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Community Consultation to Assess and Minimize Group Harms				

1.0 Purpose:

- 1.1 To explain what group harms are and to delineate the procedures that HHC researchers should take to minimize group harms in research that focuses on vulnerable populations through community consultation

2.0 Definitions:

- 2.1 **Group Harms** – When research that is designed to study a group or that retrospectively implicates a group may...result in members of the group facing, among other things, stigmatization and discrimination in insurance and employment whether or not they contributed samples to the study.
- 2.2 **Vulnerability of Groups** – There can be different types: cognitive or communicative, institutional, deferential, medical, economic, and social. Social vulnerability is defined as “a function of the social perception of certain groups, which includes stereotyping and can lead to discrimination...[These] perceptions devalue members of such groups, their interests, their welfare, or their contributions to society”
- 2.3 **Seven (7) Categories of Harms** – Physical, psychological, social, economic, legal, dignitary (“dignitary harms” are “moral harms in which people are not respected as persons, such as violation of privacy or being enrolled without consent in research for which consent should be obtained”), and relational vis-a-vis research or health care (i.e., “disrupting the relationship with important research or trusted researcher or with health care.”

3.0 Policy:

- 3.1 Section 46.107(a) of the Common Rule states that “if an IRB regularly reviews research that involves a vulnerable category of subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.” However, this may not be sufficient to minimize harms. Thus, *Community Consultation* by the researcher may be necessary.
 - 3.1.1 “Investigators should to the extent possible plan their research so as to minimize group harms and should consult, when appropriate, representatives of the relevant groups regarding study design.”
- 3.2 “Purpose of community consultation is to make the researcher more knowledgeable about the vulnerable group (i.e., its values, concerns, life experiences, and problems that are dissimilar to those of most researchers and IRBs), the potential group harms of the research, and how to minimize those harms.”
- 3.3 Efforts should be made to allow members of vulnerable groups to participate in decision making and oversight processes of research studies conducted in their communities and that include members of vulnerable groups. “Involving the community in the various staged of the research process, especially in the study planning, can be helpful in reducing stereotyping and stigmatization.”

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- 3.4 “Consultation with representatives of relevant groups may identify potential harms and other problems as well as benefits and opportunities in the proposed research that may not have been evident to the investigator. Appropriate consultation may thus minimize harms, maximize benefits, and increase the likelihood that the research will be carried out successfully.”

4.0 Procedure:

- 4.1 Many vulnerable groups are heterogeneous and do not have a recognized spokesperson. HHC researchers should consider the community as “stakeholders.” Thus, even if it may not be possible to gain a definitive or comprehensive answer, consultation by the investigator with several representatives who would have some input is encouraged.
- 4.2 Community consultation is similar to stakeholder consultation:
- 4.2.1 If a HHC researcher has already established an on-going relationship with subgroups and leaders in a community, to conduct community consultation they should:
- 4.2.1.1 Discuss the research with the individuals, in groups, and in other ways that will become apparent from these discussions (such as public meeting within the community).
- 4.2.1.2 The consultations should involve interviews, focus groups, discussions, town meetings, public surveys, or other forums. Although the structure of the consultations will vary from community to community, certain elements are essential. The consultations should:
- 4.2.1.2.1 Make clear the range and the general goals of the research that will be conducted using the data.
- 4.2.1.2.2 Make clear whether the community will be able to specify certain types of research for which data may not be used. These exclusions must be established before the data are collected.
- 4.2.1.2.3 Describe the types of investigators (i.e., academic, commercial, or other researchers, basic scientists, clinicians) who will use the data.
- 4.2.1.2.4 Point out that information learned about the samples might be stored in a Web database.
- 4.2.1.2.5 Describe the risks and benefits to the community and what will be done to minimize the risks.
- 4.2.1.2.6 Discuss where and the length of time the data will be stored.
- 4.2.1.2.7 Describe the process that will be used to keep the community informed of how the data are being used.

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4.2.1.2.8 Discuss the option for the community to specify that all data may be withdrawn at any time if they are being used in a way inconsistent with the terms of the original informed consent.

4.2.1.2.9 Describe to the community in an understandable form the plans for disseminating results of future research using the samples.

4.2.2 If an HHC researcher does not have an already established relationship with subgroups and leaders in a community, to conduct community consultation they should:

4.2.2.1 Start by asking people from or who are knowledgeable about the community for names of people with whom to discuss the research

4.2.2.2 Starting points for identifying representatives of a community.

4.2.2.2.1 What is the total number of individuals (approximately) who are part of the named population from which subjects will be recruited?

4.2.2.2.2 What communities exist within that population and what is the total number of individuals (approximately) who are part of those communities?

4.2.2.2.3 Can a particular community or communities within the larger population be identified as an appropriate forum for the consultation?

4.2.2.2.4 Is this community politically organized in any way (i.e., tribe, municipality, etc.)? If so, that political organization, or community leaders, must be consulted.

4.2.2.2.5 If not, are segments of the community politically organized? If they are, will data be collected from one or more of those organized segments? If so, each of these political units should be consulted.

4.2.2.2.6 If no local political organizations exist, then what cultural or other social organizations exist at the local level? If such cultural or social organizations do exist, they should be consulted.

4.2.2.2.7 If no organized groups exist at all, the investigator must identify other effective ways to consult the community.

4.2.3 The researcher is encouraged to engage in community consultation and document such engagement. The researcher should submit a brief summary/description of the attempts that were made to consult with the community (including the type of event, which leadership individuals and groups were consulted, when they were consulted, what was the outcome, etc.). This summary should be included with all other study

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related materials at the time of submission to the IRB for review and approval and/or at the time of continuation.

5.0 Documentation:

- 5.1 Summaries should be submitted at the time of initial review. However if the study is long term, the investigator should make provisions to re-consult the community at a time that seems relevant or appropriate and report these efforts to re-consult at the time of continuation.
- 5.2 Community Consultation by investigators is preferred by the HHC IRB. However, the IRB may review and recommend community consultation for a given study submitted for IRB approval.
- 5.3 The HHC IRB will review the summary from the investigator, and incorporate this knowledge into the assessment of group harms and how best to minimize them.

6.0 References:

- 6.1 Institutional Review Board Management and Function, Bankert, E. A., Amdur, R. J., 2nd Edition, 2006
- 6.2 National Bioethics Advisory Committee (NBAC) - <http://bioethics.gov/>

7.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	SAB/CLB	7/1/11	New Issue

Element I.4.C.