Ancillary Study Proposals
Frequently Asked Questions

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1. Where can I find APS details and study protocol?

Information on the APS Consortium, including the schedule of events and protocol (Protocol A includes details on the seven consortium-wide scientific aims), is available at https://apsconsortium.org/

All submitters must review the consortium-wide aims for potential overlap with your proposed study and provide a description and justification for any potential overlap as part of their ancillary study proposal.

2. What is the planned APS enrollment timeframe and target?

The APS enrollment period is July 2024 - April 2028. The target sample size is 4000 participants.

All 4000 participants will have samples collected in-hospital and will complete long-term outcome (LTO) surveys in the year following their enrollment

A subset of surviving participants will be followed prospectively (n=600) for LTO specimen collection and in-person assessments in the year following their enrollment

3. When will APS data and specimens be available for use in ancillary studies?

The chart below highlights the appropriate ancillary proposal submission timing to ensure a decision on your proposal prior to a grant application deadline.

Table 1. Data and specimen sharing timelines

Sample Size	**Approximate timing for data & specimen availability***
1000 (LTO for first 500)	Spring 2026
2000 (LTO for first 1000)	Spring 2027
3000 (LTO for first 2000)	Spring 2028
4000 (all LTO)^	Spring 2029^

***Actual release of data/samples may vary. ^Requests for complete datasets will not be approved until after final data collection. These requests will be reviewed and fulfilled through biodata catalyst.**

4. How do I submit an ancillary study proposal?

Proposals are submitted via a REDCap survey. The survey captures information on the request type, number and types of specimens requested, data requested, and scientific rationale. There is an option to upload additional supporting materials, such as a specific aims page. The link to the REDCap survey is available at https://apsconsortium.org/

5. When can I submit an ancillary study proposal?

There are three primary proposal submission deadlines throughout the year:

- March 15
- July 15
- November 15

In general, proposals will be processed starting on the first deadline after they are submitted. A proposal may be submitted at any time, but there is no guarantee they will be reviewed before the timelines described in Table 1. Generally, proposals are grouped together for review at the next proposal deadline. For time sensitive proposals, please follow the chart below to ensure you get a decision in time for your grant proposal.

Submission dates are based on the majority of requests we receive and are timed to coincide with standard external funding deadlines. However, proposals are not limited to those applying to external grants with deadlines during these periods. If you are applying to a grant with a different deadline or are submitting a proposal with prior funding, please submit your proposal at the submission deadline that best aligns with your project, keeping in mind the turnaround times described in Table 1.

6. What information needs to be included in an ancillary study proposal?

Below is a list of information that is requested in the ancillary study intake form. The intake form provides additional detail.

- Requested contact information and affiliation
- Study name
- Information about the funding submission (if applicable)

    - Including whether the submission will undergo an external scientific review as part of the submission review for funding. This will determine the type of review done by the ancillary study review committee.
- For requests for specimens:
    - They type of samples being requested, including timepoints, sample size, and volume for each specimen
    - Justification for sample size and volume for each specimen type
    - Requested participant characteristics
    - Any additional requirements for biospecimen samples (e.g. anticoagulant used, preservatives, etc.)
        - Changes to APS protocol and procedures will not be considered as part of an ancillary study. We will let you know if any of your requirements that are not aligned with APS biospecimen procedures.
- Description of requested data
- Description of request for radiographic images (if applicable)
- Description of request for specimen analysis results (if applicable)
- Overall sample size justification
- Brief scientific rationale
    - You will have the option to upload any additional documentation on scientific rationale if desired (e.g., specific aims page)
- Description of potential overlap with Consortium aims
    - All submitters must review the Consortium and Clinical Center aims for potential overlap with your proposed study. Consortium aims are available at https://apsconsortium.org/, and Clinical Center aims will be posted on the website in Spring 2025. Prior to Clinical Center aims being posted, the ancillary study subcommittee will review incoming requests for potential overlap with Clinical Center aims. Questions about potential scientific overlap can be directed to aps_consortium@vumc.org and should ideally be addressed prior to submission of a proposal to the committee.
- Confirmation that you will comply with the NHLBI data sharing policy if your study request is approved
    - https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing
    - https://www.nhlbi.nih.gov/grants-and-training/data-sharing-policy-faq-ancillary-studies

7. Can I request a change to the APS data or specimen protocols?

No, the APS protocol for specimen or data collection will NOT be changed for ancillary studies. However, if there is sufficient scientific interest, feasibility, and funding, it may be possible to partner with a subset of APS sites to collect additional specimens during the conduct of APS under a *separate co-enrolling study*.

- Co-enrollment proposals are reviewed by a committee separate from the Ancillary Studies Subcommittee. Please email aps_consortium@vumc.org for further information
- Approved co-enrollment studies *may also* obtain approval as ancillary studies to utilize APS data and/or specimens that are part of the existing APS protocol.

8. How long will it take for my ancillary study proposal to be reviewed?

The chart below highlights the appropriate ancillary proposal submission timing to ensure a decision on your proposal prior to a grant application deadline.

Table 2. Ancillary study review timelines

APS ancillary proposal deadline	Common Grant Deadlines	Decision issued*
Mar 15	Jun	Early May
	Jul	Early Jun
July 15	Oct	Early Sep
	Nov	Early Oct
Nov 15	Feb	Early Jan
	Mar	Early Feb

*Decision times are approximate. For proposals received by each deadline, the Ancillary Studies Subcommittee will prioritize review based on external grant application deadlines.

Proposals with time-sensitive needs, such as support letters for grant applications, will be prioritized during the review period. Prioritized proposals seeking a letter of support for a scientifically reviewed grant application will generally undergo subcommittee review within 6 weeks after the ancillary submission deadline. Letters of support will then be issued for approved ancillary proposals. If an ancillary study proposal is not approved, requesters will be notified via email with information on why the proposal was declined.

Please keep in mind both the appropriate APS deadline associated with your grant deadline as well as the ~6-week post-submission turnaround time when considering your timeline for submitting an ancillary study proposal.

9. What does the ancillary study proposal review process include?

9.1. Screening process

Proposals will be screened within 1-2 weeks after each submission deadline; additional information may be requested during this time. This screening process is to confirm specimen availability and identify whether the proposal will go through standard or extended review process.

9.2. Standard review process

The standard review process includes a review of by the full ancillary study review committee to assess feasibility and appropriateness of the request. The committee will review the proposal independently and then meet to discuss the proposal. Following this discussion, the committee may decide to a) accept the proposal as is, b) tentatively accept and request minor changes or clarifications, c) postpone decision on acceptance until additional information is received, or d) reject the proposal.

9.3. Extended review process

The extended review process varies depending on the characteristics of the proposal and why an extended review is required. It might include additional rounds of review or additional reviewers with specific areas of expertise, and it may lead to requests for additional information based on reviewer feedback. Proposals that are not undergoing external scientific review elsewhere will undergo an internal scientific review by Consortium members as part of the extended review process (see section 9.4)

Reasons a proposal might require an extended review include:

- Proposal requests a large number of specimens (for example, >=50% of an available specimen type)
- Proposals including high-priority, low volume specimen types (including buffy coat, CPT, PAXgene, NBBAL)
- Proposal has potential scientific overlap with APS Consortium of Clinical Center Aims
- Proposal is not undergoing separate external scientific review (such as by an NIH study section)

9.4. Proposal not undergoing external scientific review

Proposals that will not have scientific review as part of the funding process will undergo brief scientific review as part of the ancillary review process.

These proposals will be asked to submit a scientific proposal as an attachment to the overall intake form with the information below:

Scientific Proposal

I. statement of hypothesis and specific aims
II. background
III. preliminary data
IV. research design and methods
    A. study design
    B. data needed for this study
    C. inclusion and exclusion criteria
    D. endpoints
    E. statistical considerations (sample size, analytical plan)
V. bibliography (suggested limit of 25 references)

10. What do I do if my proposal is approved?

For requests for a letter of support, investigators will receive a signed letter of support from the APS Consortium within approximately one week following approval of the proposal.

Once your grant is scored, we request that you provide an update to the Consortium by emailing aps_consortium@vumc.org. We may ask you to complete a brief survey for tracking purposes.

10.1. Next steps if grant is not funded

If your grant is **not funded** and you will be resubmitting your application within nine months of the initial application, your ancillary study proposal will not need to go through a full review process to receive an updated letter of support if there are not substantial changes to the data and specimen request. We will need to do a brief screening to identify any changes in requested specimens before the updated letter of support can be provided. Applications that are proposing substantial changes to the initial data and specimen request will need further review. These changes should be communicated with the ancillary study subcommittee as soon as possible. Please communicate your need for a new letter of support at least 4 weeks prior to your grant submission deadline.

If you grant is not funded and you will be resubmitting your application more than nine months after initial submission, we will ask you to submit as a new ancillary study proposal for our committee to review.

10.2. Next steps if grant is funded

If your grant is **funded**, please provide proof of funding to the Consortium Coordinating Center (CCC; aps_consortium@vumc.org), and they will work with you to develop a plan for data sharing and specimen disbursement. Specimens will not be disbursed until proof of funding is received.

11. What do I do if my proposal is denied?

If your proposal is denied, we will communicate the reason for denial. Reasons a proposal might be denied include:

- Requests for the full dataset prior to completion of data collection
- Lack of alignment between APS specimen collection and specimens requested
- Overlap with Consortium or Clinical Center aims

If you would like additional information on why your proposal was denied or if you'd like to request further discussion with the committee to identify potential areas for proposal revision, please email aps_consortium@vumc.org

12. Who can I contact with further questions?

Please email us at aps_consortium@vumc.org