

Expanded Access Policy

Center for Innovation in Brain Science (CIBS)

About Our Research

The Center for Innovation in Brain Science (CIBS), led by Dr. Roberta Brinton, is dedicated to advancing therapies for age-related neurodegenerative diseases, including Alzheimer's disease and Parkinson's disease.

Our research brings together the scientific rigor of university-based discovery and the innovation and agility of biotechnology development.

Learn more about our research approach at <https://cibs.arizona.edu>.

What Is Expanded Access?

Expanded Access (also known as *compassionate use*, *treatment use*, or *pre-approval access*) allows patients with serious or life-threatening conditions, who cannot join a clinical trial and have no satisfactory treatment options, to request access to an investigational drug outside of a study.

Expanded Access can occur only when:

- The treating physician and the sponsor agree the request is appropriate
- FDA authorizes the request
- Adequate drug supply and internal resources are available

Posting this policy does not guarantee access to an investigational drug.

How We Evaluate Requests

CIBS evaluates all Expanded Access requests fairly and individually. We may request additional information as needed.

We consider general factors such as:

- The seriousness of the patient's condition
- Whether other treatment options are available
- Clinical and safety data available for the investigational drug
- Whether providing access would affect ongoing research or development
- Whether adequate drug supply and internal resources are available

All decisions made by CIBS are final and remain subject to FDA authorization.



How to Submit a Request

Patients, caregivers, or treating physicians may submit a request by contacting:

Email: allopd_eap@list.arizona.edu

Phone: 520-626-6276

Address: The University of Arizona
Center for Innovation in Brain Science
1230 N. Cherry Ave BSRL 470, Tucson, Arizona 85721

Please include:

- Your name, address, phone number, and email (or your caregiver's contact information)
- A brief summary of your diagnosis and medical history
- Your current treatments and treating physician
- A reference indicating the request (e.g., "EAP")
- Confirmation that you can meet on-site visit requirements, if applicable
- Confirmation that travel and participation costs are the responsibility of the patient
- Any additional information that may help us understand your request

Additional details may be requested during evaluation.

Response Timeline

CIBS will acknowledge receipt of your Expanded Access request within 10 business days and provide information on eligibility, next steps, or any additional information needed.

Important Notes

- Approval is not guaranteed.
- Expanded Access is permitted only after FDA authorization.
- Availability may be limited by safety considerations, research priorities, or drug-supply constraints.
- This policy may be updated as programs and resources evolve.