Nephrotic Syndrome Clinical Trial Participation Roles

Relationship Guide
Among Patient, Primary Nephrologist, and Clinical Trialist Nephrologist

The advancement of new therapies to treat rare debilitating diseases requires the participation of patients in clinical trials to demonstrate the effect of these agents. Often these trials represent the only access to investigational agents that may result in disease improvement (though never assured). This Memorandum of Understanding provides some clarity regarding the important roles of those involved with participation in a Nephrotic Syndrome clinical trial. Adherence to the suggested roles helps ensure that all parties are well informed, work collaboratively, share in valued learnings, and have an overall positive clinical trial participation experience.

Primary Nephrologist (PN)

- Serves as 'quarterback' central role in coordination of care - encourages appropriate patient referrals for screening and enrollment in trials for which they may be eligible, makes final, shared decision with patient whether to enroll in clinical trial after initial information/screening
- Works with managed care / insurance provider
- Provides needed lab and other patient data to Clinical Trialist
- Integrates closely with Clinical Trialist – notifies the study team of potential changes in medication and clinical status, shares safety/clinical concerns regarding patient's condition with clinical trialist and makes shared decision with patient to continue participation in clinical trial
- Resumes full care of patient once trial is complete or participation-completing end-point (ESRD requiring dialysis) has been reached

Clinical Trialist Nephrologist (CTN)

- Serves as point of contact for all clinical study related matters
- Primary interface with trial sponsor, IRB, and study site
- Integrates closely with Primary Nephrologist (provide updates on trial related care – including forwarding central lab results; informs PN about trial opportunities for other patients)
- Provides easily accessible contact information to the primary nephrologist (e.g. email, cellphone, etc.)
- Practices within the scope of issues related to the disease state qualifying the patient for the trial and trial related nephrology issues
- Encourages patients to follow up with their PN who will continue to manage general nephrology issues outside the scope of the study
- Refers the patient back to the primary nephrologist upon study completion or reaching a participation-completing end-point (ESRD)

Patient

- Agrees to be compliant with all Primary Nephrologist appointments
- Agrees to actively share information with both PN and CTN
- Agrees to terms of clinical trial participation