Instructions: How to Request Export Permits for Blood and/or Stem Cell Products from Mexico

The Mexican regulatory authority, COFEPRIS, requires that all blood samples and stem cell products have a permit for export from Mexico. To issue the permits without delay, it is important all information provided to COFEPRIS be accurate and correct. This permit is required prior to the start of patient conditioning or filgrastim administration. This tool includes instructions for testing laboratories and transplant centers to obtain permits for collected products from Mexico to both US and non-US based sites.

Currently, blood samples for confirmatory typing and pre-collect requests are exported to a central NMDP contracted laboratory in the US where they are inspected and sent to the transplant center designated laboratory. All IDM samples are shipped directly to an NMDP contracted IDM laboratory for testing.

Export Permit for product:	Time to Issue Permit:	Validity of Permit:
Stem Cell Products	45 days from submission[1,2]	6 months for 8 bags of stem cell product. A product divided into two bags for transport is counted as two products/bags.

[1]Note: The Mexican Ministry of Health closes for several extended holiday breaks throughout the year. These holiday breaks may result in additional delays as the backlog of requests is addressed.

[2] Note: COFEPRIS has up to 45 days from time of submission to process a permit request. Current time from submission to issue of permit is much shorter at 2-3 weeks.

For US based transplant centers, follow instructions in Section I. For non-US based sites, see instructions in Section II.

Section I. Requests for Export Permits from Mexico to US-based site

1. Obtaining an export permit for stem cell products from Mexico to US transplant center (TC).
    a. The transplant center coordinator of the receiving lab in the US is required to provide the following documents to the case manager at NMDP MX:
        - Acceptance Letter to the Establishment written by transplant center coordinator to the collection center in Mexico. COFEPRIS office requires the use of a Spanish template, the English template is used as a source of reference for Transplant Centers to use for completion of the Spanish version.
        - English Template attached.
        - Spanish Template attached.
    - FDA Human Cell and Tissue Establishment Registration (HCTERS) for transplant center. Find the TC's HCT/P registration:
        - This task will be fulfilled by NMDP.
        - Go to the FDA's Human Cell and Tissue Establishment Registry Public Query (https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm)
        - Locate the TC by using search parameters.

        - *Search results are sensitive. The TC may not be registered under the most obvious name. Try one keyword from the TC's name with the state if having trouble locating the TC*.
    - Print and save the registration as a PDF and include with the letter
b. Submit the documents to the appropriate Case Manager at NMDP MX.
c. NMDP MX applies for the permit and confirms with the laboratory when the permit has been issued.

NOTE: The address of the receiving TC on the signed letter **MUST** match the address listed on the US FDA HCT/P registration. **Discrepancies will result in delay and denial of the permit.**

Section II. Requests for Export Permits from Mexico to a non-US based site

2. Obtaining export permit of stem cell products from Mexico to non-US Transplant Center
    a. The transplant center coordinator of the receiving lab is required to provide the following documents to the case manager at NMDP MX:
        - Acceptance Letter to the Establishment written by transplant center coordinator to the collection center in Mexico. COFEPRIS office requires the use of a Spanish template, the English template is used as a source of reference for Transplant Centers to use for completion of the Spanish version.
            - English Template attached.
            - Spanish Template attached.
        - Certification showing registration of the transplant center with appropriate local health authority. This could be a sanitary license or a certificate from the Ministry of Health.
            - Ensure certificate/license is current for the correct year
            - International registries cannot apply on behalf of their transplant center. It must be the transplant center that is treating the patient who applies.
            - *Note: "Certification showing registration of the transplant center with appropriate local health authority" refers to the local health authority where the Transplant Center resides.*
    b. Submit the documents to the appropriate Case Manager at NMDP MX.

NOTE: The address of the receiving transplant center on the signed letter **MUST** match the address listed on the license, certification, registration, etc**. Discrepancies will result in delay or denial of the permit.**