Gastroparesis Clinical Research Consortium (GpCRC)
Ancillary Studies Policy

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GpCRC Ancillary Studies Policy

1.Background

The Gastroparesis Clinical Research Consortium (GpCRC) studies comprise well characterized individuals with diabetic, surgical, and idiopathic gastroparesis. To make the best possible use of this extraordinary resource, the GpCRC encourages external investigators, as well as GpCRC investigators, to develop ancillary study proposals.

2. Definition of ancillary study

An ancillary study is a study that is carried out using GpCRC patients or related materials, but is not a required part of GpCRC activities. Ancillary studies are characterized as requiring new data collection (i.e., additional to that required by the GpCRC). The new data collection might be a new questionnaire for GpCRC patients to complete, a new biologic specimen to obtain from GpCRC patients, or a new measurement on an existing GpCRC specimen. Ancillary studies are also characterized as being outside the specific scientific objectives of the GpCRC studies, sometimes requiring a separate consent form, placing an additional burden on participants, and sometimes funded by a mechanism that is separate from the GpCRC funding mechanisms. An ancillary study may involve all GpCRC patients or GpCRC patients at one or several GpCRC participating centers. An ancillary study is not a statistical analysis of previously collected data.

An ancillary study may not use the central resources of the GpCRC (e.g., Biosample Repository, Genetics Repository, Data Coordinating Center) for ancillary study purposes unless such use is agreed on by the central resource and is supported by funding from the ancillary study. The ancillary study must make its own arrangements for whatever repository, laboratory, data collection, management, and analysis support that it needs.

An ancillary study should not interfere with or duplicate activities of a main study, pilot or feasibility study. Examples of potential GpCRC ancillary studies include proposals on pathobiology or pathophysiology of gastroparesis or collecting new symptoms - or quality of life-related data in the GpCRC population.

3. Implementing an ancillary study

Investigators wishing to conduct an ancillary study must complete an application http://www.jhucct.com/gpcrc/closed/forms/admin/SP.pdf. The GpCRC Steering Committee will review the application for scientific merit (using the expertise represented by the Committee) and will assess whether the ancillary study represents undue burden for GpCRC patients or could interfere with completion of the GpCRC main study objectives. The GpCRC Steering Committee must approve the ancillary study for it to proceed. Investigators who are responding to a program announcement or applying for funding should gain GpCRC Steering Committee approval for the ancillary study before submitting their application to a funding organization. An ancillary study may be proposed by investigators outside of the GpCRC; however, in that case, a GpCRC Steering Committee member must agree to serve as the liaison between the GpCRC and the ancillary study.

4. Procedure for proposing an ancillary study

An ancillary study is proposed to the GpCRC by submission of a completed Study Proposal (SP) form (http://www.jhucct.com/gpcrc/closed/forms/admin/SP.pdf.) to the Steering Committee in care of the Data Coordinating Center. This form is available on the closed part of the GpCRC website (www.gpcrc.us). If an external investigator is proposing an ancillary study, he/she can obtain the form through the GpCRC Steering Committee member who will be the liaison for the ancillary study.

Completion of this form will require specification of the following information:

- The principal investigator for the ancillary study and his/her institutional affiliation.
- Names of other key investigators for the ancillary study and their institutional affiliations.
- Name of the GpCRC Steering Committee member who will be the liaison for the study.
- The study title, objective, and estimated start and end dates.
- A concept sheet describing the research design and methods for achieving the proposed study objectives (2 page maximum length - this is to be a concise, well organized description).
- The GpCRC resources which the ancillary study wishes to use:
  - New data or measurements that are to be collected on GpCRC patients or specimens
  - Existing GpCRC data that the study wishes to access
  - Number of patients involved
  - Quantity of specimens to be collected from patients and the conditions of specimen collection
  - If access to previously collected specimens is wanted for new measurements, the quantity and amount of specimens to be used should be specified;
  - Frequency of visits or patient contacts or specimen collection;
  - Types of interview questions or physical measures or data to be collected from patients
  - If access to previously collected GpCRC data is requested (e.g., measures on specimens or patients, treatment information), the nature of the requested data should be described.
- The primary outcome variable and sample size, with justification.
- The funding source and status of funding for the ancillary study; any unreimbursed work or personnel time expected of the GpCRC must be specified so that the Steering Committee can evaluate whether the GpCRC should assume that unreimbursed work or personnel time.
- The status of IRB approval and plans/procedures to protect patient confidentiality.
- An acknowledgment that the GpCRC ancillary studies policy, including the policy on publications and presentations arising from ancillary studies, applies to the ancillary study.

Each ancillary study must have the approval of the Principal Investigator at each GpCRC clinical center which will participate in the study.

The ancillary study activities that use GpCRC resources may not proceed until the GpCRC Steering Committee has approved the ancillary study.

5. Review process for proposed ancillary studies

The Data Coordinating Center will circulate the submitted ancillary study application to the members of the Steering Committee with instructions that they are to send their comments (see below for what they are to comment on) by a specified date. The Data Coordinating Center will assist the Chair to collate the comments and prepare a written memo to the Steering Committee specifying the recommendation for approval or disapproval. The Steering Committee will review that recommendation at their next meeting or conference call and make a decision for approval or disapproval. The principal investigator of the ancillary study and the GpCRC Steering Committee liaison will each receive a copy of the memo directing the Steering Committee to review the study application (so that they know the time frame for review) and a copy of the memo from the Steering Committee specifying the decision for approval or disapproval.

Steering Committee members will be asked to assess:

- Whether the proposed study has sufficient scientific merit.
- Whether the proposed study would interfere with other GpCRC activities.
- Whether the proposed study would hamper continued recruitment or participation in the ongoing or planned GpCRC studies.
- Whether the proposed study is consistent with the GpCRC aim of facilitating a broad range of research.
- Whether they approve/disapprove the proposed study.

6. Publications, abstracts and presentations arising from an ancillary study

Publications arising from ancillary studies do not need to be approved by the GpCRC Steering Committee prior to initiation. However, publications arising from ancillary studies must be reviewed by the GpCRC Steering Committee prior to journal submission; the purpose of the review is to assure that any statements about the GpCRC study protocol are accurate and that the GpCRC resources used in the ancillary study are appropriately acknowledged. The process for review will be:

- The draft manuscript should be sent to the Steering Committee in care of the Data Coordinating Center; the authors should specify the target journal.
- The paper will be circulated to the Steering Committee for voluntary comment directed to the corresponding author.
- The Chair will identify an internal reviewer for the paper and send the paper to that individual with a deadline for response.
- The reviewer will review the paper for accuracy of statements about the GpCRC resources

used in the ancillary study and for appropriate acknowledgment of the GpCRC.
- The reviewer will send his/her review to the Chair.
- The Chair will send a written review to the author.

If a manuscript is not accepted upon initial submission to a journal, the manuscript does not need to be re-reviewed by the GpCRC after revision and prior to resubmission to a journal, unless there have been substantive changes to the statements that relate to GpCRC resources or the acknowledgment of the GpCRC. The Chair will decide if re-review by the GpCRC is needed.

Abstracts and presentations arising from ancillary studies will not require approval from the GpCRC. However, the GpCRC welcomes being informed about such presentations and would provide review of materials if requested. It is expected that any presentation from an ancillary study will include appropriate acknowledgment of the GpCRC resources used by the ancillary study.

Authorship for publications and presentations from ancillary studies is at the discretion of the ancillary study investigators. It is expected that conventional authorship will be used, with an acknowledgment of the GpCRC.

7. Ancillary studies policy and procedures

The ancillary studies policy includes the following:

- To review applications for ancillary studies of the GpCRC and to make recommendations for approval or disapproval
- To maintain a list of all proposed ancillary studies indicating approval status and the liaison. For approved studies, the list will indicate initiation date and the GpCRC centers participating in the ancillary study.
- To maintain a list of allocations or commitments of existing or future GpCRC samples to central GpCRC and to ancillary studies.

The list of all proposed ancillary studies and the list of allocations and commitments of existing or future GpCRC samples will be available on the GpCRC website.

With respect to votes on matters decided by the Steering Committee, each Steering Committee member has one vote. In case of a tie vote, the Steering Committee will decide by mailed ballot if a meeting or conference call is not needed.

If a Steering Committee member proposes an ancillary study, collaborates on an ancillary study, or is affiliated with the institution of an investigator who proposes an ancillary study, he/she will be excused from reviewing and voting on that ancillary study proposal, similar to NIH peer review policies for avoidance of actual or perceived conflicts of interest.

The Data Coordinating Center supports the ancillary studies operations by arranging conference

calls, receiving submitted applications for ancillary studies, administering the process for review of submitted applications, writing correspondence for the Steering Committee, and maintaining the lists of ancillary studies and allocated/committed samples and the document and correspondence files relating the Committee's activities. The Data Coordinating Center relies on the named liaison for each ancillary study and the Steering Committee members in completion of these activities.

7.1. Receipt dates for study proposals

The deadlines for receipt of ancillary study proposals for review by the GpCRC Steering Committee are 1 February, 1 June, and 1 October. Proposals received by 1 February of each year will be reviewed and the proposer notified of the decision by 31 March. Similarly, proposals received by 1 June will be reviewed and the proposer notified by 31 July, and proposals received by 1 October will be reviewed and the proposer notified by 30 November. These receipt dates allow notification of the applicant of the GpCRC Steering Committee's approval or disapproval approximately two months before the NIH due dates for funding applications for new projects.

7.2. Access to GpCRC data

Access by ancillary studies to GpCRC data collected on participants in the ancillary study will be governed by the GpCRC Steering Committee and administered by the Data Coordinating Center. It is likely that access to baseline data from a GpCRC study will be permitted to an ancillary study prior to the conclusion of the GpCRC study, but only after the GpCRC has determined that the baseline data are of a quality suitable for sharing. Follow-up data and information about treatment assignment in a GpCRC clinical trial are unlikely to be available until after the GpCRC trial has ended, regardless of the timing of the ancillary study. Ancillary study investigators should be aware that there may be delays of possibly years before GpCRC data are released.

GpCRC datasets use the GpCRC Patient ID number to link patient records. Ancillary study investigators should request data on the GpCRC participants in their study by providing the GpCRC ID numbers of the patients whose data are requested. The DCC will accept SAS, Excel, Access, ASCII, and other data files of records of GpCRC ID numbers (word processing files are not acceptable, other identifiers are not acceptable).

The GpCRC data which have been approved for provision to the ancillary study will be provided in SAS data sets using whatever SAS version is in use at the DCC. Ancillary study investigators should be prepared to deal with SAS datasets.

7.3. Consent and IRB issues

Consent for the ancillary study cannot be part of any GpCRC consent – ancillary studies are separate from the GpCRC by definition. Therefore, each ancillary study must have its own consent form if needed. Each center participating in an ancillary study must have approval from their IRB for participation in the ancillary study. Each center must provide a copy of their initial notice of IRB approval of the ancillary study and a copy of their IRB-approved consent to the Steering Committee prior to initiation of ancillary study activities at the GpCRC center (IRB approval is not required for review of an ancillary study application). Copies of notices of renewal of IRB approval must also be provided to the Steering Committee annually. The DCC will maintain a file of ancillary study IRB approvals and IRB-approved consents.

7.4. Funding issues

Ancillary studies are almost always supported by non GpCRC resources. Investigators proposing ancillary studies should seek funding from outside sources to conduct their research. Examples include funding obtained through investigator-initiated NIH research grant awards (R01s), program announcements, grants from academic institutions, or private sources (e.g., drug companies, non-profit health organizations). The GpCRC Steering Committee can provide letters of support for applications for funding for ancillary studies approved by the GpCRC. Conduct of ancillary studies must comply with all existing GpCRC and NIH policies and guidelines.

An ancillary study that wishes to use the services of the Data Coordinating Center or any other GpCRC central resource may contact the principal investigator of that resource regarding participation in the ancillary study. Such participation has to be funded with non GpCRC resources.

7.5. Expiration of GpCRC approval

In general, approved ancillary studies must be initiated within one year of being approved, or the approval will be withdrawn; this will allow recycling of resources allocated to an ancillary study that does not go forward, (e.g., due to failure to obtain funding). The principal investigator of the ancillary study and the GpCRC liaison will each receive written notice 2 months before an ancillary study's approval is due to expire. The ancillary study investigator may appeal this expiration of GpCRC approval, e.g., if a funding decision is pending or if an application for funding is being revised and resubmitted. The ancillary study investigator should send a letter requesting an extension of approval to the Steering Committee. The letter should indicate the expected time line for initiation of the ancillary study and describe the actions that are being taken to meet that time line.

7.6. GpCRC liaison

An ancillary study that is proposed by an investigator outside of the GpCRC must have a GpCRC liaison. This person must be a GpCRC Steering Committee member. The liaison serves as the communications link between the Steering Committee and the ancillary study. For example, the liaison would provide status reports on the ancillary study as needed at Steering Committee meetings and would assist the Data Coordinating Center as needed in communicating with the ancillary study. The liaison may participate in the ancillary study but participation is not required.

7.7. Changes to an ancillary study's protocol

If a major change occurs to an ancillary study's protocol after it has been approved by the GpCRC (e.g., addition of a visit, addition of a specimen, or addition of a measurement on a GpCRC specimen – something that affects the impact on the GpCRC participant or resource used), the Steering Committee must approve the change before it is implemented.

7.8. Confidentiality

Confidentiality of individually identifiable data about GpCRC participants must be assured. The GpCRC provides no assurances that ancillary studies will be able to identify and contact GpCRC participants in the future, particularly after the GpCRC ends.

7.9. Ownership of data and samples

Data and samples collected using GpCRC central resources are overseen by the NIDDK; these are GpCRC data and GpCRC samples. Data and samples collected from GpCRC patients under an approved ancillary study protocol and using ancillary study resources are overseen by the ancillary study investigators. Measurements made on GpCRC samples under an approved ancillary study protocol and paid for by ancillary study resources are also overseen by the ancillary study investigators and will be incorporated into the GpCRC database.

Acknowledgments: This policy is based on the ancillary studies policy developed by the NASH CRN.