



**COMMUNITY INSTITUTIONAL REVIEW BOARD  
POLICIES & PROCEDURES**

**Association of Asian Pacific Community Health Organizations**

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## **SECTION 1: IRB GOVERNANCE AND REGULATION**

### **1.1 AAPCHO IRB MISSION**

The AAPCHO IRB will:

1. Oversee and review all activities related to human subjects research involving AAPCHO and AAPCHO member organizations according to the ethical principles and guidelines of the Office of Human Research Protection of the Department of Health and Human Services
2. Ensure the dignity, rights, privacy, safety, and welfare of all actual and potential research participants are protected through review of research protocols
3. Provide a strong foundation of knowledge to facilitate the conduct of health services research at AAPCHO and AAPCHO member organizations

### **1.2 INTRODUCTION**

The Association of Asian Pacific Community Health Organizations Policies & Procedures details the protection of human subjects in research conducted by investigators affiliated with AAPCHO member organizations. These procedures ensure that the Institutional Review Board (IRB) of the Association of Asian Pacific Community Health Organizations (AAPCHO) operates in accordance with applicable regulations and guidance issued by the federal government, and, in particular, the Office for Human Research Protections (OHRP).

AAPCHO is a national non-profit membership organization advocating for the health needs of medically underserved Asian Americans, Native Hawaiians, and Pacific Islanders. Our member health centers are at the forefront in providing community responsive, financially affordable, culturally proficient, and linguistically appropriate primary health care services that improve the health status and access for these populations. The AAPCHO Institutional Review Board (IRB) would be a beneficial tool to increase health center capacity for ethical and quality culturally and linguistically appropriate research.

An Institutional Review Board is a federally-mandated entity that reviews proposed and continuing research in order to ensure the interests of human subjects are protected, including that participants are fully informed about the research, have consented freely to participation, and are protected from undue risks. An IRB is also charged with weighing the relative risks and benefits of the research.

Any AAPCHO member researcher who is beginning a study involving human subjects may submit an application to the IRB for review and approval before the study starts. The application provides information about the research objectives, the methods to be used, the selection of human subjects, risks and benefits of the research, the process for informing potential subjects about the research and what their participation would entail, and provisions for maintaining confidentiality. Each IRB approved study must undergo continuation review at least once yearly, and any modifications to the study must be reviewed and approved before they are implemented.

### 1.3 FEDERAL REGULATIONS

The following is a list of the principal regulations, policies, and guidelines pertaining to the protection of rights and welfare of human subjects involved in AAPCHO research activities.

#### A. Federal Guidance

1. Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46) Department of Health & Human Services (DHHS) Regulations (<http://www.hhs.gov/ohrp/humansubjects/guidance/>)
2. [The Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>)
3. [OHRP \[OPRR\] Institutional Review Board Guide Book](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm) ([http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm))

#### B. IRB Federal-Wide Assurance

The AAPCHO IRB is registered and maintains a Federal-Wide Assurance with the OHRP, DHHS. In the Assurance, AAPCHO assures the DHHS that all research activities conducted by or under the auspices of AAPCHO will be performed in accordance with DHHS policies and all other applicable federal, state, and local laws and regulations that protect the rights and welfare of human research subjects. Organizations interested in listing AAPCHO as their preferred IRB on their FWA application must complete the Institutional Review Board (IRB) Authorization Agreement Form A.

### 1.4 MEMBERSHIP AND APPOINTMENTS

The IRB shall also meet the following requirements:

- The IRB will consist of at least five members.
- At least one member shall have expertise in the primary areas of research reviewed by the AAPCHO IRB, including but not limited to a health services researcher or a member with expertise in the field of public health.
- At least one member shall be a non-scientist, whose primary concern is based in nonscientific areas. He/She shall be representative of the community and knowledgeable with respect to its psychological, sociological and ethical attitudes. These members may be community health center staff and community members.
- At least one member shall be appointed who is not otherwise affiliated with AAPCHO.
- Every effort will be made to have at least one member who is trained in one or more of the behavioral sciences (e.g., psychology, sociology and/or anthropology).
- Every effort will be made to ensure that the members reflect diverse ethnic, racial, and cultural backgrounds and both genders.
- Term limits for Chairs and Vice-Chair will be a minimum of two years.
- Absence of any board member from four consecutive regular meetings of the board, unless on account of sickness or authorized by resolution of the board, shall be

sufficient cause for the remaining members of the board to declare by resolution that such board member position is vacated.

#### IRB Composition:

- Full: IRB membership status designating full participation in IRB activities as outlined in the roles and responsibilities
- Ad-hoc: An individual appointed to the IRB to serve in the same capacity as a full member, but will only be called upon for applications that require their specific knowledge or expertise. Ad-hoc members do not vote.
- Alternate: An individual appointed to the IRB to serve in the same capacity as a full member, but will only be called upon when a full member in their line of expertise is unable to participate

## SECTION 2: RESPONSIBILITIES OF THE IRB

### 2.1 IRB CHAIR

The AAPCHO IRB Chair promotes a culture consistent with the objectives of AAPCHO's Community Institutional Review Board. He/She directly oversees the protection of research participants by ensuring the proper review, approval, disapproval, or determination of exemption from further review of research submissions.

1. Participate in developing meeting agendas, policies, procedures, and education efforts to support human research protection;
2. Preside over bi-monthly committee meetings and ensure that the IRB carries out its responsibilities as required by federal regulations, ethical principles and AAPCHO's guiding principles;
3. Review and approve protocol submissions that qualify for expedited review pursuant to federal regulations, ethical principles, and AAPCHO's guiding principles, or delegate such authority to a qualified and experienced IRB member to conduct such review and approval;
4. Ensure that membership of the IRB is recruited, appointed and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to, approve (or disapprove) research protocols that represent the breadth of research submitted to the IRB by AAPCHO member researchers;
5. Ensure that reports related to safety, noncompliance, unanticipated problems in research and adverse events are reviewed, attended to and reported pursuant to federal regulations, local state laws, and AAPCHO policies;
6. Review and approve emergency use requests;
7. Respond to local and federal investigations relating to protocols and actions, as required;
8. Review responses from investigators to determine if they sufficiently address any instructions or concerns of the IRB;
9. Review and approve IRB correspondence; and
10. Facilitate constructive communication among research administrators, research investigators, research staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of

the rights and welfare of the subjects.

## **2.2 IRB VICE CHAIR**

The IRB Vice Chair's responsibilities include the following:

1. Assume the duties of the IRB Chair in his/her absence;
2. Work with the IRB Chair when requested.

## **2.3 IRB ADMINISTRATOR**

The IRB Administrator's responsibilities include the following:

1. Supervise the IRB Coordinator to review IRB applications and prepare IRB meetings;
2. Appoint a temporary Chair person based on IRB members' expertise and availability when all Chairs/Vice-Chairs are not available or have conflicts of interest;
3. Keep investigators, IRB members and staff aware of current regulations and policies/procedures;
4. Interpret and apply federal and state laws, regulations, policies, and guidelines related to human subjects research;
5. Provide orientation and training to new staff members, IRB members and investigators as appropriate;
6. Ensure compliance with the terms of AAPCHO's Federalwide Assurance (FWA);
7. Ensure that appropriate agreements are in place with entities relying on the AAPCHO IRB; determine if an assurance is needed for off-site/cooperative research;
8. Maintain IRB study-related documentation in accordance with AAPCHO policies, IRB policies, and federal regulations;
9. Develop, review, and implement AAPCHO's IRB policies and procedures to ensure compliance with current regulations;
10. Complete all training requirements and stay informed of current human subjects research-related and regulatory developments;
11. Prepare and submit reports, as appropriate, to institutional officials, study sponsors, and OHRP, of any adverse events, injuries to human subjects, other unanticipated problems involving significant risks to subjects or others, serious or continuing noncompliance, or suspension or termination of IRB approval;
12. Respond promptly to and investigate allegations/complaints and matters of non-compliance. Implement corrective action(s) as needed in accordance with federal regulations, AAPCHO policies, and IRB policies and procedures;
13. Carry out quality improvement activities to assess the effectiveness of the IRB and researchers in assuring the welfare of human subjects under federal regulations;
14. Manage IRB infrastructure, including staffing, space, and budget.

## **2.4 IRB COORDINATOR**

The IRB Coordinator will receive from investigators all research protocols that involve human subjects, will keep investigators informed of IRB decisions, and will perform administrative processing.

In addition, the IRB Coordinator will:

1. Provide a preliminary review of all submissions for completeness, if submissions are incomplete, the IRB Coordinator will communicate this to the investigator of the proposed research;
2. Review the consent document to ensure completeness, accuracy and conformance with the protocol;
3. Assign primary reviewer based on appropriate expertise for the protocol under review;
4. Provide protocol materials for review by the IRB approximately seven days prior to a scheduled meeting;
5. Work with the IRB Chair and Administrator to prepare IRB meeting agenda;
6. Generate minutes and correspondence from each meeting for the review and approval of the chair or the full IRB;
7. Provide courtesy notice to approved investigators regarding the impending expiration of IRB approval;
8. Maintain all IRB files in a manner acceptable to AAPCHO and in conformance with regulatory requirements;
9. Facilitate communication between investigators and the IRB and within the IRB itself;
10. Maintain a computerized database of all studies;
11. Update/renew FWA and IRB registration;
12. Remain informed of regulations affecting human subjects research.

## **2.5 DUTIES OF IRB MEMBERS, ALTERNATES, AND AD HOC'S**

- Familiarity with AAPCHO mission and IRB goals and objectives;
- Participation in bi-monthly 2-hour IRB Committee meetings, and voting on each presented proposal. IRB members may attend via teleconference;
- Review of assigned research and presentation of findings of review at subsequent IRB meetings. The IRB Coordinator will assign reviewers for each IRB application based on reviewers' expertise areas and availability;
- Review and approve minutes documenting IRB discussion and findings;
- Sufficient preparation to facilitate timely and complete discussion of each agenda item;
- Participation in and complete the Office of Human Research Protections (OHRP) Assurance Training and participate in on-going education related to IRB oversight and protection (approximately 6-8 hours);
- Up-to-date and informed of current research-related and regulatory developments;
- Assurance of compliance with the terms of AAPCHO's Federalwide Assurance (FWA) as well as AAPCHO's mission and goals, and federal and local state laws related to the review of human research;
- Conduct of quality assurance monitoring of research protocols and investigation of matters of non-compliance;
- Application of personal expertise to the work of the IRB;
- Consideration of the approval criteria offered in federal regulations and the Belmont Report;
- Maintenance of confidentiality regarding any privileged information obtained by virtue of participation in the IRB;



- Disclosure of any potential conflict of interest as soon as it is recognized, and withdrawal from any decision-making associated with any such potential conflict;
- Respect for the work of the IRB and provision of reasonable notice of any inability to attend a meeting;
- Familiarity with these operating procedures and all attachments to them; and
- Maintaining a current curriculum vitae/resume on file with the IRB Coordinator

## 2.6 RESEARCH INVESTIGATORS

### A. Responsibilities

Responsibilities of individual research investigators for the purposes of IRB review include the following:

1. The Principal Investigator in charge of the project (or Co-PI) must be an affiliate of an AAPCHO member health center. The project must have official approval of AAPCHO member organizational leadership (e.g. CEO) as witnessed by signature on the IRB application.
2. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects; investigators are to be trained in the protection of human subjects and must submit current documentation of such training to the IRB Coordinator.
3. Research investigators are responsible for keeping a copy of the IRB - approved and subject-signed informed consent document in each subject's study file unless the IRB has specifically waived this requirement. A signed copy is to be given to the research subject.
4. Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
5. Research investigators are responsible for reporting progress of approved research to the IRB with each request for continuation of the research (at least once per year) or more frequently as requested by the IRB.
6. The Principal Investigator will report promptly to the IRB, and, as appropriate, institutional officials and study sponsor(s), any *adverse events, injuries* to human subjects, or *other unanticipated problems* involving *significant* risks to subjects or others. The Institutional Official will notify the [Office for Human Research Protection \(OHRP\)](#) as appropriate.

## SECTION 3: PROCEDURES AND REVIEW PROCESS

### 3.1 PREPARING YOUR APPLICATION

Prepare the application single sided, staying within the margin limitations indicated on the forms. The print must be clear and legible. Researchers are advised to review their applications for errors in spelling and grammar, as failures to do so can lead to difficulties in understanding the meanings of documents. There is no fee to apply for an AAPCHO IRB review. An AAPCHO member health center can submit more than one application; however, the IRB will prioritize applications from members who submit less often. **Only FINAL documents and/or protocols should be submitted.**

### **A. Face Page**

The *Request for IRB Review* form is to be used as a cover sheet for all new applications to the IRB. All subsequent changes to the approved protocol, and/or consent forms, are to be submitted along with the *Modification to Approved Protocol* form. Once a study has been approved, the IRB will need to review it no less than once a year for the duration of the study, including any data analysis period. These continuing reviews should be submitted with a *Continuing Review Application* form. The Principal Investigator (PI) must sign the form.

### **B. Research Narrative / Proposal**

The full protocol is to be included in the application. The following information must be included for the IRB to make a determination if appropriate:

- The professional qualifications of the researcher(s) or advisor (via curriculum vitae, biosketch or other demonstration of qualification);
- The purpose or anticipated benefit of the proposed research;
- The results of previous, related research conducted by the PI or by others;
- The reason that classes of human subjects may be selected or excluded from the research;
- The design of the research protocol, including descriptions of tests or methodologies to be used in the course of the research;
- A description of the proposed handling of potential adverse reactions;
- A description of the proposed consent procedures, which considers setting, time, condition of the subjects, primary language of the subject, and the ability of the subject to make his/her own decisions;
- The method by which the privacy of the human subject is protected;
- A disclosure of extra costs which might be incurred by participants or by any third party payer on their behalf as a result of participation in the research;
- A discussion of whether compensation is available to any subject for injury arising out of the research;
- A discussion of whether any subject would receive compensation for his/her participation in the research.

### **C. Technical Assistance**

If technical assistance is required to complete your application or for research general questions, please contact the IRB Coordinator. Please provide the nature of your technical assistance request as well as your availability. We will arrange an appointment granted on an available basis from the appropriate representative.

## **3.2 SUBMITTING YOUR APPLICATION**

### **A. New Concept for IRB Review**

Submit the following in one package:

1. *Request for IRB Review* form
2. Full narrative
3. Informed consent materials
4. Questionnaires, survey instruments, focus group guides, outlines for semi-

- structured interviews, advertisements, phone scripts (as appropriate)
5. *A Financial Conflict of Interest Disclosure form*
  6. *A signed Institutional Review Board (IRB) Authorization Agreement form A*
  7. *A signed Institutional Review Board (IRB) Authorization Agreement form B*
  8. If you would like to request data from AAPCHO (i.e. PIC, aggregated UDS, and other data collected by AAPCHO), you must include a signed *AAPCHO Data Request form*.
  9. Request for Waiver of Informed Consent form, if applicable.
  10. If you are requesting a Waiver of Authorization for protected health information, please complete the Request for Waiver of Authorization form.

Researchers may submit a copy of the completed application to the IRB Coordinator at [research@aapcho.org](mailto:research@aapcho.org) or a hard copy to:

Nicole Nguyen  
IRB Coordinator  
AAPCHO  
2140 Shattuck Ave, Suite 203  
Berkeley, CA 94704

Applications will be accepted from AAPCHO members or AAPCHO partners who collaborate in current or active AAPCHO projects. These include partners working on AAPCHO-funded projects or groups who have representation from AAPCHO staff or AAPCHO partners.

## **B. Continuation Approval**

Submissions for **Continuation Approval** must include:

1. *IRB Continuing Project Application form*, including status report
2. A photocopy of the current IRB approved informed consent form, as applicable
3. Any proposed revisions to the research (protocol revisions, revised consent forms, advertisements or other documents, etc.)

## **C. Submissions for Modification**

During any approval period, including the approval pending minor modifications period, the PI may request modifications to a protocol. No modifications may be implemented until IRB approval is granted. Examples of modifications include: changes in study personnel, changes in research site, changes in number of subjects, changes in inclusion/exclusion criteria, changes in research interventions and changes in the research design. The IRB Chair will review the proposed modifications. If they are minor, the Chair has approval authority. For major changes, the application must be reviewed at a full IRB meeting. A major modification is defined as any change that materially affects the assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

**Modification** submissions must include:

1. An explanation of the requested modification, its purpose, and its justification
2. *Modification to Approved Protocol form*
3. Revised forms, if appropriate (contact letter, consent form, advertisements, etc.)
4. Supporting documentation

### 3.3 Submission and Project Tracking

#### A. Receipt of Submissions

##### RECEIPT, REVIEW, AND NOTIFICATION

Receipt of Application	Three weeks before Review
Review of Application	Second Tuesday bimonthly - tentative
Notification of Results	2 weeks after Review (For expedited reviews, e.g. for proposed modifications or IRB requested revisions, notification will be sent four weeks after receipt)

#### A. IRB Numbering System

Each study submission is assigned a unique IRB application number using a numbering system in the following format: the first 4 digits will reflect the last two numbers of the year and the month the study was initially submitted to the IRB; AAPCHO; the next 2 digits will be assigned sequentially as studies arrive to provide a unique identifier; the next lowercase letter will reflect possible sequential submissions for the same study; the next uppercase letter will reflect the type of submission (N: new submission; R: resubmission; C: continuation; M: modification); California; protocol title.

1301-AAPCHO-01aN-California-[protocol title]

### 3.4 IRB Meetings (Full Board)

#### A. Schedule

The IRB meets bimonthly. Ad-hoc meetings will be scheduled as needed.

#### B. Meeting Packets Preparation and Distribution

A copy of each agenda item will be sent to each member who is planning to attend. An extra packet will be on hand at the meeting.

Contents of Meeting Packets:

1. Agenda
2. Minutes of Previous Meeting for Board approval
3. New Projects
4. Ongoing Projects
5. Follow-up Items
6. Expedited and Exempt Review List Description of action taken by the Chair or other designated reviewer(s) to perform expedited review, to declare a study exempt, or to approve application changes required by the Board
7. Other Agenda Items

8. Other informational materials (education items and articles of interest, etc.)

### C. Meetings

1. Full Board actions require the presence of a quorum of the voting members, defined as a majority of the membership including at least one member whose primary concerns are based in nonscientific areas.
2. If the required number of members is lost during a meeting, **no action** may be taken until it is restored.
3. Convened meetings may be conducted by telephone conference calls, provided that each participating IRB member has received all pertinent material prior to the meeting and can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document which members were present via conference call, and that these two conditions have been satisfied.
4. IRB meetings are conducted in accordance with Roberts Rules of Order. At a minimum, the Chair conducts the meetings, there is a predetermined agenda, the minutes of the prior meeting are voted upon, and all actions and resolutions require the voice or show-of-hands vote of the members present following discussion and the making and seconding of a motion.

### D. Meeting Minutes

The IRB Coordinator prepares Minutes of the convened meeting. Minutes shall be prepared in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the total number of members voting and total members voting for, against, recusing and abstaining [45 CFR 46.115\(a\)\(2\)](#).

Specifically, the minutes shall include the following components if applicable:

1. Date and time in which the Chair calls the meeting to order, and the time the Chair adjourns the meeting;
2. Voting members (or alternates) present and absent;
3. Members participating via teleconference and the minutes shall document that those members received all pertinent material before the meeting and can actively and equally participate in the discussion of all protocols;
4. Representatives of vulnerable population when the presented studies include vulnerable populations;
5. Staff and guests, including consultants, present;
6. Approval of minutes of prior convened IRB meeting;
7. Members who leave the meeting briefly, are not present during a vote, and/or not counted as part of the quorum;
8. Members who arrive late or depart early from the meeting and their arrival and departure times;
9. Members leaving a meeting during discussion of an action due to conflict of interest and indication that the conflicting interest was the reason for the absence;
10. Action voted by the IRB and separate deliberation of each action;
11. For initial review and continuing review, the IRB approval period, e.g., one year or less;

12. Modifications required and/or additional information requested by the IRB, e.g., contingencies for approval;
13. The basis for requiring changes in or disapproving research;
14. A written summary of the discussion of controversial issues and their resolution;
15. Findings and determinations of the IRB required by regulation, when applicable, including waiver or alteration of the consent process, research involving pregnant women, human fetuses and neonates, children and prisoners;
16. Actions resulting from review of reports of unanticipated problems involving risks to participants or others, when applicable, or other reportable events and information;
17. Deliberations of non-compliance and stipulated remedial action, when applicable, will include the rationale for determination of the non-compliance to be serious or continuing non-compliance;
18. The approval of research contingent on specific minor conditions by the chair or designee, in the minutes of the first IRB meeting that takes place after the date of the approval.

Minutes shall be available for review and approval by the IRB at the next convened meeting. All records will be maintained for three years following the completion of the research project. Meeting minutes will not be shared with those who have a conflict of interest before the decision letter is finalized and sent out.

#### **E. Primary Reviewer**

For each protocol being reviewed at an IRB meeting, a primary reviewer is assigned from among the members. The primary reviewer:

- Is expected to conduct a comprehensive review of the application, protocol/project description, and all documents submitted for review by the committee.
- Complete the IRB check list for each assigned application.
- Should come to the meeting prepared to present the protocol to the committee.
- Should be prepared to recommend an action on the proposed study or study changes to the committee.

The primary reviewer should present his/her recommendations succinctly and concretely to the IRB. If the recommendations are substantive or detailed, it is helpful if the primary reviewer types them up for distribution at the meeting. These recommendations will form the basis of the IRB discussion; however, the ultimate decision of the IRB may or may not align with the recommendations of the primary reviewer.

#### **F. IRB Review Process**

1. An IRB shall vote to approve, disapprove, or table a research protocol. These actions mandate the vote of a majority of the members present at the meeting. If the vote is not unanimous, the minority opinion must be recorded in or attached to the minutes when forwarded for final institutional review and approval. An IRB member may abstain from voting for any reason, without explanation. An IRB may require that stipulations must be met before a protocol is approved.

Either the Chair of the IRB or the full IRB may certify that the PI has met the stipulations. The IRB may offer non-binding recommendations with its action to approve or table a protocol. PIs must respond in writing to IRB stipulations and recommendations.

2. The Chair of an IRB, or a member(s) designated by the Chair may review and approve research, which involves no more than minimal risk to participants. This expedited review procedure may also be used to review and approve minor changes in previously approved research during the period for which approval is authorized. The Chair or member(s) conducting the review must inform the full IRB of research, which has been approved by this procedure, and this information, should be documented in the minutes.
3. Protocol changes or amendments may receive expedited or full IRB review and approval depending on the nature of the amendment.

### **G. Criteria for IRB Approval of Research**

1. Approval of research by the IRB shall determine that all of the following requirements are satisfied: (1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB shall not consider possible long-range effects of applying knowledge gained in the research (e.g. the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of participants is equitable. In making this assessment, the IRB shall take into account the purposes of the research, the setting in which the research will be conducted.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the IRB's regulations on informed consent.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by the IRB's regulations on informed consent.
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. AAPCHO Community IRB reserves the right to have discretion over applications that it will review based on available expertise and other factors, especially with regard to research that involves clinical trials or vulnerable populations of pregnant women, human fetuses and neonates, prisoners, children, persons at risk for suicidality, or persons with impaired decisional capacity.

9. When appropriate, the IRB may grant a Waiver of Authorization under certain circumstances: [NIH Waiver Authorization Requirements](#).

## H. Full Board Review

Any research protocol that is not eligible for consideration by expedited review must be reviewed by the full IRB. Each protocol submitted for full IRB review will be reviewed at a convened meeting of the IRB. The Board action on a submission can be one of the following categories, and may also contain suggestions and comments:

1. **Approval:** A protocol may be approved by the IRB without revisions.
2. **Approval Pending Minor Modification(s):** A study may be considered approved pending minor modifications to the protocol based on changes requested by the IRB that are non-substantive. These non-substantive changes may include corrections of typographical or grammatical errors or investigators' responses to questions posed by the IRB that do not affect the risk/benefit analysis of the submission. A protocol that is voted by the IRB "*approved pending minor modification*" may be given full approval after administrative review and a report to the Chair or designated member unless otherwise directed by the full IRB. All modifications must be received, and final IRB approval granted, before research (or modifications) is (are) initiated.
3. **Approval After Conditions Fulfilled:** The IRB may approve a protocol if certain conditions are met. Such a protocol may require a more substantive revision than a protocol that is approved pending minor modification. After revision, the protocol must be submitted to the full IRB for another review unless the IRB has delegated authority to the Chair or another IRB member to review and approve the protocol. This may be performed by expedited review. If the IRB need only confirm the adherence of the protocol to specified conditions, the IRB may assign the IRB Coordinator to perform and document an administrative review.
4. **Disapproval:** The IRB may find it necessary to disapprove a protocol. When this happens the reasons for the disapproval will be described in the meeting minutes and communicated in writing to the investigator. The investigator may choose to appeal the decision for reconsideration of the full IRB, to revise and resubmit the protocol, or to accept the decision.
5. **Close-Out:** The IRB will close a study in accordance with the following criteria:
  - a. A principal investigator is no longer affiliated with AAPCHO or its member organization and has not transferred the protocol to another AAPCHO investigator via a modification submission.
  - b. A principal investigator submits a cover letter requesting withdrawal of the study while it is in the process of review.
  - c. A principal investigator has not responded to IRB correspondence.
  - d. The approval period has expired without application to the IRB for continuation.



### **3.5 Expedited Review**

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chair [45 CFR 46.110](http://www.hhs.gov/ohrp/policy/expedited98.html) (<http://www.hhs.gov/ohrp/policy/expedited98.html>). Any protocol or portion not approved under expedited review procedures, will be forwarded to the full Board for review at the next scheduled meeting.

### **3.6 Exempt Research Review**

Federal regulations allow exemption from IRB review for certain categories of social, educational, and economic research activities and the study of existing data, documents, records, and pathological or diagnostic specimen(s). Research activities which are exempt from IRB review must fit into one or more of the following research categories in accordance with [45 CFR 46.101\(b\)](http://www.hhs.gov/ohrp/policy/exmpt-pb.html) (<http://www.hhs.gov/ohrp/policy/exmpt-pb.html>). Investigators must check with the IRB Chair concerning the exempt status of proposed research. The IRB Chair may also defer the responsibility to a designated member of the IRB and/or to the consideration of the full IRB at a regularly scheduled meeting.

### **3.7 Urgent Review**

On rare occasions, a funding deadline may require an urgent review, and a protocol must be reviewed prior to the next scheduled IRB meeting. In this case, the IRB Chair may convene an unscheduled meeting of full IRB. If possible, the IRB Coordinator will gather quorum for an urgent meeting, and the materials for the meeting will be sent to the members for review at least one day prior to the urgent IRB meeting. If a quorum is not achieved, the protocol will not be reviewed until the next scheduled IRB meeting. Quorum is defined as a majority of the membership including at least one member whose primary concerns are based in nonscientific areas.

### **3.8 IRB Action Memoranda**

#### **A. Correspondence**

Each investigator will be notified of the decisions of the IRB in writing in a timely manner. Notification will include, as appropriate, any IRB requirements to obtain full approval of the research (i.e., consent document modifications, clarification of discussion points, etc.) and (if appropriate) a date by which the investigator must respond to avoid the matter being remanded to full Board; the reasons for disapproval if applicable; the expiration date of approval; and any suggestions offered by the Board members for informational purposes.

#### **B. Issuance of Approvals**

When an investigator has satisfied all IRB requirements for approval, an Action Memo may be issued. Action Memoranda are prepared by the IRB Coordinator on behalf of the IRB Chair. The IRB Chair may personally review and approve all notices.

#### **C. Investigator Response**

It is the responsibility of the investigator to respond to any IRB questions or need for revisions in a timely manner, and prior to the date, if any, indicated on the Board

correspondence.

#### **SECTION 4: INFORMED CONSENT**

Except as provided elsewhere in the IRB's policy, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language that is understandable to the subject or the representative. An informed consent, oral or written, may not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution or the sponsor from liability for negligence.

- A. The basic elements of informed consent shall provide the following information to each subject:
- (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
  - (2) a description of any foreseeable risks or discomforts to the subject;
  - (3) a description of any benefits to the subject or to others, which may reasonably be expected from the research;
  - (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - (6) for research involving more than minimal risk, an explanation for any compensation and an explanation for any medical treatments available if injury occurs and, if so, what they consist of, or where further information may be obtained;
  - (7) an explanation of whom to contact for questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject; and
  - (8) 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.
- B. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
- (1) the research involves no more than minimal risk to the participants;
  - (2) the waiver or alteration will not adversely affect the rights and welfare of the participants;
  - (3) the research could not practicably be carried out without the waiver or alteration; and
  - (4) whenever appropriate, the participants will be provided with additional pertinent information after participation.

## **SECTION 5: REPORTING OF ADVERSE EVENTS AND NONCOMPLIANCE**

The IRB will report promptly via letter to appropriate institutional officials, the federal Office of Human Research Protections (OHRP), sponsor, and/or any other sponsoring federal department or agency head, as appropriate, any reportable, unanticipated adverse event associated with human subjects research under the purview of the AAPCHO IRB; any instance of serious or continuing noncompliance with any regulations or the decisions of the IRB; and any suspension or termination of IRB approval for research.

An adverse event is any unanticipated reaction or event contemporary with the study that has a harmful effect on a subject, including adverse physical, psychological, or social events. Adverse events must be reported to the IRB whether or not the researcher believes the events to be caused by the study. The researcher should report any measures taken for the benefit of the subject(s) and to mitigate the potential of recurrences. All AAPCHO investigators conducting research with human subjects must report adverse events to the IRB within **five working days** of the date of occurrence or of the investigator's knowledge that an adverse event has occurred. For this purpose, an adverse event is defined as "an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention." In non-medical research an adverse event can consist of an undesirable and unintended consequence of or reaction to procedures. A breach of confidentiality may, for example, constitute an adverse event. Any possible change to the risk/benefit ratio must be evaluated, and recruitment and consent procedures may need modification. In accordance with these standards, complaints from subjects or potential subjects should be reported.

Adverse event reports should include an opinion as to whether the event was or was not related to participation in the study. Reports will be reviewed by the IRB Chair or designated reviewer and will be submitted to the full IRB at the next scheduled meeting for further review. The IRB will take action that may include the reporting of serious, unanticipated adverse events to OHRP. The IRB may also determine that an adverse event changes its assessment of the relative risks and benefits of a research activity or that new information should be conveyed to currently enrolled subjects and/or be included in a modified consent form.

The IRB Chair or a designated reviewer shall have the authority to temporarily stop the study if there is a reasonable risk of a previously unanticipated harm to other subjects.

## **SECTION 6: SELECTED TERMS FROM THE OHRP IRB GUIDEBOOK**

**ADVERSE EFFECT** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

**ASSENT** Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

**ASSURANCE** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**AUTHORIZED INSTITUTIONAL OFFICIAL** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

**AUTONOMY** Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

**AUTOPSY** Examination by dissection of the body of an individual to determine cause of death and other medically relevant facts.

**BELMONT REPORT** A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

**BENEFICENCE** An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**BENEFIT** A valued or desired outcome; an advantage.

**BIOLOGIC** Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.

**CASE-CONTROL STUDY** A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See also: Retrospective Studies.)

**CHILDREN** Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.401(a)].

**CDC** Centers for Disease Control and Prevention; an agency within the Public Health Service, Department of Health and Human Services.

**CLINICAL TRIAL** A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

**COGNITIVELY IMPAIRED** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

**COHORT** A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

**COMPENSATION** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research. (Compare: Remuneration.)

**COMPETENCE** Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity.)

**CONFIDENTIALITY** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**CONSENT** See: Informed Consent.

**CONTRACT** An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant. (Compare: Grant.)

**CONTROL (SUBJECTS) or CONTROLS** Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

**CONTRAINDICATED** Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (e.g., a drug may be contraindicated for pregnant women and persons with high blood pressure).

**CORRELATION COEFFICIENT** A statistical index of the degree of relationship between two variables. Values of correlation coefficients range from -1.00 through zero to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching -1.00 or +1.00 indicate strong relationships between the variables. However, causal inferences about the relationship between two variables can never be made on the basis of correlation coefficients, no matter how strong a relationship is indicated.

**CROSS-OVER DESIGN** A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

**DATA AND SAFETY MONITORING BOARD** A committee of scientists, physicians,

statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

**DEBRIEFING** Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

**DECLARATION OF HELSINKI** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

**DEPENDENT VARIABLES** The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

**DESCRIPTIVE STUDY** Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

**DHHS** A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

**DIAGNOSTIC (PROCEDURE)** Tests used to identify a disorder or disease in a living person.

**DRUG** Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

**EMANCIPATED MINOR** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (See also: Mature Minor.)

**EPIDEMIOLOGY** A scientific discipline that studies the factors determining the causes, frequency, and distribution of diseases in a community or given population.

**EQUITABLE** Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**ETHNOGRAPHIC RESEARCH** Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (See also: Fieldwork.)

**EXPEDITED REVIEW** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

**EXPERIMENTAL** Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (See also: Research.)

**EXPERIMENTAL STUDY** A true experimental study is one in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (See also: Quasi-Experimental Study).

**FALSE NEGATIVE** When a test wrongly shows an effect or condition to be absent (e.g., that a woman is not pregnant when, in fact, she is).

**FALSE POSITIVE** When a test wrongly shows an effect or condition to be present (e.g. that is woman is pregnant when, in fact, she is not).

**FEDERAL POLICY (THE)** The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the "Common Rule.")

**FIELDWORK** Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (See also: Ethnographic Research.)

**FULL BOARD REVIEW** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

**GRANT** Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (Compare: Contract.)

**GUARDIAN** An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

**HISTORICAL CONTROLS** Control subjects (followed at some time in the past or for whom data are available through records) who are used for comparison with subjects being treated

concurrently. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.

**HUMAN SUBJECTS** Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**INCAPACITY** Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (See also: Incompetence.)

**INCOMPETENCE** Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)

**INDEPENDENT VARIABLES** The conditions of an experiment that are systematically manipulated by the investigator.

**INFORMED CONSENT** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

**INSTITUTIONAL REVIEW BOARD** A specially constituted review body established or designated by an entity to protect the welfare of human subjects, including those about whom individually identifiable is obtained, and those recruited to participate in biomedical or behavioral research.

**INSTITUTIONALIZED** Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

**INSTITUTIONALIZED COGNITIVELY IMPAIRED** Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled (e.g., a psychiatric hospital, home, or school for the retarded).

**INVESTIGATOR** In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (See also: Principal Investigator.)

**IRB** See: Institutional Review Board.

**JUSTICE** An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.



**LEGALLY AUTHORIZED REPRESENTATIVE** A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**LONGITUDINAL STUDY** A study designed to follow subjects forward through time.

**MASKED STUDY DESIGNS** Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individual subjects. Sometimes called "blind" study designs.

**MATURE MINOR** Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (See also: Emancipated Minor.)

**MINIMAL RISK** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [See 45 CFR 46.303(d) and Guidebook Chapter 6, Section E, "Prisoners."]

**MONITORING** The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

**NATIONAL COMMISSION** National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.

**NIH** National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research.

**NONAFFILIATED MEMBER** Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).

**NONTHERAPEUTIC RESEARCH** Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.

**NORMAL VOLUNTEERS** Volunteer subjects used to study normal physiology and behavior or

who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

**NULL HYPOTHESIS** The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.

**NUREMBERG CODE** A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

**OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR)** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

**OPEN DESIGN** An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.

**PARTICIPANT** [See "Human Subjects"]

**PATERNALISM** Making decisions for others against or apart from their wishes with the intent of doing them good.

**PERMISSION** The agreement of parent(s) or guardian to the participation of their child or ward in research [45 CFR 46.402(c)].

**PHS** Public Health Service. Part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.

**PRESIDENT'S COMMISSION** President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. An interdisciplinary advisory group, established by congressional legislation in 1978, which was in existence until 1983, and which issued reports on ethical problems in health care and in research involving human subjects.

**PRINCIPAL INVESTIGATOR** The scientist or scholar with primary responsibility for the design and conduct of a research project. (See also: Investigator.)

**PRISONER** An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal

prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

**PRIVACY** Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**PROSPECTIVE STUDIES** Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

**PROTOCOL** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**QUASI-EXPERIMENTAL STUDY** A study that is similar to a true experimental study except that it lacks random assignments of subjects to treatment groups. (See also: Experimental Study.)

**RANDOM, RANDOM ASSIGNMENT, RANDOMIZATION, RANDOMIZED** Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

**REMISSION** A period in which the signs and symptoms of a disease are diminished or in abeyance. The term "remission" is used when one cannot say with confidence that the disease has been cured.

**REMUNERATION** Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) (Compare: Compensation.)

**RESEARCH** A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

**RESPECT FOR PERSONS** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**RETROSPECTIVE STUDIES** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

**REVIEW (OF RESEARCH)** The oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis.

**RISK** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: Minimal Risk.)

**SCIENTIFIC REVIEW GROUP** A group of highly regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of applications for research grants and contracts. Scientific review groups are also required to review the ethical aspects of proposed involvement of human subjects. Various kinds of scientific review groups exist, and are known by different names in different institutes of the NIH (e.g., Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).

**SECRETARY** A U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.

**SITE VISIT** A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

**SOCIAL EXPERIMENTATION** Systematic manipulation of, or experimentation in, social or economic systems; used in planning public policy.

**SPONSOR-INVESTIGATOR** An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

**STATISTICAL SIGNIFICANCE** A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

**STUDY SECTION** See: Scientific Review Group.

**SUBJECTS (HUMAN)** See: Human Subjects.

**SURVEYS** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

**UNIFORM ANATOMICAL GIFT ACT** Legislation adopted by all 50 States and the District of Columbia that indicates procedures for donation of all or part of a decedent's body for such activities as medical education, scientific research, and organ transplantation.

**VARIABLE (NOUN)** An element or factor that the research is designed to study, either as an

experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

**VOLUNTARY** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

**VULNERABLE POPULATION** A group of persons identified categorically as relatively (or absolutely) incapable of protecting their own interests in the context of research. Federal regulations do not offer an exhaustive list but mention nine examples to which special concern may apply: women, human fetuses, neonates, prisoners, children, persons with physical handicaps or mental disabilities, and persons who are disadvantaged economically or educationally. *The Belmont Report* adds three: racial minorities, the very sick, and the institutionalized.

## **SECTION 7: ACKNOWLEDGEMENTS**

AAPCHO would like to express our gratitude to our health organization and IRB members for their time in serving on the committee. We are also grateful to Waianae Coast Comprehensive Health Center, Orange County Asian and Pacific Islander Community Alliance, Cancer Prevention Institute of California, and Migrant Clinicians Network who were abundantly helpful and offered invaluable assistance and guidance, as well as templates for our materials.

## **SECTION 8: REFERENCES**

1. Cancer Prevention Institute of California. IRB Policies and Procedures.
2. Special Service for Groups IRB.
3. University of Hawaii, IRB Orientation.
4. Waianae Coast Comprehensive Health Center. IRB Policies and Procedures.

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· This definition is not provided in the OHRP IRB Guidebook.