

BACKGROUND ON SHIPPING OPTIONS

INTRODUCTION:

There are two basic choices for shipping stem cells: dry ice (or equivalent) or Liquid Nitrogen (LN₂) Shippers. The method of shipment chosen will dictate the handling of frozen samples when received and the shipping costs involved. It is important that all potential recipients of cells read this material carefully and comply with Tulane requirements for shipping of adult marrow stromal cells (MSCs).

MATERIAL TRANSFER AGREEMENT (MTA):

Before stem cells can be shipped, two original copies of signed Materials Transfer Agreement (MTA) must be signed and returned to Tulane. Upon receipt of the two signed MTAs Tulane will provide a protocol describing procedures for processing frozen stem cell preparations which describes in detail the necessary reagents and equipment and the step by step procedures for storing and expanding the cells. Recipients are urged to ensure that they have all necessary reagents at hand before requesting shipment of cells.

SHIPPING METHODS AND SAMPLE HANDLING UPON RECEIPT:

There are two basic methods of shipping: dry ice (or equivalent) or LN₂ shippers and they result in different requirements for handling the samples on receipt:

1. MSCs shipped in dry ice or dry ice equivalent **MUST NOT** be transferred to liquid nitrogen storage upon receipt. They may be left frozen in dry ice for up to 48 hours or stored at -80°C for approximately one week before recovery. MSCs must be expanded after recovery before freezing and storage in LN₂.
2. Cells shipped in LN₂ shippers may be transferred to liquid nitrogen storage and do not require immediate recovery.

The options for shipping will vary depending on destination: within the US or International.

OPTIONS FOR SHIPPING

There are various options for shipping the cells to US and International destinations.

1. **Dry Ice (No guaranteed dry ice replenishment - US only)**
DHL and Federal Express (FedEx) will deliver samples on dry ice (5 lbs max) within the US overnight. The rates are low and there is no special packaging. However, in the past, shipments have been delayed or returned by FedEx.
2. **Dry Ice (Guaranteed dry ice replenishment - US and International)**
World Courier will deliver samples shipped on dry ice (10-20 lbs) overnight in special packaging and will replenish the dry ice, if necessary. They specialize in the handling of temperature-sensitive and infectious diagnostic samples.

World Courier claims to transport approximately 95% of the world's clinical trials materials requiring the use of premium specialty courier services and to treat each and every shipment on an individual priority basis. World Courier will calculate how much dry ice is needed depending on destination and will replenish dry ice if delivery is delayed. Packages are kept in pressure-regulated cargo on planes. They will by-pass X-rays.

3. Dry Ice Equivalent (DHL only – US and International)

DHL will deliver samples using a special ThermoExpress shipping service which utilizes dry ice equivalent blocks to maintain temperature for up to 72 hours. For air and road freight, DHL is fully certified to handle all types of Dangerous Goods in accordance with IATA Dangerous Goods Regulations and in accordance with the regulations issued by country and local governing agencies.

4. LN Shippers with data loggers (US and International) ₂

Cells can also be shipped in special containers that maintain the cells at very low temperatures. MVE Vapor Shipper containers are designed for the safe transportation of biological samples at cryogenic temperatures (-130°C or colder). They employ a hydro-phobic absorbent that contains the liquid nitrogen for "spill-free" shipping. Protective shipping cartons are also available which gives the shipment a "non-hazardous" classification. The recommended vapor containers also have a data logger which ensures that the sender can monitor that cells shipped have been maintained under appropriate conditions. These may be shipped using FedEx.

TIME OF SHIPPING

Tulane Center for Gene Therapy will ship cells to destinations within the US only on Monday or Tuesday to ensure that they reach the recipient in a timely manner. Samples for international destinations will be shipped **ONLY** on Monday using dry ice with replacement or ThermoExpress dry ice equivalent. LN₂ shippers can be shipped any day of the week because the shippers will maintain LN₂ vapor phase temperatures for up to 21 days. The data logger will take temperature readings from the time it leaves the Center of Gene Therapy until the time it returns to CGT.

SPECIAL CONSIDERATIONS FOR INTERNATIONAL SHIPMENTS

Depending on the destination country, there may be some custom and import issues that may delay or possibly deny the shipment of biological materials in media containing Fetal Bovine Serum (FBS). The Center for Gene Therapy will provide whatever information may be required, although some countries may not allow the shipment, regardless. Recipients are urged to check with authorities in their country.

COSTS

Costs for packing and shipping of stem cell preparations are the responsibility of the recipient. Tulane Center for Gene Therapy will take responsibility for handling and packing of stem cell preparations. Recipients must supply a courier

(FedEx, DHL, etc.) account number or a VISA or Master Card number to cover the shipping charges. Costs depend on the shipping option selected and the container used. LN₂ shippers with data loggers may be used for MSC shipment without a deposit. **However, if the LN₂ shipper is not returned to the Center of Gene Therapy within two (2) weeks from the time of receipt of the cells, the Principal Investigator will be invoiced \$2,000.00 USD for the cost of replacement of the LN₂ shipper and data logger.** The recipient is also responsible for the shipping charges to return the LN₂ dry shipper back to the Tulane Center for Gene Therapy. If an investigator has his own LN₂ dry shipper, we will accept shipments of empty LN₂ dry shippers from investigators, we will recharge them (if necessary and if instructions are provided), put the vials of MSCs in them, and then ship the LN₂ shipper with the MSCs back to the investigator. However, there will not be a data logger unless there is one on the LN₂ dry shipper sent to us from the investigator.

CHOICE OF SHIPPING OPTIONS

<u>Transit Time</u>	<u>Carrier/Method</u>	<u>Approx. Shipping Cost</u>		<u>Processing on Arrival</u>	
		<u>USA</u>	<u>Overseas</u>	<u>Culture (1)</u>	<u>Freeze in LN₂ (2)</u>
1 Day	DHL or FedEx (3)/Dry ice	\$50	NA	Yes	No
1-4 Days	DHL ThermoExpress (4)	\$150	\$300	Yes	No
2-5 Days	World Courier (5)	\$250 to \$300	\$650 to \$1200	Yes	No
1-6 Days	FedEx in dry liquid nitrogen (LN ₂) shipper (6)	\$75 to \$220	\$450 to \$620	Yes	Yes

Notes:

(1) Expand culture before freezing for long term storage. Note: Vials may be left frozen in dry ice

- or stored at -80°C for no longer than one week.
- (2) Can freeze in liquid nitrogen immediately.
 - (3) Shipped in maximum of 5 lbs. of dry ice.
 - (4) Shipped in dry ice equivalent blocks to maintain temperature for up to 72 hours.
 - (5) Shipped in dry ice and shipper replaces dry ice enroute.
 - (6) The LN_2 dry shipper includes an automatic logger that records the temperatures the sample has been subjected to enroute. The shipping costs shown are the approximate total charges for both the shipping of the cells and the return of the container back to the Center for Gene Therapy. **There is no deposit required, however, if the LN_2 dry shipper is not returned to the Center for Gene Therapy within two (2) weeks after receipt of cells, the Principal Investigator will be invoiced for \$,2000.00 USD to cover the replacement costs of the LN_2 shipper and the data logger.**

PLEASE INDICATE:

A. CHOICE OF SHIPPING METHOD (Dry Ice, LN_2 Dry Shipper, World Courier, ThermoExpress etc): _____

B. CHOICE OF METHOD OF PAYMENT FOR SHIPPING COSTS ONLY:

YOUR BILLING NUMBER TO SHIPPER: _____

OR

MASTER CARD NUMBER: _____

Expiration Date: _____

OR

VISA CARD NUMBER: _____

Expiration Date: _____

C. SHIPPING INFORMATION: Please provide the following:

Shipping Name (person to whom the shipment should be addressed), Shipping Address and Shipping Phone number and FAX number and any internal shipping reference number, if necessary.

Please FAX completed form with requested shipping information (or email requested shipping information) to: MSC Distribution: Fax: (504) 988-7710; email: msc@tulane.edu