1. PURPOSE

1.1. Provide a standard for evaluation and response to expanded access requests for investigational drugs sponsored by Amnio Technology.

2. SCOPE

2.1. This policy applies to Amnio Technology sponsored drugs in phase II and III of the Federal Food and Drug Administration (FDA) investigational new drug (IND) process.

2.2. This policy applies to all expanded access applications: IND, Intermediate Size Patient Protocol, and Individual Patient.

3. RESPONSIBLE PERSONNEL

3.1. Quality Area Functional Leader

3.2. Regulatory Area Functional Leader

3.3. Operations Area Functional Leader

4. DOCUMENTS

4.1. Associated Documents

None

4.2. Reference Documents

21 CFR 312.300	Investigational New Drugs - General
FD&C Act 561A	Federal Food, Drug & Cosmetic Act – Expanded Access

5. DEFINITIONS

5.1. **Investigational New Drug (IND) –** drug product with a primary market purpose of gaining information about the drug from clinical trial, rather than the purpose of diagnosing or treating the patient. The product is considered an IND if it is engaged in phase II or III of the FDA's IND process.

5.2. **Expanded Access-** the availability of a drug in the IND process to a patient or patient group, that has an immediately life-threatening disease or condition, through FDA and the sponsor's approval.

6. POLICY

6.1. Amnio Technology understands the urgency and unmet public health needs that can be met by investigational new drugs.

6.2. Amnio Technology continues to engage in product development and will at times, engage in the FDA's investigational new drug regulatory pathway to introduce those products to market.

6.3. Amnio Technology will accept and review applications for Expanded Access to products engaged in the FDA's IND process.

6.3.1. There are three options for Expanded Access:

- IND
- Intermediate-Size Patient Protocol
- Individual Patient

6.3.2. To initiate interest in any of the three types of Expanded Access, the interested provider or organization should email quality@amniotechnology.com. Emails should include:

- Provider or organization name (Include NPI) and address
- Type of Expanded Access Requested
  - If IND or Protocol is requested, provide the approximate number of participants
- A brief statement outlining the reason for the request; include qualifications for immediately life-threatening disease or condition or other justification.
- Contact Information

6.3.3. Upon receipt of an Expanded Access request, the Quality Area Functional Leader will organize a meeting to include the Operations and Regulatory Area Functional Leaders.

6.3.3.1. The group will review the request and determine:

- If the patient(s) could fit the current IND criteria
- If there are resources available to potentially engage the request.
- If the provider meets the criteria to administer the drug

6.3.3.2. If any of the criteria is not met, Amnio Technology will not approve the Expanded Access and the requestor will be notified by email or post.

6.3.3.3. If the preliminary criteria are met, Amnio Technology will contact the requestor for further information and continue the evaluation process to determine risk and available resources. The requestor will be kept informed throughout the consideration process.

6.3.3.4. Every effort will be made to ensure decisions regarding Expanded Access are swift.

7. APPENDICES

Not Applicable

8. ATTACHMENTS

Not Applicable