FORM NUMBER = (FORM) FORM VERSION = (VERS)

NIH - BPH CLINICAL TRIAL

NON-SCHEDULED BIOPSY INFORMATION

This form should be completed any time after randomization that a biopsy is performed that is for a patient who is not participating in the biopsy substudy or for a patient who is participating in the biopsy substudy, but the biopsy was performed outside the study (tissue was NOT processed by the Diagnostic Center). This form should also be completed for invasive therapy procedures that entail pathology reports for prostate tissue taken.

A. Patient Identification		
1. Patient number (PATID)	clinic patient	
2. Patient's initials (INITS)	first last	
3. Patient's date of birth (DOB)	month day year	
B. <u>Visit Information</u>		
1. Date of procedure (GVSTDT)	month day year	
2. Week of visit (GVIWK)	VEC. NO	
Is the pathology information from a TRUS invasive therapy)? (GVITBX)	/Biopsy (not an	
If YES, continue. If NO, SKIP to question	C.2.	
4. Sonographer's initials (GVISONI)		
5. Reason for biopsy (Check all that apply)	first last Follow-up PSA Result (GVIRPSA)	
	Follow-up DRE (GVIRDRE)	
	Patient Choice (GVIRPC)	
	¹ Other, specify below (GVIRO)	
	(GVIROX)	
C. Biopsy Information and Results		
1. Number of cores obtained (GBICORE)		
2. Pathology Results (Check all that apply)	Cancer (Complete section a)	(GBRCAN)
	Dysplasia / PIN (Complete section	(GBRPIN)
	1 Prostatitis	(GBRPROS)
	¹ Atrophy	(GBRATRO)
	¹ Hyperplasia	(GBRHYP)
	None of the above	(GBRNONE)

Patient number Date of procedure month day year	BPH FORM P04.2 February, 2001 Page 2 of 2
a. If Cancer checked in Question C.2, complete this section	
i. Primary Gleason Score (GBCG1)	
ii. Secondary Gleason Score (GBCG2)	
iii. Gleason Sum (GBCGS)	
b. If Dysplasia / PIN checked in Question C.2, complete this section	
i. Grade (GBPGRAD) 1 Low (I) 2 High (II or III)	
3. Is a copy of the pathology report attached? (GBRRPT) YES NO 1 2	
If NO:	
a. Why not? (GBRRPTW)	