Agency	Policy/Link	Topic	Summary
Research Involving MDPH: Department of Public Health | Mass.gov			
MA Dept of Public Heath	Conduct of Human Subject Research V. 4/15/2013	References OHRP/FDA regs	MDPH policy governing human subjects research which applies to all research in which an MDPH employee or agent is engaged, consistent with guidance from OHRP.
MA Health and Human Services	Protection of Human Research Subjects Requirements	access to confidential MDPH records	Provides overview of access to confidential MDPH records and how to apply.
MA Health and Human Services	Data Access	MDPH confidential information for research	MDPH confidential information for research must have approval from the Commissioner of Public Health;
Stem Cell Research: http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/healthcare-quality/stem-cell-research/			
MA Health and Human Services	Application for Certificate of Registration to Conduct Human Embryonic Stem Cell Research	Human Embryonic Stem Cell Research Institutional Registration	"Biotechnology", requires any institution that conducts human embryonic stem cell research in Massachusetts to obtain a Certificate of Registration from the Department of Public Health.
MA Health and Human Services	Instructions for Annual Reports from Institutions Holding a Certificate of Registration	Annual Reporting for Human Embryonic Stem Cell Research	Due by January 31 for the 1-year period from January 1 – December 31 of the reporting year, Annual reports should provide a summary of the research approved to the extent required by M.G.L. c. 111L, § 3(b). The report should also include a statement representing that said research was reviewed in accordance with M.G.L. c. 111L, if applicable.
MA Health and Human Services	Electronic Transmission of Correspondence – Listserv	Human Embryonic Stem Cell Research – notifications	Institutions should subscribe to the listserv to obtain important information re: stem cell research
Mental Health Research: http://www.mass.gov/eohhs/researcher/research-rules/department-of-mental-health-research-rules-and-forms.html			
MA Department of Mental Health	Principal Investigator's Package	Department of Mental Health (DMH) Central Office Research Review	All research, regardless of funding source, must be reviewed by the CORRC if: December 1, 2011

		Committee (CORRC) review of research – guidelines for investigators; *includes protocol and consent form templates, as well as the following 4 forms as appendices.*	Division of Clinical and Professional Services Central Office Research Review Committee 2 (a) A DMH employee, as an employee, participates as a research investigator or a subject; (b) A DMH client is a subject of the research, unless the research in no way is related to DMH, or a facility or program operated or contracted for by DMH; (c) The research involves disclosure of data by DMH; or (d) The terms of an agreement or other regulations require CORRC review.
MA Department of Mental Health	Periodic Review Form	Continuing Review	At least annual monitoring (continuing review) submission form.
MA Department of Mental Health	Guidelines for reporting Adverse Events	AE reporting	A Serious Adverse Event must be reported verbally as soon as it is reasonably possible and in writing by the next business day following the Event.; A summation of all Adverse Events that do not qualify as Serious Adverse Events must be provided to the Chair of the Committee by the Principal Investigator every four (4) months, or as otherwise determined appropriate by the Department Research Review Committee.
MA Department of Mental Health	Serious Adverse Event Form		
MA Department of Mental Health	Unaffiliated Research Investigator Agreement Form	Form	Required for investigators who are not DMH employees
MA State Law			
MGL Chapter 112, Section 12J	Experimentation on human fetuses prohibited; medical procedures authorized; consent; approval; civil and criminal liability and proceedings; severability	Fetus/Fetal tissue Research	No person shall use any live human fetus whether before or after expulsion from its mother's womb, for scientific, laboratory, research or other experimentation. This section shall not prohibit procedures incident to the study of a human fetus while it is in its mother's womb or a neonate; provided that in the best medical judgment of the physician, made at the time of the study, the

			procedures do not substantially jeopardize the life or health of the fetus or neonate; and provided further that, in the case of a fetus, the fetus is not the subject of a planned abortion. (a) II. No experimentation shall knowingly be performed upon a dead fetus or dead neonate unless the consent of the parent or guardian has first been obtained; provided, however, that such consent shall not be required for a routine pathological study.
MGL Title 16, Chapter 22, Section 70G	Genetic information and reports protected as private information; prior written consent for genetic testing	Genetic Information	Informed consent is required before any genetic testing; informed consent requirements: (1) a statement of the purpose of the test; (2) a statement that prior to signing the consent form, the consenting person discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease; (3) a statement that the consenting person was informed about the availability and importance of genetic counseling and provided with written information identifying a genetic counselor or medical geneticist from whom the consenting person might obtain such counseling; (4) a general description of each specific disease or condition tested for; and (5) the person or persons to whom the test results may be disclosed;

Other			
MA State Law	Age of Majority Consent to Medical Treatment	Children (definitions)	Age of majority. Except as otherwise specifically provided by law, any person domiciled in the commonwealth who has reached the age of eighteen shall for all purposes, and any other person who has reached the age of eighteen shall with respect to any transaction governed by the law of the commonwealth, be deemed of full legal capacity unless legally incapacitated for some reason other than insufficient age. Massachusetts law recognizes two instances when teenagers under the age of 18 may have the legal capacity to consent to medical treatment. These are the emancipated minor and mature minor rules. Note that these rules concern individuals in their capacity as patients, not as subjects in research, and also that they apply only to persons in Massachusetts. These rules would not apply, for example, to research subjects living in a foreign country, although that country might have analogous rules
MA State Law	Legal Guardians and Health Care Proxies	Persons with Impaired Decision Making Capacity or Mental Disabilities	The federal regulations define “legally authorized representative” as “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.” Under Massachusetts law, this means the consent must come either from the legal guardian of the subject, or, in the case of research that is part of medical treatment, from the subject’s health care agent (either as appointed under the Massachusetts

			health care proxy law, or as designated by a health care provider under the common law for obtaining consent to the provision of medical care and associated procedures). If the subject is able to give assent (affirmative agreement) as well, this is required but the CUHS may waive the requirement to seek assent if the subject is not competent to give it. The Office of General Counsel will be consulted for each study involving adults unable to consent in Massachusetts for a determination of which individuals are legally authorized representatives under Massachusetts law to consent on behalf of subjects to their participation in the procedures involved in the research.
NCI Cancer Diagnosis Program	50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research	MA law begins on pdf page 54, slide 48 (most of this is already mentioned in links above)	Confidentiality of Health Information ■ Patients have a right to confidentiality of all records and communication. 48 [Massachusetts General Laws Annotated Chapter 111, 70E]. ■ Individuals have a general right of privacy [Massachusetts General Laws Annotated Chapter 214, 1(B)]. This privacy right also covers the confidentiality of medical information. Conditions Imposed on Genetic Testing/Use of Genetic information ■ Prior written informed consent is required for genetic testing. Genetic information and reports are protected as private information; prior written consent is required for genetic testing. Records pertaining to genetic information shall be kept confidential except that research information may be used for epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes or learning about the genetic basis of

			disease or for developing pharmaceutical and other treatments of disease. [Massachusetts General Laws Annotated Title 16, Chapter 22, Section 70G. Genetic information and reports protected as private information; prior written consent for genetic testing] ■ Massachusetts prohibits discrimination based on genetic information. Permitted Releases of Health Information or Genetic Information for Research ■ Physicians and others may disclose information under certain circumstances, including for research [Massachusetts General Laws Annotated, Chapter 112 12G). ■ Massachusetts permits the use of genetic information for research. Confidential research information is defined as any results of a genetic test maintained pursuant to pharmacological and clinical research protocols which are subject to and conducted in accordance with the review and approval of an Institutional Review Board established pursuant to the provisions of 45 CFR 46 and 21 CFR 50 and 56 and that protects the confidentiality of the individual who is the subject of the genetic test either by encryption, encoding or other means consistent with the requirements of said federal regulations, or where the identity of the individual is unknown or protected from disclosure by encrypting or encoding, or by other means consistent with the requirements of said federal regulations. [Massachusetts General Laws Annotated, Title 16, Chapter 111, Section 70G]. Definition of Genetic Test/Genetic Information Authors' note: Two definitions are used in two different sections of the law. "Genetic test," a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for

			the purpose of identifying genes, inherited or acquired genetic State Law Summary A–G 49 State Law Summary A–G abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. For the purposes of this section, the term genetic test shall not include tests given for drugs, alcohol, cholesterol, or HIV; or any test for the purpose of diagnosing or detecting an existing disease, illness, impairment or disorder. [Massachusetts General Laws Annotated, Title 16, Chapter 111] “Genetic test,” a test of human DNA, RNA, mitochondrial DNA, chromosomes or proteins for the purpose of identifying the genes, or genetic abnormalities, or the presence or absence of inherited or acquired characteristics in genetic material. [Massachusetts General Laws Annotated, Title 22, Chapter 176A]