Welcome to the Abbott Nutrition Division Investigator-Sponsored Study Portal

SUBMIT ISS REQUEST



INVESTIGATOR-SPONSORED STUDY PROGRAM MISSION

Our mission is to nourish every stage of life through advancing the science of nutrition to improve health and well-being worldwide. Abbott Nutrition is committed to learning from leading experts, research, and rigorous science to support growth in infants and children, maintain strength and vitality throughout adulthood, and address diverse clinical and therapeutic needs. Through our global Investigator Sponsored Studies (ISS) program, we support independent, original research conducted by academic and community-based investigators to expand clinical and scientific understanding of nutrition, Abbott products, and nutrition needs of related disease states—ultimately benefiting patients and helping people live fuller, healthier lives.

KEY AREAS OF INTEREST TYPES OF SUPPORT TIMING OF PROPOSAL SUBMISSION AND REVIEW QUALIFICATION OF SPONSOR-INVESTIGATORS

PROPOSAL DEVELOPMENT AND REVIEW CRITERIA/REQUIREMENTS INVESTIGATOR-SPONSORED STUDY PROCESS FAQS

KEY AREAS OF INTEREST

Adult Nutrition		Pediatric Nutrition
Malnutrition	Tolerance and GI health	Malnutrition
Muscle Health	Diabetes	Tolerance and GI health
Surgery	Oncology	Food Allergies
Wound healing		

TYPES OF SUPPORT THAT MAY BE REQUESTED FROM ABBOTT

Financial Support

- Requests must include an itemized budget.

  Please note:
  - Abbott generally does not support overhead or indirect charges such as facility rent or space, IT infrastructure, or other fees not tied to specific deliverables for studies that are sponsored and conducted by the institution. If such charges are proposed, they will be carefully reviewed to ensure they are reasonable in light of the funding Abbott is providing and may be declined, although other requests for support being provided as part of the study support.
  - Requests for funding a dedicated headcount or general staff management are discouraged.
  - Requests to purchase equipment are typically not supported if the equipment could be used beyond the scope of the study or provide ongoing institutional benefit after the study ends, such as laptops, computers, software tools for general business, and printers.

Nutritional Product Support

- Requests may include Abbott Nutrition products that are:
  - On the market and currently available in the country where the research will be conducted.

Technical Support or Study-Related Activities

- Requests may include technical expertise or assistance directly related to the study.

TIMING OF PROPOSAL SUBMISSION AND REVIEW

Timing of Review Cycle	The Abbott Scientific Research Review Committee conducts batched reviews on a quarterly basis according to the type of support requested:
	• Nutritional Product Support, Technical Support, and/or Study-Related Activity Support
	  • Proposals requesting these types of support may be reviewed quarterly.
	• Financial Support
	  • Proposals requesting financial support—either as a standalone request or in combination with other support types may be reviewed during the second and fourth quarters.

Submission Guidance	• Sponsor-Investigators are encouraged to submit proposals as soon as they are ready to facilitate confirmation that all review requirements have been met. • Upon submission, additional information related to the timing of the upcoming Scientific Review Committee meetings may be provided. • Abbott may reach out to you to ensure all requirements for review have been addressed, as only complete submissions will move forward for Scientific Review Committee review.

QUALIFICATION OF SPONSOR-INVESTIGATORS

Abbott invites research proposals from academic and community-based scientists and physicians who will serve as sponsor-investigators for their own studies. During the submission and review process, the following qualifications will be evaluated:

Research Experience	Demonstrated expertise in the proposed area of research, as outlined in a current CV.
Professional and Regulatory Standing	Good professional standing, with no history of debarment or restrictions from any regulatory or government authority related to conducting clinical research.
Medical Licensure	A valid medical license is required. If the sponsor-investigator is not a licensed physician, the study team must include a licensed physician as a sub-investigator to provide medical oversight and assess study-related adverse events.
Good Clinical Practice (GCP) Knowledge	A foundational understanding of Good Clinical Practice (GCP) to ensure the safety, rights, and well-being of research participants.

PROPOSAL DEVELOPMENT AND REVIEW CRITERIA

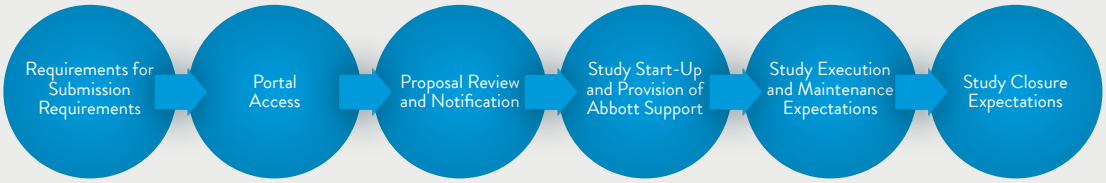
Proposals that demonstrate the following will be eligible for review by our cross-functional Scientific Research Review Committee:

- Consistency with Abbott's overall scientific strategy.
- Demonstration of scientific merit and principles, including evidence of adherence to participants' safety, rights, and well-being.
- Investigation of a legitimate need or interest that adds to the body of evidence and avoids unnecessary duplication of existing research.
- Performance of research designed to test a scientific hypothesis or to obtain observational data with the intent of enhancing clinical and/or scientific knowledge.
- Adequate attention to applicable legal and regulatory considerations.
- Studies should assess the role of nutrition in general health/wellness or in meeting the nutrition needs of a related disease state. Studies should not evaluate the use of an Abbott Nutrition product for the diagnosis, treatment, cure, or prevention of a disease.
- Alignment between the number of human participants or samples and the purpose of the research (not exceeding what is necessary to achieve the research objectives). The proposal should include power calculations and plans for statistical analysis, where applicable.

- Consideration of safety reporting requirements, including but not limited to plans for adverse events which may include procedures for the collection, documentation, assessment (including seriousness, severity, causality, and outcome), follow-up, and reporting of AEs and SAEs in accordance with ICH GCP and applicable regulatory requirements, including reporting of unexpected and product-related SAEs within 24 hours of investigator awareness.
- Determination of fair market valuations for any financial support requests.

Submission of a proposal does not guarantee approval.

INVESTIGATOR-SPONSORED STUDY PROCESS



This section provides an overview of the ISS Process from Proposal Submission through Study Closure, and insight into the expectations when Abbott support is provided.

Requirements for Proposal Submission	• The following information is required at the time of submission:
	  • Study Proposal (in English).
	  • Type of support requested from Abbott.
	  • An itemized budget is required for financial support requests.
	  Please note:
	  • Abbott generally does not support overhead or indirect charges such as facility rent or space, IT infrastructure, or other fees not tied to specific deliverables for studies that are sponsored and conducted by the institution. If such charges are proposed, they will be carefully reviewed to ensure they are reasonable in light of the funding Abbott is providing and may be declined despite other requests for support being provided as part of the study support.
	  • Requests for funding a dedicated headcount or finance and general management staff are discouraged.
	  • Requests to purchase equipment are typically not supported if the equipment could be used beyond the scope of the study or provide ongoing institutional benefit after the study ends such as laptops, computers, software tools for general business, and printers.
	  • Specification on whether the study will be funded from multiple sources.
	  • Curriculum Vitae (CV) of the Sponsor-Investigator, current within the past 2 years, signed and dated.

Portal Access	• Once the materials are ready to submit:
	  • Create a New Account on the ISS Portal or Log In using your existing account email and Password.
	  • Complete the proposal form and attach all required files prior to submitting.
	• For assistance with the submission, please contact ISS@abbott.com.

Proposal Review and Notification	• Notifications from Abbott will be issued at key stages of the process, including upon proposal receipt, if additional or clarifying information is required, and upon communication of the final review decision. • The Scientific Research Review Committee may request clarifications or recommend revisions for the probability of success.

Study Start-Up and Provision of Abbott Support	• If the proposal is approved by the Scientific Research Review Committee, Abbott will communicate the next steps related to the legal agreement and required documentation. The following must be in place prior to the provision of support by Abbott:
	  • Fully executed contractual agreement.
	  • Abbott's requisite contractual terms recognize the sponsor's ownership rights in the study data and any pre-existing intellectual property. The terms may require that Abbott be provided with reports and/or deidentified protocol-specified information for unrestricted use in future research or other lawful purpose. Any discoveries or inventions related to an Abbott product used in the study will belong exclusively to Abbott.
	  • Evidence of Good Clinical Practice Training for the Sponsor-Investigator (i.e. certificate valid within 3 years).
	  • Medical license of the Sponsor-Investigator (or Sub-Investigator for Adverse Event assessment and reporting).
	  • Ethics/IRB Approval Letter related to the current version of the protocol and informed consent form (ICF).
	  • Acknowledgement of Abbott support in the ICF and appropriate study materials.
	  • Abbott's Adverse Event Reporting training.

Study Execution and Maintenance Expectations	• For prospective clinical studies, Abbott encourages the Sponsor-Investigator to register on the FDA's ClinicalTrials.gov or other public trial registry in their applicable country, prior to enrolling participants. • Maintenance of product accountability records is required for all products provided by Abbott throughout the study. • Abbott requires quarterly status updates related to study expected timeline, enrollment, protocol changes, submissions to IRB/EC, adverse events, progress on analysis, reporting of final results and publications, including abstracts and posters. • If more than two sequential quarterly updates are not provided, or enrollment expectations are not met, the continued

	support of the study will be reviewed by the Scientific Research Review Committee and support may be withheld, and study agreement may be terminated.
Study Closure Expectations	• Documentation requirements at study closure include final reconciliation of Abbott support and receipt of the final report or other deliverable(s) in accordance with the study agreement. • Any planned publications, including abstracts and posters, must be sent to Abbott in advance of submission in accordance with the study agreement.

FAQS

WHO CAN I CONTACT WITH QUESTIONS ABOUT THE SUBMISSION PROCESS? +

If you have additional questions about the proposal submission process, please contact the Investigator-Sponsored Study Administrator at ISS@abbott.com.

WHERE DO I SUBMIT THE PROPOSAL? +

Select this link to access the account login page. You will be prompted to create a new account or log in using your existing email address and password.

HOW DO I RETRIEVE MY PASSWORD? +

Select the "Forgot Password" hyperlink on the account login page to reset your password.

WHO DO I CONTACT IF I HAVE DIFFICULTIES USING THE PORTAL? +

If you experience difficulties using the portal to submit your proposal, please contact the Investigator-Sponsored Study Administrator at ISS@abbott.com for assistance.

HOW DO I REQUEST SUPPORT FROM OTHER ABBOTT DIVISIONS? +

This site is intended for support requests from Abbott Nutrition. Each Abbott Division manages its own support requests. If your study also includes a request for support from another Abbott Division, the request will need to be made through that division's site.

WHAT TYPE OF SUPPORT CAN BE REQUESTED? +

Financial Support

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HOW OFTEN ARE PROPOSALS REVIEWED?

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HOW DO I CHECK THE PROGRESS OF MY SUBMISSION?

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- If you have additional questions about the progress of your submission, please contact the Investigator-Sponsored Study Administrator at ISS@abbott.com.

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