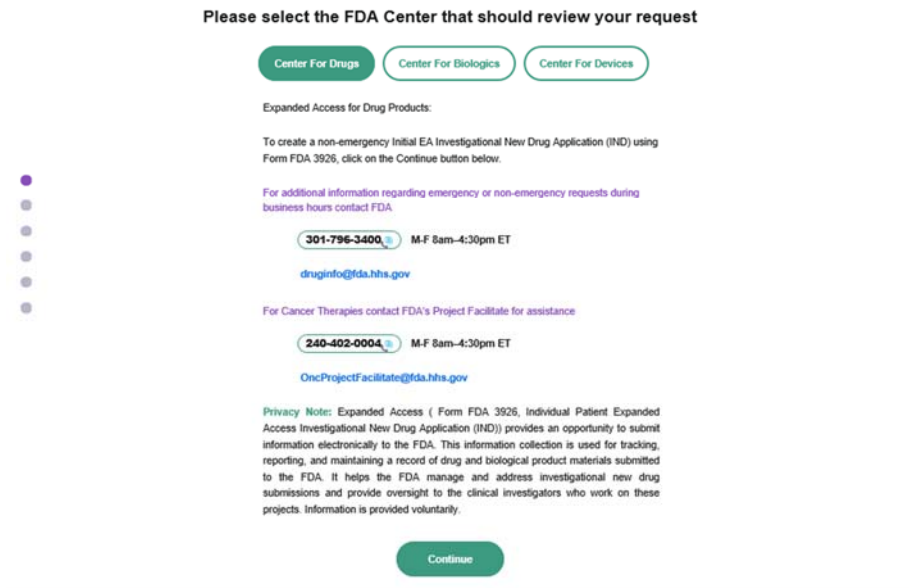
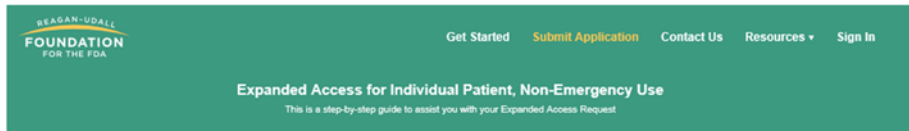
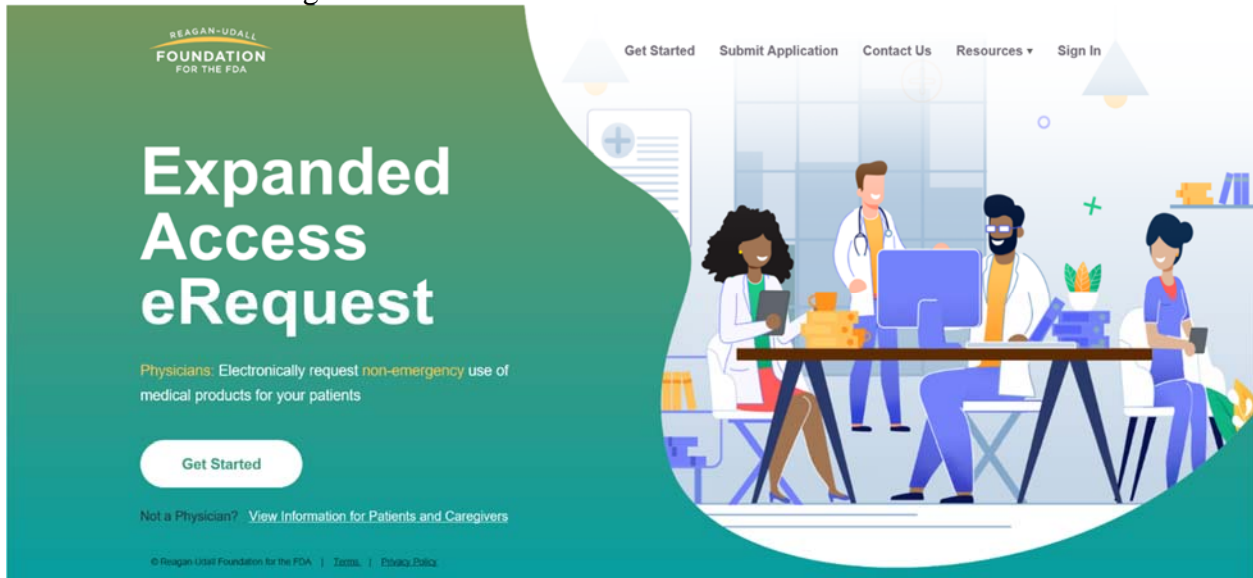


Screenshots for 0910-0814 User App:

Please note that the alignment



Expanded Access for Individual Patient, Non-Emergency Use

This is a step-by-step guide to assist you with your Expanded Access Request

Is your patient eligible for a clinical trial?

Look for ongoing clinical trials on [ClinicalTrials.gov](#). If your patient is eligible to participate in a clinical trial, please pursue enrollment in the trial.

Click 'Continue' if your patient is not eligible for a clinical trial.

Continue



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Is there already an Expanded Access Program or Protocol in place to treat the condition your patient has?

The Reagan-Udall Foundation's Expanded Access [Navigator Company Directory](#) provides EA policies and contact information for many drug and biological products manufacturers.

You can also check for existing Expanded Access program or protocol on [ClinicalTrials.gov](#) and type "expanded access" into the "Other Terms" field.

Click 'Continue' even if no prior Expanded Access program or protocol is found.

Continue



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Have you identified an IRB for reviewing the treatment plan and Informed Consent document?

- > Identify an Institutional Review Board (IRB) to review your proposed treatment plan and informed consent
- > Find registered IRBs in your area through the [Expanded Access Navigator](#)
- > Obtain approval from an IRB before treatment begins
 - Some individual patient expanded access may only need concurrence by the IRB Chair or another member of the IRB
- > Obtain the patient's [Informed Consent](#) before treatment begins

Continue

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This is a step-by-step guide to assist you with your Expanded Access Request

Do you have a Letter of Authorization (LOA) from the Manufacturer or Chemistry, Manufacturing, and Controls (CMC) Information?

You must have permission from the company that makes the drug/biological products to use it for EA. Additionally, a Letter of Authorization (LOA) lets FDA reference another application (IND) as FDA reviews your EA request. If you intend to use a biological product that you have manufactured or for which FDA does not have information on file, CMC information will need to accompany your application.

If you don't have an LOA yet, please read the information below

Directions on how to request expanded access: [Expanded Access Navigator](#)

For Company contact information:

[Expanded Access Navigator Company Directory](#)

If you do not find the company on the Reagan-Udall Foundation site, you can also search [ClinicalTrials.gov](#)

To see an example of wording for an LOA to send to the company, [click here](#).

You may continue with the application submission process for now even if you don't have the LOA or CMC information. However, you will need the LOA (or, if requesting certain biological products, CMC information) for final submission.

Continue

Expanded Access for Individual Patient, Non-Emergency Use

This is a step-by-step guide to assist you with your Expanded Access Request

Fill In and Submit Form FDA 3926

Make sure you have the following information handy to complete Form FDA 3926 and your Expanded Access request:

- ✓ Your Information (ensure your profile information is up-to-date)
- ✓ Patient and drug/biological products information
- ✓ Letter of Authorization from the manufacturing company (or, if requesting certain biological products, Chemistry, Manufacturing, and Controls information)



Proceed To Form 3926

Expanded Access for Individual Patient, Non-Emergency Use

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Useful Tips

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Mark section as complete

Basic Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0814

**Individual Patient Expanded Access Investigational
New Drug Application (IND)**

Expiration Date: **May 31, 2022**

(Title 21, Code of Federal Regulations (CFR) Part 312)

Also see: PRA Statement in the last
step of this submission

Patient Details

1. Patient's Initials (4 Char, do not use full name to preserve confidentiality) *

Enter Patient Initials

Age *

Years

Months

Months

Months

Gender *

Enter Gender

Weight *

Enter Weight

lbs

Allergies

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Useful Tips

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Enter Gender Enter Weight lbs

Allergies

Enter information about known allergies the patient has, if any

2. Date of Submission

09-04-2020

3a. Initial Submission

Select this box if this form is an initial submission for an individual patient expanded access IND, and complete only fields 4 through 8, and fields 10 and 11.

3b. Follow-Up Submission *Not Applicable*

Select this box if this form accompanies a follow-up submission to an existing individual patient expanded access IND, and complete the items to the right in this section, and fields 8 through 11.



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Useful Tips

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4. Clinical Information

Indication (200 Char) *

Enter Details

Brief Clinical History

Diagnosis *

Enter Details

Prior Therapy *

Enter Details

Response to Prior Therapy *

Enter Details

Reason for requesting this treatment *



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Prior Therapy *

Enter Details

Response to Prior Therapy *

Enter Details

Reason for requesting this treatment ⓘ *

Enter Details

Reason patient lacks other therapeutic options ⓘ *

Enter Details

If you prefer to attach your patients' history please upload, however please consider redacting personally identifiable information.

[Upload Patient History](#)

Please upload PDF, PNG or JPG format only and it must be less than 2MB

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Useful Tips

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5. Treatment Information

Name of investigational drug/biological products being requested (100 Char) *

Enter Details

Name of the entity that will supply the drug/biological products (generally the manufacturer) (200 Char) *

Enter Details

FDA Review Division (if known) (200 Char)

[Look Up a list of FDA Review Divisions](#)

Enter Details

Treatment Plan

Planned dose and schedule of administration ⓘ *

Enter Details

Route of administration ⓘ *

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Mark section as complete

Individual Patient

Planned dose and schedule of administration ⓘ *

Enter Details

Route of administration ⓘ *

Enter Details

Planned Duration Of Treatment *

Enter Details

Monitoring procedures ⓘ *

Enter Details

Planned modifications to treatment plan, if needed ⓘ *

Enter Details

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6. Letter of Authorization (LOA)

Upload LOA

Please upload PDF, PNG or JPG format only and it must be less than 2MB

I have attached the LOA for this expanded access request

Note: If you intend to use a biological product that you have manufactured or for which FDA does not have information on file, upload the CMC information here.

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Mark section as complete

7. Physician's Qualification statement

If you wish to update information in this section, please update, if you need to edit this information, please [update your profile](#) and revisit this screen prior to making your final request.

Medical School	Graduation Year	Medical License Number
gfhfgh	1915	ghdfgh
Specialty	Current Role/Employment	Job Title
gfhfgh	ghdfgh	ghgh

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8. Physician Name, Address, and Contact Information

Please review the information below for accuracy, if you need to edit this information, please [update your profile](#) and revisit this screen prior to making your final request.

Physician Name (sponsor)	Email	Telephone Number of Physician
jennifer	jennifer.wolfe@fda.hhs.gov	(301) 796-2147
Facsimile (FAX) Number of Physician	Physician's IND Number, if known	City
-	Not Applicable	silver spring
State	Zip code	
MD	20903	

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This section is not applicable to Initial type of EA submissions and may be ignored

9. Contents of Submission

This submission contains the following materials, which are attached to this form (select all that apply). If none of the following apply to the follow-up communications, use Form FDA 1571 for your submission.

- | | |
|---|--|
| <input type="checkbox"/> Initial Written IND Safety Report | <input type="checkbox"/> Change in Treatment Plan |
| <input type="checkbox"/> Follow-up to a Written IND Safety Report | <input type="checkbox"/> General Correspondence |
| <input type="checkbox"/> Annual Report | <input type="checkbox"/> Response to FDA Request for Information |
| <input type="checkbox"/> Summary of Expanded Access Use (treatment completed) | <input type="checkbox"/> Response to Clinical Hold |



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Mark section as complete

10.a. Request for Authorization to Use Form FDA 3926

- I request authorization to submit this Form FDA 3926 to comply with FDA's requirements for an individual patient expanded access IND.

Note: Successful submission is NOT the same as authorization to begin treatment. Treatment may not begin until 30 days after submission unless FDA provides earlier notification that treatment may begin.



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10.b. Request for Authorization to Use Alternative IRB Review Procedures

I request authorization to obtain concurrence by the Institutional Review Board (IRB) chairperson or by a designated IRB member, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. This concurrence would be in lieu of the review and approval at a convened IRB meeting at which a majority of the members are present.

Note: Full IRB review may still occur even if the optional procedure is requested. If you do not need to use the alternative IRB review procedures, you may leave this box unchecked.




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Do you have any other attachments to provide?

This may include attachments with information that did not fit in fields

Yes

No



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Do you wish to share any additional information

Yes

No

Enter Details

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Mark section as complete

Please select the FDA Center that should review your Expanded Access request. This choice is based on the Product Type for which you are seeking Expanded Access Use.

Your request will be routed to the appropriate FDA review division based on this selection.

Select Products

Center for Drugs

This is a cancer-related EA request

Note: that the Center for Devices category is not available here since you cannot submit requests for this category, using this app.

FDA's Center for Drugs regulates these specific biological product therapies:

- > Monoclonal antibodies for in vivo use.
- > Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except those specifically assigned to Center for Biologics Evaluation and Research (e.g., vaccines). This category includes therapeutic proteins derived from plants, animals, or microorganisms, as well as recombinant versions of these products.
- > Immunomodulators (non-vaccine and non-allergenic products intended to treat disease by inhibiting or modifying a pre-existing immune response).
- > Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease, or otherwise alter the production of

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Mark section as complete

Note: that the Center for Devices category is not available here since you cannot submit requests for this category, using this app.

FDA's Center for Drugs regulates these specific biological product therapies:

- > Monoclonal antibodies for in vivo use.
- > Proteins intended for therapeutic use, including cytokines (e.g., interferons), enzymes (e.g., thrombolytics), and other novel proteins, except those specifically assigned to Center for Biologics Evaluation and Research (e.g., vaccines). This category includes therapeutic proteins derived from plants, animals, or microorganisms, as well as recombinant versions of these products.
- > Immunomodulators (non-vaccine and non-allergenic products intended to treat disease by inhibiting or modifying a pre-existing immune response).
- > Growth factors, cytokines, and monoclonal antibodies intended to mobilize, stimulate, decrease, or otherwise alter the production of hematopoietic cells in vivo.

FDA's Center for Biologics regulates these specific biological product therapies below:

- > Cellular products, including products composed of human, bacterial, or animal cells (such as pancreatic islet cells for transplantation), or physical parts of those cells (such as whole cells, cell fragments, or other components intended for use as preventative or therapeutic vaccines).
- > Gene therapy products.
- > Vaccines
- > Antitoxins, antivenins, and venoms
- > Blood and blood products

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Useful Tips

11. Certification statement:

I will not begin treatment until 30 days after FDA's receipt of a completed application and all required materials unless I receive earlier notification from FDA that treatment may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold by FDA. I also certify that I will obtain informed consent, and that an Institutional Review Board, or (IRB) member if I opted for alternative review, will be responsible for initial and continuing review and approval of this treatment use, consistent with applicable FDA requirements. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).

Proceed to Final Submission Process

Expanded Access for Individual Patient, Non-Emergency Use

This is a step-by-step guide to assist you with your Expanded Access Request

PAPERWORK WORK REDUCTION NOTICE FOR FORM FDA 3926

Paperwork Reduction Act

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 45 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

[Continue](#)

I will not begin treatment until 30 days after FDA's receipt of a completed a by FDA. I also certify that I will obtain informed consent, and that an Investigator in accordance with all applicable regulatory requirements

WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Section 1001)

of to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold and approval of this treatment use, consistent with applicable FDA requirements. I agree to conduct the

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Useful Tips

Physician Verification Step

Select one of the verification options below

E-Signature and E-Submission

I will download, sign and send my submission via postal mail

[Proceed To E-Signature And Submission](#)