

UT MEDICAL GROUP, INC. Administration ATTN: Office of Clinical Research 66 North Pauline Street, Suite 300 Memphis, Tennessee 38105 901-448-6070 • Fax: 901-448-1512

**Instructions:** All clinical research activities involving the use of facilities, equipment, and/or personnel of UT Medical Group, Inc. (UTMG) must be reviewed and approved not less than thirty (30) days prior to study initiation. Complete this Request form and submit it with the additional documentation identified on page 3 to the Director, Office of Clinical Research at the above address.

I. STUDY				
Protocol Title:				
Protocol No.:	Sponsor Name:			
Approximate Research Start Date:	Approximate Research End Date:			
Type of Study :				
Drug(s). Investigational New Drug (IND)	Drug(s). Investigational New Drug (IND) No.:			
Drug Trial Phase: 🗌 I 🔄 II 🔄 II/III 🔄 III 🔲 IV				
Device(s). Investigational Device Exemption	Device(s). Investigational Device Exemption (IDE) No.:			
Device category: A B				
IDE Exempt Investigation? 🗌 Yes 🗌 No				
Other. Please explain:				
Will the study be conducted in a UTMG facility? 🗌 Yes 🗌 No. If Yes, please complete Section III.				
Will UTMG equipment be used for the study?	s 🗌 No. If Yes, please explain:			
Will UTMG personnel be used for the study: 🔲 Yes 🗌 No. If Yes, please explain:				
Has the appropriate departmental Director of Operations been contacted regarding the study?  Yes No. If No, please explain:				
II. PRINCIPAL INVESTIGATOR				
Name:				
Position and/or Title: Organization through which research being conducted:				
Mailing Address:				
Email: Telephone	Number: Fax:			
III. FACILITIES (UTMG facilities where any study services and/or procedures will be performed)				
Family Medicine - 1301 Primary Parkway     Family Medicine - 1999 Highway 51 South, Covington				
Medicine - 1325 Eastmoreland Ave., Suite 360	Medicine - 1325 Eastmoreland Ave., Suite 365			
Medicine - 7945 Wolf River Blvd., Suite 120	Medicine (Harbor of Health) - 718 Harbor Bend Road			
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OB/GYN - 880 Madison Ave., Suite 3D01	OB/GYN - 880 Madison Ave., Suite 3E01			

□ OBJ/GYN - 7945 Wolf River Bivd., Suite 320         □ Ophthalmology - 930 Madison Ave., Suite 200       □ Ophthalmology - 930 Madison Ave., Suite 400         □ Ophthalmology - 7945 Wolf River Bivd, Suite 240       □         □ Otolaryngology - 777 Washington Ave., Suite 110       □ Otolaryngology - 7945 Wolf River Bivd, Suite 220         □ Pediatrics - 777 Washington Ave., Suite 110       □ Pediatrics - 777 Washington Ave., Suite 240         □ Pediatrics - 777 Washington Ave., Suite 110       □ Pediatrics - 777 Washington Ave., Suite 240         □ Pediatrics - 777 Washington Ave., Suite 350       □ Pediatrics - 7945 Wolf River Bivd, Suite 250         □ Psychiatry - 1325 Eastmoreland Ave., Suite 220       □ Surgery - 1325 Eastmoreland Ave., Suite 310         □ Surgery - 1325 Eastmoreland Ave., Suite 220       □ Surgery - 7945 Wolf River Bivd., Suite 280         □ Urology - 7945 Wolf River Bivd., Suite 200       □ Urology - 7945 Wolf River Bivd., Suite 280         □ Urology - 7945 Wolf River Bivd., Suite 350       □ Urology - 1264 Wesley Dr., Suite 601         □ Other: <b>U IV. STUDY COORDINATOR</b> Name:         Name:       □         UTMG employee?       Yes       No         If No, employee of.       Maling Address:         Email:       Telephone Number:       Fax: <b>V. INSTUTIONAL REVEW BOARD</b> Name of Institutional Review Board (IRB): <td< th=""><th colspan="7">III. FACILITIES (UTMG facilities where any study services and/or procedures will be performed)</th></td<>	III. FACILITIES (UTMG facilities where any study services and/or procedures will be performed)						
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Otolaryngology - 777 Washington Ave., Suite 110       Otolaryngology - 7945 Wolf River Bivd, Suite 220         Pediatrics - 777 Washington Ave., Suite 110       Pediatrics - 777 Washington Ave., Suite 240         Pediatrics - 777 Washington Ave., Suite 350       Pediatrics - 7945 Wolf River Bivd, Suite 250         Paychiatry - 135 North Pauline St., 6 <sup>th</sup> Floor	Ophthalmology - 930 Madison Ave., Suite 200		Ophthalmology	Ophthalmology – 930 Madison Ave., Suite 400			
Image: Surgery - 1325 Eastmoreland Ave., Suite 350       Pediatrics - 777 Washington Ave., Suite 250         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 410       Surgery - 7945 Wolf River Blvd., Suite 280         Image: Surgery (Plastic) - 7945 Wolf River Blvd., Suite 290       Urology - 7945 Wolf River Blvd., Suite 350         Image: Urology - 7945 Wolf River Blvd., Suite 350       Urology - 1264 Wesley Dr., Suite 601         Image: Wirdle COORDINATOR       Name:         Image: Wirdle COORDINATOR       If No, employee of:         Mailing Address:       Telephone Number:       Fax:         Image: Wirdle COORDINATOR       If No, employee of:         Name of Institutional Review Board (IRB):       IRB No.( <i>if available</i> ):         IRB submission date:       Expected IRB review date:         V. SUBJECT RECRUITMENT       Anticipated number of subjects to be enrolled in study:         Summarize the services and/or procedures that will be used for identification and recruitment of UTMG patients as potential study subjects:         VII. BILLING INFORMATION         Will patients insured by Medicare potentially be enrolled i							
Image: Surgery - 1325 Eastmoreland Ave., Suite 350       Pediatrics - 777 Washington Ave., Suite 250         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 220       Surgery - 1325 Eastmoreland Ave., Suite 230         Image: Surgery - 1325 Eastmoreland Ave., Suite 410       Surgery - 7945 Wolf River Blvd., Suite 280         Image: Surgery (Plastic) - 7945 Wolf River Blvd., Suite 290       Urology - 7945 Wolf River Blvd., Suite 350         Image: Urology - 7945 Wolf River Blvd., Suite 350       Urology - 1264 Wesley Dr., Suite 601         Image: Wirdle COORDINATOR       Name:         Image: Wirdle COORDINATOR       If No, employee of:         Mailing Address:       Telephone Number:       Fax:         Image: Wirdle COORDINATOR       If No, employee of:         Name of Institutional Review Board (IRB):       IRB No.( <i>if available</i> ):         IRB submission date:       Expected IRB review date:         V. SUBJECT RECRUITMENT       Anticipated number of subjects to be enrolled in study:         Summarize the services and/or procedures that will be used for identification and recruitment of UTMG patients as potential study subjects:         VII. BILLING INFORMATION         Will patients insured by Medicare potentially be enrolled i							
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Psychiatry - 135 North Pauline St., 6 <sup>th</sup> Floor         □       Surgery - 1325 Eastmoreland Ave., Suite 220         □       Surgery - 1325 Eastmoreland Ave., Suite 410         □       Surgery (Plastic) - 7945 Wolf River Blvd., Suite 290         □       Urology - 7945 Wolf River Blvd., Suite 350         □       Urology - 7945 Wolf River Blvd., Suite 350         □       Urology - 7945 Wolf River Blvd., Suite 350         □       Urology - 7945 Wolf River Blvd., Suite 350         □       Urology - 7945 Wolf River Blvd., Suite 350         □       Urology - 1264 Wesley Dr., Suite 601         □       Other: <b>IV. STUDY COORDINATOR</b> Name:       UTMG employee?         UTMG employee?       Yes         Mailing Address:         Email:       Telephone Number:         Fax: <b>V. INSTITUTIONAL REVIEW BOARD</b> Name of Institutional Review Board (IRB):       IRB No.( <i>if available</i> ):         IRB submission date:       Expected IRB review date: <b>V. ISUBJECT RECRUITMENT</b> Anticipated number of subjects to be en	Pediatrics - 777 Washington Ave., S	Suite 110	Pediatrics - 777	Washington Ave., Suite 240			
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Anticipated number of subjects to be enrolled in study:         Summarize the services and/or procedures that will be used for identification and recruitment of UTMG patients as potential study subjects:         VII. BILLING INFORMATION         Will the Sponsor pay for all services and/or procedures provided under the study protocol?  Yes No. If No, please explain:         Will patients insured by Medicare potentially be enrolled in the study?  Yes No. If Yes, a Medicare coverage				w date.			
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vii. BILLING INFORMATION         Will the Sponsor pay for all services and/or procedures provided under the study protocol? Yes No. If No, please explain:         Will patients insured by Medicare potentially be enrolled in the study? Yes No. If Yes, a Medicare coverage	Anticipated number of subjects to be enrolled in study:						
Will the Sponsor pay for all services and/or procedures provided under the study protocol?       Yes       No. If No, please explain:         Will patients insured by Medicare potentially be enrolled in the study?       Yes       No. If Yes, a Medicare coverage							
Will the Sponsor pay for all services and/or procedures provided under the study protocol?       Yes       No. If No, please explain:         Will patients insured by Medicare potentially be enrolled in the study?       Yes       No. If Yes, a Medicare coverage							
explain: Will patients insured by Medicare potentially be enrolled in the study?	VII. BILLING INFORMATION						

Will the Sponsor pay for study related injuries?  $\Box$  Yes  $\Box$  No. If No, please explain:

NOTE: The UTMG Vice President, Corporate Compliance will be notified by the Director, Office of Clinical Research if third party payors and/or subjects will be responsible for payment of services and/or procedures under a study protocol.

## VIII. ATTACHMENTS

The following documents must be submitted with the Request for Approval to Conduct Research in a UT Medical Group Facility:

Protocol.

Informed Consent Form (*most recent draft acceptable*).

Protocol Billing Grid (please contact appropriate billing compliance personnel for guidance).

Investigator Curriculum Vitae (CV) or resume and professional license, if Investigator does not hold an appointment with the University of Tennessee Health Science Center.

NOTE: A Study Specific Agreement is required if UTMG resources (e.g., facility, equipment, personnel) are used (please contact appropriate contracting personnel for guidance).

NOTE: IRB and UTMG approval are necessary before study initiation.

## **REQUIRED SIGNATURES:**

By signing this Form, I certify that: (1) The information provided is complete and accurate to the best of my knowledge, (2) I accept responsibility for the scientific conduct of the study, and (3) I agree to provide additional information to the Office of Clinical Research upon request.

PI Signature

Date Printed Name

Internal Use Only		
Date Received:	Received by ( <i>printed name</i> ):	