URGENT: Study Invitation for Consideration

The National Kidney Foundation invites you to participate in a Multi-Site Cross Sectional Study estimating the prevalence of Chronic Kidney Disease in Adults with Type 2 Diabetes Mellitus; Awareness, Detection and Drug Therapy in Type 2 Diabetes Mellitus and Chronic Kidney Disease (ADD-CKD). The study will:

- **Utilize some sites with no previous research experience, as well as sites with prior research experience.**
- **Require a commitment of only one study visit for each study participant.**
- **Offer compensation to Primary Care Physicians, Primary Care Nurse Practitioners, AND study participants.**

**Study objectives**

To better understand and characterize the prevalence of CKD in adult patients with type 2 diabetes mellitus through a survey of a representative sample of adult US patients and their primary care providers.

**Study design**

This observational study will assess the care of adult patients with type 2 diabetes mellitus using the following:

- Primary care provider survey
- Patient physical exam, medical history, and medical record review
- Blood draw to determine eGFR and HbA1c (lab)
- Urine dipstick test for proteinuria (office) and a spot urine for determination of albumin/creatinine ratio (lab)
- Two short patient Quality Of Life (QOL) questionnaires

Data will be collected using a secure online electronic data capture (EDC) system. Patients will have their labs drawn at a local Quest laboratory if available. (If not available samples will be drawn in the primary care provider’s office and sent to a specified Quest central laboratory). The protocol has been approved by a single central institutional review board (IRB) prior to enrollment of any patients.

**Study population**

Each approved Practitioner will need to recruit 21 patients with type 2 diabetes mellitus over 5 months.
RETURN THIS FAX COVER SHEET

TO: ADD-CKD Study Team
FAX NUMBER: 888-955-7627

DATE: 
NUMBER OF PAGES: (Including cover)

Site Information

SI/Primary Care Practitioner First Name: ____________________________
SI/Primary Care Practitioner Last Name: ____________________________
Institution/Practice Name: ____________________________
Business Phone Number: ____________________________
Business Fax Number: ____________________________

If you are interested in participating or hearing more about this study, please submit the attached questionnaire and a signed Confidentiality Agreement within 1 week of receipt. The original Confidentiality Agreement is for you to retain for your files.

Completion of these documents does not obligate you to participate in the study. Your responses will be evaluated to assess eligibility for participation.

Please send this coversheet, Confidentiality Agreement and Questionnaire via
- FAX, toll free 888-955-7627
- or e-mail, ADD-CKDSTUDY@COVANCE.COM

If there are any necessary revisions to the Confidentiality Agreement, please contact the study team at 1-888-430-6574 and we will promptly send out a revised version.

If you are not interested in participating in the study, please only return this cover page.

☐ Yes, I am interested in participating in this study.
☐ No, I am not interested in this study. If no, what is the reason?

___________________________________________________________________________

Please forward this opportunity to a colleague who may be interested in participating.
Please contact the ADD-CKD Study team toll-free at 888-430-6574 if you have any questions.

**Site Investigator / Primary Care Practitioner**

**Site Investigator (Physician or Primary Care Nurse Practitioner) Information**

Site Investigator Name: ______________________________________________________

Organization/Institution: ______________________________________________________

Street Address: ___________________________________________________________

City: ___________________________  State: ___________  Zip Code: _____________

Phone Number: (______)________________  Fax Number: (______)_________________

Email address: _______________________________________________________________

Best time to contact (day of week and time):____________________________________

Best way to contact                                   Phone  ☐    Email  ☐

**Inclusion Criteria for Investigators: (Each of the following two boxes must be checked signifying that they apply to your practice to be eligible.)**

☐ I provide primary care

☐ I am able to use the central institutional review board (IRB)

**Specialty: (Choose those [1 or more] that best describe your practice)**

☐ Internal Medicine

☐ Family Medicine

☐ Primary Care Nurse Practitioner

☐ Other: _________________________________

How many years have you been in practice? ____________ years

**Patient Population (Please provide your best estimate)**

(1) How many patients per week with type 2 diabetes mellitus do you see? ________pts/week

(2) Do you think you could enroll 21 patients into the study within a five month period?   Yes ☐  No ☐

**Data Collection**

(1) My office has converted to electronic medical records electronic medical records (EMRs)

☐ Yes, fully converted

☐ Yes, partially converted

☐ No, has not converted

(2) Do you have a fax machine in your office?   ☐ Yes ☐ No
(3) Do you have internet access in your office?  □ Yes □ No

(4) Have you or your staff worked with a web-based electronic data collection?  □ Yes □ No

(5) Do you have a **Quest** lab within 10 miles of your office?  □ Yes □ No □ I don’t know

*Please note:* If you do not have a Quest lab within 10 miles of your office, are you or one of your staff qualified to draw patient blood samples and **centrifuge one tube** in your office with the provided lab kits?  □ Yes □ No

**Study Nurse/Study Coordinator Information**

Name: ______________________________________________________________________

Organization/Institution: __________________________________________________________

Street Address: ______________________________(Complete below if different from Site Investigator Information)

City: ____________________________ State: _____________ Zip Code: _____________

Phone Number: (______)________________       Fax Number: (________)_________________

Email address: __________________________________________________________

Best time to contact (day of week and time):__________________________________________

Best way to contact                                   Phone □       Email □

**Site and Previous Study Information**

(1) How would you best describe your practice? *(Check all that apply)*

□ Solo   □ Group   □ Medical School   □ HMP   □ Non-Government Hospital

□ Government Hospital   □ Other: ____________

(2) How would you describe the location of your practice? *(Please check one that best describes your practice)*

□ Urban   □ Suburban   □ Rural

(3) How many research studies have you participated in?

□ 0   □ 1-5   □ 6-10   □ Other: ____________

(4) Have you ever been audited by the FDA?  □ Yes □ No

If yes, during an audit have you ever received a FDA Form 483  □ Yes □ No

*(If yes, attach copies of FDA Form 483)*
ADD-CKD STUDY

SITE INVESTIGATOR CONFIDENTIALITY AGREEMENT

This Agreement is between National Kidney Foundation, Inc, a not-for-profit organization incorporated in the State of New York, with its principal address at 30 E. 33rd Street, New York, New York 10016 (“NKF”), Boehringer Ingelheim Pharmaceuticals, Inc., a Delaware corporation, with offices at 900 Ridgebury Road, Ridgefield, Connecticut 06877 (“BIPI”), Eli Lilly and Company, with offices at Lilly Corporate Center, Indianapolis, Indiana 46285 (“Lilly”), Covance Inc., a Delaware corporation whose principal place of business is 210 Carnegie Center, Princeton, New Jersey 08540 (“Covance”), and ________________________________________, (“Site Investigator”) a primary care physician or primary care nurse practitioner licensed in the State of ___________________________ who is participating in a cross sectional study estimating the prevalence of Chronic Kidney Disease (CKD) in adult Type 2 diabetic patients, known as Awareness, Detection and Drug Therapy in Type 2 Diabetes Mellitus and Chronic Kidney Disease (ADD-CKD) (the “Study”).

WHEREAS, NKF is considering engaging the services of Site Investigator in connection with the Study;

WHEREAS, Site Investigator is engaged in medical research and is considering serving as an investigator for the Study;

NOW, THEREFORE, in consideration of mutual promises, NKF, BIPI, Lilly, Covance and Site Investigator (each, a “Party” and collectively, the “Parties”) agree as follows:

During participation in the Study and in recognition of the confidential nature thereof, Site Investigator hereby agrees:

a) to receive and hold all Proprietary Information, as defined below, in confidence and to not otherwise use such Proprietary Information for his/her own benefit;

b) not to disclose any Proprietary Information to any person, other than Site Investigator’s employees, subcontractors, agents, associates or affiliates, on a need to know basis, and who are bound by confidentiality terms at least as onerous as those of this Agreement, without the prior written consent of NKF, BIPI, and Lilly; and

c) not to permit any person to do any act or make any omission prohibited by this Agreement.

The foregoing shall not apply to any Proprietary Information which:

a) is or subsequently becomes part of the public domain through no fault of Site Investigator;

b) is received from a third party under no obligation of confidentiality to NKF, BIPI, or Lilly
c) was known by Site Investigator at the time of disclosure as shown by contemporaneous written records; or

d) is required by law to be disclosed, provided, however, Site Investigator will notify NKF, BIPI, and Lilly, in writing, promptly of any such request in order to provide an opportunity for NKF, BIPI, or Lilly to seek a protective order.

For purposes of this Agreement, “Proprietary Information” includes, but is not limited to, the Study Protocol, information contained in any regulatory filling with the United States Food and Drug Administration and/or regulatory authorities of other countries, patient case report forms and/or adverse reaction report forms and other trade secrets and confidential information of NKF, BIPI, Lilly or Covance, other study related materials, business plans or information to the effect that the Study is being performed, or any results thereof.

The Parties undertake to protect Proprietary Information (including but not limited to patent-relevant, scientific or technical information) against unauthorized access by third parties. If Proprietary Information is communicated via internet mail, use of internet mail encryption technology is compulsory. Without limiting the foregoing, any failure by any Party to use such Internet mail encryption technology in its communication of any Proprietary Information shall not affect the confidential and proprietary nature of such information. Rather, such information shall continue to be Proprietary Information and subject to the restrictions of this Agreement.

The obligation of confidentiality shall apply for a period of fifteen (15) years from receipt of Proprietary Information.

Proprietary Information received or generated by Site Investigator, or any agents, shall be and remains the property of NKF, BIPI, Lilly or Covance, as applicable, and any and all documents furnished shall be promptly returned upon the request of NKF, BIPI, or Lilly.

This Agreement shall in no way be construed as the granting of a license or any right, title or interest in or to any invention or of any Proprietary Information, by BIPI, Lilly or Covance to Site Investigator, directly or indirectly, whether or not under any patent or patent application owned by the person(s) or institution(s) represented by NKF, BIPI, Lilly or Covance. Furthermore, nothing in this Agreement shall be interpreted so as to oblige any party to enter into a further agreement.

By signing below, the Site Investigator agrees that NKF and/or its affiliates, BIPI and/or its affiliates, and Lilly and/or its affiliates may retain and make use of personal information provided by the Site Investigator for inclusion in databases of the NKF, Covance and/or its affiliates, BIPI and/or its affiliates, and Lilly and/or its affiliates, which are used for the purpose of identifying skills, facilities and any other information relevant to the performance of services for the Study being conducted by NKF on behalf of BIPI and Lilly.

It is understood and agreed that nothing herein shall guarantee the Site Investigator any work and that Site Investigator can revoke the consent set forth in the immediately preceding paragraph by providing notice in writing to NKF, Covance, BIPI, and Lilly.

Each Party hereby recognizes that any disclosure of any Proprietary Information may result in irreparable harm to the disclosing Party that cannot be calculated or fully or adequately compensated by the recovery of damages. As a result, the disclosing Party shall, in addition to any other relief available to it, be entitled to the remedy of injunction without having to establish the inadequacy of any other remedy available to it.

Site Investigator has read and fully understands the terms of the aforementioned Agreement, and by its signature subscribed hereto, accepts the terms thereof.
National Kidney Foundation, Inc.:

Name ___________________________________________

Title ___________________________________________

Signature ______________________ Date

Covance, Inc.:

Name ___________________________________________

Title ___________________________________________

Signature ______________________ Date

Site Investigator:

Site Investigator [Print Name]
(If a Primary Care Nurse Practitioner is acting as Site Investigator please have MD or DO co-sign this document below).

Please Note: Do to varying State laws, two documents will require a MD or DO co-signature. This co-signature will only be required for this document and the Investigator Site Agreement. ALL OTHER DOCUMENTS only need the NP’s signature if the NP is acting as the Principal Site Investigator.

______________________________ Date

Site Investigator [Signature]

Physician Co-Signer:

If applicable Physician Co-Signer [Print Name]

______________________________ Date

If applicable Physician Co-Signer [Signature]