April 14, 1995

TO: CLEK Participating Clinic Principal Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0001

The CLEK Executive Committee discussed the CLEK Study entry criteria during this week’s conference call.

**Background:** If you recall from the Training Meeting, Harald Olafsson raised the issue of ineligibility based on non-keratoconic ocular disease with the example of an eligible patient being one with a corneal transplant in one eye and keratoconus with a cataract in the other. Loretta Szczotka reported that she’s found 20 or so examples. The solution was proposed by Tim McMahon and others that the inclusion criteria be patient-specific and that the exclusion criteria be eye-specific (ie, a seemingly eligible patient could be disqualified if both eyes were ineligible for different reasons).

**Action:** The Executive Committee decided **not to change** the entry criteria as currently described in the Operations Manual. Because the CLEK Study is an observational study to characterize a broad spectrum of patients with keratoconus, the Executive Committee is in favor of including as many patients with keratoconus as possible, including those as described above. We will allow for the possibility of performing subgroup analyses on patients in this particular category.

Please distribute this information to your CLEK Participating Clinic personnel.

cc: CLEK Executive Committee
April 28, 1995

TO: CLEK Participating Clinic Principal Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0002

The CLEK Executive Committee has finally reached a decision on videokeratography. We do not have the resources to have every Participating Clinic possess the same topography unit, nor are the companies involved inclined to donate the necessary instruments.

Thus, the Executive Committee has decided the following:

• Clinics with TMS devices will collect, store, and ship videokeratographic data as described in the Operations Manual and taught at the meeting in Columbus.

• Clinics without TMS devices will collect videokeratographic data on whatever device they do have and store it at their Clinic without centralized quality control, so that the data will be available for analysis eventually.

We realize that this is a compromise position, but we believe it is the best solution to the dilemma of wanting to collect videokeratographic data on all patients enrolled in CLEK without having the full resources to do so.
May 24, 1995

TO: CLEK Participating Clinic Principal Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0003

Enclosed you will find your official CLEK Participating Clinic light meter and accompanying protocol. The protocol is not in the last version of the CLEK Operations Manual, but it will be included in the next revision of the OM.

Thanks to Mark Bullimore, the light meters are calibrated, and the protocol for their use is straightforward.

If you are setting up and dismantling your visual acuity measurement set-up on a regular basis, you will need to follow the light meter protocol each time you do so. Otherwise, please follow the protocol weekly (on the same schedule as keratometer calibration).

In either event, please maintain a log for your Clinic that can be inspected at future site visits noting the date, EV level on your chart, and how you remediated the lighting situation (if necessary), and the final EV level.

Please call if you have any questions.

cc: CLEK Executive Committee
June 7, 1995

TO: CLEK Participating Clinic Principal Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0004

Corneal Topography Data Transfer Protocol

CLEK Participating Clinics using any topography device other than Topographical Modeling System (TMS) will save and store CLEK subject data on site. The following protocol applies only to Clinics using TMS:

1. After capturing four images for each eye, insert a floppy disk in external drive and close drive.

2. Choose the File Handling option on the TMS menu.

3. Choose Copy Video to Floppy.

4. When directory appears, highlight subject’s exam for right eye, and hit “RETURN.”

5. When data has been transferred, remove disk and label with subject’s complete ID number, OD, and date. Cover rectangular cut-out on side of disk with a write-protect label (included in box of disks).

6. Insert second disk and repeat steps 2 - 5 for the left eye.

7. Mail disks to Chairman’s office for storage.
July 7, 1995

TO: CLEK Participating Clinic Personnel Certified for Visual Acuity

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0005

Visual Acuity Protocol: Missed Letters

Some confusion has arisen over the visual acuity protocol, when to stop a given measurement, and how to record it. Here’s the official version:

1. The protocol, as adopted at the Training Meeting in April, called for stopping a visual acuity measurement when the patient missed 3 or more letters on a given acuity line on the Bailey-Lovie chart.

2. Therefore, the patient must read complete lines of letters. **Even if a patient misses the first three letters on a given line**, he or she must still attempt to read all the letters on that line.

3. For example, say a patient reads the first 10 lines without missing a letter (50 letters total correct at that point), then misses the first 3 letters on the eleventh line. He or she **should not stop** but should attempt to read the remaining 2 letters on the eleventh line. If he or she gets the last 2 letters right, the final score for that measurement is 52. If he or she misses them both, the score would be 50; if he or she only gets one of the last two letters correct, the score would be 51. This way, the result is the same, regardless of whether the three letters missed, are the first three on a line, the last three on a line, or some other combination.
July 31, 1995

TO: CLEK Participating Clinic Principal and Co-Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0006

CLEK Protocol on Grafted Eyes

At least two CLEK patients enrolled to date have been patients with one Study-eligible eye and one eye that is status post penetrating keratoplasty. In both cases, the grafted eye was considered too “fresh,” either by the referring doctor or the CLEK doctor, to permit steep-K visual acuity, FDACL, and/or dilation.

At this point in the Study, please refrain from enrolling these patients until later in the recruitment period. Remember, you can enroll patients through March 31, 1996, so these recently grafted eyes can have a chance to “settle in” and then go through the entire protocol. A good guideline would be not to enroll patients with a grafted eye less than 3 months postoperatively; however, this does not represent an exclusion criterion.

If you have any questions, please call me.

cc: CLEK Executive Committee, Michael Richman, Judy Seibert
August 23, 1995

TO: CLEK Clinic Principal Investigators and All CLEK Personnel Certified for Fluorescein

FROM: Karla Zadnik, OD PhD
CLEK Study Chairman

RE: CLEK Protocol Memo #CO-0007

FDACL on Grafts

After requests from various CLEK Participating Clinic Principal Investigators, we have decided to discontinue the requirement of the FDACL protocol on grafted eyes of eligible CLEK Patients.

The FDACL fitting set is not appropriate for grafted corneas, and we do not expect that FDACL results would yield more information than keratometry and/or videokeratography.

Thanks for working with us as we continue to evaluate and revise the CLEK protocol.

cc: CLEK Executive Committee, Michael Richman
August 28, 1995

TO: CLEK Clinic Principal Investigators and All CLEK Personnel Certified for Corneal Photography

FROM: Karla Zadnik, OD PhD
CLEK Study Chairman

RE: CLEK Protocol Memo #CO-0008

Definition of FDACL

The First Definite Apical Clearance Lens is defined on page 9-2 of the CLEK Operations Manual as the **flattest** lens that exhibits a definite apical clearance fluorescein pattern.

In some instances during the reading of certification photographs, we believe we observed that the 0.2 mm flatter than FDACL lens fluorescein pattern looked like clearance. Therefore, we wanted to remind you that it is the **FLATTEST and FIRST** lens that provides definitive apical clearance that is the FDACL lens.

Additionally, it is important to wait until the 0.2 mm flatter than FDACL lens has settled on the eye prior to photographing it.

Please be sure to photograph the lens for habitual fit, FDACLs, and 0.2 mm flatter than FDACLs when they are positioned over the corneal apex.

Also, you can decrease the illumination of the slit beam during FDACL photography to make the patient more comfortable without risking bad photographs.

Many, many thanks for all your hard work.

cc: CLEK Executive Committee, Michael Richman
September 7, 1995

TO: CLEK Clinic Principal Investigators and All CLEK Personnel
Certified for Study Coordination

FROM: Karla Zadnik, OD PhD
CLEK Study Chairman

RE: CLEK Protocol Memo #CO-0009

Presurgical Visit Scheduling

If a patient undergoes corneal surgery for his or her keratoconus within three months of a routine Baseline or Annual CLEK Study Visit, a separate Presurgical Visit does not need to be scheduled.

cc: CLEK Executive Committee, Michael Richman
November 8, 1995

URGENT  URGENT  URGENT  URGENT

TO: CLEK Participating Clinic Personnel Certified for Visual Acuity

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0010
Visual Acuity Protocol Problem

We have found that the visual acuity protocol is being followed only intermittently; it is evident that at some Clinics, when patients say they can’t read any further, they are not required to guess at smaller letters.

- Patients must be **encouraged and required to guess**.
- Patients **cannot stop** reading letters until they miss 3 letters on a given line after reading the entire line, ie, the **last line** of letters for a given acuity measurement has to have either **3, 4, or 5 missed letters** (circled) on the visual acuity worksheet.
- Immediately, please review memo CO-0005 on this topic.
- Visual acuity worksheets should be **submitted on all patients** from this point forward.
- Early next week, the Coordinating Center will be contacting you with a revised visual acuity worksheet.
- I will personally call you as soon as possible to **recertify** you on visual acuity.

cc: CLEK Executive Committee
January 5, 1996

TO: CLEK Participating Clinic Personnel Certified for Keratometry

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0011

Keratometry Off the Scale

When you use the +1.25 D lens to extend the range of the keratometer and the reading is still off the scale, please record it as:

> 60.63

with the > sign “squeezed in” just to the left of the boxes provided on the CLEK Examination Form for the keratometric reading on page 9 of the Examination Form.

cc: CLEK Executive Committee
January 5, 1996

TO: CLEK Participating Clinic Personnel Certified for Fluorescein

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0012

Clinician Grading of FDACL +0.2 mm Lens

In order that we can ultimately compare the Photography Readers’ interpretation of the FDACL +0.2 mm lens on the eye, we need to be sure that the central and peripheral fluorescein pattern of that lens are graded by the Clinician as well.

If the FDACL +0.2 mm lens was not one of the lenses originally inserted on the way to FDACL, be sure and evaluate it after the photograph and record your findings in the grids on pages 15 and 16 of the Examination Form.

cc: CLEK Executive Committee
January 29, 1996

TO: CLEK Participating Clinic Personnel Certified for Keratometry

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0013

Extension of Keratometry Range with +2.25 D

The Principal Investigator for each Clinic has received a keratometer range extension set with +1.25 D and +2.25 D lenses in it, along with a laminated keratometry extension conversion chart (courtesy of Nina Friedman). The pertinent section from the revised Operations Manual (currently in production) will read as follows. Please implement this change in protocol effectively immediately.

8.2.4 Extending the Keratometer’s Range

If the patient’s cornea is steeper than 52.00 D (i.e., off the scale) in either meridian, the range of the keratometer will need to be extended as follows:

1. Insert the supplied +1.25 D lens to the keratometer target (objective side).

2. Table 8-1 should be consulted to convert the readings with the +1.25 D lens in place to actual readings.

3. If the patient’s cornea is off the scale of the keratometer in either meridian with the +1.25 D lens in place, steps 1-2 above should be repeated with the +2.25 D lens in place, consulting Table 8-2 for the conversion of the drum reading to the actual reading.

4. If the patient’s cornea is off the scale of the keratometer in either meridian with the +2.25 D lens in place, record the keratometric meridian in that meridian as “> 68.30,” inserting the “>” sign just to the left of the keratometry reading boxes on the CLEK Examination Form.

cc: CLEK Executive Committee, CLEK DMOC
February 1, 1996

TO: CLEK Participating Clinic Principal Investigators and Co-Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0014

Fundus examination on Repeat Visit patients

In response to a Feedback Report, the CLEK Executive Committee has decided that fundus examinations are not necessary on your remaining Repeat Visit patients.

cc: CLEK Executive Committee, CLEK DMOC
April 29, 1996

TO: CLEK Personnel

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0015

Year 1 Follow-up Visit Target Window

Believe it or not, the time for CLEK Study year 1 visits is upon us. As we discussed at the April 20 Full Investigators Meeting, scheduling restraints are as follows:

- All scheduling windows are tied to the date of each patient’s Baseline Visit, the “target date.”
- The year 1 visit time window “opens” one month prior to the target date.
- The year 1 visit time window “closes” one month after the target date.
- The Coordinating Center will notify Clinics of patients who need to be scheduled and their individual time windows one month in advance of the opening of the window.
- If the patient has not been seen by 14 days after the target date, the Clinic Principal Investigator will receive a Late Visit Form so that the Clinic can provide feedback on the patient’s follow-up status. I will contact the Clinic Principal Investigator soon after the Late Visit Form if the patient has not been seen or is not scheduled to be seen.

For example, suppose your patient # A1-00001-AZ was seen on July 15, 1995 for her Baseline Visit. Her year 1 visit window opens June 15, 1996 and closes August 15, 1996. The Clinic will be advised of this schedule by May 15, 1996. If she is not seen, a Late Visit Form will be sent to the Clinic Principal Investigator on July 1, 1996 for a status report.

If you have any questions, please call me or any member of the Coordinating Center staff.

cc: CLEK DMOC
TO: CLEK Personnel  
FROM: Karla Zadnik  
RE: CLEK Protocol Memo #CO-0016  

Testing Order of Quality of Life Surveys

From this point forward, all CLEK Visits should including having the patients complete both the SF-36 (QL) form (our original quality of life form) and the NEI Visual Functions Questionnaire (VF) form (our new quality of life form).

The Visual Functions Questionnaire form should be completed before the SF-36 form. Please give the forms to the patients stacked so that they will complete the Visual Functions Questionnaire form first.

cc: CLEK Executive Committee  
CLEK DMOC
June 5, 1996

TO: CLEK Personnel

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0017

Pupil dilation for photography

The CLEK Photography Reading Center has noticed that patients’ pupils are sometimes not dilated enough for high quality photography (Table).

<table>
<thead>
<tr>
<th>Clinic</th>
<th>% not dilated</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Alabama at Birmingham</td>
<td>23%</td>
</tr>
<tr>
<td>UC Berkeley School of Optometry</td>
<td>3%</td>
</tr>
<tr>
<td>University Hospitals of Cleveland</td>
<td>22%</td>
</tr>
<tr>
<td>Gundersen Clinic, Ltd.</td>
<td>16%</td>
</tr>
<tr>
<td>Indiana University School of Optometry</td>
<td>13%</td>
</tr>
<tr>
<td>Indianapolis Eye Care Center</td>
<td>35%</td>
</tr>
<tr>
<td>University of Illinois, Chicago</td>
<td>40%</td>
</tr>
<tr>
<td>Jules Stein Eye Institute, UCLA</td>
<td>15%</td>
</tr>
<tr>
<td>University of Missouri-St. Louis</td>
<td>6%</td>
</tr>
<tr>
<td>University of Missouri St. Louis 2nd site</td>
<td>50%</td>
</tr>
<tr>
<td>Northeastern Eye Institute</td>
<td>9%</td>
</tr>
<tr>
<td>NOVA Southeastern University</td>
<td>13%</td>
</tr>
<tr>
<td>The Ohio State University College of Optometry</td>
<td>23%</td>
</tr>
<tr>
<td>Pennsylvania College of Optometry</td>
<td>20%</td>
</tr>
<tr>
<td>SUNY State College of Optometry</td>
<td>28%</td>
</tr>
<tr>
<td>Southern California College of Optometry</td>
<td>20%</td>
</tr>
<tr>
<td>University of Texas at San Antonio Health Science Center</td>
<td>34%</td>
</tr>
<tr>
<td>University of Utah Dept. of Ophthalmology</td>
<td>9%</td>
</tr>
</tbody>
</table>

Percent of Eyes Not Dilated
Please check to see that each patient’s pupils are dilated to at least 5 mm in diameter before proceeding with the oblique photographs.

cc: CLEK Executive Committee, CLEK DMOC
July 17, 1996

TO: CLEK Personnel

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0018

CLEK Protocol by Type of Visit

Please remember that the CLEK Study protocol is the same for every type of patient visit. So, whether the patient is in for a year 1 (or 2 or 3) visit, a presurgical visit, or a repeat visit, the entire protocol is followed according to the CLEK Operations Manual.

cc: CLEK Executive Committee
CLEK DMOC
November 1, 1996

TO: CLEC Personnel  
FROM: Karla Zadnik  
RE: CLEC Protocol Memo #CO-0019

Edit queries on patient-completed forms

Next week you will be receiving the first CLEC Study Quarterly Clinic Report Card. One of the variables on that report card is the % of patient-completed forms with no queries (Edit Reports from the Coordinating Center).

The range across CLEC Participating Clinics of error-free patient-completed forms is from 45% to 61%. We are causing ourselves a great deal of extra work.

Please take the few minutes it requires to review the patient-completed CLEC Study forms while the patient is still there for his or her examination (perhaps while he or she is dilating). That way, missing or incorrect data can be corrected, and you can avoid queries.

cc: CLEC Executive Committee  
CLEC DMOC
TO: CLEK Study Personnel
FROM: Karla Zadnik
RE: CLEK Protocol Memo #CO-0020

Presurgical Visits

The Executive Committee has reviewed the data from the 24 patients we know have undergone penetrating keratoplasty since their CLEK Study Baseline Visit. After considering the discussion about the need for and information gleaned from Presurgical Visits at the Full Investigator Group meeting at ARVO, the Executive Committee has decided to eliminate Presurgical Visits from the CLEK protocol.

This means that you should not schedule Presurgical Visits in the future and that you should cancel any Presurgical Visits that are currently on your appointment books.

cc: CLEK Executive Committee
CLEK DMOC

May 21, 1997

William "Joe" Benjamin, OD PhD
UAB School of Optometry
(205) 934-6763

Nina E. Friedman, OD MS
UC Berkeley School of Optometry
(510) 642-5450

Loretta Szczotka, OD MS
University Hospitals of Cleveland
(216) 844-7408

John Sterling, OD
Gundersen Clinic, Ltd.
(608) 782-7300 X2425

Timothy T. McMahon, OD
University of Illinois at Chicago
(312) 996-5410

Gerald E. Lowther, OD PhD
School of Optometry, Indiana University
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Barry A. Weissman, OD PhD
Jules Stein Eye Institute, UCLA
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Larry J. Davis, OD
UNSL School of Optometry
(314) 553-6367

Joseph P. Shovlin, OD
Northeastern Eye Institute
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Heidi Wagner, OD
NOVA Southeastern University
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Barbara Fink, OD PhD
The Ohio State University, College of Optom
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Joel Silbert, OD
Pennsylvania College of Optometry
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Timothy B. Edrington, OD MS
Southern California College of Optometry
(714) 449-7422

David P. Libassi, OD
SUNY State College of Optometry
(212) 780-5037

Harald Olafsson, OD
University of Utah
(801) 581-4248
June 12, 1997

TO: CLEK Study Personnel

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0021

Topography Protocols

The CLEK-Topography Analysis Group (TAG) provides the following protocol update. This will also be incorporated into a revision of the CLEK Operations Manual this summer, and everyone will receive the revised pages at that time.

1) CONFIDENTIALITY/USE OF PATIENT NAMES: (APPLIES TO ALL TOPOGRAPHY UNITS)
   a) Patient names should not be entered into any patient history screens or ID fields. The official CLEK ID should be used in all fields that request a patient name or ID number. In units which request separate entries for patient name and patient ID, the CLEK patient ID should be input twice. If there are separate fields for “first name” and “last name”, the CLEK ID# should be input into the “last name” field, and the patient’s initials should be put into the “first name” field. The entire 9-digit CLEK ID should be input into any remaining “patient ID” field.
   b) If a clinic requires the use of a unique patient identifier other than the CLEK ID, then such an ID format can be entered in a separate ID field as long as the CLEK ID has been entered under the patient name field and no patient names have been used.

2) NUMBER OF IMAGES CAPTURED
   a) TMS-1 sites:
      At every CLEK visit, each eye should have 4 images captured on the hard drive and downloaded to a floppy which should be sent to the Chairman’s Office until further notice. CLEK topography files should
not be deleted from a Participating Clinic’s hard drive until confirmation is received that a patient’s files have been appropriately received.

CLEK CO-0021
June 12, 1997
Page Two

b) Non-TMS sites:
At every CLEK visit, each eye should have 2 images captured, processed, and stored at the CLEK Participating Clinic until CLEK-TAG institutes back-up and collection procedures of non-TMS topography files.

3) INSTRUMENT BREAKDOWNS

During periods when an instrument is not functioning:
a) The CLEK Participating Clinic should immediately contact the manufacturer to bring the instrument back into service as quickly as possible or to arrange for a loaner unit.

b) The CLEK Participating Clinic should then notify the specified CLEK-TAG member (below) to report the time frame involved and plans to service the unit.

UNIT CLEK-TAG CONTACT:
TMS-1 Loretta Szczotka
EyeSys Tim McMahon
Alcon Tim McMahon
Humphrey Loretta Szczotka

c) If the traditional CLEK topography unit is not functioning during a CLEK patient visit and another Placido-based system is available, topography files should be collected on the available unit. Non-Placido based topography files should not be collected.

4) HARDWARE AND SOFTWARE UPGRADES

Hardware and software upgrades can result in lost data, changes in imaging, varied algorithms, etc., making the assessment of longitudinal data difficult. Prior to any potential hardware or software upgrades, the above CLEK-TAG designated member should be informed so that determination can be made as to the potential harm to the study.

cc: CLEK Executive Committee
CLEK DMOC
February 17, 1998

TO: CLEK Study Personnel
FROM: Karla Zadnik
RE: CLEK Protocol Memo #CO-0022

Topography Protocols

Note that this is a revised version of #CO-0021.

The CLEK-Topography Analysis Group (TAG) provides the following protocol update. This will also be incorporated into a revision of the CLEK Operations Manual this summer, and everyone will receive the revised pages at that time.

1) CONFIDENTIALITY/USE OF PATIENT NAMES: (APPLIES TO TMS, EyeSys, and Humphrey TOPOGRAPHY UNITS)

   a) Patient names should not be entered into any patient history screens or ID fields. The entire, 9-digit CLEK ID should be used in ALL fields that request a patient name or ID number.

   b) If a clinic requires the use of a unique patient identifier other than the CLEK ID, then such an ID format can be entered in a separate ID field as long as the CLEK ID has been entered under the patient name field and no patient names have been used.

2) NUMBER OF IMAGES CAPTURED

   a) TMS-1 sites:

      At every CLEK visit, each eye should have 4 images captured on the hard drive and downloaded to a floppy which should be sent to the Chairman’s Office until further notice. CLEK topography files should not be deleted from a Participating Clinic’s hard drive until confirmation is received that a patient’s files have been appropriately received.

   b) Non-TMS sites:

      At every CLEK visit, each eye should have 2 images captured,
July 22, 1999

TO: CLEK Study Personnel

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0023
Patient Retention

The CLEK Executive Committee has some concerns about the continuation of patients into the five-year extension. One of our Study Coordinators expressed concern that a few patients may only be interested in fulfilling their original three-year commitment to the CLEK Study.

Please add this to your protocol for contacting patients. In the event that a patient chooses to withdraw from the study, the Study Coordinator should notify the Clinic Principal Investigator immediately. The Principal Investigator will call the patient within 24-48 hours to make sure the patient understands the importance of the study and to allow the patient to reconsider his or her decision.

After that, if the Chairman’s Office can assist with any communication directly with the patient, please request it.
TO: CLEK Study Personnel

FROM: Karla Zadnik

SUBJECT: CLEK Protocol Memo #CO-0024
Patient History Form Page 8 – “Woman’s Page”

The year 05 Patient History Form has an additional last page over last year. It is the “Women’s Page” we described and discussed at the May 1999 Full Investigator Group meeting. Your Institutional Review Board will need to be notified that the form has been revised. We suggest the following language:

“One page of questions, approved by the CLEK Data Monitoring and Oversight Committee was added to the current Patient History Form. It is to be completed by the female participants and is only exploratory in nature.”

You should attach a copy of the last page of the Patient History Form for their information.

Of course, if your patients are uncomfortable answering these questions (or any others, for that matter), they can opt not to.
September 11, 2000
FYI only; Nova did not receive the wrong forms.

TO: CLEK Study Personnel

FROM: Karla Zadnik

SUBJECT: CLEK Protocol Memo #CO-0025
Patient History Form Page 8 – “Woman’s Page”

The Coordinating Center has discovered that an incorrect version of the Patient History (PH) form dated 4/1/99 was distributed to some clinics. The correct PH form is the version dated 3/1/00. The wrong version contains a preliminary page 8 “Woman’s Page”. The errors are only on this page. Pages 1-7 of the PH form dated 4/1/99 are identical to the 3/1/00 version and can be used without change.

Your clinic may or may not have both versions of the forms. Please check each patient file to guarantee that the correct version dated 3/1/00 is in the file (date is in the upper right hand corner of the page).

We are supplying you with a master and ten copies of the correct PH page 8 dated 3/1/00. Please replace page 8 for all PH forms in your possession dated 4/1/99. Record the patient’s ID number in the upper right hand corner of the correct page 8, and date and initial this change.
June 13, 2001

TO: CLEK Study Personnel

FROM: Karla Zadnik

SUBJECT: CLEK Protocol Memo #CO-0026 Surgery Forms

The surgical forms, one for patients and one for their surgeons, are enclosed in each Principal Investigator’s version of this packet. The list of patients to whom these forms should be administered now (i.e., those who have had at least one transplant since enrolling in the CLEK Study) is also included in the Clinic Principal Investigator’s version of this packet. For those Clinics that participated in the pilot version of this project, the patients for whom we have already received data are noted on your hard copy. The rest of you are receiving the memorandum only.

These forms should be administered to any patients who have undergone at least one penetrating keratoplasty since their enrollment in the CLEK Study. If they entered the study with a corneal transplant in one eye and have not had another one, they should not receive the forms at this time. Please consult the list of patients to determine who needs to receive the forms now.

From this point on, any patient who is in for a CLEK visit who has had a new transplant since his or her last CLEK visit should receive the forms. The patient completes the “Patient Post-Surgical Report: (PS)” form, including the permission to contact his or her surgeon. Only after he or she has given this permission do you send the “Surgeon Post-Surgical Report: (SS)” out to the surgeon.

You will need to obtain Institutional Review Board approval at your own institution before using this form at all. Please notify the Chairman’s Office when you have that approval by forwarding a copy of the approval.

Please note that the page providing the permission to contact the surgeon should not be sent to the Coordinating Center.
June 19, 2001

TO: CLEK Study Personnel

FROM: Karla Zadnik

SUBJECT: CLEK Protocol Memo #CO-0027 Retention of Patients

Enclosed you will find new pages for your CLEK Operations Manual detailing procedures and protocols for retaining patients in the CLEK Observational Study. Please review this information, and insert these pages into your CLEK Operations Manual.
July 9, 2001

TO: CLEK Study Personnel

FROM: Karla Zadnik

SUBJECT: CLEK Protocol Memo #CO-0028 Reimbursement Payment to Patients

The CLEK Executive Committee has decided to allow each clinical site to adjust its individual reimbursement to participating patients. The CLEK Chairman’s Office will continue to reimburse each patient $50 per annual visit.

The change is that each Clinic Principal Investigator can now decide how much more he or she would like to reimburse the patient for the cost of a CLEK visit. But, the Clinic-specific amount must be supplied to all patients, not just selected ones, and the amount must be approved by the appropriate local Institutional Review Board, and the local IRB approval must be transmitted to the Chairman’s Office.
October 3, 2002

TO: All CLEK Investigators

FROM: Karla Zadnik

RE: CLEK Protocol Memo #CO-0029
Study of the Economic Impact of Keratoconus

At our CLEK FIG Meeting in May 2002, Dr. Steven Kymes presented a proposal for evaluating the economic burden of keratoconus. I was pleased with your enthusiastic response to this proposal. We all know that this information could be helpful in making changes in insurance coverage that would benefit our patients.

The Data Monitoring and Oversight Committee (DMOC) approved Dr. Kymes’s proposal for this protocol modification on September 11, 2002. Attached is a packet for you to use when you submit this modification to your local IRB. It explains the rationale for the addition of the economic evaluation study, and an explanation of the questions being added to the EX form. Please review this information for yourself, and feel free to contact Steve (kymes@vrcc.wustl.edu) or me if you have any questions. Submit your request for approval of the protocol modification to your local IRB as soon as possible, and send the notification of that approval to Jodi Malone at the Chairman’s Office when you receive it.

You will not be able to use the Year 8 CLEK EX form with these economic evaluation questions until you receive IRB approval to this modification. Therefore, it is very important that you receive approval before December 31, 2002. If for some reason you encounter a delay, let me know as soon as possible.