GO MOMs Ancillary Studies Policy

Investigators wishing to conduct or participate in Ancillary Studies in conjunction with the Glycemic Observation and Metabolic Outcomes in Mothers and Offspring (GO MOMs) study should read the conditions for review and conduct of Ancillary Studies described below and complete the attached items. Contact the GO MOMs Biostatistics Research Center (BRC) with questions (gomoms@northwestern.edu).

1.0 General Policy

To enhance the value of the GO MOMs study, the Steering Committee welcomes proposals from investigators to carry out Ancillary Studies. To protect the integrity of GO MOMs, Ancillary Studies must be reviewed and approved by the Executive Committee, Steering Committee, and Observational Study Monitoring Board (OSMB) before the submission of a proposal to an external funding agency. Unless exempt from review according to the Common Rule, Ancillary Studies must be approved by an Institutional Review Board (IRB) prior to initiation of the study.

2.0 Definition of an Ancillary Study

An Ancillary Study is defined as research or data collection involving GO MOMs study participants or specimens, using any technique, procedure, questionnaire or observation other than those set forth in the GO MOMs protocol.

3.0 Requirements for Approval of an Ancillary Study

3.1 Considerations for Approval

All proposed Ancillary Studies must be reviewed and approved by the GO MOMs Executive Committee, Steering Committee, and, for proposals that involve additional participant procedures or data collection, the OSMB before submission to a funding agency. After funding is obtained, the proposed Ancillary Study must be reviewed and approved by the sIRB/IRB prior to implementation. As revisions are made to the proposal/protocol during this process, the Ancillary Studies Chair and Co-Chair, in consultation with National Institute of Diabetes and Digestive and Kidney diseases (NIDDK), will determine whether the changes are significant enough to need re-review by the Steering Committee and/or OSMB.

The proposed study must:

- Meet requirements of the highest scientific merit.
- Not impose an undue burden on participants (e.g., in terms of time requirements or causing physical or mental discomfort) that will interfere with the primary GO MOMs study if it involves collection of additional data or blood samples.
- Put minimal demand on scarce GO MOMs resources such as backup blood samples.
- Require the unique characteristics of the GO MOMs participants to accomplish its goals.
- Not interfere with or impede the completion of the primary or secondary objectives of GO MOMs.
- Not adversely affect participant cooperation or compliance with the GO MOMs protocol.
- Not create a serious diversion of study resources (personnel, equipment, or study samples) or investigator/staff time at the clinical centers or the BRC.
- Be relevant to GO MOMs.
- Include a statement in the consent form noting that participation in the Ancillary Study is optional, and refusal will not affect the participant's ability to participate in the main study.
- Include details about its unique opportunity for acquisition of new scientific knowledge.
- Include adequate experimental design, methodology and data analysis plans.
- Show adequacy of the investigator and research environment.
- Address the burden of the study on the enrolled GO MOMs participants and the clinical centers.

The ancillary study investigators must:

- Agree to utilize the BRC's database for data entry, management, and storage.
- Have adequate resources to effectively complete the project, including both financial support and personnel.

3.2 Personnel Requirements

Ancillary Study proposals may be submitted by investigators participating in GO MOMs, or by investigators who are not part of GO MOMs. If the GO MOMs Ancillary Study Principal Investigator is part of the GO MOMs Steering Committee, the Ancillary Study PI is the Ancillary Study Liaison between the Steering Committee and the Ancillary Study team.

If the Ancillary Study PI is not part of the GO MOMs Steering Committee, the Ancillary Study must include an Ancillary Study co-Investigator who is part of the GO MOMs Steering Committee. In this case, the Ancillary Study co-I who is part of the GO MOMs Steering Committee will be the Ancillary Study Liaison.

The Ancillary Study Liaison will be the primary point of communication between the GO MOMs study team and the Ancillary Study applicants. The Ancillary Study Liaison is responsible for the following tasks:

1. Ascertaining interest in Ancillary Study participation from all other GO MOMs clinical sites, and for informing the respective GO MOMs site PI(s) of any site's desired participation;
2. Submitting the Ancillary Study application to the BRC at all points of contact; and
3. Acting as a mentor to the Ancillary Study PI if the Ancillary Study PI is a junior investigator.

If the Ancillary Study will require additional procedures or data collection from participants that will require effort from personnel at a clinical center, the Ancillary Study must include a GO MOMs co-I or site PI from that site as an Ancillary Study co-I. For instance, if an Ancillary Study proposes to collect additional data that are not part of the parent study from participants at GO MOMs clinical center site 1, site 2, and site 3, then a GO MOMs co-I or site PI from sites 1, 2, and 3 must all be co-Is on the Ancillary Study.

If the Ancillary Study PI only wishes to use data and/or specimens from clinical centers that were obtained as part of the parent study and the Ancillary Study will not involve additional procedures or data collection from participants, then co-I involvement is not required from each site. In this case, GO MOMs co-Is or site PIs should be included as Ancillary Study co-Is based on planned scientific involvement. Refer to the GO MOMs Publications and Presentations Policy for guidance on authorship for ancillary studies.

If the Ancillary Study PI is not part of the GO MOMs Steering Committee, and does not have a potential collaborator on GO MOMs identified, the Ancillary Study PI should send a one-page proposal summary (Appendix C) to the BRC (gomoms@northwestern.edu) and ask that it be circulated to the Steering Committee in order to find interested collaborators prior to Ancillary Study application. If nobody in the Steering Committee volunteers to be an Ancillary Study Liaison, the Steering Committee will provide written feedback to the Ancillary Study proposer on the submission, and the proposal will be considered to be not approved.

Prior to submitting the Ancillary Study proposal, the Ancillary Study PI will give a 10-15 minute presentation of the ancillary study concept at a Steering Committee meeting that describes the scientific rationale, participant burden, how many sites are needed and funding plans. Steering Committee members will have the opportunity to ask questions following the presentation. Following the presentation, GO MOMs clinical center PIs may express interest in participating to the Ancillary Study Liaison. The Ancillary Study Liaison may also consult each GO MOMs clinical center PI independently about participating. No clinical center will be required to participate in an Ancillary

Study. The Ancillary Study PI is not required to include all sites and may select sites for participation based on feasibility, budgetary and/or scientific considerations.

3.3 Funding Requirements

Ancillary Studies require external funding. Examples include studies funded by National Institutes of Health (NIH) research awards or grants from academic institutions or private sources (e.g., foundations, pharmaceutical companies, etc.). An Ancillary Study must have sufficient funding to cover the costs incurred by, if applicable:

1. The GO MOMs clinical centers,
2. The GO MOMs Central Laboratory (e.g., to process shipments and ship samples, if the study wishes to utilize their services),
3. Contracts with outside laboratories for specimen management, analysis, and storage (e.g., to process and analyze samples, if the study wishes to utilize an outside lab),
4. The GO MOMs BRC (e.g., for tasks such as database development, preparing and documenting analysis files, participating in statistical analysis, and integrating the new ancillary data back into a combined database), and
5. The sIRB (if a study qualifies for using an sIRB under the Common Rule and/or funding agency policy, the study team is encouraged to utilize the Vanderbilt University Medical Center (VUMC) sIRB. If the study does not qualify for using an sIRB under the Common Rule and/or funding agency policy, the study team may utilize a local IRB).

Funds are not available for these purposes within the parent study GO MOMs budget. The Ancillary Study proposal must identify the anticipated source of funds.

3.4 Specimens, Data, and Analyses

Ancillary Study data must be collected through the existing GO MOMs database, which is housed at and maintained by the BRC. If the study wishes to utilize the GO MOMs Central Laboratory for specimen management, the Ancillary Study budget must include appropriate effort and cost for the Central Laboratory to manage these tasks; if specimens are to be sent to an outside institution for analysis, management and analysis of the specimens can be contracted to outside institutions. The costs of that contract must be included in the budget.

The investigator has the option of either working with the GO MOMs BRC statistical team for analysis of Ancillary Study data or working with an outside statistical team. If the investigator would like to work with the GO MOMs statistical team for analysis, then the investigator should work with the GO MOMs BRC to determine the most appropriate approach to funding statistical support for the study.

If a statistician other than the BRC statistician is used, the GO MOMs BRC statistician will review the final analyses as part of the Publications and Presentation Committee prior to publication.

4.0 Review of Ancillary StudY Proposals

4.1 Overview

An Ancillary Study Proposal must be reviewed and approved by the Steering Committee, OSMB (if the study involves additional participant procedures or data collection), and the sIRB/IRB prior to implementation. The GO MOMs Ancillary Studies Chair may discuss concerns about a proposal with the applicant and opportunities for clarification/revision will be provided. An Ancillary Study must receive approval from the GO MOMs Steering Committee before grant funding is requested from an external funding agency. The Ancillary Study Liaison will work with a dedicated Project Manager from the BRC to process submissions.

See Appendix A for a timeline of the review process. Overall, the applicant usually should allow 2.5-3 months for the review process, prior to submission to the funding agency.

4.2 Presentation to the Steering Committee

The Ancillary Study Liaison or Ancillary Study PI will give a 10-15 minute presentation of the ancillary study concept at a Steering Committee meeting that describes the scientific rationale, participant burden, how many sites are needed and funding plans. Slides should be sent to the BRC (gomoms@northwestern.edu) at least three days prior to the meeting so that the BRC can circulate the slides to the Steering Committee for review prior to the presentation. Steering Committee members will have the opportunity to ask questions following the presentation. The purpose of this presentation is to

1. Ensure consistency of the proposed Ancillary Study with the GO MOMs study aims;
2. Clarify the scientific rationale for the proposed ancillary study;
3. Ensure it doesn't interfere with anything already being done for the GO MOMs study or other Ancillary Studies;
4. Ensure it doesn't repeat anything already being done as part of GO MOMs or other Ancillary Studies;
5. Allow GO MOMs investigators to ask questions that may pertain to their potential involvement in the ancillary study; and
6. Identify any other general difficulties, inconsistencies, or incompatibilities.

4.3 Review by the Steering Committee

Following presentation to the Steering Committee, the Ancillary Study PI will submit the one-page proposal summary (Appendix C) and the full proposal, including budget (Appendix D) to the BRC (gomoms@northwestern.edu).

The BRC Project Manager will review the full proposal for completeness, and then send it to the Ancillary Studies Chair. The Ancillary Studies Chair will assign two reviewers to the proposal who are not on the proposal leadership team (typically defined as PI or Co-I with substantial scientific involvement exceeding recruitment of participants or use of collected samples). The reviewers will score the proposal within 1-2 weeks of receipt. The reviewers will email their full review to the BRC Project Manager, who will send the proposal and the detailed, anonymized reviews to the full Steering Committee. At a subsequent Steering Committee meeting, the Ancillary Studies Chair or Co-Chair will present a summary of the two reviews. The Steering Committee will have at least two business days to review the proposal and the scores prior to the meeting. After the presentation of the reviews of the proposed ancillary study by the Ancillary Study Chair or Co-Chair, the two written reviews will be sent to the Ancillary Study PI if the Ancillary Study PI is not a GO MOMs investigator.

The Steering Committee meets semi-monthly. Thus, if a full proposal is sent to the BRC less than 11 days prior to a Steering Committee meeting, it will be assigned to the following meeting.

Following presentation of the reviews of the proposed ancillary study by the Ancillary Study Chair or Co-Chair, the Steering Committee will vote on whether the proposal should be approved. An Ancillary Study will require a 2/3 majority vote (6 of 9 votes) by the Steering Committee to be approved. Each of the seven clinical centers will get one vote; NIDDK will get one vote; and the BRC will get one vote. Members of the Steering Committee who are also part of the Ancillary Study team are allowed to be part of the discussion and vote.

The Steering Committee will make one of four determinations (Table 1) regarding the Ancillary Study proposal, based on the criteria listed in section 3.1, Considerations for Approval. The BRC will facilitate final voting by

email after the Steering Committee discussion, to allow GO MOMs Steering Committee members to confer with other GO MOMs investigators at their site prior to sending their final vote.

The Steering Committee will also designate the timeline for progress reporting required for each Ancillary Study (see section 6.2, Progress Reports).

NIDDK will also decide if the proposal needs to be submitted to the OSMB (if the proposal involves additional clinical procedures or data collection, it will be sent to the OSMB; if the proposal involves only accessing already collected data and/or stored samples, it will not be sent to the OSMB).

Table 1. List of Steering Committee determinations

Determination	Meaning	Feedback	Resubmission Instructions
Not Approved	Fewer than six votes for approval, with no possibility of revisions.	Written reviews will be provided, explaining the decision.	N/A, resubmission is not allowed.
Tabled	The Steering Committee does not have enough information to vote.	Written reviews will be provided, explaining the additional information needed.	Respond to the feedback, send to BRC. The proposal will go back to the full Steering Committee for review and vote.
Pending Approval	The Steering Committee agrees (with at least six out of nine votes) that the proposal will be approved if certain revisions are made.	Written reviews and feedback will be provided, explaining the revisions the Steering Committee agreed on.	Respond to the feedback, send to BRC. If the Ancillary Study team agrees with the revisions requested, the revised proposal will go the Ancillary Studies Chair to determine if the revision requests have been met. If the Ancillary Study team does not agree with the revisions requested, give a detailed and supported explanation. The proposal will go back to the full Steering Committee for review and vote.
Approval	The Steering Committee agrees (with at least six out of nine votes) that the proposal is approved as written.	Written documentation of the approval will be provided.	N/A. Future revisions to the proposal must be reviewed by the Ancillary Study Chair to determine if any significant changes have been made that need to be reviewed by the Steering Committee.

4.4 Review by the OSMB

If the proposal needs to be submitted to the GO MOMs OSMB, it will be reviewed for patient safety, patient burden, patient confidentiality, and monitoring considerations.

The OSMB meets semi-annually. If the proposal is submitted within 2-3 weeks of an OSMB meeting, it will be reviewed at the semi-annual meeting. If not, the proposal will be emailed to all OSMB members to review by email and provide a response within 10 business days.

The GO MOMs OSMB (or the OSMB Chair and delegated member) will determine whether:

1. Any additional safety risks from extra procedures are within an acceptable level

2. Data confidentiality is adequately protected
3. The monitoring plan is acceptable
4. The proposal does not interfere with any safety procedures already in place
5. The proposal does not interfere with the conduct of the parent study
6. The participant burden is acceptable

Again, opportunity for revisions and clarifications will be requested, as appropriate.

Please note, this review by the GO MOMs OSMB only reviews how the Ancillary Study proposal fits in with the GO MOMs study; it does not constitute study-specific safety and monitoring. The GO MOMs OSMB may agree to act as the Ancillary Study's safety and monitoring board, but it is up to the GO MOMs OSMB to make this decision; otherwise, it is the Ancillary Study PI's responsibility to find his or her own Ancillary Study OSMB if needed.

4.5 Submission to External Funding Agency

If the Executive Committee, Steering Committee, and, if required, the OSMB approve the proposal, the applicant may proceed to write up a detailed funding proposal (e.g., a Research Strategy being submitted to NIH) to the external funding agency for funding. The applicant must send that detailed funding proposal (research strategy, specific aims, and budget) to the BRC at least two weeks prior to the funding submission deadline; the BRC will forward all materials to the Ancillary Study Chair or Co-Chair who will review the detailed funding proposal to ensure vital details haven't been changed. If the Ancillary Study Chair or Co-Chair confirms consistency of the original proposal with the full application, the Executive Committee will then provide a letter of support within 3 days after the review.

If the Ancillary Study PI wishes to utilize the VUMC sIRB, the letter of support from the Executive Committee will include an attached, generic letter of support from the VUMC sIRB indicating the VUMC sIRB's support for the GO MOMs Consortium.

4.6 Biospecimen Hold

If the Ancillary Study Proposal includes utilizing specimens already collected or being collected, then these specimens will be put on "hold" upon submission of the proposal application to the funding agency. It is the responsibility of the investigator to inform the BRC (gomoms@northwestern.edu) of the funding-agency review score, when it arrives. Based on the score and other ancillary studies that are also being considered, the Steering Committee will decide whether to continue the hold in anticipation of funding. If the applicant secures funding prior to submitting the Ancillary Studies proposal to the Steering Committee, then the hold will begin as soon as the Steering Committee approves the proposal. If funding is not acquired and/or sIRB approval is not obtained, the hold will be released and the biospecimens may be utilized or reserved for other Ancillary Studies.

4.7 Revision and Resubmission to Funding Agency

If the funding agency does not fund the proposal after the first submission, but instead offers the opportunity for the applicant to revise and resubmit during another round, the Ancillary Study Liaison should send the revised proposal introductory information (Appendix C) and full proposal (Appendix D), original critiques that were received from the review panel, one-page introduction that will be included with the resubmitted grant, specific aims, budget, and applicable summary of changes/tracked versions to the BRC. The BRC will forward the revised proposal to the Ancillary Study Chair and Co-Chair for review. The Ancillary Studies Chair and Co-Chair, in consultation with NIDDK, will review the proposal to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB.

Thus, the timeline for this step could be 3-54 days, depending on whether additional reviews by the Steering Committee/OSMB are needed. If significant changes are made, the Ancillary Study Liaison should consult with the BRC early in the process, to assess the timeline.

4.8 Review by the sIRB/IRB

Upon approval for funding, unless exempt from review according to the Common Rule, the Ancillary Study must be approved by an IRB prior to initiation of the study. If the Ancillary Study qualifies for using the sIRB under the Common Rule and/or funding-agency policy, the Ancillary Study team is encouraged to utilize the VUMC sIRB. If the study does not qualify for using the sIRB under the Common Rule and/or funding-agency policy, the study team may utilize a local IRB.

Prior to going to the sIRB/IRB, the full protocol should be sent to the BRC, who will forward it to the Ancillary Studies Chair or Co-Chair. The Ancillary Studies Chair or Co-Chair, in consultation with NIDDK, will review the protocol to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB. The Steering Committee and the OSMB, if required, will need to approve any changes prior to submitting the protocol to the sIRB/IRB.

Final approval for a proposed Ancillary Study rests with sIRB/IRB. Ancillary Studies not approved by the sIRB/IRB cannot be conducted. If the Ancillary Study utilizes the VUMC sIRB, the GO MOMs BRC will facilitate submission of the Ancillary Study to the sIRB, though the sIRB-required forms must be completed by the Ancillary Study team.

If the sIRB/IRB requires changes to the protocol, the revised protocol must go back to the Ancillary Studies Chair or Co-Chair after sIRB/IRB approval. The Ancillary Studies Chair or Co-Chair in consultation with NIDDK, will review the protocol to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB.

4.9 Changes to an Approved Ancillary Study

Once an ancillary study is approved, no changes can be made to the study without additional review. If the investigator wishes to make changes, these must be submitted for review to the BRC, who will forward them to the Ancillary Studies Chair and Co-Chair. The Ancillary Studies Chair and Co-Chair, in consultation with NIDDK, will review the protocol to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB. All changes will require submission to and approval by the sIRB/IRB.

4.10 Summary of Responsibilities of the Ancillary Studies Chair

The following are the responsibilities of the Ancillary Studies Chair. If the Ancillary Studies Chair is an Ancillary Study co-I for a single-site Ancillary Study, the Ancillary Study PI, or the Ancillary Study Liaison, these responsibilities will fall to the Ancillary Studies Co-Chair for that particular Ancillary Study:

- Assigning two reviewers to each Ancillary Study proposal that comes to the Steering Committee
- Leading the Steering Committee discussion
- Writing, or delegating the writing of, the Steering Committee decision/feedback, based on the BRC's meeting minutes
- Reviewing revisions to the Ancillary Study proposal and/or protocol, in consultation with NIDDK, to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB

5.0 Instructions for Completion of the Ancillary Study Proposal Forms

5.1 Proposal Forms

The Ancillary Study Investigator will work with a dedicated Project Manager from the BRC to process submissions. All submissions should be sent to gomoms@northwestern.edu. See Appendix A for a list of steps in the application process.

Step 1: A 10-15 presentation of the proposal ancillary study to the Steering Committee that addresses scientific rationale, participant burden, how many sites are needed and funding plans.

Step 2: A full proposal and budget is submitted to the Steering Committee. The full proposal will include:

1. Introductory Information Sheet and One-page Proposal Summary (Appendix C)
2. Ancillary Study Questionnaire (Appendix D)
    a. Attachment 1: References Cited
    b. Attachment 2: Ancillary Study Consent Form (see section 5.3, Consent Forms)
    c. Attachment 3: Any proposed questionnaires or forms to be completed by participants (if applicable)
    d. Attachment 4: Ancillary Study Budget (se section 5.2, Budget)
    e. Attachment 5: Biosketches of all investigators
    f. Attachment 6: Signed agreement stating that the Ancillary Studies personnel agree to abide by GO MOMs policies and procedures

Step 3: A full proposal without a budget will be sent to the OSMB, if OSMB review is required by NIDDK. This submission will be performed by the BRC Project Manager after the Steering Committee approval. This submission will include:

1. Introductory Information Sheet and One-page Proposal Summary (Appendix C)
2. Ancillary Study Questionnaire (Appendix D)
    a. Attachment 1: References Cited
    b. Attachment 2: Ancillary Study Consent Form (see section 5.3, Consent Forms)
    c. Attachment 3: Any proposed questionnaires or forms to be completed by participants (if applicable)

Step 4: Seven days prior to your submission to the funding agency, please send the following documents to the BRC. These documents will be sent to the Executive Committee. The committee members will review your proposal to ensure no significant changes have been made since review by the Steering Committee. The Study Chair will then return a letter of support.

1. Your final specific aims and research strategy
2. Your final budget

If the funding agency does not fund the proposal after the first submission, but instead offers the opportunity for the applicant to **revise and resubmit** during another round, the Ancillary Study Liaison should send the following to the BRC:

1. Revised proposal introductory information (Appendix C)
2. Revised full proposal (Appendix D)
3. Original critiques that were received from the review panel
4. One-page introduction section to be included with the resubmitted grant
5. Specific aims
6. Revised budget
7. Summary of changes

The BRC will forward these documents to the Ancillary Study Chair or Co-Chair for review. The Ancillary Studies Chair or Co-Chair in consultation with NIDDK, will review the proposal to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB.

Steps 5 and 6: Once funding is received and a full protocol is written, if the Ancillary Study is utilizing the sIRB, the BRC Project Manager will work with the Ancillary Study PI to ensure all sIRB reliance agreements and documents are properly submitted.

5.2 Budget

The investigator applying for an ancillary study must supply all additional funds needed to complete the study. Provision of funds for expenses incurred by GO MOMs is essential. Once a study concept is approved, the ancillary study team is expected to collaborate with the BRC to develop a budget, which adequately provides for expenses incurred by GO MOMs. Such costs include, but are not limited to:

- Statistical and data management staff for coordinating the additional data management and analyses with the BRC
- sIRB guidance by the BRC
- Costs incurred by participating clinical centers including space, personnel, equipment, supplies, and sIRB/IRB approval
- Costs for visits outside of the GO MOMs protocol
- Cost of personnel time to pull backup samples
- As appropriate, costs related to participant reimbursement/incentives for their time

5.3 Consent Forms

As part of the submission to the Steering Committee for review, Ancillary Studies are to provide an additional template consent form, attached to the Appendix D, describing in detail procedures to be performed, and possible risks and benefits to the participant. Participation in the Ancillary Study must be described as optional. Consent for the Ancillary Study is only to be sought after the mother has consented to GO MOMs. Consent for GO MOMs main study is the highest priority. Those mothers who agree to participate in GO MOMs but do not agree to an Ancillary Study are to remain as GO MOMs participants.

The source documentation of signed Ancillary Study consent forms must be maintained in each participant's shadow chart. An electronic file of all scanned, signed ancillary consent forms must be maintained by the clinical centers. A copy of this file must be delivered to the GO MOMs BRC upon completion of the Ancillary Study.

6.0 Requirements after an Ancillary Study is Approved

6.1 Ancillary Study Agreements

The release of data and specimens between sites must adhere to the individual institutional requirements (e.g., data use agreement, material transfer agreements). All agreements must be reviewed and approved by the NIDDK Technology Advancement Office prior to initiating the Ancillary Study.

6.2 Progress Reports

The PI of an Ancillary Study will be responsible for providing written progress reports on the Ancillary Study according to the timeline designated by the Steering Committee (typically, annual reports will be required). If funding is provided by the NIH, copies of annual RPPR reports may be provided to the Steering Committee for this purpose.

6.3 Ancillary Study Papers

Ancillary Studies may not publish data from the GO MOMs study prior to publication of relevant findings from the parent GO MOMs study. If you have questions about publication timelines, please list that in Appendix C under question 6, labeled, “Please list any other comments, questions, or notes you have about your submission.” Exceptions to this policy must be approved by both the Steering Committee and the Publications and Presentations Committee.

Presentation and publication of the results of an Ancillary Study are subject to the guidelines specified in the GO MOMs Publications and Presentations Committee policy.

Collaborating investigators in Ancillary Studies will prepare papers in cooperation with the clinical centers and the BRC. Output from data analyses not performed by the BRC must be provided to the BRC for review and verification along with the proposed presentation or manuscript. The final text and authorship must be approved by the Publications and Presentations Committee before it is submitted for presentation and/or publication.

Appendix A: Timeline of Ancillary Study Review Process

Overall, the applicant usually should allow 2.5-3 months for the review process, prior to submission to the funding agency. See section 5.1, List of Proposal Forms, for a complete list of materials to submit at each step.

	Reviewer	Submission	Review Timeline	Notes
Step 1	Steering Committee	10-15 minute presentation to Steering Committee, followed by time for questions		
Step 2	Steering Committee	Send the full proposal (Appendices C & D), including budget & attachments, to BRC	3-33 days	
Step 3	OSMB (if applicable)	N/A (BRC will forward your full proposal to the OSMB)	14-21 days	GO MOMs OSMB review is required for proposals that involve patient procedures or data collection.
Step 4	Letter of Support for Funding-Agency Submission	Send your final specific aims, research strategy, and budget to BRC	4-7 days	· Prior to submission to the funding agency, the Executive Committee will review your final aims and research strategy and provide a letter of support. · After submission to the funding agency, notify BRC within three business days of receiving a funding-agency review score. · Resubmissions to the funding agency will need a re-review by the Ancillary Studies Chair or Co-Chair/Steering Committee/OSMB (see section, 4.7, Review and Resubmission to Funding Agency).
Step 5	Ancillary Studies Chair	Send the protocol to BRC	3-54 days	The Ancillary Studies Chair or Co-Chair, in consultation with NIDDK, will review the protocol to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB.
Step 6	sIRB/IRB	Submit (or work with the BRC to submit) your protocol and associated materials to the sIRB/IRB	Typically 2-3 months	
Step 7	Ancillary Studies Chair (if applicable)	Send the revised protocol to BRC	3-54 days	The Ancillary Studies Chair, in consultation with NIDDK, will review the protocol to determine if any significant changes have been made that need to be reviewed by the Steering Committee/OSMB.
Step 8	Study Start Up		Varies	Upon sIRB/IRB approval, work with the BRC on study start up.

Appendix B: List of Abbreviations

BRC	Biostatistics Research Center
co-I	Co-Investigator
GO MOMs	Glycemic Observation and Metabolic Outcomes in Mothers and Offspring
IRB	Institutional Review Board
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institute of Health
OSMB	Observational Study Monitoring Board
PI	Principal Investigator
sIRB	single Institutional Review Board
VUMC	Vanderbilt University Medical Center

Appendix C: GO MOMs Ancillary Study Introductory Information Sheet and One-Page Proposal Summary

Please complete the following items describing the proposed ancillary study

Introductory Information

1. Title of proposed study: Click or tap here to enter text.

2. Name of Ancillary Study PI: Click or tap here to enter text.

3. Contact information of Ancillary Study PI:
   Site: Click or tap here to enter text.
   Address: Click or tap here to enter text.
   Phone Number: Click or tap here to enter text.
   Email: Click or tap here to enter text.

4. Is the Ancillary Study PI already affiliated with GO MOMs?

☐ Yes, the Ancillary Study PI is a member of the GO MOMs Steering Committee

☐ The Ancillary Study PI is a GO MOMs co-I, but not a member of the GO MOMs Steering Committee

- Name of the designated GO MOMs Investigator who will act as Ancillary Study Liaison: Click or tap here to enter text.
- ☐ **The GO MOMs site PI at my location has been informed of this proposal, and approves its submission**

☐ No, the Ancillary Study PI is not affiliated with the GO MOMs study

- ☐ An Ancillary Study Liaison has been identified: Click or tap here to enter text.
- ☐ An Ancillary Study Liaison has NOT been identified. The Ancillary Study PI requests that this proposal be circulated among the GO MOMs Steering Committee to request an Ancillary Study Liaison.

5. Select what IRB will be used for this study.

☐ sIRB

- ☐ VUMC sIRB (recommended)
- ☐ Other, please specify: Click or tap here to enter text.

☐ Local IRB (recommended if only one accrual site)

☐ IRB exemption

- Briefly explain reason for exemption: Click or tap here to enter text.

6. Names and clinical centers of participating co-I:
   NOTE: If applicable, include the Ancillary Study Liaison in the list of co-Is. Additionally, if the Ancillary Study PI wishes to use data and/or specimens from a clinical center, the Ancillary Study must include a GO MOMs co-I or site PI from that site as an Ancillary Study co-I (see section 3.2, Personnel Requirements).

Co-I Name	Co-I Clinical Center
Click or tap here to enter text.	Click or tap here to enter text.
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(Add more lines as needed)

7. Please list any other comments, questions, or notes you have about your submission:
   Click or tap here to enter text.

One-Page Proposal Summary

Title of proposed study: Click or tap here to enter text.

Describe the background, significance, goals, impact on parent study participants (e.g., samples, procedures), endpoints, and hypothesis/es of the proposed Ancillary Study.
Click or tap here to enter text.

Appendix D: GO MOMs Ancillary Study Full Proposal Form

For Questions 1-10, please limit your response to each question to no more than 500 words.

1. Describe the data to be collected, when those data will be collected (e.g., during each patient visit, at the end of each patient's participation in GO MOMs, after all patients have completed GO MOMs), and the methods to be used for data collection:
   NOTE: If the study involves additional specimen collection, indicate how each sample needs to be processed/handled/shipped, what will be measured in each sample, and the proposed laboratory for the assays/analysis. Also, provide the type and volume for each sample, and the time the sample or samples will be collected in relation to other GO MOMs study procedures. If the Ancillary Study PI requests a current copy of the GO MOMs protocol, please email the GO MOMs BRC at gomoms@northwestern.edu.

Click or tap here to enter text.

2. Indicate what GO MOMs core data are required as part of the ancillary study. If the Ancillary Study Liaison requests a current copy of the GO MOMs Case Report Forms, please email the GO MOMs BRC at gomoms@northwestern.edu.

Click or tap here to enter text.

3. Indicate what GO MOMs resources will need to be utilized for this study, and how the utilization of those resources will be funded.

Click or tap here to enter text.

4. Provide a power analysis justifying the number of participants to be included.

Click or tap here to enter text.

5. Indicate where the data analyses are to be done and the statistical methods that will be used.
   NOTE: If the Ancillary Study PI requests assistance from a GO MOMs BRC statistician for study analyses, the budget must include effort for that statistician.

Click or tap here to enter text.

6. Describe the participant burden of participating in the Ancillary Study (the length of time to complete each questionnaire or procedure, etc.).

Click or tap here to enter text.

7. Describe the study personnel burden (what will the GO MOMs personnel need to do in order to complete the procedures, collect the data, and process the specimens for your Ancillary Study?).

Click or tap here to enter text.

8. Describe the measures taken to ensure participant safety and confidentiality.

Click or tap here to enter text.

9. Are funds available to support this study?

☐ Yes Funding Source: Click or tap here to enter text.

☐ No Proposed Funding Source: Click or tap here to enter text.

Attachments

Please attach the following forms to this proposal submission, and email to gomoms@northwestern.edu.

Attachment 1: References Cited

Include an attachment listing the references cited in the proposal. Also include references for the validation and use of the proposed questionnaires (attachment 3).

Attachment 2: Consent Form

Ancillary Studies are to provide an additional template consent form, attached to the Proposal Form, describing in detail procedures to be performed, and possible risks and benefits to the participant. Participation in the Ancillary Study must be described as optional. Consent for the optional study is only to be sought after the mother has consented to GO MOMs. Consent for GO MOMs is the first priority. Those mothers who agree to participate in GO MOMs but do not agree to an Ancillary Study are to remain as GO MOMs participants.

If the Ancillary Study will utilize the VUMC sIRB, the proposal submission must use the VUMC sIRB Master Consent Form. To access this document, either:

1. Go to the Vanderbilt sIRB Help Page: https://www.vumc.org/irb/node/28
    a. Scroll down and click on “2-Part Consent for sIRB”
    b. Click on “Part 1 Master Consent”
2. Or, email gomoms@northwestern.edu, and we can provide you with the latest template consent form

If the Ancillary Study will utilize a different sIRB or a local IRB, the proposal submission should include a that sIRB’s/IRB’s consent form.

Attachment 3: Proposed Questionnaires or Forms

Attach any questionnaires or forms that will be completed by the study participants. Be sure to cite the validation of each questionnaire in your references (attachment 1).

Attachment 4: Budget

A budget for the proposed Ancillary Study must be attached to the GO MOMS Ancillary Study full proposal. The investigator applying for an Ancillary Study must supply all additional funds needed to complete the study. It is essential to provide funds for expenses incurred by GO MOMs. Ancillary Studies investigators are expected to collaborate with the GO MOMs clinical centers to develop a budget, which adequately provides for expenses incurred by GO MOMs. Such costs include, but are not limited to: statistical and data management staff for coordinating the additional data management and analyses with the BRC; sIRB costs; costs incurred by participating clinical centers including space, personnel, equipment, and IRB approval; costs for visits outside of the GO MOMs protocol; and personnel costs for pulling backup samples.

The budget should include as much detail as is typically included in an NIH Request for Application proposal submission; namely, if applicable, personnel effort, laboratory analysis, sIRB, shipping, equipment, travel, participant reimbursement, training, etc. costs broken down by year.

Click here for the budget template:
https://northwestern.box.com/s/um9bmdn627b7qky2sq4h9l9ucn7p7z19

Alternatively, you may use your institution’s budget template, as long as all necessary costs are included. Please submit the budget as a spreadsheet or editable attachment. The BRC will hide salary information before sending it to be reviewed.

Attachment 5: Biosketch of each Proposed Investigator

Information on creating an NIH Biographical Sketch can be found here:
https://grants.nih.gov/grants/forms/biosketch.htm

Attachment 6: Signed Agreement

Attach a signed agreement stating that the Ancillary Studies personnel agree to abide by GO MOMs policies and procedures, including the Publications and Presentations Policy and this Ancillary Studies Policy. This statement should be signed by the Ancillary Study PI.

Click here for a template agreement:
https://northwestern.box.com/s/awx09l3thwb6hcueww9x6r6lrl7nv3a9

Use institutional letterhead. Electronic and digital signatures are acceptable.