Expanded Access allows for use of an investigational drug, biologic, or device to treat a patient who does not have a comparable alternative therapy or has exhausted all options to treat a disease or condition. ***The intent is treatment, not research****.* For more information please watch the FDA’s [Introduction to Expanded Access](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-1-introduction-may-2019).

1. [**Emergency Use of Drugs and Biologics**](#Header1)
2. [**Non-Emergency Use of Drugs and Biologics**](#Header1)
3. [**Emergency Use of a Device**](#Header2)
4. [**Compassionate Use of a Device**](#Header3)

**EMERGENCY & NON-EMERGENCY USE OF DRUGS & BIOLOGICS**

Expanded access allows for the use of unapproved drugs and biologics outside of a clinical trial for patients with serious diseases or conditions when there is no satisfactory alternative therapy to treat the patient’s disease or condition.

**Criteria as determined by the FDA**:

1. Patient must have a serious or immediately life-threatening disease or condition for which there is no comparable alternative
2. Patient must be unable to participate in a clinical trial for the investigational product
3. Potential benefits must justify potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition being treated
4. Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access us

**Types of Expanded Access for Drugs and Biologics**

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| **Emergency Use Individual Patient IND Submitted by Physician (21 CFR 312.310)**  *Physician must contact FDA for authorization, and then treatment can begin. Form 3926 is submitted retrospectively. For more information watch* [*How to Submit a Single Patient IND*](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-2-how-submit-single-patient-ind-september-2019) | |
| 1. Obtain Letter of Authorization from Medical Developer | Physician must request [Letter of Authorization (LOA)](https://www.fda.gov/news-events/expanded-access/example-wording-letter-authorization-loa-individual-patient-expanded-access-ind) from the medical developer  \**If an LOA is not available, sufficient information must be provided with the submission of Form 3926 to assure the FDA of the product’s quality* |
| 1. Notify the IRB | Prior to treatment except when there is insufficient time, Physician should notify the LSUHSC IRB.   * Consult [WORKSHEET Emergency Use (HRPP 322)](https://www.lsuhsc.edu/administration/academic/ors/checklist_worksheet.aspx) to evaluate compliance with FDA requirements * Complete and submit the *Before Use* section of the [Expanded Access for a Test Article (EATA) application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) * Notify the IRB Office of submission of the application to ensure timely review |
| 1. Request Emergency Use Authorization from FDA | Physician must request FDA Emergency Use Authorization from the appropriate [FDA review division or organization](https://www.fda.gov/news-events/expanded-access/fdas-expanded-access-contact-information) by telephone or other rapid form of communication   * IND for an Investigational Drug: (855) 543-3784 *or* (301) 796-3400 *or* [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) * IND for an Investigational Biologic: (880) 835-4709 *or* (240) 402-8020 *or* [industry.biologics@fda.hhs.gov](mailto:industry.biologics@fda.hhs.gov) * On Nights and Weekends, FDA Emergency Call Center: (866) 300-4374 *or* (301) 796-8240 |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individual receiving the treatment. The LSUHSC [Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template should be used.  *If consent cannot be obtained, treating physician and independent physician must certify in writing that:*   * *this is a life-threatening situation necessitating use of the drug/biologic* * *there is no alternative treatment*   *Please use the* [*Independent Physician's Certification: Emergency Use of a Test Article Without Informed Consent*](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) *template.* |
| 1. If authorized, proceed with treatment | If FDA authorization is received, Physician can proceed with treatment. Authorization may be given over the phone. |
| 1. Notify/follow-up with the IRB | Within 5 business days of emergency use, Physician should notify or follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) (or the entire application if there was insufficient time to complete Step #2) |
| 1. Submit Form 3926 to FDA | Within 15 business days of emergency use, Physician must submit Form 3926 and the LOA to the FDA via mail  [How to Complete Form FDA 3926 – Initial Submission](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-3-how-complete-form-fda-3926-initial-submissions-september-2019) |
| 1. Submit follow-up reports | Submit any follow-up reports to the FDA using Form 3926.  [How to Complete Form FDA 3926 – Follow-Up Submission](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-4-how-complete-form-fda-3926-follow-submissions-september-2019) |

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| **Emergency Use Individual Patient IND Submitted by Sponsor**  *Sponsor must contact FDA for authorization* | |
| 1. Obtain Sponsor Approval | Physician must request approval from the sponsor for emergency use under company’s IND or IDE  \**If sponsor declines permission to use IND/IDE, follow the steps for* [***Emergency Use Individual Patient IND Submitted by Physician***](#EIND1) |
| 1. Notify the IRB | Prior to treatment except when there is insufficient time, Physician should notify the LSUHSC IRB.   * Consult [WORKSHEET Emergency Use (HRPP 322)](https://www.lsuhsc.edu/administration/academic/ors/checklist_worksheet.aspx) to evaluate compliance with FDA requirements * Complete and submit the *Before Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) * Notify the IRB Office of submission of the application to ensure timely review |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individual receiving the treatment. The LSUHSC [Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor.  *If consent cannot be obtained, treating physician and independent physician must certify in writing that:*   * *this is a life-threatening situation necessitating use of the drug/biologic* * *there is no alternative treatment*   *Please use the* [*Independent Physician's Certification: Emergency Use of a Test Article Without Informed Consent*](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) *template.* |
| 1. *Sponsor Request Emergency Use Authorization from FDA* | *The Sponsor is responsible for submitting Forms 1571 and 1572 to the FDA to request Emergency Use Authorization.* |
| 1. If authorized, proceed with treatment | If FDA authorization is received by the Sponsor, Physician can proceed with treatment. |
| 1. Notify/follow-up with the IRB | Within 5 business days of emergency use, Physician should notify or follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) (or the entire application if there was insufficient time to complete Step #2) |
| 1. Notify Sponsor | Within 5 business days of Emergency Use, Physician should notify Sponsor. |

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| **Non-Emergency Individual Patient IND Submitted by Physician(21 CFR 312.310)**  *Physician must contact FDA for authorization, and then treatment can begin. Form 3926 is submitted prospectively. For more information, watch* [*How to Submit a Single Patient IND*](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-2-how-submit-single-patient-ind-september-2019) | |
| 1. Obtain Letter of Authorization from Medical Developer | Physician must request [Letter of Authorization (LOA)](https://www.fda.gov/news-events/expanded-access/example-wording-letter-authorization-loa-individual-patient-expanded-access-ind) from the medical developer  \**If an LOA is not available, sufficient information must be provided with the submission of Form 3926 to assure the FDA of the product’s quality* |
| 1. Submit Form 3926 to FDA | Physician must submit Form 3926 and the LOA to the FDA via mail  [How to Complete Form FDA 3926 – Initial Submission](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-3-how-complete-form-fda-3926-initial-submissions-september-2019) |
| 1. Obtain IRB Approval | Prior to treatment, Physician must complete and submit the *Before Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/).   * Physician may request authorization from the FDA (on Form 3926) to obtain concurrence from the IRB Chair/designated member in lieu of Full Board Review. This should be documented in the application. |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individual receiving the treatment using the approved LSUHSC template. The LSUHSC [Non-Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor |
| 1. Proceed with treatment | 30 days after application is sent to FDA, or sooner if contacted by the FDA, the drug/biologic can be shipped and treatment can begin. |
| 1. Follow-up with the IRB | Within 5 business days of use, Physician should follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) |
| 1. File Follow-up with the FDA | Physician must re-complete and submit Form 3926 to the FDA via mail  [How to Complete Form FDA 3926 – Follow-Up Submission](https://www.fda.gov/drugs/information-health-care-professionals-drugs/expanded-access-part-4-how-complete-form-fda-3926-follow-submissions-september-2019) |

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| **Non-Emergency Individual Patient IND Submitted by Sponsor**  *Sponsor must contact FDA for authorization* | |
| 1. Obtain Sponsor Approval | Physician must request approval from the sponsor for emergency use under company’s IND or IDE  \**If sponsor declines permission to use IND/IDE, follow the steps for* [***Non-Emergency Individual Patient IND Submitted by Physician***](#NEIND1) |
| 1. *Sponsor Request Non-Emergency Use Authorization from FDA* | *The Sponsor is responsible for submitting Forms 1571 and 1572 to the FDA to request a Non-Emergency Individual Patient IND.* |
| 1. Obtain IRB Approval | Prior to treatment, Physician must complete and submit the *Before Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/).   * Physician may request authorization to obtain concurrence from the IRB Chair/designated member in lieu of Full Board Review. This request should be documented in the application. |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individual receiving the treatment. The LSUHSC [Non-Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor |
| 1. Proceed with treatment | 30 days after application is sent to FDA, or sooner if contacted by the FDA, the drug/biologic can be shipped and treatment can begin. |
| 1. Follow-up with the IRB | Within 5 business days of use, Physician should follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) |
| 1. Notify Sponsor | Within 5 business days of use, Physician should notify Sponsor. |

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| **Non-Emergency Intermediate-Size Patient Group IND Submitted by Physician(21 CFR 312.315)**  *Physician must contact FDA for authorization, and then treatment can begin. Form 1571 and Form 1572 are submitted prospectively.* | |
| 1. Obtain Letter of Authorization from Medical Developer | Physician must request [Letter of Authorization (LOA)](https://www.fda.gov/news-events/expanded-access/example-wording-letter-authorization-loa-individual-patient-expanded-access-ind) from the medical developer  \**If an LOA is not available, sufficient information must be provided with the submission of Form 3926 to assure the FDA of the product’s quality* |
| 1. Submit Form 1571 and Form 1572 to FDA | Physician must submit Form 1571 and Form 1572 in triplicate (1 original and 2 copies), and the LOA to the FDA via mail |
| 1. Obtain IRB Approval | Prior to treatment, Physician must submit a [Full Board application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/). |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individuals receiving the treatment. The LSUHSC [Non-Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor. |
| 1. Proceed with treatment | 30 days after application is sent to FDA, or sooner if contacted by the FDA, the drug/biologic can be shipped and treatment can begin. |
| 1. Follow-up with the IRB | Within 5 business days of use, Physician should follow-up with the LSUHSC IRB. |
| 1. File Follow-up with the FDA | Physician must re-complete and submit Form 1571 to the FDA via mail |

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| **Non-Emergency Intermediate-Size Patient Group IND Submitted by Sponsor**  *Sponsor must contact FDA for authorization* | |
| 1. Obtain Sponsor Approval | Physician must request approval from the sponsor for emergency use under company’s IND or IDE  \**If sponsor declines permission to use IND/IDE, follow the steps for* [***Non-Emergency Intermediate-Size Population IND Submitted by Physician***](#ISPIND1) |
| 1. *Sponsor Request Non-Emergency Use Authorization from FDA* | *The Sponsor is responsible for submitting Forms 1571 and 1572 to the FDA to request a Non-Emergency Individual Patient IND.* |
| 1. Obtain IRB Approval | Prior to treatment, Physician must submit a [Full Board application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/). |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individuals receiving the treatment. The LSUHSC [Non-Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor. |
| 1. Proceed with treatment | 30 days after application is sent to FDA, or sooner if contacted by the FDA, the drug/biologic can be shipped and treatment can begin. |
| 1. Follow-up with the IRB | Within 5 business days of use, Physician should follow-up with the LSUHSC IRB. |
| 1. Notify Sponsor | Within 5 business days of use, Physician should notify Sponsor. |

**Types of Expanded Access for Devices**

**EMERGENCY USE OF A DEVICE**

Normally, an unapproved medical device is only used on Human Subjects through an approved clinical trial that a subject qualifies for and the device is only used in accordance with the approved protocol. However, under the following circumstances, a physician may use an unapproved device to save the life of a patient or to help a patient suffering from a serious disease or condition for which there no other alternative therapy exists:

* An IDE for the device does not exist; or,
* Physician wants to use device in a way not approved under the IDE; or,
* Physician is not an investigator under the IDE.

**Criteria for Emergency Use of a Device**:

1. Patient must have a serious or immediately life-threatening disease or condition, for which there is no comparable alternative, that needs immediate treatment
2. Physician has substantial reason to believe that benefits exist
3. Because of the immediate need to use the device, there is no time to obtain FDA approval

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| **Emergency Use of Unapproved Device** | |
| 1. Obtain Letter of Authorization from Medical Developer, if an IDE exists | Physician must request [Letter of Authorization (LOA)](https://www.fda.gov/news-events/expanded-access/example-wording-letter-authorization-loa-individual-patient-expanded-access-ind) from the medical developer if an IDE exists |
| 1. Notify the IRB or Obtain IRB Chair Concurrence | Prior to treatment, except when there is insufficient time, Physician should notify the LSUHSC IRB.   * Consult [WORKSHEET Emergency Use (HRPP 322)](https://www.lsuhsc.edu/administration/academic/ors/checklist_worksheet.aspx) to evaluate compliance with FDA requirements * Complete and submit the *Before Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) * Notify the IRB Office of submission of the application to ensure timely review |
| 1. Obtain an Independent Physician Assessment\* | Treating physician should request an assessment by an independent physician not participating in the treatment. Please use the [Independent Physician's Certification: Emergency or Compassionate Use of an Unapproved Device template](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx).  *If there is not enough time for an independent assessment, the treating physician must determine and document:*   * *the disease or condition is life-threatening* * *there is an immediate need for treatment* * *there is no alternative therapy* * *there is no time for FDA approval of an IDE* * *there are potential benefits that outweigh risks* * *substantial reason to believe benefits will occur*   *This evaluation should be reviewed/evaluated in writing by an independent physician. Report must be submitted to IRB within 5 business days. Please use the* [*Treating Physician's Certification: Emergency Use of an Unapproved Device without Prior Independent Physician Assessment*](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) *template.* |
| 1. Obtain Informed Consent\*\* | Physician must obtain informed consent from the individual receiving the treatment. The LSUHSC [Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template should be used.  *If consent cannot be obtained, treating physician and independent physician must certify in writing that:*   * *this is a life-threatening situation necessitating use of the device* * *there is no alternative therapy*   *Please use the* [*Independent Physician's Certification: Emergency Use of a Test Article Without Informed Consent*](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) *template.* |
| 1. Proceed with treatment | Physician can proceed with treatment. |
| 1. Notify/follow-up with the IRB | Within 5 business days of emergency use, Physician should notify or follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) (or the entire application if there was insufficient time to complete Step #2) |
| 1. Notify the Sponsor or FDA | If an IDE exists, Physician must notify the sponsor after emergency use of the device. The sponsor is responsible for reporting to the FDA.  If an IDE does not exist, Physician must notify the FDA of emergency use. Physician should provide:   * a written summary of the emergency use * patient protection measures * any scientific results |

**COMPASSIONATE USE OF A DEVICE**

The Compassionate Use provision provides access to an investigational device for patients who are not eligible for the clinical trial when treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. It may be used only during the clinical trial for which the device is being tested.

**Criteria for Compassionate Use of a Device**:

1. Patient must have a serious disease or condition that the device is intended to treat or diagnose
2. There is no comparable device or therapy available

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| **Compassionate Use of A Device with IDE**  *Sponsor must contact FDA for concurrence* | |
| 1. Obtain Letter of Authorization from Medical Developer\* | Physician must request [Letter of Authorization (LOA)](https://www.fda.gov/news-events/expanded-access/example-wording-letter-authorization-loa-individual-patient-expanded-access-ind) from the medical developer.  \**If the developer does not agree with the compassionate use, Physician cannot move forward.* |
| 1. Medical Developer Submits IDE Supplement to FDA\*\* | The Developer is responsible for submitting the IDE supplement to the FDA requesting approval for a protocol deviation.  *\*\*FDA Concurrence must be obtained prior to compassionate use* |
| 1. Devise Patient Monitoring Schedule | The physician should devise a schedule for patient monitoring that addresses the specific needs of the patient and detects any possible problems that may arise |
| 1. Obtain IRB Chair Concurrence | Prior to treatment, Physician should obtain Concurrence from the Chair. |
| 1. Obtain an Independent Physician Assessment | Treating physician should request an assessment by an independent physician not participating in the treatment.  Please use the [Independent Physician's Certification: Emergency or Compassionate Use of an Unapproved Device template](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx). |
| 1. Obtain Informed Consent | Physician must obtain informed consent from the individual receiving the treatment. The LSUHSC [Non-Emergency Use of a Test Article Consent](https://www.lsuhsc.edu/administration/academic/ors/forms_templates.aspx) template can be used if one is not provided by sponsor |
| 1. Proceed with treatment | Physician can proceed with treatment. |
| 1. Report Any Problems | If problems arise during and after use of the device, report problems to the LSUHSC IRB and the Medical Developer |
| 1. Follow-up with IRB | Within 5 business days of use, Physician should follow-up with the LSUHSC IRB.   * Complete and submit the *After Use* section of the [EATA application in Kuali](https://lsuhsc.kuali.co/cor/main/#/apps/) |
| 1. Notify the Sponsor | Physician must write a summary of the use of the device and provide it to the Medical Developer |