

National Physicians Cooperative of the Oncofertility Consortium[®]

Section 4. FDA Registration: Updating or Establishing your Registration

Background:

1. All centers that are involved in processing or storing donor tissue or cells must register initially with FDA and update that registration every December.
2. We are treating the cryopreserved ovarian tissue as though it from an anonymous donor of leukocyte tissue in case the patient must use a gestational surrogate or other method to establish a pregnancy.
3. Therefore, all NPC centers performing ovarian tissue freezing must register with the FDA.
4. If you are already registered with the FDA, you must update your registration to include ovarian tissue.
5. If you already process donor tissues or cells such as donor eggs or embryos, bone marrow, etc. you should already be registered with the FDA so you must just update that status.
6. Under FDA regulations, you must do this NO LATER than 5 Days after beginning to freeze ovarian tissue.
7. You must update this registration every year in December.

How to Update/Establish your FDA Registration:

1. Locate your current FDA registration form, you will need the identification numbers on it. If you usually update this form online, you will also need your user name and password for <http://www.fda.gov/Cber/tissue/tisreg.htm>
2. Click Tissue Establishment Registration (FDA form 3356) link on the left side and login.
 - If you do not already have a user name and password, you can create a new account on this page.
 - If you already have an account but have forgotten your username and password you can retrieve it on this page.
 - If you have never registered with the FDA, this is the place to do that too.
3. **Your current form will be visible if you have one.**
4. Update your FDA Registration to include ovarian tissue
 - Insert ovarian tissue on one of the blank lines that begins on Line J.
 - You do not have to differentiate SIP, etc.
 - **Check off all columns EXCEPT “test”** (according to the definitions of these terms, you will not be testing; testing means that your lab is performing the serology itself). For definitions, refer to: http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr1271_07.html.
5. Registration must be established or updated **NO LATER than 5 days after** beginning to freeze ovarian tissues. If you have already missed this time frame, do it immediately.
6. Update this registration every year in December. This can be done online.