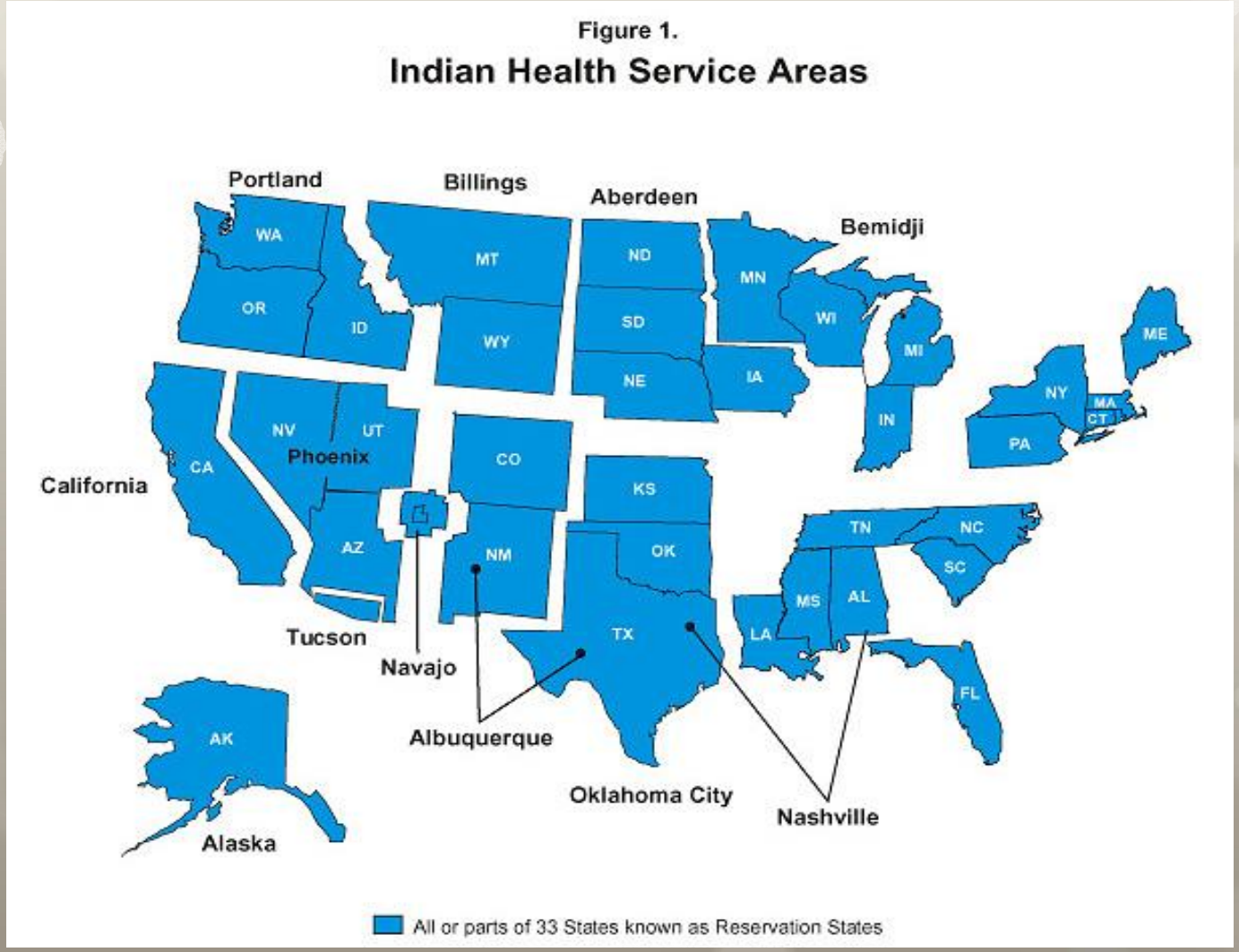
Presentation Outline

OHRP
- Understanding the partners
- Assessing the recipe

&
- Standard Operating Procedures (SOPs)
- Protocol Review

IRB
- Training, continuing education
- Registration, Federal Wide Assurance

566 Federally Recognized Tribes



11 IHS/Tribal IRBs; 10 Independent Tribal IRBs

Indian Health Service Institutional Review Boards (IRB)

National IRB (NIRB) at IHS Headquarters, Rockville, Maryland: IRB00000646

Alan Trachtenberg, MD, MPH, Chair, IHS National IRB (NIRB) IHS Human Research Protections Administrator Ms. Mary Eve Mahsetky	801 Thompson Ave. TMP Suite 450 Rockville, MD 20852	301-443-4700 301-443-0114 (fax) 888-228-6155 (toll free) Submit projects electronically to irb@ihs.gov with *complete* hard copy c/o Ms. Mary Eve Mahsetky

Aberdeen Area: IRB00000635

Dewey Ertz, PhD Chair, Aberdeen Area IRB Marsha Rernleitner AAIRB Coordinator	115 4th Avenue, S.E. Room 215 Aberdeen, SD 57401	605-226-7493 605-226-7595 (fax) 866-331-5794 (Toll Free) marsha.rernleitner@ihs.gov

Alaska Area: IRB00000636

Drs. Shanda Lohse and Michael Engel Co-Chairs, Alaska Area IRB Terry Powell Administrator, Alaska Area IRB	4315 Diplomacy Drive - RMCC Anchorage, AK 99508 ATTN: Terry J. Powell	shandalohse@southcentralfoundation.com 907-729-3924 907-729-2082 (fax) tjpowell@anmc.org

Bemidji Area**

Dawn Wyllie, MD, MPH Chair, Bemidji Area Publication Review Committee Human participants research clearance is referred to the NIRB	522 Minnesota Avenue, NW Bemidji, MN 56601	218-444-0491 218-444-0498 (fax) dawn.wyllie@ihs.gov

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Indian Health Service Institutional Review Boards (IRB)

Billings Area IHS/Rocky Mountain Tribal: IRB00000638

L.Jace Killsback Co-Chair Cheryl Belcourt, Coordinator	Rocky Mountain IRB 175 North 27th St. Suite 1003 Billings, MT 59101	406-252-2550 406-254-6355 (fax) http://www.mtwytlc.org/irb/rmtirb-home.html

Nashville Area: IRB00000640

Palmeda Taylor, PhD Co-Chair, Nashville Area IHS IRB	711 Stewarts Ferry Pike Nashville, TN 37214	615-467-1534 615-467-1585 (fax) palmeda.taylor@ihs.gov

Navajo Area: IRB00000641

Beverly Becenti-Pigman Chair, Navajo Nation Human Research Review Board (and Navajo Area IHS IRB) Louise Joe Administrative Assistant	P.O. Box 1390 Administration Building Window Rock, AZ 86515	928-697-2525 928-871-6263 (fax) bbp_pqh@yahoo.com 928-871-6350 928-871-6255 (fax) Louise.Joe@nndoh.org

Oklahoma City Area: IRB00000642

Julie A. Erb-Alvarez, MPH Co-Chair John Farris, MD Co-Chair	701 Market Drive Oklahoma City, OK 73114	405-951-3946 405-951-3904 (fax) julie.erb-alvarez@ihs.gov 405-951-3776 John.farris@ihs.gov

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Indian Health Service Institutional Review Boards (IRB)

Phoenix Area: IRB00000643

Cynthia Claus, PhD, MPH Chair, Phoenix Area IHS IRB	Two Renaissance Square 40 North Central Avenue Suite 600 Phoenix, AZ 85004	602-364-5169 cynthia.claus@ihs.gov

Portland Area: IRB00000645

Rena Macy Chair, Portland Area IHS IRB	Portland Area IHS 1414 NW Northrup St Suite 800 Portland, OR 97209	503-414-7778 503-414-7776 (fax) pairb@ihs.gov

Tucson Area**

Karen Higgins, PhD Chair, Tucson Area Publication Review Committee (Human participants research clearance is referred to the NIRB)	7900 South J. Stock Road Tucson, Arizona 85746	520-295-2532 520-295-2569 (fax) Karen.Higgins@ihs.gov

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Independent Tribal IRBs

American Indian Healing Center, Inc.: IRB00008253 IORG0006887

John Andrews, MPH Executive Director	12456 E. Washington Blvd. Whittier, CA 90602	562-693-4325 562-693-1115 (fax) J.Andrews@AIHCHealer.com

Assoc American Indian Physicians: IRB00002261 IORG0001788

Margaret Knight Executive Director	1225 Sovereign Row, Suite 103 Oklahoma City, OK 73108	405-946-7072 405-946-7651 (fax) mknight@aaip.com

Blackfeet Nation: IRB00005802 IORG0004865

Francis Onstad Executive Director	P.O. Box 850 850 Agency Square Browning, MT 59417	406-338-5180 406-338-5660 (Fax) francis_onstad@yahoo.com

California Rural Indian Health Board (CRIHB): IRB00004400 IORG0003711

Susan Dahl, MHA, RHIA, CHC, CHP Chair, CRIHB IRB	4400 Auburn Blvd., 2nd floor Sacramento, CA 95841	916-929-9761 Ext 1010 916-929-7246 (fax) susan.dahl@crihb.net
Carol Korenbrot, PhD Co-Chair, CRIHB IRB	4400 Auburn Boulevard, 2nd Floor Sacramento, CA 95841	919-929-9761 , Ext. 1040 916-929-7246 (fax) carol.korenbrot@crihb.net
Virginia Myers Outreach Coordinator		916-929-9761 916-929-7246 (fax) virginia.myers@crihb.net

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Independent Tribal IRBs

Cherokee Nation: IRB00001237 IORG0000872

Sohail Kahn, MBBS, MPH, CIP Co-Chair, Cherokee Nation IRB Gloria Grim, MD Co-Chair, Cherokee Nation IRB	P.O. Box 948 Highway 62 Tahlequah, OK 74465	918-453-5602 918-431-4148 (fax) Sohail-Khan@cherokee.org

Chickasaw Nation: IRB00004394 IORG0003705

Sheryl Goodson, Chair Chickasaw Nation Research Review Committee (RRC) Bobby Saunkeah, RN, BSN, CDE RRC Secretary	Carl Albert Indian Health Facility 1001 N. Country Club Road Ada, OK 74820	580-421-4548 580-421-6208 (fax) Sheryl.Goodson@chickasaw.net 580-421-4532, Ext. 800 580-521-4572 (fax) bobby.saunkeah@chickasaw.net

Choctaw Nation: IRB00004293 IORG0003613

David F. Wharton, MPH, RN Facilitator, Choctaw Nation IRB	Choctaw Nation Health Services Choctaw Nation Health Clinic - Idabel 902 E Lincoln Road Idabel, OK 74745	580-286-4724 580-286-4718 (fax) dfwharton@cnhsa.com

College of Menominee Nation: IRB00007956 IORG0006633

Donna Powless, PhD Vice-President of Academic Affairs	P.O. Box 1179 N172 State Hwy 47/55 Keshena, WI 54135	715-799-5600, Ext. 306 715-799-5951 (fax) dpowless@menominee.edu

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Independent Tribal IRBs

Haskell Indian Nations University: IRB00003557 IORG0002948

Freda Gipp Administrative Assistant	155 Indian Avenue Lawrence, KS 66046	785-749-8407 785-749-8411 (fax) fgipp@haskell.edu

Muscogee (Creek) Nation: IRB00007518 IORG0006250

Bert Thomas, PhD Consultant	Box 1883 ATTN: Director of Health 1801 East 4th Street McAlester, OK 74502	918-423-0592 918-423-0592 drbcthomas@allegiance.tv

If your Tribal IRB is not listed, please email the information about it to irb@ihs.gov or call Dr. Alan Trachtenberg at 301-443-0578.

http://www.ihs.gov/research/index.cfm?module=hrpp_irb

Understanding the partners

Feds

- **SACHRP** - http://www.hhs.gov/ohrp/sachrp/
- Secretary's Advisory Committee on Human Research Protections

- **OHRP** - http://www.hhs.gov/ohrp/
- Office for Human Research Protections

- **AAHRPP** - http://www.aahrpp.org/
- Association for the Accreditation of Human Research Protection Programs

OHRP
OFFICE FOR HUMAN RESEARCH PROTECTIONS

Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation

July 10-11, 2013

Understanding the partners

AZ

- **Arizona Department of Health Services**
- http://www.azdhs.gov/ops/oacr/privacy/humansubjects.htm

- (602)542-1020
- Biomedical and behavioral research sponsored by ADHS

- Requests for the use or access to copies of vital records or other personally-identifiable records collected and maintained by ADHS

Human Subjects Review Board
Arizona Department of Health Services
1740 West Adams, Room 203
Phoenix, AZ 85007

Arizona Department of Health Services

AZ.GOV

Understanding the partners

- **University of Arizona**
- http://orcr.arizona.edu/hspp
- Mariette Marsh, Assistant Director, (520) 626-7575
- marshm@email.arizona.edu

- **Arizona State University**
- http://researchintegrity.asu.edu/humans
- Tiffany Dunning, Sr Coordinator, (480) 639-7396
- Tiffany.Dunning@asu.edu

- **Northern Arizona University**
- http://nau.edu/Research/Compliance/Human-Subjects/
- Paula Garcia McAllister, IRB Director, (928) 523-4236
- IRB@nau.edu

Understanding the partners

Other

- **John's Hopkins University**
  http://www.hopkinsmedicine.org/institutional_review_board/
- **University of New Mexico**
- http://hsc.unm.edu/som/research/hrrc/

- **New Mexico State University**
- http://research.nmsu.edu/compliance/IRB/IRB.html
- **University of Utah**
- http://irb.utah.edu/

- **University of Colorado**
- http://www.colorado.edu/vcr/irb
- **University of Nevada**
- http://www.unr.edu/research-integrity


Assessing the recipe

1 cup
- Determine the need
- Determine the support

1 cup
- Establish standard operating procedures
- Review **protocols**

1 cup
- Identify the key individuals
- Educate members on federal regulations

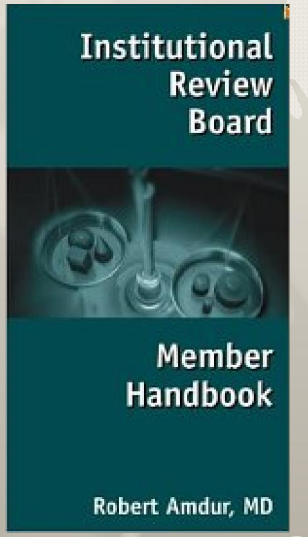
Standard Operating Procedures – Who, What, Where, When, How, Why

- Do not recreate the wheel
- Must meet ***all*** federal requirements

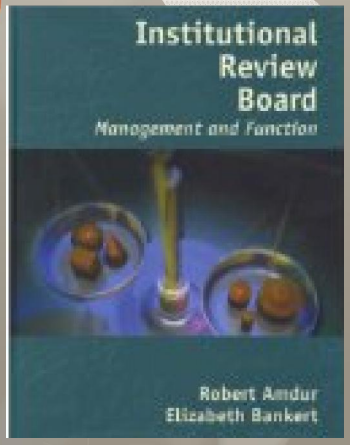
- Existing IHS or Tribal IRBs
- Huron Click Commerce, Jeffrey Cooper

- Robert J. Amdur. Institutional Review Board Member Handbook.

- Robert J. Amdur, Elizabeth A. Bankert. Institutional Review Board: Management and Function. ISBN 0763716863.



$0.01 - $40.00



$60.00 - $205.00

Checklists

- http://www.hhs.gov/ohrp/policy/consentckls.html
- http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

§46.116 - Informed Consent Checklist - Basic and Additional Elements

A statement that the study involves research
An explanation of the purposes of the research
The expected duration of the subject's participation
A description of the procedures to be followed
Identification of any procedures which are experimental
A description of any reasonably foreseeable risks or discomforts to the subject

A description of any benefits to the subject or to others which may reasonably be expected from the research

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

( ) Research Qs
( ) Rights Qs
( ) Injury Qs

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional elements, as appropriate

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

Any additional costs to the subject that may result from participation in the research

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject

The approximate number of subjects involved in the study

Federal Regulations

- Is this **research**? 45 CFR 46.102(d)
  - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- Is this **human subjects** research? 45 CFR 46.102(f)
  - A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- Required constitution of the IRB, for example, minimum of 5 members, both men and women, medical doctor/scientist, unaffiliated member (may have alternate members)

Federal Regulations

- Members must submit a resume, commit to serve, attend meetings, sign confidentiality statements
- Given elements of the meeting, for example, quorum established and maintained throughout the meeting, conflicts of interest, vote, determination, risk level, timeframe to return for follow-up review
- Required elements of the informed consent form
- Representative for vulnerable populations, category
- Thorough and complete documentation, records keeping
- Once approved, any changes to the protocol *must* be reviewed and approved by the IRB

Federal Regulations

- Determination of risk level –
  - **Exempt** – below minimal risk (category specification), 1-2 IRB member review
  - **Expedited** – at or slightly above minimal risk (category specification), 1-2 IRB member review
  - **Full** – more than minimal risk, full committee review
- **Risk**: Minimal Risk generally means that the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in routine medical, dental, or psychological examinations.
- IRB Decision –
  - Approve as is
  - Approve with contingencies
  - Disapprove
  - Defer

Protocol Review

- Reviewers cannot make any assumptions
- It should be clear how the project will go from A to B, B to C,…
- Clear justification for the need to do the project
- Complete packet:
  - Application, protocol, consent forms, assent forms, questionnaires, scripts, letters of support, letters of approval, tribal resolutions, other IRB approvals, budget, timeline, NIH grant application, resumes, brochures, fliers

Protocol Review

- **Methods** – survey, focus group, interviews, medical chart reviews, secondary data analyses, clinical trial
- **Recruitment** – number, sex, age, means, inclusion/exclusion criteria

- **Privacy and confidentiality** – protected health information, security, access
- **Risk and benefits** – individual, family and community levels

- **Analyses** – types of tests, interpretation of the findings, ability to assess what is proposed
- **Reporting, dissemination plan** – ongoing regular updates, participant reports, tribal review prior to release or publication

Training, continuing education

- **OHRP** - **http://www.hhs.gov/ohrp/**
- 1101 Wootton Parkway, Suite 200, Rockville, MD 20852
- Toll free within USA 866-447-4777

- **PRIM&R** - Public Responsibility in Medicine and Research
- **ARENA** - Applied Research Ethics National Association
- **http://www.primr.org**

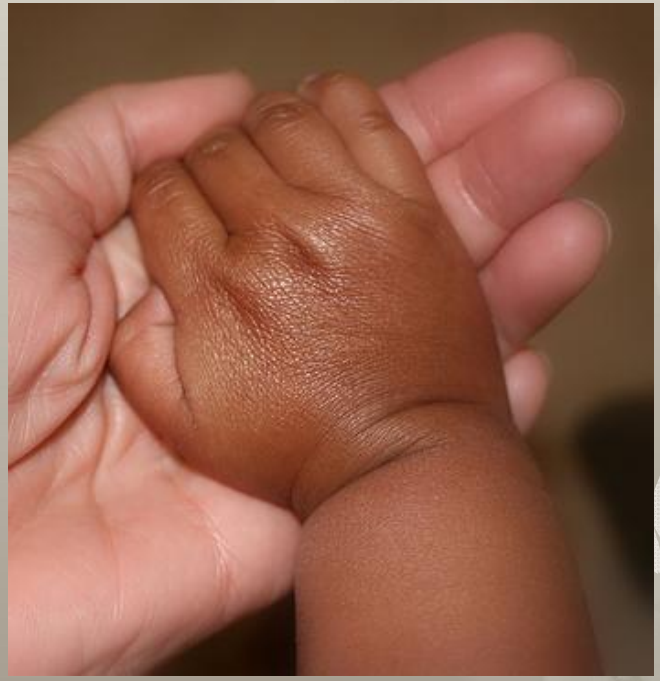
- The **Belmont Report,** the basic ethical basis for human research protection
  - **http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm**
- **45 CFR 46, the basic regulations**
  - **http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm**

Tribal Review Boards

- Review boards protect human participants in research from possible harms.
- Although the federal regulations do not require it, tribal reviews can also consider possible harms to families and tribal communities in research.
- Non-tribal universities and institutions are less likely to consider and know what potential research harms are in the local tribal situation and how to minimize them.
- Non-tribal universities and institutions are less likely to consider and know what potential benefits are and how to maximize them.

An opportunity to shape….

- Understanding and good communication, transparency
- Concerns and opinions of families and community
- Due respect, rights and dignity
- The demystification of research
- Accessibility of information
- Feed-back and findings, in a timely manner
- Due respect for the autonomy and decisions of involved parties
- Sharing of results of the research with patients, subjects, communities
- The building of community capacity



IRB Registration

IRB

- OHRP website
- http://www.hhs.gov/ohrp/assurances/index.html#registernew
- Request a service number, username and password

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- Designation as Tribal government
- Chair/President/Governor, contact info
- Administrator, Coordinator, contact info

FWA

- Specify there is one IRB
- Active protocols reviewed annually (new and continuing)
- Number of full-time and half-time IRB FTEs
- Roster – name, credentials, specialty area, affiliated, alternate

Federal Wide Assurance

IRB

- OHRP website
- **http://www.hhs.gov/ohrp/assurances/assurances_index.html#domestic**
- Request a service number, username and password

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- Signatory Official (individual responsible for the IRB)
- The Belmont Report – and additional tribal documentation
- The Common Rule and subparts B, C, and D of the HHS Regulations at 45 CFR 46

FWA

- IRB's Registration Number
- Administrator
- Automated receipt confirmation
- Final documentation with approval dates and specifications

Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Transportation, VA, EPA, National Science Foundation, Consumer Product Safety Commission, National Aeronautics and Space Administration

Thank you!

Francine C. Gachupin, PhD, MPH, CIP

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Assistant Director, Cancer Disparities Institute, Arizona Cancer Center
Assistant Director, Native American Research and Training Center

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