STEM CELL SCIENCE, ETHICS, AND POLICY

PST 4803 - AL / PUBP 4803 - AL

Classroom: CULC 423

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| Prof. Aaron Levine | Email: aaron.levine@pubpolicy.gatech.edu |
| School of Public Policy | Office phone: (404) 385-3329 |
| DM Smith 216 | Office hours: Wednesday 10:45 to 11:45 or by appt |

**Cross-listing:**

This class is cross-listed as PUBP 4803 – AL, which carries the social science attribute and PST 4803-AL, which carries the humanities attribute. Please be sure you are enrolled in the correct version of the course. This cannot be changed after the end of the first week of classes. Because this is a special topics course, it does not officially fulfill Georgia Tech’s Ethics requirement, but it is accepted for this requirement by many programs. I suggest you check with your academic advisor if you need this class to fulfill your ethics requirement.

**Description:**

Stem cells and related technologies offer the potential to advance our understanding of human diseases and lead us to a new era of regenerative medicine.  Yet scientific research using stem cells raises profound ethical questions and deciding whether to support and how to regulate stem cell science has posed challenges for policymakers in the United States and around the world.  This class will explore the history, current state of the art and likely future of stem cell science.  To do so, we will examine different types of stem cell science (e.g. adult stem cells, embryonic stem cells) and research in related fields, such as cloning.  For each topic, we will assess the current state of scientific knowledge and examine relevant ethical issues and policy considerations.  At the end of the course, students will have a solid grounding in the stem cell debate, complemented by an ability to assess ethical issues and participate in and contribute to policy debates on the development of emerging technologies in the life sciences.

When you finish this course, you should be able:

* Understand key elements of stem cell science and related technologies
* Articulate and assess ethical arguments about stem cells and other emerging biotechnologies
* Understand the historical development of stem cell policies
* Assess policy arguments and evaluate the impact of stem cell policies

# Summary of Course Requirements:

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|  | **Requirement** | **Percent of Grade** | **Date** |
| 1 | Participation | 30% | Throughout the semester |
| 2 | Exams (3) | 30% | Exam #1: Wed, Oct 5 (in-class)  Exam #2: Wed, Nov 9 (in-class)  Exam #3: Wed, Dec 14 at 8am |
| 3 | Policy Memos (3) | 30% | Memo #1: Wed, Sept 21 before class (t-square)  Memo #2: Wed, Oct 26 before class (t-square)  Memo #3: Wed, Nov 30 before class (t-square) |
| 4 | Policy Debates | 10% | Mon, Dec 5 (in-class)  Mon, Dec 7 (in-class) |

# Detailed Descriptions of Course Requirements:

1 – Participation

A key component of this class will be the discussion of a wide variety of readings, including book chapters, peer-reviewed scientific articles, ethical reports and policy analyses. Reading is assigned on a weekly basis. Each student is expected to complete the reading for the week before coming to the first class meeting of the week, and to participate actively in class discussion during both weekly class meetings. To facilitate discussion, each student should prepare a written response to the readings before the first class meeting of the week. There is no set format for these response papers. They should not be, however, merely a summary of the readings. Rather they should focus on your reactions to the material. You may find it helpful to discuss what you judge to be the most important, interesting, confusing or surprising components of the readings. These responses should be typed and roughly one page in length. They will be collected at the end of the first class meeting of the week and will be one element in your attendance and participation grade. You are allowed to skip one response paper for any reason with no penalty.

The response papers are designed to prepare you to participate in class, but they are not a substitute for actual contributions in class discussion. In addition to the response papers, your participation in class discussion will be tracked and assessed. It is impossible to participate if you don’t attend class. I realize that some absences are unavoidable, but frequent unexcused absences will reduce your participation grade and may lead to deductions from your overall final grade. Repeated tardiness will lead to reductions in your participation grade.

2 – Exams

There will be three exams in this class. They will be in-class, short answer and short essay format. They will require thoughtful integration of material from lectures, discussion, readings, and other materials presented in class, along with your own original reflection and analysis. You will be graded on accuracy, breadth, clarity, and originality. The second and third exams will be cumulative.

3 – Policy Memos

Most of the formal writing assignments in this class will be in the form of policy memos. These are short assignments designed to give you practice in concise analytic writing. For each assignment you will be assigned a topic relevant to stem cell policy and asked to develop a memo arguing for a particular policy choice. More details about these assignments will be provided in class and posted to t-square.

4 – Stem Cell Policy Debates

The last week of classes, we will have in class debates on issues related to stem cell policy. Students will be assigned to groups and tasked with arguing for a particular position. You will be expected to show mastery of the relevant science, ethics and policy issues in these debates. More details about the debates and the deliverables you will need to submit will be provided in class and posted to t-square.

# Course Policies:

Atmosphere: To maintain a professional and collegial atmosphere, I ask that you arrive on time to class and keep disruptions during class to a minimum. For instance, I expect that cell phones and other similar devices will be turned off during class. You are welcome to use laptops in class to take notes or for educational classroom activities. Please refrain, however, from using your laptop for purposes not related to class. If laptop use becomes a distraction, it may become necessary to prohibit their use in class.

Communication: Email is the best way to contact me and I will usually respond promptly. I check email less frequently on the weekend and may not be able to respond to inquiries until Monday. You are, of course, encouraged to ask questions before or after class or stop by my office hours. If my office hours are not convenient for your schedule, please email me to arrange an alternate time.

T-Square: T-Square will be used to organize electronic materials and submit most papers (excluding response papers). You should find copies of lecture outlines, review material, links to electronic versions of readings (when available), etc.

Late Assignments: Response papers are collected in class at the end of the first class meeting of the week. Partial credit is available for late response papers, as long as they are submitted before the second meeting of the week. Late policy memos will generally not be accepted.

Students with Disabilities: Georgia Tech offers accommodations to students with disabilities. If you need a classroom accommodation, please provide me with the appropriate ADAPTS paperwork in office hours as early in the semester as possible.

Honor Code: You are expected to abide by the Georgia Tech Honor Code guidelines at all times (for details, see <http://www.honor.gatech.edu/>). In the context of this course, tests should be completed on your own without any unauthorized aids. We will discuss the policy memos in class, but you should write them on your own. In general, all writing is expected to represent your own work, completed specifically for this course. This means that you cannot copy text from other papers, websites, encyclopedias, etc without quoting any copied material and fully and accurately citing your sources. In addition, if you refer to, use, or build upon ideas from other work, even if you don’t quote that work exactly, you should fully acknowledge your sources. For any questions involving these or any other Academic Honor Code issues, please consult me or see <http://www.honor.gatech.edu/>.

# Required Texts

1. *Renewing the Stuff of Life: Stem Cells, Ethics and Public Policy* by Cynthia Cohen, Oxford University Press (1st Edition, June 25, 2007)
2. Various articles. Available in library or on t-square.

Codes: [B] = Cohen book, [T] = Available on T-square, [L] = Available from library

**Detailed Schedule & Preliminary Reading List (Subject to Change)**

**Week 1: Introduction**

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| Aug 22 | Introduction / Syllabus Review |
| Aug 24 | Biology Basics / What are stem cells? |
| Weekly  Reading | * Levine, AD (2007). *Cloning: A Beginner’s Guide*. Oxford, UK: Oneworld Publications, Chap. 2 (“A Cloning Parts List”) [T] * Cohen, Chapter 1 [B] * *Stem Cells: Scientific Progress and Future Research Directions.* Department of Health and Human Services. June 2001, Chapter 1 [T] |

**Week 2: Introduction to Policy and Ethics**

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| Aug 29 | Introduction to Governance and Policymaking |
| Aug 31 | Introduction to Ethical Reasoning |
| Weekly  Reading | Whitehouse.gov *Introduction to the U.S. Government* [T]  *Elements of Moral Philosophy* by James Rachels and Stuart Rachels, McGraw-Hill (2009), Chapter 1 (“What is Morality?”)[T] |

**Week 3: Precursors to Stem Cell Research**

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| Sep 5 | No Class – Labor Day |
| Sep 7 | Developmental Biology Preludes / IVF  **[Response paper due in class]** |
| Weekly  Reading | * Parson, A (2004). *The Proteus Effect.* Washington, DC: Joseph Henry Press. Chapter 1-2 [T] * Solter, D (2006). “From teratocarcinomas to embryonic stem cells and beyond: a history of embryonic stem cell research.” *Nature Reviews Genetics* 7: 319-27. [L] |

**Week 4: Early Ethics and Policy Debates**

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| Sep 12 | Abortion and Embryo / Fetal Research Debates  **[Response paper due in class]** |
| Sep 14 | IVF Policy | Guest Presentation  Renee Whitley, RESOLVE: The National Infertility Association |
| Weekly  Reading | * Kass, LR (1971). “Babies by means of in vitro fertilization: unethical experiments on the unborn?” *New England Journal of Medicine*: 285(21):1174-9. [T] * Roe v Wade Supreme Court Decision * Bellamo, M (2006). *The Stem Cell Divide*. New York: Amacom, Chapter 8 (“From Roe to Dickey”) [T] * The Dickey-Wicker Amendment [T] * Krawiec, K (2009). “Why we should ignore the ‘Octomom’” *Northwestern University Law Review Colloquy*. 104: 120-31. [T] |

**Week 5: Human Embryonic Stem Cell Research**

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| Sep 19 | Human Embryonic Stem Cell Derivation and Research  **[Response paper due in class]** |
| Sep 21 | Human Embryonic Stem Cell Research | Guest Presentation  Todd McDevitt, Associate Professor, Department of Biomedical Engineering  **[Policy Memo #1 due online before class – submit using t-square]** |
| Weekly  Reading | * Thomson, JA *et al*. (1998). “Embryonic stem cell lines derived from human blastocysts.” *Science* 282(5391):1145-47. [L] * Marshall, E (1998). “A versatile cell line raises scientific hopes, legal questions.” *Science* 282(5391):1014. [L] * Scott, CT (2005). *Stem Cell Now: From the Experiment that Shook the World to the New Politics of Life*. Pi Press. Chapter 1 (“The Experiment that Shook the World.”) [T] |

**Week 6: Ethics of hESC Research**

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| Sep 26 | Ethics of hESC Research  **[Response paper due in class]** |
| Sep 28 | Ethics of hESC Research |
| Weekly  Reading | * Cohen, Chapter 3-4 [B] * George, RP and Gómez-Lobo, A (2005). “The Moral Status of the Human Embryo.” *Perspectives in Biology and Medicine* 48(2): 201-10 [T] * Green, RM (2002). “Part III – Determining Moral Status.” *The American Journal of Bioethics* 2(1):20-30 [T] * Walters, K (2004). “Human embryonic stem cell research: An intercultural perspective.” *Kennedy Institute of Ethics Journal* 14(1): 3-38 [Optional] |

**Week 7: Catch-up, Review & Exam #1**

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| Oct 3 | Catch-up / Exam Review. Come with questions |
| Oct 5 | **[Exam] Exam #1 in-class** |

**Week 8: Ethics of hESC Research**

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| Oct 10 | Embryo Disposition  **[Response paper due in class]** |
| Oct 12 | Ethics of hESC Research | Guest Presentation  Daniel Becker, Georgia Right to Life |
| Weekly  Reading | * Cohen, Chapter 2 [B] * Lyerly, AD and Faden RR (2007). “Willingness to donate frozen embryos for stem cell research.” *Science* 317:46-7. [L] * Beauchaine, J (2009). “The next frontier of the stem cell debate: ‘Snowflake’ babies, embryo ‘adoption,’ and being pre-born again.” *The Village Voice*. June 17. [T] * Lobron, Alison (2009). “The Maybe-Baby Dilemma” *Boston Globe*, Nov 22. [T] * Lyerly, AD *et al*. (2006). “Factors that affect infertility patients’ decisions about the disposition of frozen embryos.” *Fertility and Sterility* 85(6): 1623-30. [L] [Optional] |

Note: Oct 14 is the last day to drop classes with a grade of ‘W’

**Week 9: Somatic Cell Nuclear Transfer & Egg Donation**

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| Oct 17 | No Class – Fall Break |
| Oct 19 | Somatic Cell Nuclear Transfer / Egg Donation  **[Response paper due in class]** |
| Weekly  Reading | * Levine, AD (2007). *Cloning: A Beginner’s Guide*. Oxford, UK: Oneworld Publications, Chapter 5 (“Embryonic Stem Cells and the Promise of Therapeutic Cloning”) [T] * President’s Council on Bioethics (2002). *Human Cloning and Human Dignity: An Ethical Inquiry*, Chapter 6 [T] * George, K (2007). “What about the women? Ethical and policy aspects of egg supply for cloning research.” *Reproductive BioMedicine Online* 15(2): 127-33. [T] |

**Week 10: Alternatives to hESCs**

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| Oct 24 | The Search for Alternatives to hESCs  **[Response paper due in class]** |
| Oct 26 | Induced Pluripotent Stem Cells  **[Policy Memo #2 due online before class – submit using t-square]** |
| Weekly  Reading | * President’s Council on Bioethics (2005). *Alternative Sources of Human Pluripotent Stem Cells: A White Paper.* [T] [Read Introduction (1-7) and either section I (8-23), section II (24-35) or section III (36-49).] * De Souza, N (2010) “Primer: Induced pluripotency.” *Nature Methods* 7(1) 20-1. [T] * Krauthammer, C (2007). “Stem Cell Vindication” *Washington Post*, November 30. [T] * Hyun I *et al*. (2007). “New advances in IPS cell research do not obviate the need for human embryonic stem cells.” *Cell Stem Cell* 1(4): 367-8. [T] * Zarzeczny, A *et al*. (2009). “IPS cells: Mapping the policy issues.” *Cell* 139(6): 1032-7 [T] [Optional] |

**Week 11: US Stem Cell Policy**

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| Oct 31 | Clinton / Bush Administration Policies  **[Response paper due in class]** |
| Nov 2 | Obama Administration Policies |
| Weekly  Reading | * Cohen, Chapter 7 (pages 166-183) [B] * Rabb Letter (“Federal Funding for Research Involving Human Pluripotent Stem Cells”) [T] * Speech by President George W. Bush regarding human stem cell research, August 9, 2001 in Cohen book, p233-37. [B] * Lefkowitz, JP (2008). “Stem cells and the President – An inside account.” *Commentary*, January 2008 [T] * Kaplan K and Cline E (2006). “Stem Cell Limits Have Scientists Seeing Double.” *Los Angeles Times*, August 9, p. A19. [T] * Speech by President Obama regarding human stem cell research, March 9, 2009 [T] * Wadman, M (2011). “Court quashes stem cell lawsuit.” *Nature* 476:14-15 [T] * Levine, AD (2011). “Policy uncertainty and the conduct of stem cell research.” *Cell Stem Cell* 8(2):132-35 [T] [Optional] |

**Week 12: Catch-up, Review & Exam #2**

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| Nov 7 | Catch-up / Exam Review. Come with questions |
| Nov 9 | **[Exam] Exam #2 in-class** |

**Week 13: State Stem Cell Policy and Impact of Stem Cell Policies**

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| Nov 14 | The State Policy Patchwork  **[Response paper due in class]** |
| Nov 16 | Impact of Stem Cell Policies |
| Weekly  Reading | * Bellamo, M (2006). *The Stem Cell Divide*. New York: Amacom, Chapter 6 (“California Dreaming”) [T] * Wadman, M (2008) “Stuck in New Jersey.” *Nature* 451: 622-626. [L] * Sulmasy, DP (2009). “Deliberative democracy and stem cell research in New York State: The good, the bad, and the ugly.” *Kennedy Institute of Ethics Journal* 19(1): 63-78. [L] * Levine, AD (2006). “Research policy and the mobility of US stem cell scientists.” *Nature Biotechnology* 24(7): 865-6. [L] * Levine, AD (2008). “Identifying under- and over-performing countries in research related to human embryonic stem cells.” *Cell Stem Cell* 2: 521-4. [T] * Scott, CT *et al*. (2009). “And then there were two: use of hESC lines.” *Nature Biotechnology* 27(8): 696-7. [L] |

**Week 14: Adult Stem Cells**

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| Nov 21 | Hematopoietic & Other Adult Stem Cells (including adult SC plasticity)  **[Response paper due in class]** |
| Nov 23 | Cord Blood Stem Cells |
| Weekly  Reading | * Parson, A (2004). *The Proteus Effect.* Washington, DC: Joseph Henry Press. Chapter 3 (“The Purple Cell.”) [T] * Scott, CT (2005). *Stem Cell Now: From the Experiment that Shook the World to the New Politics of Life*. Pi Press. Chapter 5 (“Hunting Adult Stem Cells.”) [T] * Holden, C & Vogel, G (2002). “Plasticity: Time for a Reappraisal?” *Science* 21(296): 2126-9. [T] * Bellamo, M (2006). *The Stem Cell Divide*. New York: Amacom, Chapter 16 (“Banking on Cord Blood”) [T] * American Academy of Pediatrics (2007). “Cord blood banking for potential future transplantation.” *Pediatrics* 199(1): 165-70. [T] |

**Week 15: The Future of Stem Cell Research**

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| Nov 28 | Translational Stem Cell Research |
| Nov 30 | The business of stem cells  **[Policy Memo #3 due online before class – submit using t-square]** |
| Weekly  Reading | * Pollack, A. (2001). “Another Stem Cell Debate; Ethics Aside, a Good Business Model Remains Elusive.” *New York Times*, July 28 [T] * Regalado, A. (2005). “Big Companies Quietly Pursue Research on Embryonic Stem Cells.” *Wall Street Journal*, April 12, pg A1 [T] * Enserink, M. “Selling the Stem Cell Dream” *Science* 313: 160-163 [L] * Hyun, I *et al*. “New ISSCR guidelines underscore major principles for responsible translational stem cell research.” *Cell Stem Cell* 3: 607-9. [T] * Lau, D *et al*. (2008). “Stem cell clinics online: The direct-to-consumer portrayal of stem cell medicine” *Cell Stem Cell* 3: 591-4. [T] |

**Week 16: Stem Cell Policy Debates**

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| Dec 5 | Stem Cell Policy Debate #1 (in-class) |
| Dec 7 | Stem Cell Policy Debate #2 (in-class) |

**Exam #3 Wednesday, December 14 at 8:00 am**