

COLORADO RIVER INDIAN TRIBES

HUMAN AND CULTURAL RESEARCH CODE

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## HUMAN AND CULTURAL RESEARCH

### ARTICLE 1. HUMAN AND CULTURAL RESEARCH CODE

[NOTE: Except as otherwise noted, the provisions of Article 1 of the Human and Cultural Research Code were enacted on October 1, 2009 by Ordinance No. 09-04, and are effective on November 1, 2009.]

#### CHAPTER 1. GENERAL PROVISIONS

##### Section 1-101. Purpose.

This Code is intended to carry out the following purposes:

- (1) To create a uniform standard in how research on the Colorado River Indian Reservation (“Reservation”) is to be conducted.
- (2) To create a specific and formal authorization body to provide protection of the Colorado River Indian Tribes’ (“CRIT” or “Tribe”) property including physical, real, cultural and intellectual property and communal property such as blood and tissue samples from the Tribe in large scale human subjects research.
- (3) To provide protection for CRIT’s land.
- (4) To preserve and protect the unique and distinctive languages, cultures and traditions of the Tribes.
- (5) To protect all persons within the territorial jurisdiction of the Reservation from unreasonable, harmful, intrusive, ill-conceived or otherwise offensive research and investigation procedures.

##### Section 1-102. Definitions.

- (a) “Conflict of Interest” means any situation in which an ERB Member is in a position to exploit his/her professional or official capacity in some way for ERB Member’s personal benefit in financial gains or in-kind gains in the form goods, commodities, or services.
- (b) “ERB” means the Ethics Review Board that is the administrative body with the responsibility for implementing and enforcing the provisions of this Code.
- (c) “Human Participant” means a living or non-living individual, including human remains, about whom a researcher, whether professional or student, conducting research obtains private information or data through intervention or interaction with the individual, involving physical procedures by which data are gathered, for example, blood draws, and/or manipulations of the

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participant or the participant's environment.

(d) "Informed Consent" means a prospective participant's voluntary agreement, based upon full disclosure and adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, the participant may not waive or appear to waive any legal rights to applicant researcher, the funding source, or agent. Additionally, the participant may not release or appear to release the applicant researcher, the funding source or agent from liability for negligence.

(e) "Research" means the use of systematic methods to gather and analyze information for the purpose of proving or disproving a hypothesis, evaluating concepts or practices or otherwise adding to knowledge and insight in a particular discipline or field of knowledge or to demonstrate or investigate theories, techniques or practices. For the purpose of this Code, research includes the following:

- (1) Basic and clinical research.
- (2) Behavioral studies including studies of wildlife and domestic animals.
- (3) Anthropological and archaeological studies.
- (4) Community and cultural based research including interviews, questionnaires, and surveys.
- (5) Feasibility and other studies designed to develop, test and evaluate basic data in all phases of environmental and public health.
- (6) Geological and botanical research.
- (7) Linguistic research.

(f) "Researcher" means any person, organization, business or other entity which conducts research within the territorial jurisdiction of CRIT.

(g) "Reservation" means the land area inside boundaries of the Colorado River Indian Reservation.

(h) "Work-For-Hire" means the creator's work product is not the copyrighted product of the creator. The copyright belongs to the entity that hired the creator to do the work.

### **Section 1-103. Application.**

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This Code is applicable to all research done within the boundaries of the Reservation by all agencies:

- (1) Non-CRIT governmental agency;
- (2) Non-CRIT not-for-profit or for-profit agency, organization or institution;
- (3) CRIT governmental department, agency or enterprise; and
- (4) All other not-for-profit or for-profit agency, organization, business or institution originating on the Reservation.

### **CHAPTER 2. ETHICS REVIEW BOARD**

#### **Section 1-201. Ethics Review Board.**

- (a) CRIT Ethics Review Board ("ERB") is the administrative body with the responsibility for implementing and enforcing the provisions of this Code.
- (b) The ERB shall review all proposals, notwithstanding other Institutional Review Boards' approvals, for human research which will occur within the territorial jurisdiction of CRIT. The ERB shall issue permits for those projects which are consistent with the terms and intent of this Code after its recommendation to and approval from the Tribal Council to proceed with said projects. The ERB, as appropriate, review and approve the results of such studies before publication.
- (c) The ERB shall consider, when appropriate, to coordinate with CRIT Archives, Museum, and Environmental Protection Agency to avoid conflicts.

#### **Section 1-202. Composition and Term.**

- (a) ERB shall be composed of seven (7) individuals, appointment by the Tribal Council: one (1) legal expert; one (1) Tribal member who is a local practicing physician or researcher; four (4) Tribal members that have thorough knowledge of CRIT's four (4) tribes; one (1) member of the Tribal Council.
- (b) The term of an appointment by the Tribal Council shall be three (3) years from appointment. The term of appointment shall be staggered.
- (c) The Tribal Council shall appoint a temporary ERB member in event of a recusal by a conflicted ERB member. The temporary appointment shall last until the conflicted ERB member resumes his/her post.

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(d) A Chair Person shall be designated by the ERB through a majority vote of a quorum. Voting to select a Chair Person shall be anonymous.

### **Section 1-203. Meetings, Quorum.**

The ERB shall meet at least quarterly, but as often as necessary. Four (4) members shall constitute a quorum. A decision shall be made through a majority vote of the quorum.

### **Section 1-204. Purposes of the ERB.**

The purposes of the ERB are to assure that research and publication activities:

- (1) Are consistent with the cultural, health and education goals and objectives of CRIT.
- (2) Do not endanger the well-being of individuals or communities or aesthetics of the Reservation.
- (3) Require informed consent of all affected individuals or their legal representatives.
- (4) Are culturally relevant to the extent possible and are appropriate clinically, technically, epidemiologically and statistically.
- (5) Present only reasonable risks to participants in relation to anticipated benefits.
- (6) Select participants equitably. In making this assessment, the ERB shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which participants will be recruited.

### **Section 1-205. Powers of the ERB.**

Consistent with the requirements of this Code, the powers of the ERB shall include:

- (1) The review of research proposals and make the final recommendation to the Tribal Council.
- (2) The review and grant final approval of presentation materials and manuscripts, including thesis, dissertations and abstracts, prior to publication.
- (3) The negotiation of additional and/or revised procedures, methodologies, and approaches to research and publication with researchers.

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- (4) The ERB may request assistance from other persons with specialized knowledge in the review of any application, proposal or manuscript. When research is reviewed involving a category of vulnerable participants, e.g., prisoners, children, and individuals who are mentally disabled, the ERB shall include in its reviewing body one or more individuals who have a particular expertise and concern for the welfare of these participants.
- (5) The ERB may conduct public hearings if any research proposal may involve participants of particular concern, controversy, or sensitivity to the Tribes in order to obtain feedback from the members of CRIT.
- (6) Pursuant to the approval of the Tribal Council, the ERB shall adopt/amend appropriate rules and procedures regarding: confidentiality of participants; storage of specimens and other research materials; monitoring of research activities; amendments to any research proposals; financial disclosure regarding the research; payments to participants; adverse reactions of any participants; applications and their contents; fees for permits and other services; and other procedures to implement this Code.
- (7) The ERB will coordinate with other appropriate CRIT boards and committees and other Institutional Review Boards and cultural board and committees.

### **Section 1-206. Conflict of Interest.**

(a) Persons. No ERB Member shall participate directly or indirectly in the administration, review and/or approval of a research project or the selection of a paid expert consultant if an actual or foreseeable conflict would be involved. Such conflict would arise when a financial or in-kind interest in the form of goods, commodities or services in the research project or the expert consultation is held by:

- (1) The ERB Member.
- (2) The ERB Member's relative, grandfather, grandmother, father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, husband, wife, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, and half sister.
- (3) The ERB Member's business partner.
- (4) An organization which employs, is negotiating to employ, or has any arrangement concerning prospective employment of any of the above persons.

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(b) **Disclosure.** When there is an actual or foreseeable conflict under Section 1-206 (a), the ERB Member must disclose the conflict in writing as soon as the fact is known to the ERB Member.

(c) **Resolution.** When a conflict has been confirmed by the ERB, the ERB may do the following to resolve the conflict:

- (1) The ERB may waive the conflict if there are valid reasons; waiver must be in writing stating the reason for such a waiver; or
- (2) Request the conflicted ERB Member to recuse himself/herself from the administration, review and/or approval of the research project or the selection of a paid expert consultant.

## **CHAPTER 3. RESEARCH ADMINISTRATION**

### **Section 1-301. Research Proposal Packet.**

Research Applicant must submit a research proposal packet to the ERB for review and approval that includes all of the following:

- (1) Cover sheet titled "CRIT ERB Research Protocol Application"
- (2) Abstract/Executive Summary
- (3) Research Project Description
  - (A) Introduction
  - (B) Background
  - (C) Purpose
  - (D) Methods, including involvement of local community
  - (E) Benefits and Risks: including steps that will be taken to protect participants
  - (F) Protection of Privacy and Confidentiality Assurance; must disclose group identification
  - (G) Funding Source and Budget

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- (H) Time line for Survey or Research
- (I) Informed Consent Form for research that involves individuals; consent form from heir/relatives must be obtained for research that involved human remains, sound recordings, photographs, and the like of deceased individuals
- (J) Intent or plan to publish research and potential for royalties
- (4) Curriculum Vitae of the Principal Investigator and any Co-Principal Investigator.
- (5) Approval and requirements of any sponsoring educational and other institution's human subjects or institutional review board. Researcher must provide contact information of sponsor(s).
- (6) A provision that results will be presented to the ERB and that all publications must be reviewed and approved by ERB.
- (7) A provision that the Researcher shall be governed by and construed in accordance with the laws of the Colorado River Indian Tribes now in force and effect or that may be hereafter in force and effect. Researcher, his/her agents and employees hereby consent to the jurisdiction of the Tribal Court of the Colorado River Indian Tribes. Such jurisdiction shall include, without limitation, jurisdiction to enter judgments for compensatory and punitive damages.

### **Section 1-302. Informed Consent Form.**

The Participant's Informed Consent Form that shall include the following:

- (1) The voluntary nature of participant's involvement;
- (2) The project purpose and use;
- (3) Selection criteria for participants;
- (4) Duration of participant's involvement;
- (5) Research procedures;
- (6) Risks and benefits to the participant;
- (7) Confidentiality measures;



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- (8) Involvement;
- (9) Project contacts;
- (10) Non-waiver of Liability; and
- (11) Participant's/ parent's/ guardian's/ custodian's signature(s).
- (12) One (1) witness signature.

### **Section 1-303. Record Retention.**

(a) The ERB shall develop and maintain an up-to-date file on all research projects, past and ongoing, approved and disapproved. Records of research projects will be maintained at least ten (10) years after the ERB receives the proposal or five (5) years after publication of a paper derived from the research activity, whichever is longer. The ERB shall maintain a file of reprints of publications resulting from all research projects conducted within the territorial jurisdiction of CRIT.

(b) Researcher shall provide CRIT Archive a copy of the final official written report/thesis/dissertation/publication at end of each stage of the research project.

### **Section 1-304. Research Permit.**

(a) Prior to undertaking any human research within the territorial jurisdiction of CRIT, Researcher must apply for a permit by submitting a Research Proposal Packet to the ERB.

(b) The ERB shall make its final recommendation to the Tribal Council to grant a Research Permit.

(c) Once the research is approved by the Tribal Council by resolution, the Researcher must enter into a Memorandum of Agreement with the Tribe prior to the issuance of the Research Permit. The Research Permit shall be signed by the ERB Chair Person and the Tribal Chairman.

### **Section 1-305. Administrative Fees.**

(a) The ERB may assess reasonable costs associated with the review of proposals and other materials; any monies generated are for the exclusive use of the administration of this Code. Administrative fees are subject to change.

(b) The Researcher shall be responsible for the ERB's consulting fees in the event that the ERB require outside professional expertise.

(c) Research originates from the Tribal government, tribal members, and not-for-profit Tribal organizations or institutions are exempt from the Administrative Fees.

**CHAPTER 4. RESEARCH POLICY**

**Section 1-401. Confidentiality and Security.**

There must be stringent assurance that the data and information generated during the conduct of research is protected from unauthorized access and misuse consistent with informed consent provisions, CRIT's confidentiality policy, and other CRIT's information technology. The ERB may demand proof of confidentiality and security.

**Section 1-402. Progress Reports on Research.**

(a) Researcher shall report to the ERB the progress of their research as often and in the manner required by the ERB. The Progress Report shall contain the following information:

- (1) Status of research
- (2) Preliminary data, if appropriate for disclosure at this point
- (3) Deviations from Research Proposal Packet

(b) Researcher shall promptly report any injuries or adverse impacts, including violations of an individual's privacy, to human participants to the ERB.

(c) Researcher shall promptly report any unanticipated problems such as death, illness and injury, which involve risks to the human research participants or others to the ERB.

**Section 1-403. Continuing Review of Research Activities.**

The ERB shall regularly review all research activities conducted within the territorial jurisdiction of CRIT. If, during the course of research activity, the research conditions change, the ERB may require Researcher to amend their application consistent with the changed conditions. Proposed changes by Researcher must go through the approval process of this Code. If the ERB determines that a research project is no longer viable because of changes in the scope or effect of this research, it may rescind any research permit or otherwise limit the scope of research activities which may be conducted under the permit. Appeal procedures under Section 1-501 are applicable for all actions taken under Section 1-403.

**Section 1-404. Publication Review Procedures.**

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All individuals whether or not affiliated with the original researcher or research entity proposing publishing the results of any research covered by this Code are required to submit a manuscript to the ERB for approval, in advance of publication. The manuscript will be reviewed for technical content and validity, organization of content, readability, sensitivity of material or deemed harmful to individual Tribal members or CRIT, as well as assurance that they are consistent with the goals, intent and policies of this Code. All references to or descriptions of CRIT culture, history, or language the ERB deems sacred, inaccurate, or in violation of CRIT's intellectual property rights must be removed or corrected prior to publication.

While CRIT understands that academic publications rarely result in royalties, if any publication for any purpose results in the payment of royalties, an agreement for the sharing of such royalties with CRIT must be negotiated in good faith.

### **CHAPTER 5. APPEAL PROCEDURES**

#### **Section 1-501. The Appeal Procedures.**

(a) Researchers who are denied a research permit can request a one-time reconsideration by the ERB of their application upon a showing of good cause. A request for reconsideration shall be deemed to have shown good cause if it:

- (1) Presents significant relevant information not previously considered by the ERB;
- (2) Demonstrates that significant changes have occurred in the factors or circumstances considered by the ERB in reaching its decision; or
- (3) Demonstrates that the ERB failed to follow its adopted procedures in reaching its decision.

(b) A request for reconsideration must be received within thirty (30) days after Researcher is notified of a decision of the denial.

(c) If good cause is found by the ERB, reconsideration shall be conducted within thirty (30) days after receipt of the appeal request.

(d) All appeal decisions made by the ERB are final.

### **CHAPTER 6. PROTECTION OF RIGHTS**

#### **Section 1-601. Ownership of Property.**

(a) CRIT shall retain all ownership, property, trademark, copyright, and other rights to cultural,

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linguistic, and historic information that is not the intellectual property of Researcher. Non-CRIT employee participants or researchers or both in the research shall sign a Work-for-Hire Agreement for research projects that are designated as property of CRIT.

(b) Researcher shall credit CRIT, when applicable, as the appropriate source of all information used to develop their intellectual property.

(c) Individuals on whom research will be conducted have the right to the information and intellectual property that is provided to Researcher. Researcher shall provide CRIT and each individual with a statement of the individual's rights as it pertains to the information collected from the individual and the statement of rights shall be in plain language. Individuals retain the right to cease involvement in any research at any time.

### **CHAPTER 7. INTELLECTUAL PROPERTY**

#### **Section 1-701. Copyrighted Works.**

(a) Use of CRIT's copyrighted works such as literary works, musical works including any accompanying words, dramatic works including any accompanying music, pantomimes choreographic, pictorial, graphic, audiovisual, architectural, motion pictures and sculptural works and sound recordings shall be granted on a case by case basis.

(b) CRIT may permit use of its copyrighted works for the following purposes: criticism, comment, news reporting, teaching, including multiple copies for classroom use, scholarship, or research.

#### **Section 1-702. Trademark.**

Use of CRIT's trademark(s) such as words, phrases, symbols or designs, or a combination of words, phrases, symbols or designs, that identifies CRIT as the source may be granted on a case by case basis. CRIT shall enforce federal trademark rights afforded under the Lanham Act, 15 U.S.C. §§ 1051 - 1127, and common law trademark rights.

#### **Section 1-703. Patent.**

CRIT shall enforce its patent rights under United States and International patent laws.

### **CHAPTER 8. ENFORCEMENT**

#### **Section 1-801. Remedies.**

Whenever it appears that Researcher or other person or entity has violated the provisions of this

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Code or the terms of the permit, the ERB on its own initiative may petition the Tribal Court for injunction or other appropriate relief. If the Court, after a hearing, finds that this Code or the permit has been violated, it shall ban the researcher(s) from any future research at CRIT, assess civil penalties of up to five hundred dollars (\$500) per violation, award restitution to CRIT or research participants as appropriate, enter orders for injunctive and equitable relief, and award any other monetary damages resulting from the violation.

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