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| The purpose of this worksheet is to provide support for IRB staff and Committee members reviewing research that will be conducted in joint effort that involves researchers and community representatives in all phases of the research. The joint effort engages community members, employs local knowledge in the understanding of various issues and the design of interventions, and invests community members in the processes and products of research. This worksheet is to be used. It does not need to be completed or retained. | | | | | | | |
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| 1. Community Definition (Check if “Yes.”) | | | | | | | |
|  | A group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings. Some common elements of community are:   * A sense of place – city, village, neighborhood, workplace, etc. * Sharing common interests and perspectives. * Joint actions that bring people together * Social ties (family, friends) * Diversity | | | | | | |
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| 1. The Extent of Community Engagement in the Research Enterprise (Check if “Yes.”) | | | | | | | |
|  |  | | **Traditional:** Researcher Control; Community does not have input or decision-making power | **Outreach Consultation:** Researcher seeks passive, general input; little or no bi-directional communication; Researcher retains decision-making power | **Involved Consultation:**  Community actively provides input through bi-directional communication; Researcher retains final decision-making power | **Collaborative / Shared Leadership:**  Community is a full partner in the research enterprise; Bi-directional Communication; Decision-making power is shared | **Empowered:** Community Control; Community has decision-making power; Researcher implements the decisions of the community |
| Research Objective | |  |  |  |  |  |
| Study Design | |  |  |  |  |  |
| Recruitment & Retention | |  |  |  |  |  |
| Instrument Design | |  |  |  |  |  |
| Data Collection | |  |  |  |  |  |
| Analysis & Interpretation | |  |  |  |  |  |
| Dissemination | |  |  |  |  |  |
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| 1. Based on the context of the research should the community be more or less involved in the research process? (Check if “Yes”) | | | | | | | |
|  | The community engagement plan is acceptable. | | | | | | |
|  | The community engagement plan is not acceptable Explain: | | | | | | |
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| 1. Based on the context of the research are individual community representatives engaged in research (Check if “Yes”) | | | | | | | |
|  | Individual community representatives are “engaged” in research per the DHHS definition? (If **“Yes”**, check the appropriate statement below) | | | | | | |
|  |  | The community has an IRB and/or approval process | | | | | |
|  |  | UC Davis will be the IRB of record for the community (If **“Yes”**, all below should be checked) | | | | | |
|  |  | An agreement that UC Davis IRB will be the IRB of record for the community has been completed  All engaged community personnel engaged in research activities are listed as research personnel  Community partners listed as research personnel have completed UC Davis required researcher training | | | | | |

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| 1. IRB Considerations for the Criteria for Approval (Check if “Yes”, all must be checked) | |
|  | The risks of the research are minimized.   * Is the study designed to minimize the risks to the individual participant? * Is the study designed to minimize the risks to individuals who are members of unstructured groups based on inherited traits like race/ethnicity, gender, or ancestry? * Is the proposed degree of collaboration, which can introduce risks to the individual by group association or to the group as a whole, appropriate for the potential benefits that the research can produce? Consider:   + Physical and psychosocial identity risks of the research interaction to the individual by group association   + Physical and psychosocial risks of research findings to the individual by group association   + Risk of undermining personal autonomy/authority to the individual by group association   + Risk of group decisions undermining personal autonomy/authority to the individual by group association   + Risks to group’s structure and function because of engagement in research   + Risks to group’s structure and function because of research findings   + Risk of undermining the group’s moral and sociopolitical authority * If there are plans to collaborate with community partner(s), have the community risks been identified and has a management plan been developed? * If there are plans to enroll members of a community, is the study designed to minimize the risks to the community (as well as the individual participants)? |
|  | The risks to subjects are reasonable in relation to anticipated benefits.   * What are the risks to individual members as individuals and as members of communities? * What are the risks to participating communities? * What are the expected benefits to the individual, to the individual by association to the group or to the group as a whole? * Is the benefit: risk ratio favorable for the individual? * Is the benefit: risk ratio favorable for the community? * Are there ways to increase the benefit: risk ratio? * Is there a Data Safety Monitoring Plan that provides for appropriate monitoring of the risks and the benefit: risk ratio? * Do the academic researchers have an obligation to ensure that the benefits accrued during the research can be maintained, even after research funding expires? |
|  | The selection of subjects is fair.   * Is the population from which the research participants are selected the same population that can be expected to benefit from the research? * Are the community members appropriate subjects of investigation for the project? * Who will recruit potential participants? How will undue influence, favor, or exclusion be avoided? |
|  | Each participant gives a voluntary and informed consent.   * Have the risks and benefits been made transparent to the potential participants as individuals and as a group? * Do the individual members understand that their individual consent is necessary and that their participation is voluntary? * Do the individual members understand that they can withdraw at any time from the research without affecting their community membership or their right to seek care at the academic institution? * How will group decisions be made by the community? * If made by community representatives, can the community representatives be expected to be inclusive and responsive? * Have the recruiters had adequate human subjects protection training to understand that potential participants must give a voluntary consent and that their right to refuse should be respected? * What type of monitoring, if any, will occur in the consent process? |
|  | When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.   * Who is responsible for ensuring data monitoring? * Who is responsible for reporting adverse events? * Who will monitor emerging social risks to individuals and community structures? * How will the researchers respond to adverse events? * When are specific stopping rules needed? * Who should be able to halt research, even if temporarily, if data monitoring suggests unexpected risks, adverse events, or breaches of privacy and confidentiality? |
|  | There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.   * Who will collect data, where will it be stored, and who will have access to stored data, including individual contact information? * How will personnel be trained about privacy and confidentiality in research that is being conducted under a Certificate of Confidentiality or similar? * How will data be managed at a remote site, and how will it be backed up? What procedures are in place to routinely protect data that is obtained and transported off site and may become lost or stolen? * Is there a possibility that individual participants will be identifiable to data collectors who have access to their data? If so, how can privacy and confidentiality of the subjects be assured? |
|  | Conflicts of interest are transparent and appropriately managed.   * What are the primary and secondary interests of the academic investigator? * What are the secondary interests of the community research partner or the organization (e.g., Community-based Organization) that represents the community? * Does the academic institution have a financial conflict of interest with respect to the proposed research? * Do individual community members or the community itself have a conflict of interest with respect to the proposed research? * Who is responsible for disclosing the various conflicts of interest (academic researcher, academic institution, community research partner, community)? * Who is responsible for managing the various conflicts of interest and/or determining the adequacy of Conflict of Interest management plans? * When is a conflict of interest so great that the research should not go forward? |
|  | Consideration is given to what additional protections, if any, are needed for vulnerable populations.   * Does the community partner adequately represent all of its community members? In particular, does the community partner adequately represent its vulnerable members? * Is it appropriate to enroll vulnerable populations? That is, does the research address a problem that is particular to the vulnerable population or does the research offer significant benefit that may not be available outside of the research setting? |
|  | Proper training in human subjects protections is provided for research personnel.   * Are the training methods culturally sensitive and comprehensible to the community research partners who may not have prior research experience or familiarity with medical terminology? * What additional human subjects protection issues need to be incorporated into training of research personnel when the community is a research partner? |