Policy & Procedure

Subject: Research Engagement Guidelines		
AAAHC Standard: 19A-F		
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Distribution: Board of Directors		

Background / Purpose
Denver Indian Health and Family Services, Inc., (DIHFS) has collaborated, successfully, with partners in health research for many years. Most of the work done has been community-based, socio-behavioral; such as diabetes maintenance research, weight loss research, mental health services utilization, and quality assurance/quality improvement, etc. Through the years, our participation has been based on trust with our research partners; and that has worked well to serve our community, our clinic, and most importantly, our patients. However, the Board has noticed an increased number of requests for research participation. While these opportunities can represent powerful, positive situations for our patients, we recognize that ***all*** research engagement involves risk, no matter how minimal. Thus, guidelines for research engagement can be a powerful tool to improve communication and minimize (or ideally, eliminate) problems before they occur. The purpose of these guidelines is to elucidate the basic elements of our collaborative approach toward the goal of helping our people while minimizing risks inherent in research engagement.

Termination
It is important for all individuals and entities involved with DIHFS to understand that our relationship is based upon *full and equal* partnership. Researchers and DIHFS staff and Board should strive to meet the spirit of these guidelines. If DIHFS staff, Board, or clients feel, at any time, that the spirit put forth in these guidelines has been breached; the Board reserves the right to remove DIHFS from any research engagement at any time, for any reason. These guidelines establish a minimum level of expectation; it should be understood that researchers working in good faith with DIHFS will exceed these expectations. The DIHFS Board expects all studies will be based on a Community-Based Participatory Research (CBPR) model and research investigators will be expected to demonstrate knowledge of CBPR principles. Failure to do so may result in termination of the research partnership.

Role of the DIHFS Board in Research Engagement
DIHFS has a unique role in research as a community partner. The DIHFS Board of Directors maintains neither its own IRB (Institutional Review Board), nor its own RRB (Research Review Board). The DIHFS Board relies upon the Indian Health Service Institutional Review Board (IHS IRB) and investigator-related IRBs (for example, the University of Colorado's IRB, "COMIRB") for evaluation of the safety and efficacy of research.

The role of the DIHFS Board is twofold. First, the DIHFS Board must consider research proposals to determine whether the proposed research engagement is fair, reasonable, meets community priorities, is culturally appropriate, and demonstrates full compliance with IRB requirements. Second, the DIHFS Board will monitor the progress of the any research endeavors to ensure the spirit of full and equal partnership in any project is met throughout the project. This includes the dissemination of findings and publications to the community.

Roles of our Research Partners: Review Boards and Principal Investigators
No research involving people (often referred to as "human subjects" or "participants") is *entirely* risk-free, so *all* research involving people is subject to sets of rules designed to protect people. All research with human subjects must be reviewed, at least annually, by an institutional review board (IRB), whose job is to apply the rules of research (with or without human subjects). There are different kinds of review boards and they go by many different names. Some are called research review boards, bioethics review boards, research ethics boards, etc. Each board operates under different priorities and reviews research proposals from different perspectives.

The boards involved in research are determined by the entities involved in the research. For example, in academic research, each institution (i.e. university) has its own IRB which reviews all research proposals conducted with its employees or resources, for safety and efficacy.

The leader of the study team (often called the principal investigator, or "PI") is responsible for ensuring that all necessary reviews are conducted and documented.

Research conducted with DIHFS, a non-profit entity that receives funds from the Indian Health Service (IHS), is subject to review from one board, in particular. The IHS has its own IRB that reviews research, and DIHFS is covered under the IHS IRB's Federal-Wide Assurance. That means all research conducted with the DIHFS or its clients must be reviewed for safety and efficacy by the IHS IRB.

Other IRBs may be involved in research with DIHFS, as well. For example, if a study conducted with DIHFS utilizes IHS resources (staff or other) ***and*** resources from the University of Colorado, both the IHS IRB and COMIRB (the Colorado Multiple Institution Review Board; which reviews all UCD-related research) must review the study. If a study involves a drug or biologic, the US Food and Drug Administration (FDA) may review the study, as well. In reservation communities, many tribes (like the Navajo Nation, and the Oglala Sioux Tribe) have developed their own *tribal* research review boards or institutional review boards.

Data Ownership
Information, or "data," can be collected in many different ways, and in many different forms. No matter how data are collected, they must always be "owned" meaning; collected, maintained, protected, properly shared, monitored for unintended breaches, and ultimately, properly destroyed. Typically, the entity that financially supports the research "owns" the data, and takes responsibility for their care. However, it is important to understand that ownership does not mean *exclusive access*. The DIHFS Board has a responsibility to maintain free access and use of all data collected with the clinic or its patients, and this should be explicitly documented. Data sharing "plans" may not be adequate to guarantee this access and to provide the necessary protections of data. Therefore, the Board requires actual data sharing/use agreements to be executed with all research leaders and/or their sponsoring entities.

Capacity Building and Research Support:
As an organization, DIHFS expects full reimbursement for DIHFS employees' time and/or work; payments for space rental and such office services as copying documents, filing them, and possibly other tasks; compensation for pow-wow (or other event) costs, and other, miscellaneous compensation for working with a research team. Further (consistent with CBPR principles) research activities conducted with DIHFS should always have a goal that supports research/evaluation capacity building for the organization and community.

Benefits and Risks in Research

Benefits –

Research that is well-designed and well-executed provides a good opportunity for eligible participants to:

- Play an active role in their health care through participation in the development of new treatment options, programs, and services.
- Gain access to cutting-edge research interventions before they are widely available.
- Obtain expert or specialty health care (often, at no cost for the care, and with compensation provided for time and effort) at leading health care facilities during the research.
- Help others by contributing to research, including social determinants of health, disease prevention, or other areas.
- Help themselves and their own community to learn how to be healthy and well.

Risks -

- There may be unpleasant, serious or even life-threatening side-effects to "experimental" research.
    - Note: DIHFS expects full disclosure of any expected risks, reports of unanticipated problems, and changes made to the protocol *at the time that events occur* not later, at annual IRB review, for example.
- Risks may come in different forms; some may be physical, some may be emotional. For example, some surveys may bring up traumatic memories, or otherwise emotionally stress study participants.
- Risks to privacy or confidentiality may exist, or risks to the community as a whole. For example, if a neighborhood is reported to carry a high burden of a particular disease, property values could be affected. If a specific tribe is named in research, that tribe could suffer from negative public exposure.
- Experimental treatments may not be effective for participants.
- For participants, the protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.
    - Note: It is the responsibility of the study team to compensate participants for any non-routine (or non-standard-of-care) expenses incurred during participation in research. The study team (not DIHFS) is responsible for documenting expenses and/or reimbursing participants. Any complaints regarding compensation must be reported to the DIHFS Board.
- Depending on the company or condition being studied, private health insurance (and/or IHS or CMS) *may not* cover costs for treatment provided if harm is suffered by a research participant. Many study teams are not aware of these potential consequences for participants.
    - Note: It is the responsibility of the study team to investigate any potential health insurance complications or risks. All identified risks must be reported in writing to the Board and documented communication must be presented to all research participants.
- As an organization, DIHFS could be at legal risk if a participant is harmed in research conducted with DIHFS.
    - Note: Again, it is the study team's responsibility to communicate with DIHFS legal (or insurance) representation to determine any risks to DIHFS as an entity.

The question to the Board
When a PI approaches the Board hoping to partner with DIHFS in a research study, he/she could mean that he/she wants to access information we already have about DIHFS clients or wants to collect *new* information from clients.

The Board must decide whether (or not) to help a PI with his/her research study. To make this decision, the Board must always – as its primary concern – act in the best interest of DIHFS clients (remembering that the study will be reviewed for safety and efficacy by appropriate ethics boards). However, the Board has an additional obligation to protect the staff from undue burden, to be sure that the clinic is fairly compensated for any involvement, and that research activities *enhance* - never divert – any clinic resources from patient care.

Staff/Board actions:

- Upon initial contact with a PI, DIHFS staff shall consider community, organizational, and medical priorities. The DIHFS medical director, community advisory group, and/or medical advisory group (if extant) should review the project including draft protocol and draft consent forms. The staff should then advise the Board regarding next steps. For example, if presented with two research studies simultaneously (e.g., a cancer study and a diabetes study) and the staff decides the clinic should only commit to one of the studies; the staff, with the medical director and advisory groups should determine which disease is most significantly affecting DIHFS clients, and should advise the Board accordingly.
- DIHFS CEO or Executive Director, may then, provide a letter of support to a potential PI *with no further obligation to engage in the project;* indicating that the community has reviewed a draft of the proposal and is interested in seeing the work conducted. It should be clear that the purpose of the letter is to provide support for the PI to begin the IRB approval process, and it should be clear that there is no obligation on the part of DIHFS to become a research partner once IRB approvals are obtained.
    - This action requires only that the Staff notify the Board of this action (provide a copy of the support letter) at the next regularly-scheduled Board meeting.
- Alternatively (or in conjunction with providing a support letter), staff may request that a PI present a project to the Board, directly.
- Upon initial contact, DIHFS staff or Board should provide the PI with a copy of these Research Guidelines and the DIHFS Standards for Research Engagement.

Next steps

- Once IRB approvals are obtained, a PI should approach the DIHFS Board in person for an initial interview. The PI must provide the Board with a description of the proposed project in non-technical (lay) terms.
- During the initial interview, the Research Engagement Standards should be discussed, and the Board should interview the PI (see below). The PI should be given the opportunity to review, clarify, and discuss the Research Engagement Standards with the DIHFS Board. The PI should, then, be excused from the meeting so the Board may discuss options.
- The Board should take official action (whether to support, request changes or more information, or decline participation) on the proposed research study.

DIHFS Checklist of initial interview questions for a PI:
(including, but not limited to):

- Which ethics Boards (IRBs, RRBs, or other) will be reviewing your study and when do you expect to receive your approvals?
- Can you describe the proposed study activities (number of interactions you expect to have with participants, location and duration of each interaction, study procedures, etc.)?
    - Describe the burden to the participant; to include travel time, child care, study time, any time required outside the clinic for the study - for example completing journals or logs, survey questionnaires, etc.
- Will you define DIHFS as "engaged in human subjects research?" DIHFS must review your MOU, DUA, or other agreement, defining the relationship between your work and DIHFS' engagement with it (i.e. you must specify whether or not DIHFS is engaged in human subjects research).
- Describe which DIHFS resources you might need for your study, and any tasks associated with clinic engagement. Will you need staff assistance? Volunteers? Space in the clinic? Internet access?
    - Describe how you will compensate (pay for event/pow-wow registration? Rent space? Compensate volunteers? Pay utilities?)
- Describe the expected risks and benefits to both participants and our community, of your study.
    - Do the risks, patient burdens, burden to DIHFS outweigh the potential good/benefits?
- What is your plan when the unexpected happens? Describe your plan for dealing with unanticipated problems.
- Describe what your study team will do, and who will pay for care, if a participant is hurt in your study. "Hurt" can mean emotionally distressed, financially or otherwise strained, etc.
- When is your study expected to begin enrolling participants and when will it conclude with study-related interactions with participants?
- Who will "own" any data collected? Where will it be stored, how and with whom will it be shared (including sharing with DIHFS)? When and how will it be destroyed?
- Describe how will you meet the DIHFS Research Engagement standards.?
- How will you disseminate findings to the community (in lay language)?
- How will you support capacity building for research and evaluation within the community and/or for DIHFS?

DIHFS checklist of pre-launch requirements:
If the Board decides to participate in a research study, before work may begin, the Board must be presented with the following:

- copies of the IRB-approved study protocol, consent forms, and participant materials
- copies of IRB approval certificates
- Confirmation of PI-attendance at DIHFS Board meetings and community participation.

Standards for Research Engagement

(Reminder: a copy of the DIHFS Research Guidelines and the DIHFS Standards for Research Engagement should be provided to each PI prior to the introductory meeting with the Board)

Requests for the following items are not expected to unduly burden PI's or their study teams as all of the items listed below are commonly required by Good Clinical Practice guidelines[i], and/or Community Based Participatory Research[ii] standards.

For each study presented to DIHFS, the PI shall:

- Present the Board with **a list of ethics boards involved** in determining safety and efficacy of the research (i.e. COMIRB, IHS IRB, Oglala Sioux Tribe Research Review Board, etc.), a copy of the proposed protocol (in lay language), and a copy of a proposed consent form using language that can be understood within the community.
- **Present copies of the annual IRB** (and other ethics boards) approval certificates before the study begins.
- Provide the Board with information regarding **insurance/indemnity** to cover any claims, loss, death or injuries to persons or property based on, created by or resulting from the study.
- Notify DIHFS at the same time as a study team alerts their lead IRB when **unanticipated problems** occur, including descriptions of proposed remedial actions.
- Provide a copy of the **study protocol** and approved IRB annual **continuing review** documents. Data access, storage, destruction, and ownership should all be reviewed with the Board prior to study initiation.
- **Personally introduce** themselves (and any study staff who plan to interact with DIHFS clients) (at least) at the beginning and conclusion of a study (i.e. participant enrollment and data collection).
- **Compensate** (demonstrated in the study budget) DIHFS for participation in the research. This could include items such as: space rental, pow-wow registration (if, for example, a PI would like to distribute study flyers on a DIHFS table), compensation for personnel (if volunteers or staff are needed to help with study recruitment events, special training, etc.), and other activities.
- **Participate in the community:** If a PI wishes to engage the DIHFS community in research, all PIs (personally) must participate in at least one (preferably, more) community event(s) per year, during the active course of the study
    - "Active" meaning, having an active, approved protocol with an IRB.
    - **"**Participation" means *in-person* service <u>in the community</u> (such as, attendance at a pow-wow, fund-raiser, community sporting event, health screening, or other event). A PI should consult with DIHFS staff (CEO, President, Medical Director, others) to find the most appropriate and valuable community events. This community engagement is designed to be mutually beneficial for all involved.
- **Revisit with the Board at the conclusion of data collection:** the PI must again present in-person to the Board, with a summary of initial study findings and their applicability, if any, to DIHFS' clientele and the community.
- **Understand** that any breach of these policies may, per the terms of any agreements (for example, MOUs, Data Use Agreements, etc.) may result in termination of DIHFS participation and/or legal action.

All publications resulting from a study with DIHFS must be submitted to the Board in draft stage. The Board has an ethical obligation to review information collected with DIHFS clients before it is made public.

I have received copies of the DIHFS Research Guidelines and the DIHFS Standards for Research Engagement and agree to fully comply with same.

Signature of Principal Investigator Date

Signature on behalf of DIHFS Board Date

General information for the DIHFS Board of Directors

Understanding Research vs. Clinical Standard of Care

The ethical and legal codes that govern medical practice also apply to health research.[1] Yet, the "research world" may differ from the "clinical world." In normal ("standard of care") clinic visits, a provider (doctor, nurse, etc.) exercises his/her judgment to deliver care, within ethical codes of conduct. In the research world, however, *everything* that a PI does, measures, provides, etc., must be pre-approved by the IRB unless there exists an overwhelming safety issue that overrides pre-approval. The document that governs everything in a research setting is called the "research study protocol," a study plan. It is important to understand DIHFS' role in the protocol for every study presented to DIHFS.

As a study progresses, researchers may report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Upon request, and at reasonable intervals, such results should also be made available to DIHFS. Individual participants' names remain secret and are not typically mentioned in these reports, but sometimes communities (specific tribes, neighborhoods, or groups) may be mentioned by name, so it is important for the DIHFS Board to know how the staff of any research study plan to handle confidentiality (i.e., what words/terms the study staff plan to use when referring to study subjects or groups of subjects).

"Clinical trials" are research studies that involve people as participants. There are two types of clinical trials: **interventional** and **observational**.

- During *interventional* studies, participants are given some type of "intervention" for a health condition, like cancer, diabetes, or smoking. The interventions can include a new medicine, a new program designed to change behavior, or even a new safety measure (like a new helmet or seatbelt).
- During **observational** studies, researchers observe people without trying to make a change or give a new medication. The researcher lets events take their natural course and records them as they happen to learn more about which factors might influence different health outcomes.
- You may hear the terms "**prospective**" and "**retrospective**." Prospective means; any research that will collect data, going ahead, in time. Retrospective means; analyzing data that have already been collected. Both have risks and benefits, and it is important to understand how a study will engage DIHFS and our clients.

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[i] International Conference on Harmonisation (ICH) Good Clinical Practice (GCP): is an international quality standard that is provided by ICH, an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. See: http://www.ich.org/. (Source: http://en.wikipedia.org/wiki/Good_Clinical_Practice)

[ii] Community Based Participatory Research: is research that is conducted as an equal partnership between traditionally trained "experts" and members of a community. In CBPR projects, the community participates fully in all aspects of the research process. *Community* is often self-defined, but general categories of community include geographic community, community of individuals with a common problem or issue, or a community of individuals with a common interest or goal. CBPR encourages collaboration of "formally trained research" partners from any area of expertise, provided that the researcher provide expertise that is seen as useful to the investigation by the community, and be fully committed to a partnership of equals and producing outcomes usable to the community. Equitable partnerships require sharing power, resources, credit, results, and knowledge, as well as a reciprocal appreciation of each partner's knowledge and skills at each stage of the project, including problem definition/issue selection, research design, conducting research, interpreting the results, and determining how the results should be used for action. CBPR differs from traditional research in many ways. One of the principal ways in which it is different is that instead of creating knowledge for the advancement of a field or for knowledge's sake, CBPR is an iterative process, incorporating research, reflection, and action in a cyclical process. (Source: http://en.wikipedia.org/wiki/Community-based_participatory_research)

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