#### SUBSTITUTE FOR

## SENATE BILL NO. 647

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 2685, 2690, 2691, and 2692 (MCL 333.2685, 333.2690, 333.2691, and 333.2692) and by adding sections 2693 and 2696.

# THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- 1 Sec. 2685. (1) A-EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION
- 2 (3) AND SUBJECT TO SECTION 2693, A person shall not use a live
- 3 human embryo, fetus, or neonate for nontherapeutic research if, in
- 4 the best judgment of the person conducting the research, based upon
- 5 the available knowledge or information at the approximate time of
- 6 the research, the research substantially jeopardizes the life or
- 7 health of the embryo, fetus, or neonate. Nontherapeutic research
- 8 shall not in any case be performed on an embryo or fetus known by

- 1 the person conducting the research to be the subject of a planned
- 2 abortion being performed for any purpose other than to protect the
- 3 life of the mother.
- 4 (2) For purposes of subsection (1) the embryo or fetus shall
- 5 be conclusively presumed not to be the subject of a planned
- 6 abortion if the mother signed a written statement at the time of
- 7 the research, that she was not planning an abortion.
- 8 (3) PURSUANT TO SECTION 27 OF ARTICLE I OF THE STATE
- 9 CONSTITUTION OF 1963, A PERSON SHALL NOT CONDUCT RESEARCH THAT
- 10 SUBSTANTIALLY JEOPARDIZES THE LIFE OR HEALTH OF A HUMAN EMBRYO
- 11 UNLESS ALL OF THE FOLLOWING REQUIREMENTS ARE MET:
- 12 (A) THE RESEARCH IS PERMISSIBLE UNDER FEDERAL LAW AND
- 13 CONDUCTED PURSUANT TO THE REQUIREMENTS OF FEDERAL LAW.
- 14 (B) THE HUMAN EMBRYO WAS CREATED FOR IN VITRO FERTILIZATION
- 15 PURPOSES.
- 16 (C) THE HUMAN EMBRYO WAS IN EXCESS OF THE CLINICAL NEED OF OR
- 17 WAS NOT SUITABLE FOR IMPLANTATION IN THE INDIVIDUAL SEEKING THE IN
- 18 VITRO FERTILIZATION SERVICES AND WOULD OTHERWISE BE DISCARDED.
- 19 (D) THE HUMAN EMBRYO WAS DONATED FOR RESEARCH WITH THE
- 20 VOLUNTARY AND WRITTEN INFORMED CONSENT BY THE INDIVIDUAL SEEKING
- 21 THE IN VITRO FERTILIZATION SERVICES AND THE PERSON DOES EITHER OF
- 22 THE FOLLOWING:
- 23 (i) OBTAINS A COPY OF THE WRITTEN INFORMED CONSENT GIVEN UNDER
- 24 SECTION 2694 FROM THE PHYSICIAN OR HEALTH FACILITY OR AGENCY THAT
- 25 PROVIDED THE IN VITRO FERTILIZATION SERVICES.
- 26 (ii) OBTAINS WRITTEN INFORMED CONSENT THAT MEETS THE
- 27 REQUIREMENTS OF SECTION 2694 FROM THE INDIVIDUAL WHO OBTAINED THE

## Senate Bill No. 647 as amended April 21, 2010

- 1 IN VITRO FERTILIZATION SERVICES AND IS DONATING THE HUMAN EMBRYO
- 2 FOR RESEARCH.
- 3 (E) THE HUMAN EMBRYO HAS NOT BEEN ALLOWED TO DEVELOP MORE THAN

3

- 4 14 DAYS AFTER CELL DIVISION BEGINS, NOT INCLUDING ANY TIME DURING 5 WHICH THE EMBRYO WAS FROZEN.
- 6 (F) THE RESEARCH INVOLVES THE EXTRACTION OR UTILIZATION OF TEMBRYONIC STEM CELLS FROM THE HUMAN EMBRYO.
  - <<(4) A PERSON THAT CONDUCTS RESEARCH USING LIVE HUMAN EMBRYOS AS PERMITTED IN SUBSECTION (3) SHALL ESTABLISH A STEM CELL RESEARCH OVERSIGHT COMMITTEE SUBSTANTIALLY IN ACCORDANCE WITH THE GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH ISSUED BY THE NATIONAL RESEARCH COUNCIL AND THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES IN 2005. NOT LESS THAN ONCE PER YEAR, THE STEM CELL RESEARCH OVERSIGHT COMMITTEE SHALL CONDUCT CONTINUING REVIEW OF RESEARCH USING LIVE HUMAN EMBRYOS IN ORDER TO ENSURE THAT THE RESEARCH CONTINUES TO MEET THE STANDARDS OF THIS PART. PURSUANT TO ITS REVIEW UNDER THIS SUBSECTION, A STEM CELL RESEARCH OVERSIGHT COMMITTEE MAY REVOKE ITS PRIOR APPROVAL OF RESEARCH UNDER THIS SUBSECTION AND REQUIRE MODIFICATIONS TO THE PLAN OR DESIGN OF A CONTINUING RESEARCH PROJECT BEFORE PERMITTING THE RESEARCH TO CONTINUE. A STEM CELL RESEARCH OVERSIGHT COMMITTEE MAY PROVIDE SCIENTIFIC AND ETHICAL REVIEW OF RESEARCH CONSISTENT WITH THIS PART.>>
- 8 Sec. 2690. (1) A person shall not knowingly sell, transfer,
  9 distribute, or give away DONATE an embryo, fetus, or neonate for a
  10 use which THAT is in violation of sections 2685 to 2689.
- 11 (2) A PERSON SHALL NOT, FOR VALUABLE CONSIDERATION, PURCHASE
  12 OR SELL, OFFER TO PURCHASE OR SELL, OR ATTEMPT TO PURCHASE OR SELL
  13 A HUMAN EMBRYO OR OOCYTE FOR STEM CELL RESEARCH OR STEM CELL
  14 THERAPIES AND CURES AS ALLOWED UNDER SECTION 27 OF ARTICLE I OF THE
  15 STATE CONSTITUTION OF 1963, OR FOR ANY OTHER PURPOSE.
- 16 Sec. 2691. A person who violates sections 2685 to 2690 OR
- 17 SECTION 2693 is guilty of a felony -punishable by imprisonment for
- 18 not more than 5 years OR A FINE OF NOT MORE THAN \$5,000.00, OR
- 19 BOTH.
- 20 Sec. 2692. As used in sections 2685 to <del>2691, "nontherapeutic</del>
- 21 2696:
- 22 (A) "CREATED FOR IN VITRO FERTILIZATION PURPOSES" MEANS
- 23 CREATED FOR IMPLANTATION AND GESTATION IN A WOMAN'S UTERUS BY
- 24 EITHER OF THE FOLLOWING:
- 25 (i) IN VITRO FERTILIZATION.
- 26 (ii) THE INTENTIONAL DIVISION OF A HUMAN EMBRYO CREATED BY IN
- 27 VITRO FERTILIZATION.

# Senate Bill No. 647 as amended April 21, 2010

- 1 (B) "HEALTH FACILITY OR AGENCY" MEANS THAT TERM AS DEFINED IN
- 2 SECTION 20106.
- 3 (C) "HUMAN EMBRYO" MEANS AN ORGANISM CONSISTING ENTIRELY OF
- 4 BIOLOGICAL COMPONENTS OF THE SPECIES HOMO SAPIENS CAPABLE OF
- 5 DIFFERENTIATION AND MATURATION, REGARDLESS OF THE MEANS OF
- 6 CREATION, INCLUDING, BUT NOT LIMITED TO, FERTILIZATION AND SOMATIC
- 7 CELL NUCLEAR TRANSFER, BEGINNING FROM THE SINGLE CELL STAGE THROUGH
- 8 THE SEVENTH WEEK OF DEVELOPMENT.
- 9 (D) "NONTHERAPEUTIC research" means scientific or laboratory
- 10 research, or other kind of experimentation or investigation not
- 11 designed to improve the health of the research subject.
- 12 <<(E) "NOT SUITABLE FOR IMPLANTATION" MEANS THAT THE HUMAN
- 13 EMBRYO EXHIBITS GENETIC OR MORPHOLOGICAL CHARACTERISTICS THAT, IN
- 14 THE BEST JUDGMENT OF THE ATTENDING PHYSICIAN, NEGATIVELY AFFECT THE
- 15 POTENTIAL FOR SUCCESSFUL IMPLANTATION, GESTATION, OR HEALTHY
- 16 DEVELOPMENT OF THE EMBRYO; OR LEAD TO A DISEASE LIKELY TO BE FATAL
- 17 TO THE EMBRYO OR ANY HUMAN DERIVED FROM THE EMBRYO. NOT SUITABLE
- 18 FOR IMPLANTATION DOES NOT INCLUDE GENETIC CHARACTERISTICS THAT DO
- 19 NOT AFFECT THE HEALTH OF THE HUMAN EMBRYO OR ANY HUMAN DERIVED FROM THE EMBRYO, INCLUDING, BUT NOT LIMITED TO, GENDER OR PHYSICAL APPEARANCE.>>
- 20 (F) "PHYSICIAN" MEANS A PHYSICIAN LICENSED UNDER PART 170 OR
- 21 PART 175, OR AN INDIVIDUAL PERFORMING AN ACT, TASK, OR FUNCTION
- 22 UNDER THE DELEGATORY AUTHORITY OF THAT PHYSICIAN.
- 23 (G) "UNIQUE IDENTIFIER" MEANS A NUMBER OR OTHER IDENTIFIER
- 24 ASSIGNED BY PROTOCOLS ESTABLISHED BY THE DEPARTMENT.
- 25 (H) "VALUABLE CONSIDERATION" MEANS THE PAYMENT OR PROVISION OF
- 26 ANYTHING OF VALUE, INCLUDING, BUT NOT LIMITED TO, CASH, GIFTS,
- 27 REDUCED OR WAIVED FEES FOR SERVICES RENDERED, MEDICAL TREATMENT, OR

- 1 PAYMENT FOR EXPENSES OR ACCOMMODATIONS. VALUABLE CONSIDERATION DOES
- 2 NOT INCLUDE MEDICAL TREATMENT OR SERVICES PROVIDED AT NO COST AS
- 3 PART OF A CLINICAL TRIAL OR EXPERIMENTAL THERAPY RELATED TO THE
- 4 TREATMENT OF INFERTILITY WHERE THE TRIAL OR EXPERIMENT IS NOT
- 5 CONDUCTED BY A PERSON DIRECTLY INVOLVED IN RESEARCH AUTHORIZED
- 6 UNDER SECTION 2685.
- 7 SEC. 2693. (1) A PERSON SHALL NOT CREATE OR ATTEMPT TO CREATE
- 8 A HUMAN EMBRYO FOR THE PURPOSE OF CONDUCTING NONTHERAPEUTIC
- 9 RESEARCH UPON THAT EMBRYO.
- 10 (2) A PERSON SHALL NOT CREATE OR ATTEMPT TO CREATE A HUMAN-
- 11 ANIMAL CHIMERIC EMBRYO CONSISTING OF BIOLOGICAL COMPONENTS FROM THE
- 12 SPECIES HOMO SAPIENS AND 1 OR MORE OTHER SPECIES WHERE THE EMBRYO
- 13 IS CAPABLE OF DIFFERENTIATING AND MATURING IN A MANNER
- 14 SUBSTANTIALLY SIMILAR TO THE EMBRYONIC MATURATION PROCESS OF EITHER
- 15 A HUMAN EMBRYO OR OF AN EMBRYO OF ANY OF THE OTHER SPECIES
- 16 CONSTITUTING THE CHIMERIC EMBRYO.
- 17 SEC. 2696. (1) EXCEPT AS OTHERWISE PROVIDED IN THIS
- 18 SUBSECTION, A PERSON THAT CONDUCTS RESEARCH USING LIVE HUMAN
- 19 EMBRYOS AS PERMITTED UNDER SECTION 2685 SHALL ANNUALLY SUBMIT A
- 20 REPORT AS DESCRIBED IN SUBSECTIONS (2) AND (3) ON FORMS PRESCRIBED
- 21 AND PROVIDED BY THE DEPARTMENT, USING THE UNIQUE IDENTIFIER
- 22 PROVIDED BY THE DEPARTMENT, AND AT THE TIME AND IN THE MANNER
- 23 PRESCRIBED BY THE DEPARTMENT. IF THE PERSON IS REQUIRED TO FILE A
- 24 REPORT UNDER FEDERAL LAW, RULE, REGULATION, OR GUIDELINE APPLICABLE
- 25 TO RESEARCH USING LIVE HUMAN EMBRYOS, WHICH REPORT CONTAINS ALL OF
- 26 THE INFORMATION REQUIRED TO BE REPORTED UNDER SUBSECTIONS (2) AND
- 27 (3), THE PERSON MAY FILE THE REPORT REQUIRED UNDER FEDERAL LAW,

## Senate Bill No. 647 as amended April 21, 2010

- 1 RULE, REGULATION, OR GUIDELINE TO COMPLY WITH THIS SECTION. <<A PERSON THAT CONDUCTS RESEARCH USING LIVE HUMAN EMBRYOS IS NOT REQUIRED TO FILE THE REPORT REQUIRED UNDER THIS SUBSECTION UNTIL THE DEPARTMENT HAS DEVELOPED AND MADE THE FORM AVAILABLE UNDER SUBSECTION (4).>>
- 2 (2) A PERSON THAT CONDUCTS RESEARCH USING LIVE HUMAN EMBRYOS
- 3 SHALL COLLECT AND REPORT THE FOLLOWING INFORMATION TO THE
- 4 DEPARTMENT AS REQUIRED UNDER SUBSECTION (1):
- 5 (A) NAME OF THE COMPANY, CORPORATION, ACADEMIC INSTITUTION, OR
- 6 OTHER PERSON MANAGING OR OVERSEEING THE RESEARCH.
- 7 (B) NAME AND ADDRESS OF THE PHYSICIAN'S OFFICE OR HEALTH
- 8 FACILITY OR AGENCY WHERE EMBRYOS WERE DONATED AND THE NUMBER OF
- 9 EMBRYOS ACQUIRED FROM EACH OFFICE OR FACILITY OR AGENCY.
- 10 (C) NUMBER OF EMBRYOS THAWED FOR USE IN RESEARCH.
- 11 (D) NUMBER OF EMBRYOS DISCARDED WITHOUT BEING UTILIZED FOR
- 12 RESEARCH.
- 13 (E) NUMBER OF EMBRYOS HELD IN STORAGE AT THE BEGINNING AND
- 14 ENDING OF THE REPORTING YEAR.
- 15 (3) A PERSON THAT CONDUCTS RESEARCH USING LIVE HUMAN EMBRYOS
- 16 SHALL REPORT ITS RESEARCH, OVERSIGHT, AND REVIEW POLICIES AND
- 17 PROCEDURES WITH REGARD TO THE RESEARCH CONDUCTED. THE PERSON THAT
- 18 FILES A REPORT UNDER THIS SUBSECTION SHALL CERTIFY THAT ITS
- 19 RESEARCH, OVERSIGHT, AND REVIEW POLICIES AND PROCEDURES WITH REGARD
- 20 TO THE RESEARCH CONDUCTED ARE IN COMPLIANCE WITH FEDERAL LAW,
- 21 RULES, REGULATIONS, AND GUIDELINES APPLICABLE TO THAT RESEARCH. A
- 22 VIOLATION OF A FEDERAL LAW, RULE, REGULATION, OR GUIDELINE
- 23 APPLICABLE TO RESEARCH USING LIVE HUMAN EMBRYOS IS A VIOLATION OF
- 24 THIS SECTION.
- 25 (4) THE DEPARTMENT SHALL DO ALL OF THE FOLLOWING:
- 26 (A) <<ON OR BEFORE THE EXPIRATION OF 1 YEAR AFTER THE EFFECTIVE DATE OF THIS SECTION,>> DEVELOP AND MAKE AVAILABLE IN PRINT AND ELECTRONIC FORMAT
- 27 A FORM FOR PERSONS TO UTILIZE IN FILING THE REPORT REQUIRED IN

- 1 SUBSECTION (1).
- 2 (B) MAKE AVAILABLE ANNUALLY IN AGGREGATE A STATISTICAL REPORT
- 3 SUMMARIZING THE INFORMATION SUBMITTED IN EACH INDIVIDUAL REPORT
- 4 REOUIRED BY THIS SECTION. THE DEPARTMENT SHALL NOT IDENTIFY THE
- 5 PERSON WHO CONDUCTS RESEARCH USING LIVE HUMAN EMBRYOS TO WHOM ANY
- 6 SPECIFIC INFORMATION APPLIES.
- 7 (C) DESTROY EACH REPORT REQUIRED BY THIS SECTION AND EACH COPY
- 8 OF THE REPORT AFTER RETAINING THE REPORT FOR 5 YEARS AFTER THE DATE
- 9 THE REPORT IS RECEIVED.
- 10 (D) ESTABLISH A PROGRAM THAT WILL ISSUE TO EACH PERSON
- 11 REQUIRED TO SUBMIT A REPORT UNDER SUBSECTION (1) A UNIQUE
- 12 IDENTIFIER UNDER WHICH THE PERSON IS TO SUBMIT THE REPORT.
- 13 (5) A PERSON SUBMITTING A REPORT UNDER SUBSECTION (1) SHALL
- 14 NOT INCLUDE THE NAME, COMMON IDENTIFIERS SUCH AS SOCIAL SECURITY
- 15 NUMBER OR MOTOR VEHICLE OPERATOR'S LICENSE NUMBER, OR OTHER
- 16 INFORMATION OR IDENTIFIERS THAT WOULD MAKE IT POSSIBLE TO IDENTIFY
- 17 IN ANY MANNER OR UNDER ANY CIRCUMSTANCES AN INDIVIDUAL WHO HAS
- 18 OBTAINED IN VITRO FERTILIZATION SERVICES AND WHO SUBSEQUENTLY
- 19 DONATED HUMAN EMBRYOS FOR RESEARCH PURPOSES. A STATE AGENCY SHALL
- 20 NOT COMPARE DATA IN AN ELECTRONIC OR OTHER INFORMATION SYSTEM FILE
- 21 WITH DATA IN ANY OTHER ELECTRONIC OR OTHER INFORMATION SYSTEM THAT
- 22 WOULD RESULT IN IDENTIFYING IN ANY MANNER OR UNDER ANY
- 23 CIRCUMSTANCES AN INDIVIDUAL WHO DONATED HUMAN EMBRYOS FOR RESEARCH.
- 24 A PERSON SHALL NOT MAINTAIN STATISTICAL INFORMATION THAT MAY REVEAL
- 25 THE IDENTITY OF AN INDIVIDUAL WHO HAS DONATED HUMAN EMBRYOS FOR
- 26 RESEARCH.
- 27 (6) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A PERSON

- 1 SHALL NOT DISCLOSE CONFIDENTIAL IDENTIFYING INFORMATION ABOUT AN
- 2 INDIVIDUAL WHO OBTAINS IN VITRO FERTILIZATION SERVICES. THE REPORTS
- 3 REQUIRED UNDER THIS SECTION ARE STATISTICAL REPORTS TO BE USED ONLY
- 4 FOR MEDICAL AND HEALTH PURPOSES AND SHALL NOT BE INCORPORATED INTO
- 5 THE PERMANENT OFFICIAL RECORDS OF THE SYSTEM OF VITAL STATISTICS.
- 6 EXCEPT FOR THE STATISTICAL REPORT UNDER SUBSECTION (4)(B),
- 7 INFORMATION SUBMITTED TO THE DEPARTMENT BY A PERSON WHO CONDUCTS
- 8 RESEARCH USING LIVE HUMAN EMBRYOS UNDER THIS SECTION IS
- 9 CONFIDENTIAL AND IS NOT SUBJECT TO THE DISCLOSURE REQUIREMENTS OF
- 10 THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.231 TO 15.246,
- 11 EXCEPT THAT DISCLOSURE OF THAT INFORMATION MAY BE MADE IN ANY OF
- 12 THE FOLLOWING CIRCUMSTANCES:
- 13 (A) WITH THE WRITTEN CONSENT OF THE PERSON WHO CONDUCTS
- 14 RESEARCH USING LIVE HUMAN EMBRYOS.
- 15 (B) PURSUANT TO A COURT PROCEEDING.
- 16 (C) THE DISCLOSURE IS MADE TO AN AGENT OR EMPLOYEE OF THE
- 17 DEPARTMENT.
- 18 (D) THE DISCLOSURE IS MADE TO AN AGENT OR EMPLOYEE OF A STATE
- 19 OR THE FEDERAL GOVERNMENT AUTHORIZED BY LAW TO SEE OR REVIEW THE
- 20 INFORMATION.
- 21 (7) A PERSON THAT VIOLATES THIS SECTION BY DISCLOSING
- 22 CONFIDENTIAL IDENTIFYING INFORMATION OR BY VIOLATING A FEDERAL LAW,
- 23 RULE, REGULATION, OR GUIDELINE IS GUILTY OF A FELONY PUNISHABLE BY
- 24 IMPRISONMENT FOR NOT MORE THAN 1 YEAR OR A FINE OF NOT MORE THAN
- 25 \$5,000.00, OR BOTH. A PERSON WHO VIOLATES THIS SECTION BY FAILING
- 26 TO FILE A REQUIRED REPORT IS RESPONSIBLE FOR A STATE CIVIL
- 27 INFRACTION AND MAY BE ORDERED TO PAY A CIVIL FINE OF NOT LESS THAN

- \$5,000.00 PER VIOLATION. 1
- Enacting section 1. This amendatory act does not take effect 2
- unless Senate Bill No. 649 of the 95th Legislature is enacted into 3
- law. 4