

## **Procedure for Handling Questions Regarding Eligibility**

Circumstances may arise in which a patient being evaluated for entry into a study may not meet all eligibility criteria in a strict sense, yet an Investigator may feel that the spirit of the criteria are still being met. Alternatively, there may be a question about applying an eligibility criterion in a particular case. In these circumstances, the Investigator should not make a unilateral decision to randomize the patient but should seek approval. It is intended that granting such exceptions to eligibility criteria should be rare. Allowing patients who are technically ineligible into the trial requires making explanations (to the DSMB and in trial publications) that ultimately can have a negative impact on how the study is perceived. This must be balanced against the slightly faster accrual resulting from granting exceptions to eligibility criteria.

When these circumstances arise, the Investigator should contact the BCC (ATTN: Kim Dandreo) and provide a written explanation of the situation providing enough information to allow an informed adjudication process. An Eligibility Committee comprised of the Chair of the Steering Committee, PI (or Co-PI) of the Coordinating Center, a representative from NIDDK, and two SC-approved site PIs (i.e. one urologist and one urogynecologists), will discuss the matter, typically by email.

Recognizing that it may be difficult to contact Committee members on short notice, a minimum of three members should discuss and agree to a decision. If they do not agree or do not feel comfortable with making a decision without additional input, they may call upon additional expertise as appropriate. An Investigator should not be involved in adjudicating a case from his/her own site (or subsites of that center).

If appropriate, an explanation of the issue and decision should be documented on Form 90 (Unexpected Event or Protocol Deviation).