

UNIVERSITY OF KENTUCKY
APPLICATION FOR CHANGE IN EXISTING COURSE: MAJOR & MINOR

1. Submitted by College of Health Sciences Date August 9, 2007
Department/Division offering course Clinical and Reproductive Sciences
2. Changes proposed:
(a) Present prefix & number CSC 624 Proposed prefix & number CSC 624
(b) Present Title Gamete and Embryo Cryopreservation
New Title Cryopreservation of Reproductive Tissues
(c) If course title is changed and exceeds 24 characters (Including spaces), include a sensible title (not to exceed 24 characters) for use on transcripts:
Cryopreservation of Repro Tissues
(d) Present credits: 1 Proposed credits: 2
(e) Current lecture: laboratory ratio 1:1 Proposed: 1:1
(f) Effective Date of Change: (Semester & Year) Fall, 2008
3. To be Cross-listed as: _____
Prefix and Number Signature: Department Chair
4. Proposed change in Bulletin description:
(a) Present description (including prerequisite(s): Principles of cryopreservation will be covered; includes sessions on cryopreservation of human sperm and mouse embryos. Legal, ethical and policy issues associated with cryopreservation will be introduced. Prereq: CSC 620 and CSC 621.

(b) New description: Principles of methods of cryopreservation and will be covered and procedures for freezing human oocytes, embryos, and ovarian and testicular tissues will be detailed. Legal, ethical and policy issues associated with cryopreservation will be introduced. Prereq: CSC 620 and CSC 621. Laboratory sessions will focus on freezing human spermatozoa and mouse gametes and embryos.

(c) Prerequisite(s) for course as changed: CSC 620 and CSC 621
5. What has prompted this proposal? Significant advances have been made in the cryopreservation of human reproductive tissues since the development of this course, including successful freezing of blastocysts, mature and immature oocytes and testicular and ovarian tissues. In order to remain current these topics must be included in the CSC 624 course. The change in credit hours is the results of both the added objectives and, based on experience, the time required to progress through the course.

6. If there are to be significant changes in the content or teaching objectives of this course, indicate changes:
Objectives will be added to cover cryopreservation of: (1) blastocysts; (2) mature oocytes; (3) immature oocytes following maturation in the lab; (4) ovarian tissue; and (5) testicular tissue. Objectives addressing the policy, ethical and legal issues resulting from the freezing of these human oocytes and tissues also will be added.

7. What other departments could be affected by the proposed change? None

8. Is this course applicable to the requirements for at least one degree or certificate at the University of Kentucky?
 Yes No

Although CSC 624 is a required course for the Master of Science in Clinical Sciences, reproductive laboratory science (RLS) track an increase of one credit hour does not affect degree requirements because students must complete a minimum of 30 credit hours to earn the degree. There is a range in credit hours depending on the student's background and selected courses. For example, clinical laboratory science graduates do not take CSC 528 and hours for statistics, science and research courses vary (see table below). Currently the required courses in RLS are 19-23 hours and would increase to 20-22 credit hours. The remaining hours required for the degree will be fulfilled with statistics and science courses. Note also that students must complete 3 credit hours of RLS research and one hour in RLS seminar, but may elect to take additional hours in these courses.

Masters of Science in Clinical Sciences - Reproductive Lab Science

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| Statistics 3-4 credit hours | Requirement may be fulfilled by taking: <ul style="list-style-type: none"> • CSC 605 Epidemiology & Biostatistics (3 credit hours) <i>or</i> • CSC 606 Advanced Laboratory Statistics & Administrative Analysis (3 credit hours) <i>or</i> • STA 570 Basic Statistical Analysis (4 credit hours), or equivalent |
| Physiology or Pathophysiology 3-4 credit hours | Requirement may be fulfilled by taking: <ul style="list-style-type: none"> • CSC 600 Pathophysiology (4 credit hours) <i>or</i> • NURS 653 Pathophysiology (3 credit hours), or equivalent |
| Science courses 3-6 credit hours (depending on background) | To be selected from the following areas: <ul style="list-style-type: none"> • Cell & Molecular Biology • Genetics • Endocrinology • Microbiology • Other: Courses are selected in consultation with the student's advisory committee (3-6 credit hours minimum) |

Reproductive Laboratory Science Courses

| Course (semester hour credit) | Delivery Method * |
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| CSC 615 Reproductive Laboratory Science (1) | DL |
| CSC 616 Andrology (1) | DL |
| CSC 617 Reproductive Microbiology & Immunology (1) | DL |
| CSC 528 Laboratory Techniques (2) <i>Students not having an acceptable laboratory</i> | M, 2 weeks of 8 wk Summer Session |

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| <i>background will also be required to complete CSC 528</i> | |
| CSC 618 Labs in Andrology, Reproductive Microbiology & Immunology (1) | M, 1 week of Fall Semester |
| CSC 621 Embryology & ART (3) | Fall Semester |
| CSC 624 Gamete & Embryo Cryopreservation (1) | Fall Semester |
| CSC 625 Mgt, Policy, Ethical & Legal Issues in ART (2) | Fall Semester |
| CSC 626 Andrology Clinical Practicum (2) | 1 weeks TBD |
| CSC 627 ART Clinical Practicum (3) | 2 weeks TBD |
| CSC 628 RLS Seminar (1-2) | TBD |
| CSC 630 RLS Research (3-5): | |
| Students already employed in assisted reproductive technology may complete portions of the research project at their place of employment under the supervision of a qualified laboratory director. A UK faculty member will direct the research project and collaborate with the ART supervisor. | |
| * DL = Distributive learning. DL courses include web-based instruction and testing, and self-paced, interactive CDs. DL courses are offered during the spring semesters to both Lexington campus students and distance learners. | |
| * M = Modular. Modular courses are taught at the UK campus. Classes meet for approximately 8 hours/day. | |
| * TBD = To Be Determined | |
| NOTE = All Clinical practica will take place in Assisted reproduction laboratories in the U.S. under the supervision of Directors appointed as clinical faculty by the University of Kentucky. | |

CSC 624 Cryopreservation of Reproductive Tissues

PROFESSOR: Doris J. Baker, Ph.D., HCLD(ABB), MT(ASCP), CLS(NCA)
OFFICE: 126E CTW Building, 900 South Limestone Street, Lexington, KY
40536-0200
PHONE NUMBER: (859) 323-1100 ext. 80854
E-MAIL dbake0@email.uky.edu
ED. COORDINATOR: Kim Campbell M.S., MT(ASCP)
PHONE NUMBER: (859) 323-1100 ext. 80853
E-Mail kkcamp1@email.uky.edu

Course Description: **Gamete & Embryo Cryopreservation; 2 credit hours; Lecture/Lab 1:1 credit hour.** Prerequisites: CSC 620, and CSC 621 or consent of instructor. **Lecture:** Principles of cryopreservation will be covered. Protocols for freezing spermatozoa, testicular tissue, oocytes, ovarian tissue and embryos at various stages of development will be detailed. Problems associated with freezing particular tissue types also will be discussed. **Laboratory:** Students will cryopreserve human sperm and mouse embryos using both manual and automated methods. They will then thaw the frozen gametes and embryos and assess survival and survival rates using standard criteria. Legal, ethical and policy issues associated with cryopreservation of human reproductive tissue will be introduced, including potential for transmission of infectious disease and issues associated with the term of storage of embryos.

By the end of the course, the student will demonstrate that he/she will/can:

Lecture:

- Understand the principles of cryopreservation, including factors that affect survival of cryopreserved cells, effects of physical stress from freezing, and damage caused during the thawing process.
- Compare advantages and disadvantages of rapid and slow cooling methods.
- **Describe vitrification and discuss advantages and drawbacks of using this method.**
- Determine the warming rate for specific reproductive tissues.
- Describe the action of cryoprotectants and demonstrate knowledge of intracellular and extracellular cryoprotectants, including when each should be incorporated in the procedure.
- Freeze hamster and murine gametes and embryos using both manual and automated freezing methods for reproductive tissue.
- Outline appropriate record keeping for the cryobiology lab including patient consent, monitoring, and terms of storage.
- Describe at least one acceptable protocol for freezing semen, embryos, and blastocysts. Describe the methods for freezing human oocytes; explain the problems associated with freezing metaphase oocytes and discuss options using prophase I oocytes.
- Diagram the steps for freezing and storage of human embryos using at least two different

automated protocols.

- Describe methods for freezing human oocytes and discuss problems associated with cryopreserving oocytes.
- Describe protocol for freezing testicular tissue, including tissue preparation.
- Describe protocol for cryopreserving oocytes (mature and process for maturing and cryopreserving immatures) and ovarian tissue.
- Discuss oocyte maturation followed by vitrification.
- Describe microbiological and genetic testing for sperm donors, oocyte donors and embryo donors.
- Discuss problems associated with cryopreservation of human embryos.
- Use resources available, including the web, to identify case studies that demonstrate legal and ethical issues associated with cryopreservation of human reproductive tissue.
- Outline protocol for freezing reproductive tissue for patients undergoing radiation and/or chemotherapy; identify problems based on the type of malignancy and the age of the patient.
- Discuss current and impending regulation for reproductive tissue banking.
- Fully describe all FDA regulations and ASRM guidelines for cryopreservation and storage of human oocytes, cleavage stage embryos, spermatozoa, testicular tissues and ovarian tissues.
- Fully describe FDA regulations and ASRM guidelines for donating all types of reproductive tissues.

Laboratory:

- Freeze, store, thaw and perform post-thaw assessment of human sperm using a manual method and two different automated methods.
- Prepare cryoprotectants and appropriate media for cryopreservation of reproductive tissue, including
 - Human sperm
 - Mouse oocytes
 - Mouse embryos
 - Mouse blastocysts.
- Outline preparation of cryoprotectants and appropriate media for cryopreservation of human oocytes, early stage embryos and blastocysts.
- Perform vitrification of mouse oocytes and embryos.
- Freeze, store, thaw and perform post-thaw assessment for the following reproductive tissue:
 - Mouse embryos
 - Mouse blastocysts
 - Human spermatozoa
 - Set-up and perform quality assurance for cryobanking.

Required Text: None

References:

Books:

Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy. The New York Task Force on Life and the Law. New York, New York. April, 1998.

An Atlas of Human Gametes and Conceptuses. Lucinda L. Veeck. Parthenon Publishing. New York. 1999.

Basic Techniques in Clinical Laboratory Science. Third edition. Jean Jorgenson Linne and Karen Munson Ringsrud. Mosby - Yearbook, Inc. St. Louis. 1992.

Blastocyst Update. Edited by Kay Elder and Thomas Elliott. World Wide Conferences on Reproductive Biology. Ladybrook Publishing. 1999.

A Clinical Guide for Contraception. 2nd. Edition. Leon Speroff and Philip Karney. Williams & Wilkins. Baltimore. 1996.

Diagnostic Microbiology 10th. Ed. Bailey & Scott. Mosby Publishing Co. St. Louis, MO. 1998.

Fertility and Reproductive Medicine. Editors: R.D. Kempers, J. Cohen, A.F. Haney and J.B. Younger. Elsevier. Amsterdam. 1998.

Gamete and Embryo Quality. Edited by L. Mastroianni, Jr., H.J.T. Coelingh Bennick, S. Suzuki and H.M. Vemer. Parthenon Publishing. New York. 1994.

Handbook of Andrology, American Society of Andrology, Lawrence Kansas. Robarie, R Pryor, J, Terasler JM, Editors. Allen Press, Lawrence Kansas, 1992.

Handbook of Assisted Reproduction Technology. Ed. by Brooks A. Keel, Jeffrey V. May * Christopher J. DeJonge. CRC Press. Boca Raton. 2000.

Handbook of In Vitro Fertilization. Second Edition. Edited by Alan O. Trounson and David K. Gardner. CRC Press. Boca Raton. 1999.

Handbook of the Laboratory Diagnosis and Treatment of Infertility. B.A. Keel and B.W. Webster. CRC Press. Boca Raton. 2000.

In Vitro Fertilization. Second edition. Kay Elder and Brian Dole. Cambridge University Press, 2000.

Practical Laboratory Andrology. David Mortimer. Oxford University Press. New York. 1994.

Reproductive Tissue Banking: Scientific Principles. Edited by Armand M. Karow and John K. Critzer. Academic Press. San Diego. 1997.

Safe Cryopreservation of Gametes and Embryos. Edited by Eileen McLaughlin, Allan Pacey and Thomas Elliott. World Wide Conferences on Reproductive Biology. Ladybrook

Publishing.1999.

Scientific Essentials of Reproductive Medicine. Editors: SG Hillier, HC Kitchener, JP Neilson. W.B. Saunders. Philadelphia. 1996.

Standards for Tissue Banking. The American Association of Tissue Banking. 2001.

The Use of Testicular and Epididymal Sperm in IVF. Edited by Kay Elder and Thomas Elliott. World Wide Conferences on Reproductive Biology. Ladybrook Publishing, 1998.

WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction. 3rd. Edition. Patrick J. Rowe, Frank H. Comhaire, Timothy B. Hargreave and Heather J. Mellows. World Health Organization.. Cambridge University Press. Cambridge. 1992.

WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction. Fourth Edition. World Health Organization.. Cambridge University Press. Cambridge. 1999.

WHO Manual for the Standardized Investigation and Diagnosis of the Infertile Couple. . World Health Organization. Fourth Edition. Cambridge University Press. Cambridge. 1992.

WHO Manual for the standardized investigation, diagnosis and management of the infertile male. World Health Organization. Cambridge University Press. Cambridge. 2000.

PUBLIC BILLS AND LAWS

1. United States Congress. House of Representatives. Committee on Energy and Commerce. Subcommittee on Health and the Environment. Hearing on H.R. 3940, A Bill to Provide for the Certification of Embryo Laboratories. Washington, D.C. : U.S. Government Printing Office, 1992.
2. Public Law #102-493, The Fertility Clinic Success Rate and Certification Act of 1992. 102nd Congress, Second Session, 1992.
3. Department of Health and Human Services, HCFA Public Health Service, HCFA Public Health Service, et al. Clinical laboratory Improvement Act of 1988, Final Rule (42 CFA 405), Federal Register, Part II, February 28, 1992.
4. CDC Implementation Plan, May 22, 1996. Centers for Disease Control and Prevention; Implement of the Fertility Clinic Success Rate and Certification Act of 1992.
5. United States Congress. Office of Technology Assessment. Artificial insemination practice in the United States; summary of 1987 Survey [OTA ABP-BA-48], Washington, D.C. U.S. Government Printing Office, 1988.

GUIDELINES, WORKSHOP SUMMARIES, ACCREDITATION PROGRAMS

1. OSHA Directory U.S. Dept. Of Labor Occupational Safety and Health Administration Regional Offices. Bloodborne Pathogens. Boston: Jones and Bartlett Publishers, 1993
2. College of American Pathologists and American Fertility Society, College of American Pathologists Reproductive Laboratory Accreditation Program, Chicago: CAP, Publishers 1992.
3. American Fertility Society Post-Graduate Course. Accreditation of andrology and ART laboratories: understanding the legislation, administration and implementation. Montreal, Canada, AFS, 1993.
4. American Society of Clinical Pathologists and the College of American Pathologists. CLIA '88. The final rules. Chicago: CAP Publisher, 1992.
5. Archives of Pathology & Laboratory Medicine. Arch Pathol Lab Med Vol 116, April, 1992.
6. College of American Pathologists and the American Fertility Society. Reproductive Laboratory Accreditation Program. Standards for Accreditation. Chicago: CAP, publisher, 1992.
7. Guidelines of Human Embryology and Andrology Laboratories. The American Fertility Society. Fertil Steril. 1992; 58 (supplement 1).
8. New Guidelines for the Use of Semen Donor Insemination: 1990. The American Fertility Society. Fertil Steril. 1990;53(supplement 1).
9. Ethical Considerations of the New Reproductive Technologies. The Ethics Committee of the American Fertility Society. Fertil Steril. 1986;46 (Supplement 1).
10. Ethical Considerations of the New Reproductive Technologies. The Ethics Committee of the American Fertility Society. Fertil Steril. 1986;49 (Supplement 1).
11. Ethical Considerations of the New Reproductive Technologies. The Ethics Committee of the American Fertility Society. Fertil Steril. 1990;53 (Supplement 2).
12. Ethical Considerations of the New Reproductive Technologies. The Ethics Committee of the American Fertility Society. Fertil Steril. 1997;67 (Supplement 1).
13. Guidelines for Gamete Donation: 1993. The American Fertility Society. Fertil Steril 1993;59 (Supp 1).
14. IFFS Surveillance 98. Ed. Howard W. Jones, Jr. And Jean Cohen Coordinator. Fertility & Sterility. Supplement 2. May 1999.
15. Code of Practice. Human Fertilisation and Embryology Authority. 2nd Rev. Paxton House.

Great Britain. Dec. 1995.

16. FDA Regulation of Reproductive Tissue Labs 21 CFR Part 1271
www.fda.gov/cber/tissue/hctregestabl.htm o
17. www.fda.gov/cber/tissue/tissregdata.htm
18. www.fda.gov/cber/tissue/trg.htm
19. www.access.gpo.gov/nara/cfr/waisidx_05/21cfr1271_05.html (complete)

Guidelines and newsletters as applicable:

1. American Society for Reproductive Medicine Newsletter
2. The American Fertility Society Guidelines for Practice
3. ASRM Net News
4. Androlog
5. EmbryoMail
- 6.. Kaiser Newsletter
7. Alpha International
8. FertiNet

Journals:

American Journal of Obstetrics & Gynecology
American Journal of Reproductive Endocrinology
Andrologia
Biology of Reproduction
Clinical Obstetrics & Gynecology
Contraception
Development
Developmental Biology
Endocrinology Reviews
Fertility & Sterility
Gamete Research
Human Reproduction
International Journal of Developmental Biology
Journal of the American Medical Association
Journal of Andrology
Journal of Assisted Reproduction
Journal of Reproduction & Fertility
Journal of Assisted Reproduction & Genetics
Journal of Clinical Endocrinology & Metabolism
Journal of In Vitro Fertilization & Embryo Transfer
Journal of Microbiology
Journal of Reproduction and Fertility

Journal of Reproductive Medicine
Molecular Human Reproduction
Molecular Reproductive Development

Grading: CSC 624

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| Exam I | 40% |
| Exam II | 40% |
| Lab reports | 20% |

Grading Scale:

90-100% = A

80-89% = B

70-79% = C

below 70% = E

Course Policies:

- Students are expected to review materials received prior to the commencement of CSC 624.
- Laboratory reports are to be completed by the student without assistance.
- Class attendance is expected for all sessions. Please notify the professor directly if you find it necessary to miss a session. If a student is absent for more than 20% of the lectures/labs, s/he will be dropped from the course.
- Please see the professor during the first two days of class if you have any conflicts in scheduling due to religious observances.

University Policies:

Excused absences: Acceptable reasons for excused absences are listed in *Student's rights and Responsibilities, Section 5.2.4.2*. Briefly, these include serious illness, illness or death of someone in the student's immediate family, University sponsored trips, major religious holidays, and other circumstances the instructor finds reasonable. NOTE: If you intend to be absent to observe a major religious holiday, you must notify Dr. Stewart *in writing* by Jan 29.

When there is an excused absence, you will be given the opportunity to make up missed work and/ or exams. It is the student's responsibility to inform the instructor of the absence, preferably in advance, but no later than one week after the absence.

Senate Rule 5.2.4.2 states that faculty have the right to request "appropriate verification" when students claim an excused absence because of illness or death in the immediate family. The University Health Services (UHS) will no longer give excuses for absences from class due to illness or injury. UHS forms can be date stamped to show that students went to the trouble of going to University Health Service, but it does not mean that students actually saw a physician or a nurse. If the faculty member wants further verification that a student kept an appointment with University Health Services (especially when there have been multiple or prolonged absences from class), the student will need to sign a release of information form (available from UHS) that will give permission for the staff to talk with the faculty member.

Inclement weather: In case of inclement weather or emergencies, class will be held unless the University administration cancels classes. For University closing of classes and offices, call the UK Infoline at 257-5684 or check UKTV Cable Channel 16. Students should use their judgment about coming to class.

- [Severe Weather: UK Policy/Information:](#)

It is the policy of the University of Kentucky to keep all offices open and classes meeting as scheduled except under extraordinary conditions.

If severe weather should result in changes to the university schedule, the university will follow specific procedures about when those decisions are made and how they will be announced. Details of those procedures are available at http://www.uky.edu/PR/News/severe_weather.htm .

All faculty, staff and students should note that announcements regarding the cancellation of classes and closure of offices, or a delayed opening will normally be made by 6 a.m. through the local news media. The most up-to-date and complete information will be available from the UK Infoline at 257-5684, UK TV Cable Channel 16, or the UK Web site at <http://www.uky.edu/>
Cheating and plagiarism: Descriptions of what constitutes cheating and plagiarism are found in *Student Rights and Responsibilities, Sections 6.3.1 and 6.3.2*. Be aware that the minimum consequence for either offense is an “E” in the course. Suspension and dismissal from the University are also options.

Classroom and Learning Accommodations: Instructors will make reasonable accommodations for physical and/or learning disabilities that could inhibit student academic success. The Disability Resource Center certifies the need for and specifies the particular type of such accommodations on a student-by-student basis. Students seeking accommodations must submit this certification to the faculty. Contact the Center staff at 257-2754.

Writing Skills: Helping promote scholarship is more than simply teaching the subject matter -- all students need to improve and refine their skills in verbal and written expression. Regardless of discipline, faculty has the right -and the obligation- to expect students to use English properly in all aspects of the course (S.R.5.2.4.3). Instructors may ask students to rewrite papers, make writing style one of the grading criteria, and report a seriously deficient student to his/her college for remedial work.

Example Calendar – Modular Course

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| Cryopreservation Principles and Applications – Dr. Gao Principles applicable to ART laboratories – Dr. Baker | Lab Reports due- dates TBD |
| Lectures – Drs. Baker and Witmyer <ul style="list-style-type: none"> • Embryo assessment and handling • Cryopreservation of Day 2 and Day 3 Embryos | |
| Lab – Drs. Baker and Witmyer, Ms. Campbell <ul style="list-style-type: none"> • Complete freezing run • Embryo storage • Embryo assessment • Prep for Tuesday’s lab • Discuss troubleshooting | |
| Exam I | |
| Lecture – Drs Baker and Witmyer <ul style="list-style-type: none"> • Embryo assessment and handling • Cryopreservation of blastocysts | |
| Lab – Dr. Witmyer, Ms. Campbell <ul style="list-style-type: none"> • Complete freezing run • Thaw Day 2 and Day 3 embryos • Embryo culture | |
| Lecture- Dr. Witmyer <ul style="list-style-type: none"> • Embryo assessment and handling • Cryopreservation of embryos in straws | |
| Lab – Dr. Witmyer, Ms. Campbell <ul style="list-style-type: none"> • Complete freezing run • Thaw blastocysts and embryos from morning run | |
| Lecture - Drs. Angle and Baker <ul style="list-style-type: none"> ➤ Vitrification | |
| Lab – Dr. Angle and Ms. Campbell | |
| Lecture: Dr. Baker <ul style="list-style-type: none"> ➤ Freezing testicular and ovarian tissues ➤ Cryopreservation of immature oocytes | |
| Lecture: Dr. Baker <ul style="list-style-type: none"> ➤ FDA regulations and ASRM guidelines for cryopreservation of reproductive tissues. | |
| Exam II | |