DCLG Supplemental Material

Meeting Summary

Doubletree Hotel
Rockville, Maryland
April 30, 1998 - May 1, 1998

Thursday, April 30, 1998

The meeting was jointly chaired by DCLG members, Ms. Venus Ginés, Ms. Susan Leigh, and Mr. Dan Moore.

Patient/Consumer Issues in Population and Genetic Studies - Part I

Presenters: Richard D. Klausner, M.D., Director, National Cancer Institute (NCI)
Patricia A. Barr, Chair, National Action Plan on Breast Cancer,
Biological Working Group Ethics Subcommittee

The opening session of the meeting was designed to respond to the DCLG's request at their initial meeting in December 1997 for more in-depth orientation to genetic research, particularly population-based studies. Dr. Klausner discussed the role of genes in the etiology of cancer and explained the purpose of research studies that focus on particular populations. Key points of his presentation included:

- The genes in the DNA molecule provide instructions to the body. Variations (altered spellings) in those instructions can lead to disease.
- Almost all genetic "spellings" (99.9 percent) are identical in all population groups; the remaining 0.1 percent are distributed through humankind. Variations *within* groups we identify are as large as those *between* groups.
- Finding genetic misspellings can give us important insights into disease and how to treat it.
- Populations with a common "historically extended" and "genetically-related" family are of interest in genetic research because misspellings are easier to identify in a group with a shared ancestry.
- Studies of genetically-related populations must take steps to avoid the misuse of resulting knowledge to discriminate against, or stigmatize, those populations.
- Genes can change risk but they do not determine fate.

Ms. Barr participated in the meeting via videoconference. She discussed genetic testing, the level of protection against the use of test results, the importance of population-based genetic research, the ethical considerations surrounding it, and how to address them. She said that personally secured genetic tests--not subject to the requirements of publicly supported research--pose the greatest potential for misuse. Her presentation also focused on a community-based study of the BRCA1 gene in the Washington, D.C. area, and its successful approach to involving the target community and securing its support.

General discussion followed the presentations and focused on what Dr. Klausner characterized as a two-

pronged approach to protecting the individual while preserving important genetic research:

1. A credible education process, aimed at the public and policy makers, with credibility--not authority. (The participation of advocates is important to ensuring credibility.)
2. Establishment of operating principles for the use of human tissue specimens in research, including archived specimens.

Education must include explaining the importance of archival tissue for cancer research, identifying the protections that already exist to prevent disclosure of information regarding individual risk, and describing the record of publicly sponsored research in protecting confidentiality.

Dr. Klausner asked the DCLG to review and comment on a draft set of operating principles (attached) to guide genetic studies in specific populations, including populations that are genetically related like the Ashkenazi Jews. Discussion of the principles touched on a number of issues:

- A community or population being considered for study must understand why it is being selected, and should be invited to participate in the study design.
- All diverse communities must participate and benefit from clinical studies.
- Providers must be involved in trials in order to feel comfortable referring patients to them. Principles like those proposed need to apply to clinical trials as well as genetics and informed consent process for tissue donation.
- Limitations of the current health care system reduce provider time available to participate in trials and recruit patients.
- When NCI seeks a community's help, it must expect the community to ask for NCI's help as well.

Action Item: ***DCLG members will provide their input and comments on the proposed operating principles to Dr. Klausner.***

NCI Updates

The session began with Ms. Butler's videotaped introduction of Vice President Gore in January at the Administration's announcement of its plans for increased cancer research funding. The point was made later in the meeting that this video would be an effective promotion piece for NCI clinical trials.

National Cancer Advisory Board

Ms. Nealon reported about DCLG activities to the NCAB's at their February meeting. Ms. Ginés represented the DCLG at the meeting. Dr. Michael Bishop, NCAB chair, expressed support for having NCI, through the DCLG take the lead to integrate consumers into the peer review process.

Clinical Trials Information System Design Meeting

Ms. McCarthy reported on the February meeting which she, Mr. Katz, and Mr. Moore attended as representatives of the DCLG. Participants at the meeting generated a number of recommendations for re-designing NCI's PDQ database describing clinical trials. These included changing the name and making it possible to access as much or as little information as desired.

NCI Bypass Budget

NCI invited a member of the DCLG to join scientists in developing the next three-year bypass budget for the Institute. Several meetings in the fall and a review process in the spring of 1999 will be required. If

interested, members should let Ms. Nealon know. The DCLG representative will be contacted by the NCI Office of Science Policy.

Action Item: ***DCLG members interested in participating in development of the Bypass Budget should submit their name to Ms. Nealon.***

Office of Cancer Survivorship

A conference in March 1998 on research issues in cancer survivorship was attended by Ms. Leigh, Mr. Zebrack and Ms. Stewart. Ms. Leigh presented at the meeting and noted that scientists and researchers are beginning to incorporate the language of survivorship. She also noted the need to address issues of *quality* of life as well as longevity for survivors. Ms. Stewart pointed out that the unexpectedly large response to the conference could be indicative of the response to the proposed DCLG co-sponsored Clinical Trials Forum.

Clinical Trials Initiative

Ms. Mary S. McCabe, RN, Director, Office of Clinical Research Promotion, provided an update on the development of the informed consent templates. Planned focus groups have been completed. DCLG comments were extremely helpful and were incorporated into the revised templates. Once the templates are formatted and produced, the next step will be dissemination.

Action Item: ***Ms. McCabe will provide the DCLG with copies of the revised informed consent templates once they are produced, along with the report from focus groups.***

The clinicalTrials Web site has already been launched--ahead of schedule--in order to publish timely information about the recently announced tamoxifen study. DCLG members are invited to visit the site and offer comment. The site is intended for the public. The URL address is: http://cancertrials.nci.nih.gov and promotional efforts are underway.

Tissue Collection Informed Consent

Dr. Sheila Taube, Associate Director, Cancer Diagnosis Program, updated the DCLG about progress in developing the model informed consent form for tissue collection and the process for using it. A number of institutions have been asked to field test the model, modified as needed for their institution. Participating institutions will be involved in designing the data collection process, and funds will be provided to support that data collection. The experience at one institution, which administers the consent with the assistance of knowledgeable counselors, suggests that the majority of people are willing to provide tissue samples for research.

Working Lunch: Patient/Consumer Issues in Population and Genetic Studies - Part II

Presenters: Sheila E. Taube, Ph.D., Associate Director, Cancer Diagnosis Program, DCTD, NC
Margaret A. Tucker, M.D., Chief, Genetic Epidemiology Branch, DCEG, NCI

The purpose of the session was to respond to the DCLG's request for further orientation on issues discussed at their initial meeting in December 1997. Dr. Taube asked the DCLG to role-play as if they were members of an Institutional Review Board (IRB) being asked to rule on the use of archived tissue. The Group worked through a number of increasingly complex examples, identifying and discussing issues related to

the protection of the individuals from whom the specimens were obtained. Among the issues discussed were:

- How to determine if a specific study represents the "best" use of the specimens.
- The advantages and disadvantages to making study participants or the general public aware of research findings.
- The role of the specimens archivist in protecting the privacy of the donors of coded specimens.
- Barriers to obtaining re-consents (may be expensive and/or not feasible).
- Variations in state laws regarding requirements for tissue retention.
- The Certificate of Confidentiality and the Privacy Act.
- The need to balance the value of research (for both the individual and society) against the potential risk to the individual, and to distinguish between the *perceived* risk versus the *real* risk.
- The distinction between notification of risk related to a gene that directly confers risk and those that may be involved in processes that may or may not be related to disease.
- Legal ramifications of notification of risk.
- Equitable notification across all study participants.

Wrap-up Discussion on Patient/Consumer Issues in Population and Genetic Studies

Facilitator: Tom Kean, M.P.H., President, Strategic Health Concepts, Inc.

Mr. Kean opened the session by summarizing issues addressed thus far in the meeting:

- Genetics primer
- Principles for genetic studies in specific populations.
- Varying standards of protection for privacy and consent for research participants (government-funded research versus clinical practice).
- Community trust (how to build it).
- Tissue Use - Retrospective (use of archived tissue).
- Tissue Use - Prospective (setting standards for conduct of future research).
- Clinical trials (accrual issues).

Ms. Ginés noted that the DCLG's proposed diversity council is a strategy for addressing cultural aspects of many of these issues.

Primer on Genetic Research and Population Studies

A "draft" version of the primer has been prepared for the DCLG in response to their request for more information on how genetic research and population studies contribute to knowledge about the causes of cancer; how they can lead to new strategies for prevention and treatment for cancer; and how an individual's rights should be protected. The DCLG agreed to review the draft primer and provide comments to OLA on the content within two weeks. Distribution of the primer will be discussed with the DCLG.

Action Item:	***The DCLG will review the primer on genetics research and population studies and provide feedback to the OLA, NCI, within two weeks***.
Action Item:	***Ms. Nealon will try to obtain synopses of pending legislation as requested by the DCLG regarding these issues.***

Principles for Genetic Studies in Specific Populations

Further discussion of the operating principles introduced many of the issues and comments offered during the morning discussion:

- The operating principles apply across a number of research areas.
- The objectives, benefits, and other aspects of a study should be articulated to the study population in understandable language.
- Development of a research study should be an interactive process between the researchers and the study population. ("Interact with" rather than "Involve" the community).
- Alternatives to the use of the word "specific" in referring to the study population are needed to make sure the terminology doesn't carry negative connotations.
- Availability of the resources needed to ensure community interaction must be considered.
- Culturally-sensitive approaches to making these principles operational are essential.

The DCLG will provide its comments on each of the principles to OLA.

Next Steps

The DCLG discussed the implications of the morning's discussion of patient/consumer issues in population and genetic studies for them as a group. More information on a number of issues is needed, for example:

- Are there data to verify that federal research protection standards are adequate?
- What do we know about public attitudes/trust regarding medical research?
- What are the arguments *against* informed consent or the use of archived tissue?

The DCLG expressed the need for clarification of NCI's expectations for the Group. Given the limit on time and resources, what should the DCLG being trying to achieve? Ms. Nealon indicated that one of NCI's goals is to have the DCLG advise the Institute on ways to preserve research while protecting the individual. A specific step the Group is now taking now is to review the primer, which will assist in public education around the issues it covers. Ms. Nealon also noted that the issues they are grappling with are difficult ones, and it may take time to develop good strategies, or tactics, for addressing them. The DCLG asked that the NCI identify some "tactical areas," or tangible tasks, on which they can focus their energies.

Mr. Kean summarized the "next steps" on the issues covered during meeting discussion to this point:

- Help NCI complete the primer and principles by providing review and comment to NCI.
- Assemble more information, from existing sources, about the issues being addressed.
- Request NCI to identify short-term tasks or tactics that the DCLG can help with.

A suggestion was made that interactive role-playing might be an effective strategy for pursuing issues at future meetings. It was also suggested that materials such as the primer and principles be tested with non-advocate members of the public as part of the development process.

Action Item:	***OLA will collect additional, existing information on issues identified for the DCLG's consideration, e.g., public perceptions of cancer research.***
Action Item:	***The NCI will identify some specific tasks they want the DCLG to accomplish.***

Cancer Control Future Directions

Presenters: Barbara Rimer, Dr.PH, Director, Division of Cancer Control and Population

Sciences, DCCPS, NCI
Bernard Glassman, Special Expert, Health Informatics, NCI

Dr. Rimer introduced the session by describing the infrastructure and functions of the newly created Division of Cancer Control and Population Sciences (DCCPS). She provided the following definition of cancer control:

> *Cancer control is defined by NCI's Cancer Control Review Group as the conduct of basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that independently, or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity and mortality.*

Dr. Rimer identified the three major components of DCCPS:

1. Epidemiology and genetics (examining cancer causation; includes the Cancer Genetics Network)
2. Surveillance (Data collection and monitoring, e.g., the SEER program)
3. Behavioral Research (Basic bio-behavioral research)

She then described some of the programmatic emphases within DCCPS, such as tobacco control, cancer screening, diet and physical activity, health communications and informatics, and applied demographics. The Applied Demographics Branch will identify special populations that are underserved and conduct research on topics related to their needs, and work with other NCI units on these topics as well. The Office of Cancer Survivorship is also located within the Division, and with growing interest and support, it is expected to be a rich research area.

The DCCPS is seeking strong candidates for positions that are currently open. Ms. Ginés requested information about these positions be shared with the DCLG members, who may be able to facilitate this recruitment process through their own networks of contacts.

(Note added after meeting. Up-to-date information about these positions are available on the NIH Web site at: http:/www.nih.gov/news/jobs and in professional and scientific journals.)

Mr. Glassman provided an overview of some of the new directions in communications utilizing emerging technology. This technology offers an array of opportunities to enhance, although not replace, one-on-one interaction. Some of these new opportunities include:

- Internet, e.g., new NCI cancerTrials site; new Clinical Trials Information System, re-design of PDQ, NCI-sponsored e-mail messages and e-conference with advocates.
- Smart tools (e.g., "smart" phones, "smart" cards, personal digital assistants).
- Tailored materials (using common computer technology to create information that is tailored to personal needs and other characteristics).

Dr. Rimer offered examples of the use of tailored materials from her own research. This research is attempting to determine if tailored materials are effective in helping people make decisions and in changing behavior. In closing remarks, Mr. Glassman expressed an interest in teaching organizations how to develop tailored materials and urged DCLG members to contact him (bernard_glassman@nih.gov) if they are interested.

The Thursday session ended with a presentation by Ms. Ginés on the Hispanic health fair she organized in Atlanta. The fair was culturally appropriate for the targeted community, received broad support from the Hispanic business community and others, attracted a large audience, and resulted in a number of women

obtaining mammography screening.

Friday, May 1, 1998

DCLG Subcommittee Reports

Brief reports from each subcommittee were supplemented by printed copies of subcommittee meeting summaries.

Informed Consent

Ms. Stewart reported on the subcommittee's teleconference. NCI has asked the DCLG to help develop a plan for promotion and dissemination of the revised informed consent templates. The subcommittee met briefly following the April 30th meeting to discuss this issue. Ms. Stewart reviewed some of their preliminary thoughts about promotion strategies and dissemination outlets**.** The point was made that the responsibility for ensuring patient participation in clinical trials is not solely that of the patients.

Communication

Mr. Zebrack reported for the subcommittee. A main theme of their subcommittee discussion has been how to enhance the DCLG's public presence and visibility. Mechanisms for communicating with the broader advocacy community and the public were discussed. As a chartered advisory committee the DCLG will be listed on the advisory boards and groups site available through the NCI Web home page. Further discussion is needed on the type of dialogue the DCLG members can have with the public via the Web site, as well as through the use of other media. One subcommittee suggestion is that a brief news item (on one issue) be developed after each meeting and circulated to the members' organizations and network of contacts.

Genetics Research and Tissue Collection

Ms. McCarthy noted that the DCLG is "under-educated" on genetic research issues, and NCI has responded with the development of the primer. The subcommittee believes that the current focus should be on public education. One approach might be for Dr. Klausner to prepare a brief article on the promise of genetics research that could be made available to organizational newsletters. A presentation on this subject might also be appropriate at next fall's march. The DCLG also needs to think about how they, as advocates, might use the primer. Ms. Nealon encouraged them to think in terms of a broader promotion plan for the primer.

General Discussion Points

- NCI is restricted in its ability to conduct surveys, but the DCLG members may want to discuss issues of concern to NCI that they can address with their constituencies.
- The DCLG is free to request briefings and presentations by NCI staff on issues and programs of interest to them.
- Decisions about presentations at the MARCH have not yet been made. Ms. Leigh will send information to the DCLG via the listserv once the day's agenda is developed.
- The DCLG Web site would be a way of linking to announcements about grants and projects that will be of special interest to the public.

Patient/Consumer Issues in Clinical Trials

Presenters: Mary S. McCabe, R.N., Director, Office of Clinical Research Promotion, NCI
Rosemary Padberg, R.N., Assistant to Associate Director, Early

Detection/Community Oncology Program, DCP, NCI
Richard L. Mowery, Ph.D., Chief, CTMB, CTEP

The session on patient/consumer issues in clinical trials opened with the announcement of a joint NCI/DCLG forum planned for the fall, to address these issues, particularly as they relate to informed consent. DCLG members who volunteered to serve on the planning subcommittee are:

- Ms. Susan Butler
- Mr. Michael Katz
- Mr. Dan Moore
- Ms. Susan Stewart

Ms. McCabe identified three main issues that her office wants to explore with the DCLG and the constituencies it represents: 1) the need to fully inform patients when they are considering participation in clinical trials; 2) the growing workload for Institutional Review Boards (IRBs and centralized IRBs); and 3) privacy and confidentiality of research information. Presentations on these issues were made by Ms. Padberg and Dr. Mowery.

Key points made as part of the discussion following the presentations included:

- Separating the supplemental information from the signed, informed consent document was recommended as a way of making the information more understandable.
- It is important to emphasize is that informed consent is a *process*, not a document.
- Patients are often under great stress when making decisions about treatment in a clinical trial.
- Health care providers, too, often feel time pressures. The current health care system does not place a high value on provider-patient time for interaction, and ways must be found to deal with this problem.

Implications of the central IRB pilot test for the forum:

- Ms. McCabe suggested that, given the lack of knowledge among much of the public about existing safeguards for patients participating in clinical trials, it may be important to make this information available in advance of discussing ways of improving the system.
- Dr. Mowery suggested having a representative from OPRR as well as the chair of a local IRB participate in the Clinical Trials Forum. He voiced the hope that, as a result of that meeting, 1) participants will be better informed about IRBs and 2) will use that information to educate their constituencies and perhaps promote the concept of a central IRB with local institutions.

Plans for the Clinical Trials/Informed Consent Workshop

Mr. Kean facilitated discussion to plan the Clinical Trials Forum. Ms. Nealon opened the discussion by reviewing some of her thoughts about the forum:

- It should not be a one-time event, but the springboard for a continuing effort.
- The DCLG, if it wishes, can provide ongoing leadership for NCI interaction with the greater advocacy community on informed consent issues after the forum.
- Once the outcomes are defined, a call to action would provide further opportunity to engage the advocacy community.

Proposed forum outcomes:

- Education (for both NCI and the advocacy community).
- Dialogue and discussion on the three issues outlined earlier (informing patients, the IRB workload, and privacy and confidentiality).
- Action plans related to each of these issues (for implementation by both NCI and the advocacy community) that will play out over time as the three issues evolve. The nature of these action plans will vary with the issue, depending on their stage of development.

A question was raised about the level of interest among advocates in the IRB issue, and what NCI hoped to obtain from the advocacy community around this issue. Dr. Mowery stated that education of the advocacy community about IRBs--what they are and how they work--is important. He also thinks that this background will help in getting support for the central IRB concept, if it proves workable.

Other comments:

- Couch the discussion in terms of a debate, presenting viewpoints on both sides of the central IRB issue. (Consider inviting IRB members, OPRR representatives and patients who have participated in trials.)
- NCI staff, as well as DCLG and advocates, need more education on the IRB issue.
- Discussion of the IRB issue at the forum may be more informational than action-oriented.
- Identify participants who are active and articulate to participate in an unrehearsed roundtable.
- Provide the framework for why this issue is being addressed (What is the problem?)
- Identify what NCI wants from the advocacy community on the IRB issue and, conversely, determine where the advocacy community is on this issue.

A discussion took place regarding who will be participating in the forum. A variety of viewpoints were expressed. While including only selected organizations and groups has clear drawbacks, there are practical constraints on the number of people to be involved--particularly if it is to be a working meeting with specific tasks/outcomes to be accomplished. At the same time, the range of participants should be broad, e.g., IRB members and representatives from smaller, regional advocacy groups, as well as national advocacy organizations. Resources are limited.

The point was made that the forum is the starting point in a process that has yet to construct the messages it wants to deliver. Perhaps the NCI and the DCLG should be circumspect in this initial effort to avoid the possibility of having events move too quickly without a focus and a process. Since some of the issues are still ill-defined in terms of what the DCLG wants to accomplish or educate others on use the forum to identify the messages and strategies to be taken to a wider audience.

Based on the discussion, the DCLG members concluded that:

- The DCLG should solicit input and interest regarding the meeting from a wide range of groups.
- A specified number of people, based on availability of resources and other factors, will be invited from among those interested. Determining who will be invited depends on further delineation of meeting plans and objectives. The objective will be to be as inclusive as possible in terms of viewpoints represented, while having a manageable size group attend.
- It will be important to place the forum in the context of a larger process that will provide further opportunities for participation and input on a range of issues related to clinical trials.
- Part of the work of the group will be to identify ways of communicating beyond the individuals and groups represented at the meeting.
- The roles of the DCLG in the meeting will be of high visibility. For example, they will co-chair all sessions, and participate on panels.
- Funds need to be provided to support participants who otherwise would not be able to come.

Identification of Topics for Future Discussion

Mr. Kean reviewed the list of topics which the DCLG identified at their initial meeting as being important for future consideration. These include:

- The Human Genome Project
- Orientation for advocates recruited to work with NCI, when appropriate.
- Setting realistic expectations of what the DCLG can accomplish, and maximizing their impact within those parameters.
- Complementary and alternative medicine (CAM), including a briefing on the Office of Alternative Medicine at NIH.
- Education to generate an interest in health information among people who currently under-utilize or do not seek this kind of information.
- Briefings on the range of NCI communications efforts

Future meetings of the DCLG were discussed. DCLG members decided that a day following the Clinical Trials Forum will probably be needed to address the issues raised during the workshop. A regular DCLG meeting was proposed for November. OLA will establish a meeting schedule for FY 1999 and 2000.

During the course of planning for future meetings, members will be asked to identify priorities for consideration. DCLG members agreed that future meetings need to be more interactive, providing greater opportunity for dialogue. Also presenters need to clarify for the DCLG what outcomes they are seeking, and what role they want the DCLG assume.

Action Item:	***A meeting of the DCLG will be held in the fall.***
Action Item:	***OLA will begin developing a DCLG meeting schedule for future years.***
Action Item:	***Co-chairs for the fall meeting will solicit input from other DCLG members regarding priority issues for consideration.***

External Communications

Concerns were raised at the DCLG meeting about the volume of calls and requests to the DCLG members. A log kept by the members showed that the DCLG is not being inundated at this time, although this may change after the Clinical Trials Forum. It was suggested that an external e-mail address be established for the DCLG, separate from the one used for internal communication among members, and that individual e-mail addresses also be considered so that DCLG members can have published addresses that are not their personal or corporately-sponsored ones. Ms. Nealon stated that the OLA will explore these possibilities. One consideration that must be kept in mind is NCI's responsibility for incoming mail. It will important to have a sensitive acknowledgment that directs writers to other sources of information, e.g., the Cancer Information Service (CIS), as needed. Non-electronic communication options were also discussed.

Action Item: OLA will explore the possibilities of external communications mechanisms.

Mechanisms for Selection of New DCLG Members

Presenter: Marianne Alciati, Ph.D., Management Solutions for Health

Dr. Alciati reviewed the findings of her evaluation of the process for nominating and selecting the initial

DCLG members. All DCLG members, as well as a representative sample of other applicants and staff involved in the process were interviewed. The DCLG members have each received a copy of the evaluation report, which reported a generally high level of satisfaction with the process. Her report was followed by a brief discussion of what to do with report. Ms. Nealon pointed out, NCI will be able to identify mechanisms for sharing the results, e.g., presentations at meetings or preparation of journal articles.

Mr. Kean facilitated a review of the eligibility requirements and candidate criteria to nominate and select new DCLG members when the terms of current members expire. DCLG members agreed to keep the current eligibility requirements and candidate criteria (attached) with the following caveats:

- Modify or clarify use of the term "constituency."
- Provide examples of how requirements and criteria played out in current DCLG members.
- Encourage applicants by urging them not to exclude themselves on the basis of a single requirement or criterion about which they have questions (err on the side of applying).

Mr. Kean also led a discussion related to criteria to be used for identifying appropriate consumers to serve on peer review panels. Criteria used to select DCLG members were reviewed for their relevance and appropriateness for screening consumer candidates. The Group agreed on the following DCLG eligibility requirements and criteria to screen potential consumer representatives for peer review:

- Involvement in the cancer experience: a cancer survivor, a person affected by the suffering and consequences of cancer (i.e., a parent or family member), or a professional/volunteer who works with survivors or those affected.
- Cancer advocacy experience (*broadly defined*: self-advocacy can be valuable experience; even submitting an application demonstrates an "advocacy" orientation.)
- Ability to communicate *and* advocate a position effectively.
- Ability to think critically.
- Ability to represent broad issues, think "globally."
- Ability to contribute to an effective group process.

The members agreed that the requirement to represent a constituency was probably not essential for serving on peer review committees, since the consumer representative would not be expected to communicate with the broader advocacy community about his/her experience. Leadership ability, in the usual sense of that term, would also not be essential; however, there was also agreement that consumer representatives need to be sufficiently outspoken (and unintimidated by other committee members) that they can effectively voice their views.

Action Item: Provide DCLG with list of organizations on OLA's its mailing list.

Mechanisms for Identifying Consumer Advocate Representatives on other NCI Committees (including peer review)

Presenter: Marvin R. Kalt, Ph.D., Director, Division of Extramural Activities

Requirements/Criteria

Dr. Kalt thanked the DCLG for their assistance in the development of screening criteria for use in selecting consumer representatives for peer review committees or other committees with similar mandates. He noted that such criteria will be used as "indicators" of consumer appropriateness for an assignment, but will not necessarily be the only basis for selection. Many NCI grantees have their own networks of consumers, for

example, and may identify individuals for service. Dr. Kalt also pointed out that, with the anticipated growth in NCI's research budget, there will be the need for large numbers of committee members. Any criteria developed should be viewed as "markers" that can help identify the best candidates, but should not be rigidly applied in an exclusionary fashion.

Dr. Kalt noted that orientation planned by NCI will help prepare consumer members to be active, vocal participants, and that an educational process for NCI staff is also needed. Feedback mechanisms for evaluating committee experience were recommended to help refine the process by which committees operate. Dr. Kalt stated that review staff are responsible for both getting individual feedback and addressing problems in the review process "on the spot."

These proposed criteria will be forwarded to NCI for their consideration.

Action Item:	***DCLG members should submit names and resumes of potential consumer representatives directly to Dr. Kalt.***
Action Item:	***NCI will provide the DCLG with a brief description of what is entailed in membership on peer review and various other NCI committees, and examples of the range of opportunities that may be available.***

The meeting adjourned at approximately 2:00 p.m. on Friday, May 31, 1998.

Prepared by:

Eleanor Nealon
October 9, 1998

Attachment 1

Genetic Studies in Specific Populations

Principles

- Involve Community in the Design, Discussion, Description and Implementation of Research
- Establish Agreed Upon Vocabulary and Language for the Study
- Establish a Plan for Dissemination of Results, Meaning of Outcomes and Plans for Follow-Up
- Establish Principles of Confidentiality and Informed Consent
- Establish Plan for Education Associated with the Research
- Raising Consciousness

RK Draft 4/29/98
National Cancer Institute

created: 18aug98 Lorrie Smith revised: 24jan00

Attachment 2

National Cancer Institute Director's Consumer Liaison Group

Eligibility Requirements & Candidate Criteria

Eligibility Requirements

Two eligibility requirements were established as minimum requirements for participation in the DCLG. All nominees were initially screened for these requirements. A member of the DCLG had to:

- **Be involved in the cancer experience: a cancer survivor, a person affected by the suffering and consequences of cancer (i.e., a parent or family member), or a professional/volunteer who works with survivors or those affected.**
- **Represent a constituency with which s/he communicates regularly on cancer issues and be able to serve as a conduit for information both *to and from* his/her constituency.**

Candidate Criteria

Once eligibility was established, nominees were assessed based on five candidate criteria. A numeric score was used to score all eligible nominees according to these criteria, based on information provided in their nomination package. These criteria included:

- **Cancer advocacy experience**
- **Ability to communicate effectively**
- **Ability to represent broad issues, think "globally"**
- **Ability to contribute to an effective group process**
- **Leadership ability**