GpCRC

SP – Ancillary Study Proposal

Purpose: To describe the participants, design, methods, and resources of the proposed ancillary study.
When: Whenever an ancillary study is proposed that involves GpCRC patients, GpCRC staff, or other GpCRC resources.
Completed by: Investigator proposing the ancillary study.
Instructions: This form should be completed by the proposing investigator for an ancillary study and should be signed by the proposing investigator. The liaison (who must be a GpCRC Steering Committee member) must also sign the form. Electronic signatures are acceptable. The form should be completed electronically by typing into the space provided for the items below. Completed forms (along with any supporting materials) should be emailed to Laura Miriel (laura.miriel@jhu.edu) and Laura Wilson (lwilson9@jhu.edu) at the SDRC.

A. Administrative Information

1. Name, institution, and contact information (telephone and email) for principal investigator for the proposed study:

2. List other collaborators (name, email, institution, state/country):

3. GpCRC liaison (must be a GpCRC Steering Committee member):

4. There must be no significant overlap or conflict with ongoing studies involving GpCRC patients. Before completing the remainder of this study proposal, the GpCRC liaison should review the objectives of all ongoing GpCRC studies and all currently active ancillary study proposals to be sure that there is no substantial overlap or conflict with your proposed study. Also, you should review all disapproved ancillary study proposals in order to avoid submitting a similar study proposal, which would likely be disapproved. The full list of all study proposals is available on the GpCRC website: http://jhuccs1.us/gpcrc/open/ancillary/ancillary.htm. At the end of this study proposal you will be required to sign to certify that you have completed these reviews and have found no substantial overlap or conflict, or that any potential overlap or conflict has been discussed with the co-chairs of the Ancillary Studies Committee and has been resolved to the degree that the proposal may be submitted for review. By continuing with this proposal, I attest that I understand the foregoing. GpCRC liaison initial here: ☐

B. Study Design

5. Study title:

6. Study objective:

7. Primary outcome:

8. Estimated start and end dates of study:

9. GpCRC population to be used *(check all that apply)*

☐ Registry ☐ GpR2 ☐ GpR3 ☐GpR4

☐ NORIG ☐ GLUMIT-DG ☐ APRON ☐BESST

☐ PGpR ☐ PGpR2

☐ PSAGS

☐ Other *(describe)*:

10. Concept sheet: Describe concisely the research design and methods for achieving the study objectives. This abstract is meant to serve as a succinct and accurate description of the design of the proposed work. **DO NOT EXCEED THE 2 PAGES PROVIDED. References can be submitted as a separate attachment to the proposal form.**

11. Sample size justification: specify 1. type I and type II error rates, 2. primary outcome variable, 3. minimum clinically meaningful difference (in units), and 4. method of analysis for the primary outcome variable, and 5. the statistical software used for the sample size justification.

C. GpCRC Resources

12. Does the study require new data (questionnaires, measurements, specimens) to be collected on GpCRC patients?

☐Yes ☐No

13. ←

If Yes, specify the types of data to be collected, the collection procedure, and the frequency of collection. Specify the impact on ongoing GpCRC staff and patients and whether the new data would interfere with data collection for the main studies.

13. Does this study require access to previously collected GpCRC data items?

☐Yes ☐No

14.

If Yes, specify the relevant study, data forms, and specific items. Specify the time frame for which data are needed (e.g., baseline data needed or specific follow-up data points or both).

Study	Visit	Form	Items

14. DNA specimens

a. Does the study require access to DNA specimens?

☐Yes ☐No

15.

b. Quantity of DNA requested per patient sample (µg): ___ ___

c. Number of DNA specimens requested:

Number of DNA specimens requested				
Registry	NORIG	GLUMIT-DG	APRON	GpR2

15. Serum specimens

a. Does the study require access to serum specimens?

Yes ( ) No ( )

16.

b. Number of serum specimens requested:

Registry	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR2	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR3	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR4	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

BESST	Baseline	f4	f6
# of patients			
# of 0.5mL aliquots per patient-visit			
Total # of aliquots			

PGpR	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

PGpR2	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

c. Specifications for serum specimens (describe any special requirements for specimens, e.g., baseline and follow-up specimens must be paired):

16. Plasma specimens

a. Does the study require access to plasma specimens?

☐Yes ☐No

17. ←

b. Number of plasma specimens requested:

Registry	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR2	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR3	Baseline	f048	f096	f144	f192
# of patients					
# of 0.5mL aliquots per patient-visit					
Total # of aliquots					

GpR4	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

NORIG	Baseline	f12	f15
# of patients			
# of 0.5mL aliquots per patient-visit			
Total # of aliquots			

GLUMIT-DG	Baseline	f12	f14
# of patients			
# of 0.5mL aliquots per patient-visit			
Total # of aliquots			

APRON	Baseline	f4
# of patients		
# of 0.5mL aliquots per patient-visit		
Total # of aliquots		

BESST	Baseline	f4	f6
# of patients			
# of 0.5mL aliquots per patient-visit			
Total # of aliquots			

PGpR	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

PGpR2	Baseline	f048	f096	f144
# of patients				
# of 0.5mL aliquots per patient-visit				
Total # of aliquots				

c. Specifications for plasma specimens (describe any special requirements for specimens, e.g., baseline and follow-up specimens must be paired):

17. PBMC specimens

a. Does the study require access to PBMC specimens?

☐Yes ☐No

18. ←

b. Number of PBMC specimens requested:

GpR3	Baseline	f048
# of patients		
# of 2.0mL aliquots per patient-visit		
Total # of aliquots		

PGpR	Baseline
# of patients	
# of 2.0mL aliquots per patient-visit	
Total # of aliquots	

18. Stool specimen

a. Does the study require access to stool specimens?

☐Yes ☐No

19.

b. Number of stool specimens requested:

PGpR	Baseline
# of patients	
# of 2.0mL aliquots per patient-visit	
Total # of aliquots	

19. Urine specimen

a. Does the study require access to Urine specimens?

☐Yes ☐No

20.

b. Number of urine specimens requested:

PGpR	Baseline
# of patients	
# of 2.0mL aliquots per patient-visit	
Total # of aliquots	

20. Does this study require analysis by the SDRC?

☐Yes ☐No

( ) ( )

21.

If Yes, please explain:

21. Does this study require any other GpCRC resources, including staff, equipment, or space?

☐Yes ☐No

22.

If Yes, please explain:

D. Funding and IRB Approval

22. Estimated budget:

23. Will this study require a Letter of Support from the GpCRC:

Yes ( ) No ( )

24.

a. If yes, type of grant(s) being submitted:

b. Date that the Letter of Support is due: _____ _____ - _____ _____ _____ - _____ _____
day mon year

24. Is this study contingent on additional funding:

☐Yes ☐No

25.

If Yes, check the item and provide a description:

( ) Funding is available (list source and amount):

( ) Request for added funding is pending (list agency to be approached for funding and amount to be requested):

( ) Request for added funding will be submitted once a letter of support from the NASH CRN is available (list expected date of submission):

25. Has this proposal been reviewed and approved by your IRB?:

☐Yes ☐No

a. **b.**

a. If Yes, date approved: _____ _____ - _____ _____ _____ - _____ _____
day mon year

b. If No, status of IRB approval:

☐ Pending

☐ Not submitted (specify why not)

c. Will the study have a consent statement? ☐Yes ☐No

Send a copy of your approved statement to the SDRC once IRB approval is granted.

E. Investigator Assurance and Sign-off

☐ I acknowledge that the GpCRC Ancillary Studies Policy, including the policy on publications and presentations arising from ancillary studies, applies to the ancillary study proposed herein.

☐ I have reviewed all GpCRC protocols and ancillary studies listed on the GpCRC website and certify that this study does not overlap or conflict with any active or completed study, including the GpCRC main study. Or I certify that if potential conflict or overlap has been identified, I have gained permission from the GpCRC Steering Committee to submit this proposal for review.

☐ I understand that if there is a change to one or more of the aims or if additional GpCRC resources are needed, I must submit an amendment to the ancillary study and gain approval from the GpCRC Steering Committee to proceed.

☐ I understand that ancillary studies are funded by a mechanism that is separate from the GpCRC funding mechanisms.

☐ I understand that ancillary study must make its own arrangements for whatever repository, data collection, management, and analysis support that it needs.

☐ I understand that the clinical dataset will be provided by the GpCRC SDRC at the time of, or after completion and receipt of the generated new data (e.g., genomic, proteomic measures) from the ancillary study. The specified timeline for the receipt of the clinical dataset in relation to the return of the new data should be included in the study proposal, with justification of any special arrangements requested, such as a "new data/clinical data" simultaneous exchange or the use of an external public-use repository and approved by the Steering Committee.

☐ I understand that the GpCRC must be granted access to all datasets acquired during the performance of an approved ancillary study prior to presentation or publication of results and upon request.

☐ I understand that the new data derived from the ancillary study must be completed within 27 months of receipt of the specimens, or 3 months prior to the termination date of the GpCRC final grant funding cycle. If additional times is required, I understand that Steering Committee approval of a written amended timeline with justification is required.

26. Date form submitted to GpCRC: _____ _____ - _____ _____ _____ - _____ _____
day mon year

27. Signature of proposing investigator: _____
(An electronic signature is acceptable.)

28. Signature of GpCRC liaison (must be a GpCRC Steering Committee member):
(An electronic signature is acceptable.)

_____

F. Scientific Data Research Center Use

29. Date received at SDRC: _____ Staff Member_____
dd/mon/year