



# Allergan Investigator Initiated Trial Submission Details

Allowing qualifying external investigators to submit proposals to Allergan for support to conduct clinical and non-clinical investigator-initiated research.

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## SUMMARY OF INVESTIGATOR INITIATED TRIAL PROCESS

	<b>Investigator Sponsor</b>	<b>Allergan</b>
Application & Review	<u>Step 1:</u> Concept Discussion with Allergan MSL and/or Medical Director	A. Concept Review processing B. Communication of decision to decline or request Full Proposal submission
	<u>Step 2:</u> If your preliminary concept was accepted by Allergan, then proceed to submit a Full Proposal in <a href="#">IIT Portal (VISTA)</a>	A. Conduct debarment check B. Initiate Fair Market Value (FMV) Assessment C. Request for additional information - as needed D. Communication of decision to decline or approve
Study Contract Execution	<u>Step 3:</u> Study Details <ul style="list-style-type: none"> <li>- Applicable Approval from:                             <ul style="list-style-type: none"> <li>o IRB/EC or equivalent</li> <li>o IND/IDE (US-only)</li> <li>o Competent Authority (non-US)</li> </ul> </li> <li>- CT.gov registration (if applicable)</li> </ul>	A. Review all submitted final documents and finalize budget B. Approve final budget and payment milestones C. Negotiate, finalize, and execute contract D. Issue first drug shipment (When applicable and issued only upon all approvals received)
Study Execution and Reporting	<u>Step 4:</u> Conduct Study and submission of a quarterly report	A. Monitor progress
	<u>Step 5:</u> Results Reporting and Study Closure. <ul style="list-style-type: none"> <li>- Reconciliation of study funds and product (if applicable)</li> <li>- Attestation of results posted on CT.gov (if applicable)</li> </ul>	A. Review submitted Final Study Report and/or a high-quality draft manuscript

## DETAILS REQUIRED FOR SUBMISSION OF AN INVESTIGATOR INITIATED TRIAL (IIT) BUDGET

The submission of a comprehensive, well-constructed budget will help you and Allergan through the grant process in an efficient manner. As per policy, a Fair Market Value assessment is required for all submissions containing financial support. Below are some requirements and tips for creating a comprehensive budget that will enable Allergan to effectively conduct the Fair Market Valuation.

- Please provide as much details as possible to each line item /request
- If you would like to use the Allergan Budget Template, you can retrieve and download this during submission under the “Budget” section. Budget template available for download during your application submission process.
- Budget costs to be considered for IITs include but are not limited to:
  - o **Procedure Costs**
    - List of procedure(s)
    - Cost of each procedure
    - # of times the procedure is performed
    - # of patients
  - o **Site Costs**
    - Study Coordination (# of hours and cost per hour)
    - Statistician (# of hours and cost per hour)
    - IRB / EC Fees (Approval, Renewal, Amendment, etc.)
    - Supplies (Example: paper / forms, printer ink, pens, testing supplies, shipping, etc.)
- When requesting in budget for **procedures/tests/assessments**:
  - o Provide the name of the procedure
    - Example: Physical Exam, Urine Pregnancy Test, Slit Lamp Exam
  - o Provide proposed cost of each procedure
    - When applicable, provide description of activity being performed
  - o Provide number of times the procedure is performed per patient
  - o Provide number of total patients
  - o Supporting documentation (i.e. quote/estimate) is required if procedures are being conducted by external/third party
  - o \* Do not duplicate request to perform procedure/activity and hourly rate to conduct procedure
- When requesting in budget **salary request**:
  - o Provide role and description
    - Example: Study Coordinator to coordinate patient visit and maintain study records
  - o Provide hourly rate
  - o Provide proposed total number of hours

- \* Do not duplicate request to perform procedure/activity and hourly rate to conduct procedure
  
- When requesting in budget for **Supplies**:
  - This is not for Allergan related product.
  - Provide quote/estimate of cost
    - Example: Fee schedule listing, web listed price, estimate from vendor
  
- Standard Items Not Supported
  - Budget cost for Protocol/study design development.
  - Publication/presentation support (Example: travel cost, poster print, etc). When ready, a Publication Grant can be submitted for financial support relating to publications and presentations.
  - Budget cost to write a final study report.
  - Non-Allergan products/non-Allergan devices will not be provided. Financial support can be considered for non-Allergan product, but no direct in-kind supplementation of non-Allergan product/device will be given.

# HOW TO APPLY

## WHO MAY APPLY

Allergan will accept proposals worldwide for Investigator Initiated Trial support from qualifying external investigators in good standing who are affiliated with hospitals, academic institutions, research centers and group practices.

Allergan will not consider requests for the following:

- Funding to individuals
- Proposals tied to prescribing, purchasing, formulary status, reimbursement or any quid pro quo arrangement
- Infrastructure development
- Requests that are deemed in excess of fair market value
- Proposals that are not aligned with currently supported Allergan products
- Purchase of capital equipment

## GRANT TYPES

Allergan accepts Initial (synopsis / concept) submissions and Full Proposal submissions for Investigator-Initiated Trial grant requests. If an initial submission is of interest, a follow up request for a full proposal submission will be issued. A full proposal submission must be received in order for a request to be considered for approval for the following:

- IIT (Preclinical, Clinical)
- Publication Grants (related to Allergan IIT Only)
- In-Kind Product

## HOW TO APPLY

Grant requests must be submitted at least 60 days prior to the activity start date.

### Concept Review – Initial Proposal

An Initial proposal, (synopsis / concept), submission must contain an adequate amount of information that will allow Allergan to determine interest in receiving a full proposal. When submitting an Initial proposal, the following information will be requested:

- Grant Type: Investigator Initiated Trial (IIT)
- Grant Sub Type: Clinical or Pre-Clinical
- Submission Type: Initial
- Geographic Region
- Therapeutic Area of Interest
- Institution / Affiliation Information
- Grant Title
- Scientific Basis / Rationale
- Summary of Initial Review
- Primary Objectives
- Primary Endpoints
- Study Enrollment (if applicable)
- Study Duration



- Grant Support: Funding, Product (Drug / Device) or Both
- Total Funding Requested (if applicable)
- Primary Allergan Drug or Device (if applicable)
- Formula, Strength, Quantity (if applicable)
- Upload current Curriculum Vitae or brief Bio

## Full Proposal

A full proposal submission must contain enough detail about the research study and the grant request to enable Allergan to make a final evaluation regarding support. When submitting a Full proposal, the following information will be requested:

- Grant Type: Investigator Initiated Trial (IIT)
- Grant Sub Type: Clinical or Pre-Clinical
- Submission Type: Full Proposal
- Geographic Region
- Therapeutic Area of Interest
- Institution / Affiliation Information
- Grant Title
- Scientific Basis / Rationale
- Hypothesis
- Primary and Secondary Objectives
- Inclusion/Exclusion Criteria (if applicable)
- Primary and Secondary Endpoints
- Treatment Regimen (if applicable)
- Trial Design
- References
- Statistical Analysis Plan
- Number of Study Sites
- Study Enrollment (if applicable)
- Study Duration
- Target Start and End Dates
- Publication Plans
- Grant Support Type: Funding, Product (Drug / Device) or Both
- Total Funding Requested (if applicable)
- Primary Allergan Drug or Device (if applicable)
- Formula, Strength, Quantity (if applicable)
- Upload Protocol
- Upload current Curriculum Vitae or brief Bio
- Upload Itemized Budget (if applicable)

## BUDGET

If you are requesting financial support for your trial, please note the following:

### Fair Market Value

Allergan will consider reasonable requests for financial support of a trial. To inform our decision, Allergan will conduct a fair market valuation of your submitted budget using an industry standard tool. This tool provides contemporary cost ranges paid for specific actions taken (procedures, tests, etc.) in the conduct of the trial. Ranges are based on other, similar, recently conducted trials and adjust for local markets and currencies. Allergan is

required to use such a tool to help ensure that any support provided is appropriate for the proposed trial.

## Budget Template

Any trial request seeking funding support must include a detailed budget. You may upload your own format or use the template provided by Allergan that can be downloaded in the budget section of your request. If you use your own format, please be sure to provide adequate detail so that Allergan can conduct the FMV analysis described above. For example, please be sure to indicate specific actions required for each aspect of the trial, such as trial visits and procedures (e.g., physical exam, blood work, slit-lamp exam) and cost. Areas that are vague or unclear will delay the processing of your request and require resubmission by the requester.

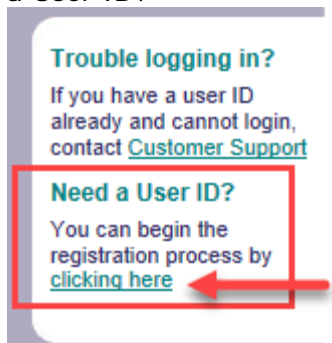
If requesting salary, be sure to clearly indicate hours and rate. Please include an estimate from the vendor for any unusual or study-specific items that you require. Please reference the uploaded budget template as an example of the detail required even if you use your own format.

Please refer to "[Details Required for Submission of an Investigator-Initiated Trial \(IIT\) Budget](#)" at the beginning of this document for additional information.

## HOW TO REGISTER AS A NEW USER

In order to be able to submit a grant request to the Allergan Investigator-Initiated Trials system, you must register as a user:

1. Open the Allergan Investigator-Initiated Research Trial Homepage and locate: Need a User ID?



2. Complete all fields on the Registration pop-up window
3. Click "OK" after completing the form

After submitting your request, a registration confirmation will be sent to the e-mail address provided.

## UNABLE TO REGISTER

If you encounter difficulty with user registration, it may be due to:

1. Information entered as part of your registration was invalid. Please see the error message and re-enter correct information.

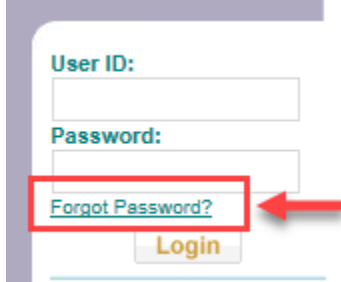
2. An email address or username was entered during registration that has already been registered with the Allergan Investigator-Initiated Trials system. Please choose a different username or email address.

If you are still unable to register, please click on the Customer Support link located at the top left of the login screen for assistance.

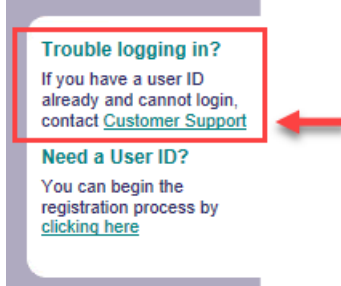


## FORGOTTEN USERNAME OR PASSWORD

You may request a new password by clicking on "Forgot my Password" on the top left side of the Allergan Investigator Initiated Trials system login screen.



If you have forgotten your User ID or cannot login, please click on the Customer Support link located at the top left of the login screen for assistance.



## USERNAME/PASSWORD UPDATE

You may change your User Name and Password at any time by locating the "Change Password" link on the left side of the Allergan Grant Management System homepage. Please keep in mind the following parameters:

- Minimum Characters: 8
- Password Configurations: Minimum Characters: 8
- Current password cannot be reused as the new password

- Last 10 passwords cannot be reused as the new password

At least one character from three (3) of the following categories must be used in a password:

- Upper-case letter
- Lower-case letter
- Number
- Upper and lower case
- Alphanumeric character
- Special character (e.g. !@#\$%^&\*?/)

## TIME ALLOTTED FOR ENTRY

Your application session will time out after 60 minutes, and you will be prompted to re-enter your Username and Password information.

User accounts lock out after five (5) invalid login attempts. If you are locked out of the system after five (5) failed login attempts, you will need to request a new password.

## CONTACT US

For technical assistance with the request management system, please call toll-free at (866) 257-0272, or email at [vtsupport@envisionpharma.com](mailto:vtsupport@envisionpharma.com).

For any questions related to the funding request process, please email Allergan's IIT Medical Affairs Department at [IR-IITRequest@Allergan.com](mailto:IR-IITRequest@Allergan.com).

Please reference your study ID # if your question is regarding an IIT that has already been submitted.

# FREQUENTLY ASKED QUESTIONS

## WHICH GUIDELINES AND/OR REGULATIONS DOES THE ALLERGAN MEDICAL AFFAIRS DEPARTMENT ADHERE TO?

Allergan provides grants to support investigator-initiated research in compliance with all applicable regulations, as well as the principles and guidelines of organizations such as the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Associations of the British Pharmaceutical Industry (ABPI), the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers Association (PhRMA) guidelines.

## WHAT IS ALLERGAN'S POLICY ON RESEARCH SUBMISSION?

Allergan is committed to supporting investigator-initiated research in accordance with corporate policy.

As part of an industry that is highly regulated, by state and federal laws as well as by self-imposed guidelines and standards, compliance with the laws and regulations that govern our industry is a responsibility we focus on every day. Allergan's policies are designed with not only these requirements in mind but also the Company, our employees, our customers, the healthcare community and, most importantly, patients.

All materials submitted must be non-confidential and should not contain any markings indicating confidentiality. By submitting your materials to Allergan for review, you understand that we will not treat the information as confidential or proprietary. It is necessary to refer a submission to various different persons in the Company to ascertain whether or not a research proposal is of interest. Thus, while we have no intention of publicizing a submission, we can assume no obligation to keep it confidential. It is our fixed policy to consider investigator-initiated research proposals from persons outside the company upon the following conditions:

1. That the submission is not made in confidence and is not accompanied by any reservation or condition whatever which imposes upon Allergan any obligation or restriction with regard to its use.
2. That the submitter's rights shall be only those given under the patent laws and/or under any written contract to which the submitter and Allergan may mutually agree.
3. That the submitter is the originator of the information and materials or has been authorized by the originator to provide information and materials on their behalf.

## WHAT ARE ALLERGAN'S THERAPEUTIC AREAS OF INTEREST FOR EDUCATIONAL SUPPORT?

\*\* Please note that generally, Allergan will not support research on patented concepts or methods.

Areas of Medical Affairs Research Interest:

- Eye Care
- Glaucoma

- Ocular Surface Disease/Dry Eye
- Anterior Segment Surgery
- Retinal Disease
- Neurosciences
- Urology
- Medical Aesthetics
- Non-Surgical Facial Aesthetics and Rejuvenation
- Breast Augmentation and Reconstruction
- Dermatology
- Acne Vulgaris

## WHAT TYPES OF SUPPORT CAN BE REQUESTED?

Money, drug / device or both.

## WHAT ARE AN INVESTIGATOR'S REGULATORY AND ETHICAL OBLIGATIONS?

As the sponsor of the study, the investigator and/or institution must ensure that the study is conducted in accordance with the provisions of the ICH GCP Guidelines and all applicable local and regulatory requirements. The Principal Investigator must assume all regulatory responsibilities including, but not limited to, IRB/IEC approvals, regulatory approvals, and any and all reporting obligations to local Regulatory Authorities.

## WHAT ARE THE REQUIREMENTS FOR IIT COLLABORATION?

Upon approval of your full proposal, there are several documents that Allergan requires before it can initiate support (drug / device and/or funding). Allergan requires:

- Fully executed Letter of Agreement or Research Agreement
- Final study protocol
- IND submission and acceptance by FDA (if required)
- Approval by the governing body (e.g., IRB, Ethics Review Board, etc.)
- Registration on [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

## WHAT ITEMS ARE NECESSARY FOR COMPLETING A CONCEPT (INITIAL) PROPOSAL SUBMISSION?

A concept, or initial, proposal submission must contain an adequate amount of information in order for Allergan to determine interest in receiving a full proposal. When submitting a concept proposal, the following information will be requested:

- Preliminary Study Title
- Study Type: Clinical or Pre-Clinical
- Grant Request: Funding, Drug / Device or both

- Primary Allergan Drug or Device (if applicable)
- Number of study sites
- Inclusion/Exclusion Criteria (if applicable)
- Target Enrollment (if applicable)

## WHAT ITEMS ARE NECESSARY FOR COMPLETING A FULL PROPOSAL SUBMISSION?

A full proposal submission must contain enough detail about the research study and the grant request to enable Allergan to make a final evaluation regarding support. When submitting a Full proposal, the following information will be requested:

- Preliminary Study Title
- Study Type: Clinical or Non-Clinical
- Grant Request: Funding, Drug / Device or both
- Primary Allergan Drug or Device (if applicable)
- Formula, Strength, Quantity
- Number of study sites
- Country of Primary Site
- Total Funding Requested (if applicable)
- Outside Support (if applicable)
- Non-Allergan drug(s) or device(s) as part of the study
- Study Synopsis
- Needs Assessment
- Brief Study Rationale
- Primary and Secondary Outcomes
- Study Design
- Statistical Analysis Plan
- Inclusion/Exclusion Criteria (if applicable)
- Target Enrollment (if applicable)
- Treatment Plan or Dosing Regimen (if applicable)
- Study Duration
- Target Start and End Dates
- Publication Plans
- Upload current Curriculum Vitae or brief Bio
- Itemized Budget (if applicable)
- Payment Contact Information

## WHAT IN-KIND PRODUCTS MAY I REQUEST THROUGH AN IIT GRANT?

Allergan may only provide in-kind product in connection with an educational grant if the activity is conducted by an ACCME-accredited provider and/or if it is an independent medical education activity conducted for the education of residents, fellows or other physicians in training. The following products may be requested:

- Botox® Cosmetic vials
- Botox® Therapeutic vials
- Juvéderm® Ultra XC and Ultra Plus XC syringes

- Juvéderm Voluma® XC syringes
- Kybella® vials
- EMG Needles (for Neurosciences only)
- Anatomical Models (for Neurosciences only)

## MAY I REQUEST PRODUCT ONLY?

Yes. The process is the same to request money or in-kind product.

## WILL A BUDGET BE REQUIRED?

Yes. Before submitting your budget, please ensure that all study-related expenses have been appropriately itemized and included and are commensurate with fair market value.

Do not include publication costs (e.g., preparation of manuscript, travel, etc.) as this can be submitted as a separate PUBLICATION GRANT request once the study is completed.

## HOW CAN I SUBMIT A REQUEST FOR FUNDING FOR PUBLICATIONS?

If your trial is conducted as approved, Allergan may provide funding for reasonable and customary publication costs at fair market value. Once your trial begins enrollment, please contact your Allergan Study Manager for information about how to submit a publications request, reasonable and customary publication costs at fair market value. You will be contacted by Allergan with information regarding how to submit your separate PUBLICATION GRANT request.

## WHEN ARE GRANT REQUESTS ACCEPTED?

Grant requests are accepted and approved throughout the year. Requests for grant funding must be submitted at least eight (8) weeks before the scheduled activity start date.

## WHAT INFORMATION WILL I RECEIVE FROM THE ALLERGAN MEDICAL AFFAIRS DEPARTMENT REGARDING MY REQUEST?

You will receive an acknowledgement e-mail once the Allergan Medical Affairs Department has received your completed synopsis or full proposal. After your request has been completely reviewed by the Allergan Review Committee, Allergan will provide you a written response regarding your request. If your request is approved, the response will be accompanied by a Letter of Agreement (LOA), which must be signed and returned to the Allergan Medical Affairs Department. Please do not consider any request approved until you have received written documentation from the Allergan Medical Affairs Department stating that your trial request has been approved.



## WHAT IS ALLERGAN'S STANDARD GRANT REVIEW PROCESS/PROCESSING TIME?

Allergan will acknowledge receipt of all grant submissions. The review process is conducted by an Allergan Grant Review Committee and decisions are made based upon medical and scientific merit, as well as available resources and research priorities. Consideration criteria include whether the proposed study is novel, innovative and/or verifies existing data and contributes to the scientific community. The Grant Review Committee is made up of members of the Medical Affairs, Legal, Compliance and Regulatory Affairs departments. A formal notification on the status of your application will be sent once a decision is reached.

Review times vary from grant to grant; however, our normal grant processing time is a minimum of eight to ten (8-10) weeks.

## CAN I COMPLETE PART OF THE ONLINE SYNOPSIS OR FULL PROPOSAL AND COME BACK TO IT LATER?

Yes. If you are unable to complete your synopsis or full proposal in one sitting, you may save the request and come back to it later by clicking save button at the bottom of the page. Each tab has a designated Save button, please ensure you select the Save button at the bottom of each page to save your latest work. At any time before the submission of a grant request, you will have the opportunity to come back and make changes to the request.

## WHAT SHOULD I DO IF MY PROPOSAL HAS ALREADY BEEN SUBMITTED AND I NEED TO ADD ADDITIONAL INFORMATION?

Please contact the Allergan Medical Affairs Department at [IR-IITRequest@allergan.com](mailto:IR-IITRequest@allergan.com) for assistance.

## HOW CAN I FIND THE STATUS OF MY GRANT REQUEST?

Log into the IIT System for the current status of each request you have submitted.

## CAN I SUBMIT A GRANT REQUEST FOR SUPPORT OF A TRIAL THAT HAS ALREADY OCCURRED?

No. Allergan will not review nor approve grant requests for trials that have already concluded.

## CAN I SUBMIT A PAPER PROPOSAL?

No. Paper proposals will not be accepted. Only online applications will be reviewed.

## WHEN CAN WE EXPECT PAYMENT ONCE THE GRANT HAS BEEN APPROVED?

You can expect a check approximately four (4) weeks after Allergan has received the signed Letter of Agreement. All parties (i.e., Provider and Educational Partner, if applicable) must sign the Letter of Agreement in order for payment to be issued.

## WHAT IS A “REQUEST FOR ADDITIONAL INFORMATION” AND HOW MUCH TIME DO I HAVE TO RESPOND?

A Request for Additional Information is made when additional information is needed to consider your grant request. The request will be sent via email to the contact listed in the grant request. If the Allergan Medical Education Department has not received the requested information within 10 business days of the follow-up request, the grant request may be declined.

## WHAT IF I HAVE MY OWN LETTER OF AGREEMENT?

All activities supported by an Allergan IIT or Publications grant must abide by the Letter of Agreement issued by Allergan. If you have any questions on the agreement terms, please contact the Allergan Medical Affairs Department at [IR-IITRequest@allergan.com](mailto:IR-IITRequest@allergan.com)

## DOES PREVIOUS SUPPORT OF IITs BY ALLERGAN GUARANTEE FUTURE SUPPORT?

No. Each proposal is evaluated on its individual merit. Funding is not guaranteed until you receive formal written documentation from Allergan’s Investigator-Initiated Trial office approving your proposal. A verbal commitment from any company employee does not guarantee funding.

## ARE THERE COSTS THAT ALLERGAN WILL NOT COMPENSATE AN INVESTIGATOR FOR?

YES:

- General educational and training activities
- Support for ongoing clinical programs that are part of an organization's routine operations
- Purchases of capital equipment unrelated to the study or that would generate revenue
- Construction funds to build new facilities
- Hiring of staff that are not dedicated to the study

## ARE PERIODIC STUDY UPDATES REQUIRED?

Allergan requires at least one study status update per quarter. Updates are expected to include information on enrollment (if applicable), projected publications and study completion dates. Any payment to a Healthcare Professional from funds provided by Allergan should also be reported on a quarterly basis. Additionally, Allergan requires submission of any periodic updates or documentation of continuing review made to the investigators governing body (e.g., IRB, Ethics Review Board, etc.) as well as notification of any amendment to the original protocol after the research has begun.

## WILL SUPPORT OF MY TRIAL BY ALLERGAN BE DISCLOSED PUBLICALLY?

Yes. All funding to you will be made public. Allergan needs to ensure that any payment or benefit provided to a healthcare professional on behalf or by of Allergan be reported on a publicly available website. If portions of the funding provided to you are subcontracted out to other HCPs, you may provide an updated payment or benefit information in the form of an HCP declaration to allocate the percentage of funds received from Allergan that directly benefits other individual healthcare professional(s). Note that the disclosure may be included as part of an aggregate disclosure, along with other funds provided by Allergan (e.g. Advisory Boards, Speaker Engagements).

## WHAT ARE THE REQUIREMENTS FOR STUDY CLOSURE?

An investigator conducting an IIT is contractually required to provide Allergan with a written report of the final study results. Any planned publications must be sent to Allergan in advance of submission in accordance with the IIT contractual agreement. Upon study closure, the investigator will be required to certify that the study was conducted and the Allergan grant funds and/or drug / device were used solely to conduct the study and that all safety reporting obligations were met. Reconciliation of all study costs will also need to be submitted to Allergan in order to receive final payment. Allergan will require that any unused funds be returned and any unused drug or device be destroyed at the completion of the study. Allergan may request the return of funds if they cannot be fully accounted for.

## WILL A PHYSICIAN IND BE REQUIRED?

An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application. This includes approved drugs that are being used for an indication that is different than the one that the drug is marketed under. Detailed information for Sponsor-Investigators submitting IND Applications can be found at the following page on the FDA website (includes links to the each of the forms): <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm>.

To complete your IND application, you must submit the following to the FDA:

- Form FDA 1571
- Form FDA 3674
- Cover letter
- Statement of Qualification: Curriculum Vitae and a copy of the signed Form FDA 1572 for each principal investigator at a research site.
- Copy of cross-reference letter to FDA from Allergan (once the contract is signed)
- Protocol
- US Package Insert

Any additional information supporting the use of the drug for the proposed protocol (e.g., literature references, data from previous studies, etc.)

## WHAT ARE THE POST-STUDY REQUIREMENTS?

Results from the study must be submitted to Allergan in a format suitable for publication.

## WHAT HAPPENS IF I DO NOT FOLLOW THROUGH WITH POST-STUDY REQUIREMENTS?

If Allergan does not receive required post-study materials after study completion, you may not be eligible to apply for future support. Additionally, for research support that includes funding, final payment is dependent on submission of results in a format suitable for publication.

## WHAT ARE ALLERGAN'S SAFETY REPORTING REQUIREMENTS?

Investigator will ensure disclosure to the appropriate governing body (e.g., IRB, ethical review board, etc.) and also the U.S. Food and Drug Administration (FDA) of any Serious Adverse Event(s) that occur during the course of the Study. The Investigator will also provide notice to Allergan and to the appropriate governing body (if required) of any adverse event(s), serious or otherwise, before publishing any such findings.

Furthermore, Investigator will have the sole responsibility to inform the appropriate governing body of any protocol deviation that occur during the course of the Study, to submit any amendments to the protocol to the governing body prior to initiating any changes to the research, as well as provide all periodic updates as required by the governing body.

## WHO WILL BE ABLE TO ASSIST ME WITH THE ONLINE PROCESS AND KEEP ME APPRISED OF MY APPLICATION STATUS?

Only the Allergan Investigator-Initiated Trials office may assist you with your proposal. Their assistance is limited to providing responses to general technical, logistical or system-related issues. No other Allergan personnel may assist you with your proposal. Submission of your proposal by any Allergan personnel will lead to automatic declination of your request.

## WHAT ARE THE BASIC SYSTEM REQUIREMENTS FOR INTERFACING WITH ALLERGAN'S IIT PORTAL?

This system supports most major browsers on Windows operating systems. No additional software is necessary to install on desktop PCs or laptops.

## CORRECTING THE INTERNET EXPLORER SETTINGS

If you are using Internet Explorer, it may be necessary to alter your download settings in order to see the PDF printout. If nothing happens when you click "Print," please follow the instructions below:

1. Select and click on "Internet Options" from the "Tools" menu
2. Select the tab called "Security" and then the "Custom Level"
3. Scroll down to the "Downloads" section and make sure all three options (Automatic prompting for downloads; File download; Font download) are set to "Enable," then click "OK"

## HOW DO I SAVE AN APPLICATION?

A successful save will display a message on the screen stating the application has been saved, and the system will provide you with a temporary tracking number. Once in the system, you will see a list of selections below your login name on the left side of the webpage.

- You can locate a saved application by either clicking on "Task List" or "All My Applications." Note: If you have applications pending, they will be listed as tasks waiting for you. You will be able to view those applications under the "Task List" tab.
- Within the "Actions" column, there are links called "Complete Grant" or "View Grant"
- Click on the link to view your application
- You may click on "Tracking Number" to open the entire application

## HOW DO I PRINT OR REFRESH MY APPLICATION?

You may generate a PDF of your entire application at any time. The "Print" icon is located in the "Application Toolbar" next to the "Save" and "Submit" buttons.

## HOW DO I ATTACH A DOCUMENT?

1. Click on the "Attachments" tab at the top of the webpage
2. Click the paperclip icon to attach a required document or click the "Post New" to attach an additional attachment
3. A pop-up window will display, click "Browse" to locate your attachment
4. Click "OK" to save your attachment or "Cancel" to go back to the previous screen
5. Required attachments are identified by an asterisk (\*)

## WHAT IF MY NEEDS ASSESSMENT, AGENDA, BUDGET, ETC. DO NOT FIT INTO THE ALLOTTED SPACE?

Documentation may be uploaded at the end of the Grant Request Form prior to submission.

## WHAT FILE FORMAT MUST I USE FOR MY ATTACHMENTS?

Allergan prefers all documentation to be provided in PDF files.

## LOCKOUT CONFIGURATIONS

- User accounts will lock out after five (5) invalid login attempts
- You may contact Grant Management System support by clicking on the "Contact Us" link on the left side of the homepage screen
- Select "Technical Support" in the "Address to" field
- Select your subject and provide a message

## LOCKOUT AFTER FAILED ATTEMPTS

If you are locked out of the system after (5) failed login attempts, you will need to request a new password. After receiving a new password, close all open browser windows, re-open and try again. You may also need to clear any cached pages from your browser. Please follow the instructions below if you continue to receive a "Failed Login" message.

1. On the browser menu, click on "Tools"
2. Click on "Internet Options"
3. On the "General" tab under "Browsing History" click on the "Delete" button
4. Mark the box for "Temporary Internet Files" and click the "Delete" button once again
5. Click "OK"

## IT IS IMPORTANT THAT YOU USE THIS "PRINT" BUTTON AND NOT THE PRINTING FUNCTION OF YOUR WEB BROWSER

- You may refresh the page at any time after you have clicked on "Save"
- "Save" and "Submit," as well as the "Print" icons, are located on the right-hand side of the Application Toolbar
- The "Refresh" icon is located on the right-hand side of the Application Toolbar

## WHAT IF I DO NOT RECEIVE EMAIL NOTIFICATIONS?

Please perform the following actions:

- Check SPAM and/or Junk email folders - once located, right-click on the email and select the option under "Junk Email" to "Add Sender's Domain to Safe Senders list."
- Alternatively, you can also manually add IR-Medicalaffairsresearch@allergan.com to the safe senders list by taking these steps:
  - Click on Actions, then locate the "Junk Email Options"
  - Click on the tab for "Safe Senders"
  - Click "Add", type in IR-Medicalaffairsresearch@allergan.com, and click "OK"
- Confirm your email address was entered correctly on your profile during the registration process.

## IS THERE A SYSTEM USER GUIDE AVAILABLE?

Please click on this link to open the Allergan Visiontracker IIT User Guide for your reference.

## WHOM DO I CONTACT IF I HAVE ANY QUESTIONS?

You may contact the Contact Information for Allergan IIT Medical Affairs:  
[IR-IITRequest@allergan.com](mailto:IR-IITRequest@allergan.com). For technical assistance, you may also email [vtsupport@envisionpharma.com](mailto:vtsupport@envisionpharma.com).