Participants:
CLEK Data Monitoring and Oversight Committee: Gary T. Cutter, PhD (Chair), Bruce A. Barron MD, Robin L. Chalmers, OD.
CLEK Executive Committee: Joseph T. Barr, OD MS, Timothy B. Edrington, OD MS, Donald F. Everett, MA, Mae O. Gordon, PhD, Karla Zadnik.
Guests: Joel Achtenberg, Michael Richman, Ken Schechtman, PhD, Gloria Scott-Tibbs, and Judy Seibert.

Additional Materials for the DMOC
DMOC members will receive all three CLEK Resource Center grants and the four manuscripts from CLEK pilot studies that are in press or preparation.

DMOC Responsibilities
Revisions were made to Section 16.4.2 of the CLEK Operations Manual.

Topography Reading Center
The recommendation was made that videokeratographic data be collected at all 14 Participating Clinics and that a Topography Reading Center be established. It was decided to approach Tomey, Inc. about loaning TMS devices to the 6 CLEK Clinics without TMS devices. Failing that, Clinics will collect videokeratographic data with whatever device they do have. Four inquiries have been received about analyzing videokeratographic data, and the decision about a Topography Reading Center was deferred.

The Chairman’s Office will work out a system to electronically back up the videokeratographic data.

Length of Study
The rationale behind the length of follow-up for CLEK Study patients was discussed.

Forms Production and Processing
Forms production and processing were discussed at length. The Coordinating Center will work on all proposed revisions, eliminating the need for the patient ID # and date on every page, color coding by form type, the possibility of NCR forms, etc. It was suggested that forms be produced at the Coordinating Center and distributed to the Clinics. The forms will be pilot tested by Clinic personnel after the next iteration.

Eligibility
One entry criterion was amended to “cornea scarring characteristic of keratoconus.” There will be an Eligibility Form that Clinics complete on all prospective CLEK Study patients and submit to the Coordinating Center, regardless of final eligibility status.

**Referral Guidelines**
Referral guidelines will be established for abnormal findings, including what to report back to referring doctors.

**Fundoscopy and IOP Measurement**
It was recommended that these measures be trained and certified.

**Visual Acuity and Refraction**
It was recommended that a contact lens-based visual acuity measurement in spectacle wearers be instituted. It was decided that a trial lens equal in base curve to the steep keratometric reading with over-refraction will be used to measure high and low contrast visual acuity in each and both eye(s) of spectacle wearers will be added to the protocol.

Provision for a 1m test distance and measurement of vertex distance will be added to the protocol.

**Scarring and Staining**
Clinicians will draw scars. 3 and 9 o’clock staining will be graded as two stained areas.

**Photography Reading**
All photographs on eyes scored as “probably yes” or “probably no” scarring status will be read by a second Reader.

**Human Subjects Approval**
There was a discussion about individual IRB requirements.

**Surgery**
There was a discussion about identifying CLEK Study patients who are going to surgery. This information will largely depend on the patient supplying it.

Next meeting: Friday, October 13, 1995; location to be announced.
CLEK DMOC Meeting
October 13, 1995
Hotel Durant, Berkeley, California

Participants:
CLEK Data Monitoring and Oversight Committee: Gary R. Cutter, PhD (Chair), Bruce A. Barron MD, Robin L. Chalmers, OD
CLEK Executive Committee: Joseph T. Barr, OD MS, Timothy B. Edrington, OD MS, Donald F. Everett, MA, Mae O. Gordon, PhD, Karla Zadnik, OD PhD
Guest: Michael Richman

Note: Consult DMOC meeting binder for detailed support materials.
Recommendation: Increase reimbursement to patients after a certain level of recruitment. The specifics are to be discussed by the Executive Committee and a proposal submitted to the National Eye Institute.

Action Plan:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible Person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longevity of CPRC Readers</td>
<td>JTB to develop plan for orderly, overlapping transition</td>
</tr>
<tr>
<td>Proactive encouragement of recruitment in December now via Clinic conference calls; tell them new payment scheme (&gt;60 patients or 75% of initial recruitment goal = an increase of 50% in payments across the Study)</td>
<td>KZ to schedule for early November.</td>
</tr>
<tr>
<td>Compare Hispanics to white for baseline differences</td>
<td>MOG</td>
</tr>
<tr>
<td>Compare primary vs. tertiary sites for baseline differences</td>
<td>MOG</td>
</tr>
<tr>
<td>Probation letter to Jules Stein, cc: Mondino</td>
<td>KZ, after NEI approval, with review and approval by DMOC; administrative site visit to Jules Stein (MOG and KZ)</td>
</tr>
<tr>
<td>Letters of concern to P1 and U1, not on probation because of recent upswing, cc: department chairman; will be closely monitored</td>
<td>KZ with approval by DMOC</td>
</tr>
<tr>
<td>Letters of praise to high recruiting Clinics (n=4 have exceeded their goal) cc: department chairman</td>
<td>KZ with approval by DMOC</td>
</tr>
<tr>
<td>Topic</td>
<td>Responsible Party</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>DMOC praise article for all Clinics’ contribution to the Study</td>
<td>11/1/95 newsletter lead article</td>
</tr>
<tr>
<td>Close out recruitment at end of March 1996 for everyone?</td>
<td>Executive Committee to discuss</td>
</tr>
<tr>
<td>Add Clinics?</td>
<td>Executive Committee to initially evaluate Edmonds (Tucson), Miami, Washington DC, Connecticut. Decision within 1-3 weeks maximum.</td>
</tr>
<tr>
<td>Age distribution of enrolled patients by Clinic</td>
<td>MOG</td>
</tr>
<tr>
<td>Retention</td>
<td>Executive Committee to address with Clinic PIs 12/95</td>
</tr>
<tr>
<td>Correspondence between Screening Study patients and current CLEK patients</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>For test-retest analysis; combine steep-K VA with cls + OR in RGP lens wearers and plot; add ± 2 SDs; plot hidden observations</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>Within- vs. between-observer on FDACL</td>
<td>Coordinating Center/TBE</td>
</tr>
<tr>
<td>Consequences of the “Probably no” skip pattern on scarring and staining</td>
<td>Executive Committee to discuss</td>
</tr>
<tr>
<td>Individual photo showing and discussion by individual Clinic in New Orleans 12/95</td>
<td>JTB</td>
</tr>
<tr>
<td>Recertification on photography only based on quality of photographs taken, not number (95% or greater gradability on the most recent photographs)</td>
<td>JTB, KZ in OM</td>
</tr>
<tr>
<td>Recertification month in May of each year</td>
<td>KZ to OM</td>
</tr>
<tr>
<td>Reread corneal photo sample directed by CC should be a random, stratified sample; “probably no” and “probably yes” on scarring need to be oversampled for re-reading</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>FDACL and FDACL +0.2 comparing readers and clinicians 2x2 for 9/95, after FdACL clarification</td>
<td>JTB</td>
</tr>
<tr>
<td>Slide labeling system at the CPRC to be re-evaluated</td>
<td>JTB</td>
</tr>
<tr>
<td>Topic</td>
<td>Responsible Party</td>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>Storage of TMS data in addition to floppy disks</td>
<td>KZ to investigate</td>
</tr>
<tr>
<td>Storage of non-TMS topography data at Clinics</td>
<td>Executive Committee to discuss</td>
</tr>
<tr>
<td>Missing data on TMS Clinic patients reconciled with enrolled patient list</td>
<td>KZ + MR</td>
</tr>
<tr>
<td>Should local IRBs be notified about CLEK Web page?</td>
<td>DFE</td>
</tr>
<tr>
<td>Report on data completeness, error rate, how many forms completed for how many patients</td>
<td>CC to Executive Committee, Full Investigators Group, and DMOC</td>
</tr>
<tr>
<td>Linkage process (missing TMS, forms processing time), also useful for PI Study Group meeting in New Orleans</td>
<td>Coordinating Center, CPRC, Chairman’s Office; report to DMOC</td>
</tr>
<tr>
<td>What analyses will be done? DMOC wants more information about characteristics of patients being recruited, eg, how many scarred.</td>
<td>Executive Committee discussions; report to DMOC</td>
</tr>
<tr>
<td>Pockets of data to stimulate Clinic PIs’ interest for the future. What papers to write? Involve Clinic PIs, beginning with 12/95 meeting.</td>
<td>Executive Committee</td>
</tr>
<tr>
<td>DMOC would like analysis of an issue at the next meeting in 3/96</td>
<td>Coordinating Center to schedule next DMOC meeting</td>
</tr>
<tr>
<td>New Centers: “straggler” vs. cutoff approaches or extend past March for all Clinics</td>
<td>Executive Committee discussion</td>
</tr>
<tr>
<td>Documentation system for describing data sets</td>
<td>Coordinating Center present to Executive Committee; report to DMOC</td>
</tr>
<tr>
<td>Quality control report on existing data</td>
<td>Coordinating Center: number of patients with forms, timeliness of forms, error rate, edit resolution time</td>
</tr>
</tbody>
</table>

**Next DMOC meetings:**
- Conference call week before the Academy meeting
- Conference call last week in January: issues of recruitment extension
- Meeting March 1996.
CLEK Data Monitoring and Oversight Committee Meeting
April 5, 1996
Women’s Faculty Club
University of California, Berkeley

Attendees:
DMOC members: Gary Cutter (chair), Bruce Barron, and Robin Chalmers
Executive Committee members: Joe Barr, Tim Edrington, Don Everett, Mae Gordon, and Karla Zadnik
Joel Achtenberg, Michael Richman, Ken Schechtman, Gloria Scott-Tibbs

Congratulations to all on achieving the CLEK recruitment goals!

<table>
<thead>
<tr>
<th>Activity</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Recertification and turnover issues</td>
<td>All; bring up specific issues as they occur, especially PI shifts</td>
</tr>
<tr>
<td>Corporate sponsorship of film supplies</td>
<td>JTB; contact Kodak</td>
</tr>
<tr>
<td>Resource Center budgets for year 03</td>
<td>Approved by DMOC</td>
</tr>
<tr>
<td>Repeat Visit refusals: present data at FIG meeting, analyze key Baseline</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>variables of participants vs. refusals</td>
<td></td>
</tr>
<tr>
<td>Visual acuity stopping rule</td>
<td>Insufficient information to concur with visual acuity decision.</td>
</tr>
<tr>
<td></td>
<td>Worried about impact on patients being told they would be called back at 1 year.</td>
</tr>
<tr>
<td></td>
<td>Worried that there are hidden VA stopping rule errors outside the group of 146 patients.*</td>
</tr>
<tr>
<td>Manuscript suggestion</td>
<td>Paper comparing effects of standardization of measures from CLEK Survey data to CLEK Study baseline data</td>
</tr>
<tr>
<td>Future meetings</td>
<td>Conference call re: retention October 1996; January 1997</td>
</tr>
<tr>
<td>FIG meeting 12/96</td>
<td>Science writer presentation to Clinic Investigators</td>
</tr>
</tbody>
</table>

*How many of the 146 patients have an inaccurate VA stopping rules all across the board?  
*Look at the VAs that come from the subset compared to everyone else (within and between Clinics).  
*Prevalence of violation of the stopping rule across an examination. 
*How many have Repeat Visits, especially those that straddle when we corrected the problem?
CLEK Data Monitoring and Oversight Committee Meeting
Conference Call
January 17, 1997

Attendees:
DMOC members: Gary Cutter (chair), Bruce Barron, and Robin Chalmers
Executive Committee members: Joe Barr, Tim Edrington, Don Everett, Mae Gordon, and Karla Zadnik
Joel Achtenberg, Teresa Roediger, Ken Schechtman, Gil Pierce, Brad Wilson

<table>
<thead>
<tr>
<th>Activity</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Include “patients yet to be seen” column in Report Card</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>Count patient deaths as “seen within target window,” ie, eliminate them from denominator and presentation</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>Evaluate tracking of visual acuity stopping rule adherence (consider QC/QA sampling)</td>
<td>Executive Committee</td>
</tr>
<tr>
<td>Repeat Visit refusals: present data at FIG meeting, analyze key Baseline variables of participants vs. refusals</td>
<td>Coordinating Center</td>
</tr>
<tr>
<td>CPRC gradability reports by photographers ok, but group them further by Clinic, too</td>
<td>CPRC</td>
</tr>
<tr>
<td>Publication motivation for photographers</td>
<td>CPRC</td>
</tr>
<tr>
<td>Translate ungradable photographs into the proportion of patients with no endpoint ascertainment (scar/no scar). Note: the CPRC has required retakes on 26 patients (not including those with unexposed film).</td>
<td>CPRC/Coordinating Center</td>
</tr>
<tr>
<td>CLEK publication list: some years missing; needs to be updated</td>
<td>Chairman’s Office</td>
</tr>
<tr>
<td>More divisions in visual acuity tables: 20/41 to 20/70; 20/71 to 20/199; worse than 20/200</td>
<td>Baseline Writing Committee</td>
</tr>
<tr>
<td>Executive Committee-approved ancillary studies to DMOC for final approval (only McMahon and Begley impression cytology study)</td>
<td>Executive Committee</td>
</tr>
<tr>
<td>Authorship: need to bring the Clinic Investigators along with primary responsibility for Writing Committees; some focus on less experienced Investigators; generate matrix of manuscripts by Clinics to monitor representation</td>
<td>Full Investigators Group; discuss at FIG meeting in 5/97</td>
</tr>
<tr>
<td>Twice annual list of Writing Committees, progress on papers, etc., to DMOC</td>
<td>Chairman’s Office</td>
</tr>
<tr>
<td>DMOC to receive quarterly Clinic Report Cards, periodic reports to DMOC asking for its help with specific issues</td>
<td>Executive Committee</td>
</tr>
</tbody>
</table>
From 4/96 DMOC minutes: Science writer presentation to Clinic Investigators

• Communications, monitoring of Clinics, retention are all excellent.
CLEK Data Monitoring and Oversight Committee  
June 15, 1998

Participants: Joe Barr, Julia Beiser, Bruce Barron, Robin Chalmers, Gary Cutter (Chairman), Tim Edrington, Don Everett, Mae Gordon, Lisa Jones, Jodi Malone, Tim McMahon, Pat Nugent, Teresa Roediger, Ken Schechtman, Gloria Scott-Tibbs, Brad Wilson, Karla Zadnik

Surgical information
Access presurgical information from surgeons and patients in those patients who have gone to PK. (See Tim McMahon’s paper on this topic from several years ago; first author: Mohamed Dana.)

PCO
Conference call with Barker, Everett, Zadnik, Silbert to discuss more money for coordinator, patients, etc.

UAB and Indiana
To be scheduled this summer (Tim M.: UAB; Tim E.: Indiana). Karla to conduct educational seminar for UAB CLEK patients in early fall.

Study information to patients
Patient-specific Coordinating Center information not advisable. Karla to communicate this decision to Loretta Szczotka (originator of the idea at the 1998 FIG meeting) and the Clinics. Survey PIs and Co-PIs as to what Clinics are telling patients. Look at numbers of PKs and refits by Clinic.

Best corrected visual acuity
Recommended to use “best contact lens corrected visual acuity” as more precise language in publications.

Contact lens-induced changes?
Maybe do a sub-study of patients who would volunteer to not wear a lens for a few days.

Topography data on a web site
No confidentiality issues. Suggests being able to track who’s been in. Robin suggested a “Lotus Notes”-based system.

Baseline correlates of scarring
Multivariate analysis: dummy variable for contact lens wear.

The future
• Support for two years more follow-up, maybe longer (10 years total).
• Support for clinical trial with appropriate effect size, entry criteria, outcome measure, etc.

**Recommendations**
• DMOC never received Protocol memorandum on Presurgical Visits.

• DMOC reviewed PCO, and Executive Committee should “solve the problem.”

• Superb data on retention and quality of follow-up.

• Strong recommendation for continued follow-up of the cohort. More time would be advantageous to assess scarring incidence rates, develop more information on the cohort. Timing and frequency left to our discretion. Very enthusiastic about continuation. Quick timetable to put together an application. May discuss mechanisms with NEI short of a separate grant proposal because we won’t have the requisite data from year 03 to support going forward with year 04. They would sign a letter supporting and endorsing the work done, amazing job of recruitment, retention, etc. (We would draft it.)

• Separate themselves from the clinical trial (representing a new venture), presuming it would have its own DSMC (NEI-appointed) that may or may not include the current DMOC. They would endorse the performance and quality of what’s gone on. “You need to plan it.” Could even represent a conflict of interest between the observational study and the proposed clinical trial. Enthusiasm for going forward with applications, separate from their role on existing CLEK Study.

• Writing Committees: “You have gone overboard in getting other people involved. Now, be just as productive as you can. Problem we picked on earlier is dead.”
CLEK Data Monitoring and Oversight Committee
Conference Call
June 7, 1999

Participants: Joe Barr, Bruce Barron, Robin Chalmers, Tim Edrington, Don Everett, Mae Gordon, Tim McMahon, Ken Schechtman, Karla Zadnik

Retention of patients
• Clinics doing well: Berkeley, Cleveland, Gundersen, Jules Stein, Ohio State
• Clinic on a “downward trend”: Utah
• Clinics to watch: Northeastern Eye Institute, Pennsylvania

Recommendations
• Consider streamlining visual acuity stopping rule vigilance to 10% with more oversight of new people.

• Okay to move to less vigilance on quality grading at the CLEK Photography Reading Center (CPRC), to be determined by CPRC, Coordinating Center, and Executive Committee.

• Consider summary papers/reviews/lectures, etc. periodically to “tell the whole CLEK story”.

• Issue of advisability of a postoperative questionnaire for surgeons raised for advice from the DMOC.

• CLEK at meetings schedule?
The conference call began at 1PM. The purpose of this call was to conduct an executive session for the prior DSMB meeting. The group summarized the issues of the prior meeting. The study continues to go very well and the group was commended for their continued hard work and success. The only difficult issue that arose during the prior meeting was the continued problem of the surgical cases. The committee agreed that the approach developed at the last call to pilot the collection of surgical data in conjunction with annual patient-centered recall of the surgical event was reasonable. However, what was still missing from the discussion was a plan for the analysis of this data with or without the confirmatory reason for surgery. The analysis issue was raised at the meeting in St. Louis and there was not a clear discussion of what progress, if any, had been made in considering this difficult issue of handling informative censoring.

With the number of patients experiencing surgery that are in the same range as the number of patients with new scarring, the analysis issues may not be trivial. The suggestion was made that one of the next periodic conference calls by the Study become dedicated to this issue. Although there have been recognized difficulties in obtaining the data on the reason for surgery, the analysis problems are already present in the dataset and the issue how this will be handled must be brought to a close. There should be estimated numbers of surgeries as it relates to the efforts involved and the potential impact on analyses. From the data presented it appears to be roughly a few per center per year. Recognizing that the pilot study of “friendly” surgeons should provide some immediate information on collecting the reason data and the fact that this issue cannot wait to be resolved until the next meeting, the DSMB requests a report on this issue by early fall with recommendations from the study group.

A second issue discussed was the status of data and the details of the monitoring of the Coordinating Center. While again, the efforts of the Study and the Coordinating Center were praised, it was suggested that 60 days should be sufficient for closing the data files and getting the reports ready for our meetings and/or conference calls. It was recognized that the report presented to the DMOC was one used for the ARVO Investigators meeting and while we are not suggesting duplicating massive efforts for the sake of an arbitrary time window, some of the data could have been more timely. Future cutoffs of 60 days seems reasonable and if a combined report is seen as essential, then scheduling of calls should take this into account. Coupled with this discussion was a request that now that the study is a mature study, a little more information on process of paper production would be useful. Given that we routinely see information on the exemplary performance by the clinics in data collection, transmission and error correction, the DMOC feels that seeing some data on the performance of the investigators and Coordinating Center in meeting the needs of paper writing and
Presentations would be useful. The actual report is left to the judgement of the investigators, but some data that might be useful would be the time from creating a formal paper writing committee to first draft, time from first draft to submission and time from acceptance or rejection to revision. If there are important details on how the system of interaction between investigators and the Coordinating Center works that would be helpful. How this process fits into the process of how priorities are set would also be useful.
CLEK Data Monitoring and Oversight Committee  
Conference Call  
August 24, 2000

Participants: Gary Cutter (DMOC Chairman), Joel Achtenberg, Joe Barr, Bruce Barron, Robin Chalmers, Tim Edrington, Don Everett, Mae Gordon, Tim McMahon, Ken Schechtman, Karla Zadnik

IRB approval status  
Lapse in Pennsylvania College of Optometry’s (PCO) approval (from 7/7/00 to 8/16/00). Karla to call Felix Barker, Director of Research at PCO, to determine the cause of the lapse, eg, were the CLEK clinic personnel late in submitting renewal materials or was there a problem with the timeliness of scheduled IRB meetings. The institution should examine their IRB approval system.

CLEK patient deaths  
Do not report “believed to be unrelated” for patient T1-20011 whose cause of death is unknown.

Do we know there have not been additional, unreported deaths? Missed Visit Forms allow clinics to report deaths. ChoicePoint may report such deaths (Karla to check).

Retention of patients  
• 82 patients have missed their last two consecutive visits. 28 of those have withdrawn participation. Devise centralized system to figure out where the 54 missing have gone.

• How to improve downward trend of “visits completed within target windows” and “visits completed within 6 months” (eg, Alabama, Cleveland)? Think of ways to reverse that trend. Rethink Late Visit Report system, training meeting, etc.

Reports were made from the CPRC, CTRC, and the Coordinating Center (see 8/24/00 binder).

Recommendations from the DMOC  
• Karla Zadnik to contact Pennsylvania College of Optometry officials regarding IRB issues.

• Executive Committee to craft strategies to improve patient retention.

• Institute surgery forms for patients and surgeons.

• Analysis issues: progress made, much more to do, including interpretation of data from a clinical point of view. DMOC encourages brainstorming on how to approach
these issues over the next year. Consider working on it outside Writing Committees alone.
CLEK Data Monitoring and Oversight Committee
Conference Call
August 23, 2001

Participants: Gary Cutter (DMOC Chairman), Joe Barr, Bruce Barron, Robin Chalmers, Tim Edrington, Don Everett, Mae Gordon, Tim McMahon, Karla Zadnik

Discussion of patient withdrawal (page 2.5)
Draft plan for allowing patients to appropriately withdraw from the study when they want to and consider having a signed form for permanent withdrawal.

Letters of commendation to Berkeley, Gundersen, Indiana, Ohio State (page 2.10)
Karla to draft generic letter for DMOC review and production.

Letters of concern to UMSL, Northeastern, PCO, SUNY (page 2.10)
Karla to draft individual letters for DMOC review and production to include general and specific areas to be addressed with a formal response to the DMOC about what will be done to improve performance.

CPRC report
• Website up and running for internal quality control and feedback to photographers.
• Remote reading by Dr. Marjorie Rah at the New England College of Optometry is going very well.

Incident scarring analyses
Consider looking at ROC analyses to provide an efficient summary of the sensitivity and specificity results as well as associated covariates.

Reports were also made from the CTRC, and the Coordinating Center (see 8/23/01 binder)

Recommendations from the DMOC
• Continue the excellent efforts that have been maintained throughout the study.
• Review and implement methods to enhance retention, being mindful of the ethical issues for patient withdrawal.
• Continue to work on analyzing surgical data from a variety of perspectives as well as the natural history data, which can take this censoring into account.
CLEK Data Monitoring and Oversight Committee
Conference Call
September 11, 2002

Participants: Gary Cutter (DMOC Chairman), Joe Barr, Bruce Barron, Robin Chalmers, Tim Edrington, Don Everett, Mae Gordon, Tim McMahon, Karla Zadnik

The DMOC notebook is very nice, and the Resource Centers should be commended on the report.

The report was presented by various resource centers, following and clarifying, where necessary, the report prepared for this meeting. No major issues were identified as part of the report.

Recommendations from the DMOC
• Continue to pursue transplant reasons and collecting high quality post-surgical data. Push the Centers that are dragging their feet on IRB approval.

• HRT data. Need a better plan on what to do with those data, exactly what will be looked at and how.

• Transition plan for end of CLEK Observational Study should be started soon.

• Death surveillance by the Chairman’s Office: National Death Registry.

• Continue discussions of “legitimizing” patient withdrawal.

• Think about clinic personnel incentives for patient completion.

• Economic evaluation assessment approved by the DMOC from a respondent burden point of view.
CLEK Data Monitoring and Oversight Committee
Conference Call
August 29, 2003

Participants: Gary Cutter (DMOC Chairman), Joe Barr, Bruce Barron, Robin Chalmers, Tim Edrington, Don Everett, Mae Gordon, Tim McMahon, Karla Zadnik

The DMOC was very pleased with the study conduct, results presented, and overall performance.

The DMOC encouraged the CLEK Study about the idea of long-term follow-up. They encouraged the Executive Committee to further consider issues of public use, close-out of patients, and tracking of patients. They were willing to write a letter supporting a grant proposal on long-term follow-up.

Recommendations from the DMOC
• Dr. Barron recommended that the CLEK Study use a website to identify patients who have died:
  http://ssdi.genealogy.rootsweb.com
  or

• The Coordinating Center should document navigation of the databases for future use including documentation of data, programs, variable names, etc.