

# Objectives:



6. Discuss the IRB new study application process

7. Identify available resources

IRB = Institutional Review Board

Objective 6:

Discuss the IRB new study  
application process

# 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


# What is a Protocol?

- The plan or blueprint for your research study
- Should include:
  - Purpose, rationale, and significance of the research
  - Methods and procedures
  - Recruitment and informed consent process
  - Risks and benefits
  - Costs and compensation
  - Privacy and confidentiality
- The protocol may be modified over time, where as the application is specific to the initial review, an amendment, a continuing review, etc.

# Protocol Review

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

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

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- **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

## Particular attention to studies involving:

- \* Minors
- \* Prisoners
- \* Pregnant women and fetuses
- \* Students
- \* Cognitively Impaired

### Research Involving Children Attachment 2

1. Provide the age range of the children to be enrolled in the research:

2. Where will the children participate?

a. Check all that apply:

- ☐ Home
- ☐ School [Documentation of permission or letter(s) of support are required]
- ☐ University lab/office
- ☐ Hospital
- ☐ Other – Specify:

b. Describe the details of the setting for this research:

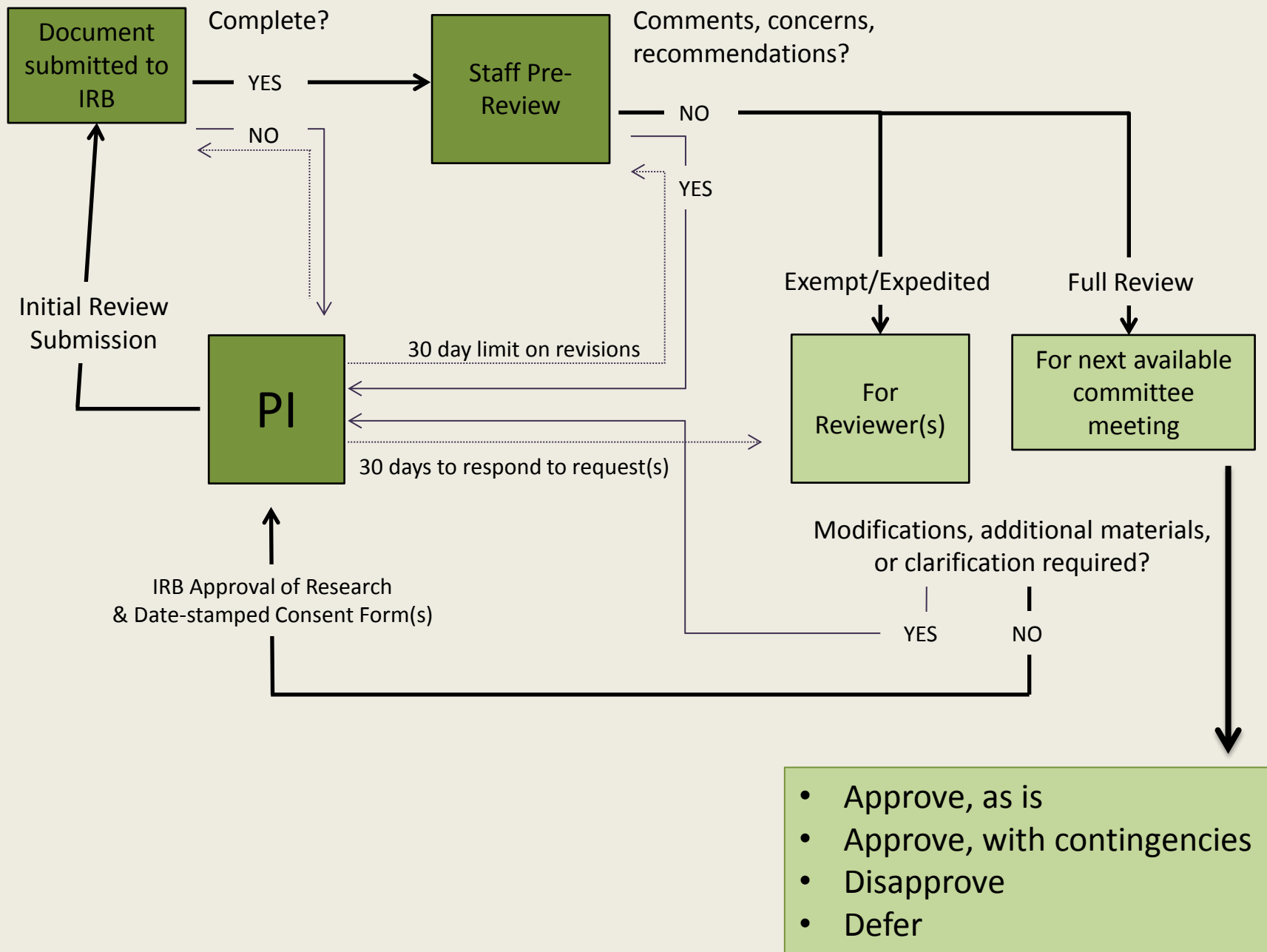
# Required Elements of Consent

1. Purpose, Duration of Participation, and Procedures (inclusion criteria, audio/video recording, etc.)
2. Risks (side effects, discomforts, etc.)
3. Benefits (to the participant, to society, etc.)
4. Alternatives to Participation
5. Confidentiality
6. Emergency Treatment & Compensation for Injury (if more than minimal risk)
7. Questions
8. Withdrawal



# Additional Elements of Consent

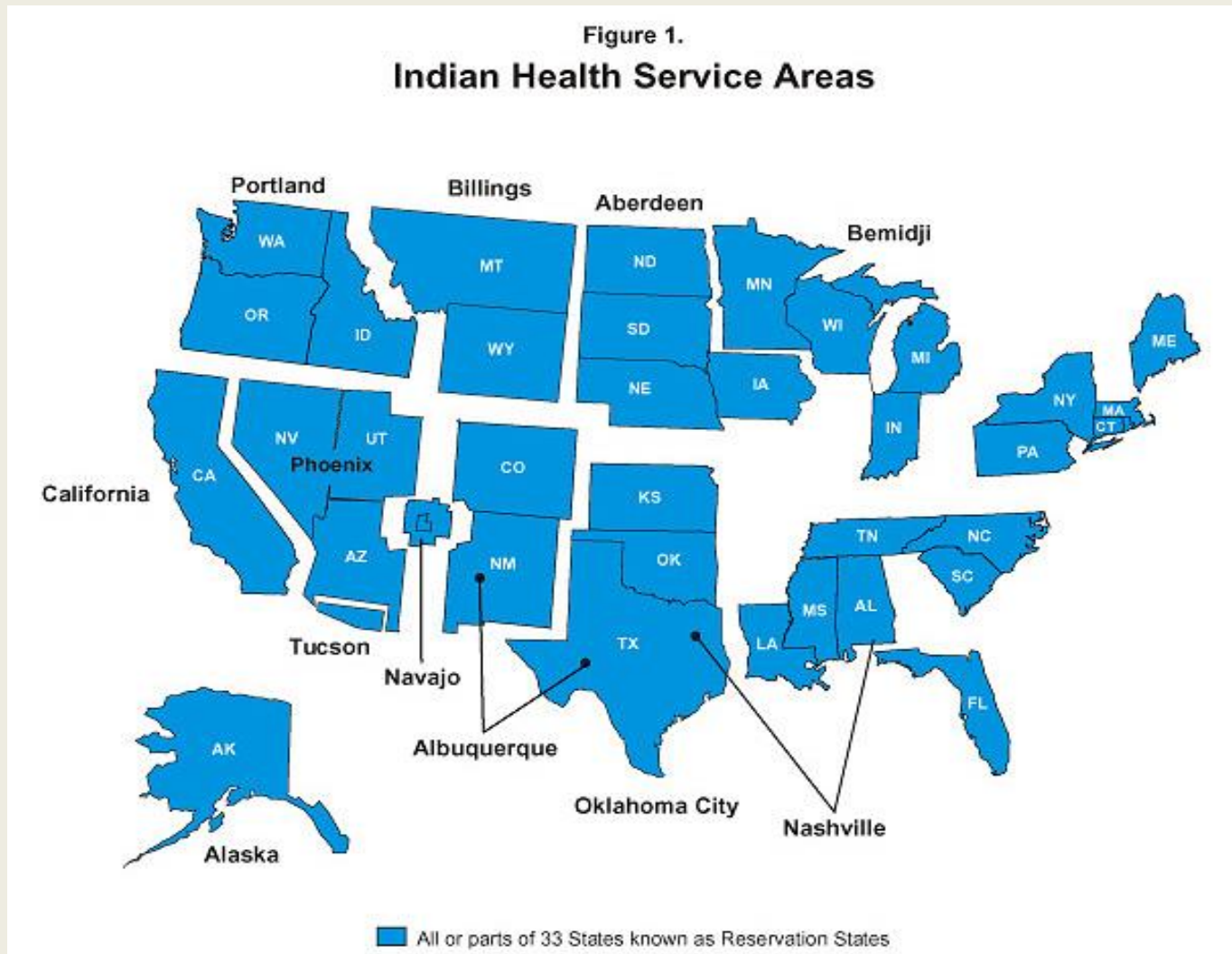
1. **Pregnancy** (risk to subject, embryo, or fetus is subject may become pregnant)
2. Termination by Investigator
3. Additional Cost to Subject
4. Consequences of Withdrawal
5. New Findings
6. Number of Subjects Involved



Objective 7:

Identify available resources  
(Need Help?!!)

# 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	801 Thompson Ave. TMP Suite	301-443-4700
National IRB (NIRB) IHS Human Research	450	301-443-0114 (fax)
Protections Administrator	Rockville, MD 20852	888-228-6155 (toll free)
Ms. Mary Eve Mahsetky		Submit projects electronically to <a href="mailto:irb@ihs.gov">irb@ihs.gov</a> with <i>complete</i> hard copy c/o Ms. Mary Eve Mahsetky

## Aberdeen Area: IRB00000635

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

## Alaska Area: IRB00000636

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

## Bemidji Area\*\*

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

# 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](mailto: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](mailto:bbp_pqh@yahoo.com)  
928-871-6350  
928-871-6255 (fax)  
[Louise.Joe@nndoh.org](mailto: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](mailto:julie.erb-alvarez@ihs.gov)  
405-951-3776  
[John.farris@ihs.gov](mailto:John.farris@ihs.gov)

# 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](mailto: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](mailto: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](mailto:Karen.Higgins@ihs.gov)

# 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@AIHChaler.com](mailto:J.Andrews@AIHChaler.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](mailto: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](mailto:francis_onstad@yahoo.com)

## **California Rural Indian Health Board (CRIHB): IRB00004400 IORG0003711**

Susan Dahl, MHA, RHIA, CHC, CHP Chair,      4400 Auburn Blvd., 2nd floor  
CRIHB IRB      Sacramento, CA 95841  
Carol Korenbrot, PhD Co-Chair, CRIHB IRB      4400 Auburn Boulevard, 2nd Floor  
Virginia Myers Outreach Coordinator      Sacramento, CA 95841

916-929-9761 Ext 1010  
916-929-7246 (fax)  
[susan.dahl@crihb.net](mailto:susan.dahl@crihb.net)  
919-929-9761 , Ext. 1040  
916-929-7246 (fax)  
[carol.korenbrot@crihb.net](mailto:carol.korenbrot@crihb.net)  
916-929-9761  
916-929-7246 (fax)  
[virginia.myers@crihb.net](mailto:virginia.myers@crihb.net)

# 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](mailto: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](mailto:Sheryl.Goodson@chickasaw.net)  
580-421-4532, Ext. 800  
580-521-4572 (fax)  
[bobby.saunkeah@chickasaw.net](mailto: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](mailto: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](mailto:dpowless@menominee.edu)

# 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](mailto: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](mailto:drbcthomas@allegiance.tv)

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

[http://www.ihs.gov/research/index.cfm?module=hrpp\\_irb](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



July 10-11, 2013

# Understanding the partners



- **Montana State University**
- <http://www2.montana.edu/irb/>
- Administrator, Cheryl Johnson 994-4706
- [cherylj@montana.edu](mailto:cherylj@montana.edu)



- **University of Montana**
- <http://www.umd.edu/research/compliance/IRB/default.php>
- Chair, Paula Baker, (406) 243-6672
- [IRB@umontana.edu](mailto:IRB@umontana.edu)



- **Wyoming Department of Health**
- <http://www.health.wyo.gov/main/irb/index.html>
- Co-Chair, Karl Musgrave, (307) 777-5825
- [karl.musgrave@wyo.gov](mailto:karl.musgrave@wyo.gov)

# Understanding the partners



- **University of Wyoming**
- <http://www.uwyo.edu/research/compliance/human-subjects/>
- Director, Colette Kuhfuss, (307) 766-5322
- [IRB@uwyo.edu](mailto:IRB@uwyo.edu)

- **City College, Gallatin College, Great Falls College, Montana Tech, Missoula College, Helena College, Highlands College, Bitterroot College, Dawson Community College, Flathead Valley Community College, Miles Community College**

- **Casper College, Central Wyoming College, Eastern Wyoming College, Laramie County Community College, Northwest College, Sheridan College, Western Wyoming Community College, Wyoming Catholic College, University of Phoenix, Wyoming Technical Institute**

# Understanding the partners

## **Blackfeet Community College**

P. O. Box 819  
Browning, MT 59417  
406-338-7755  
fax: 406-338-3272  
[www.bfcc.org](http://www.bfcc.org)



## **Fort Peck Community College**

P. O. Box 398  
Poplar, MT 59255  
406-768-6300  
fax: 406-768-5552  
[www.fpcc.edu](http://www.fpcc.edu)

## **Chief Dull Knife College**

P. O. Box 98  
Lame Deer, MT 59043  
406-477-6215  
fax: 406-477-6219  
[www.cdkc.edu/](http://www.cdkc.edu/)

## **Stone Child College**

RR1, Box 1082  
Box Elder, MT 59521  
406-395-4875  
fax: 406-395-4836  
<http://www.stonechild.edu>

## **Little Big Horn College**

P. O. Box 370  
Crow Agency, MT 59022  
406-638-3100 (main number)  
fax: 406-638-3169  
[www.lbhc.edu](http://www.lbhc.edu)

## **Fort Belknap College**

P. O. Box 159  
Harlem, MT 59526  
406-353-2607  
fax: 406-353-2898  
[www.fbcc.edu/](http://www.fbcc.edu/)


## **Wind River Tribal College**


P.O. Box 8300  
Ethete, WY 82520  
307.335.8243  
fax: 307.335.8148  
[www.wrtribalcollege.com](http://www.wrtribalcollege.com)


## **Salish Kootenai College**


P. O. Box 117  
Pablo, MT 59855  
406-275-4800  
fax: 406-275-4801  
[www.skcc.edu](http://www.skcc.edu)

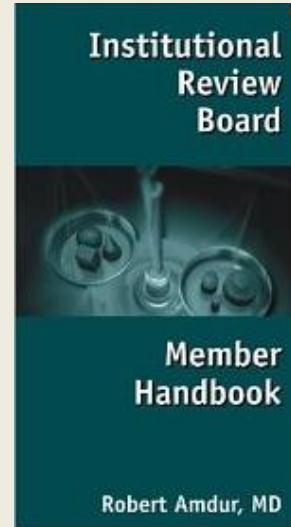
# Standard Operating Procedures – Who, What, Where, When, How, Why

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

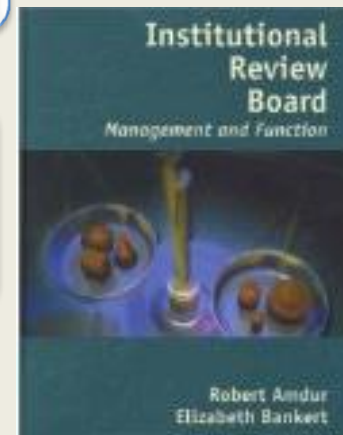
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- Existing IHS or Tribal IRBs
  - Huron Click Commerce, Jeffrey Cooper

- 
- 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

- 45 CFR 46 Subpart A, Office for Human Research Protections:  
<http://www.hhs.gov/ohrp/>
- Health Insurance Portability and Accountability Act of 1996 Privacy and Security Rules: <http://www.hhs.gov/ocr/privacy/>
- 21 CFR Part 50, Federal Drug Administration:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?cfrpart=50>
- HITECH Act Enforcement Interim Final Rule:  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/enforcementrule/hitechenforcementifr.html>

## Additional Resources

- NCI Best Practices for Biospecimen Resources:  
<http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>
- National Conference of State Legislatures, Genetic Privacy Laws:  
<http://www.ncsl.org/issues-research/health/genetic-privacy-laws.aspx>
- Presidential Commission for the Study of Bioethical Issues,  
<http://bioethics.gov/cms/about>

## Additional Resources

# Questions?

