


FDA Update: Regulation of Reproductive Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps)

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Applicable FDA Requirements

- Registration and listing if the establishment performs any manufacturing function and doesn't fit any of the 1271.15 exemptions
 - Donor eligibility (DE) required for donors of semen and oocytes if anonymous or directed
 - Good Tissue Practices – only
 - 1271.150(c) manufacturing arrangements
 - 1271.155 exemptions and alternatives
 - Inspections and enforcement
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Registration and Listing

- 606 establishments list reproductive HCT/Ps
 - 2322 total HCT/P establishments
 - Semen – 72 registered that list semen
 - Oocytes – 13 registered that only list oocytes
 - Embryos – 481 list embryos (IVF clinics)
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Annual Registration

- Required every year in December
 - Make changes if needed
 - Sign and date
 - Mail/FAX or complete on the web at <http://www.fda.gov/cber/tissue/tisreg.htm>
 - This year – in November:
 - If you registered by mail/FAX annual forms will be mailed
 - If you registered electronically – you will only be reminded by email. Make sure your reporting official's email address is correct and not blocked
 - Public query on the web www.fda.gov/cber/tiss.htm
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Donor Eligibility Determination

- Required for anonymous/directed donors
 - Procedures/records required
 - Summary of records must accompany the HCT/P
 - Required testing within specific time periods from recovery
 - Required screening
 - Current donor medical history interview
 - Current physical assessment
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Donor Eligibility - Semen

- Anonymous
 - 6 month quarantine (cryopreserved)
 - Negative (re-)test/screen before release
 - Test within 7 days before initial recovery
 - Directed/known
 - No quarantine
 - Recent screen
 - Test within 7 days before recovery
 - If test/screen positive the donor is ineligible
 - still can be used with physician notification and labeling
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Donor Eligibility - Oocytes

- Anonymous
 - Recent negative screening
 - Test negative within 30 days before recovery
 - Directed/Known
 - Recent screening
 - Tested within 30 days before recovery
 - If test/screen positive the donor is ineligible
 - still can be used with physician notification and labeling
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Donor Eligibility - Embryos

- Not required for use by sexually intimate partners
 - Not required if excess embryos intended for sexually intimate partners are subsequently cryopreserved and then donated
 - Required for gamete donors intended to form embryo for use in gestational carrier
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Embryo Donation

- Cryopreserved excess embryos intended for use by a sexually intimate couple or individual can be donated
 - Anonymous or directed
 - Couple or individual
 - Gestational carrier
 - Test/screen recommended at time of donation
 - Special labeling required
 - If a qualified 3rd party donor is used – embryos can still be donated
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Relevant GTP's

- Manufacturing arrangements
 - Ensure that an establishment that performs a step in manufacture for you (under contact, agreement, or other arrangement) is in compliance (testing lab) with applicable requirements
 - Guidance published – September 2006
 - Exemptions and Alternatives
 - From DE or GTP requirements
 - Must be consistent with the goals of protecting the public health and/or preventing the introduction, transmission, or spread of communicable diseases
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Other Issues

- Failure to register
 - 95 repro
 - 368 total
 - Improper testing of donors
 - Use of diagnostic tests rather than donor screening tests
 - NAT testing using pooled samples rather than individual test samples
 - Distribution of gametes from donors residing in countries where there is a CJD/vCJD risk identified
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In Progress

- Final Donor Eligibility Guidance
 - Draft GTP Guidance
 - Guidance on Testing Using Pooled Samples or Diagnostic Tests
 - Finalization of Interim Final Rule of 5/25/05

 - *For Published Documents:*
 - <http://www.fda.gov/cber/tissue/docs.htm>
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U.S. Food and Drug Administration



CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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