ARTIFICIAL WOMB - CRÈME DE LA CRÈME TO EXTRICATE PREMATURE BABIES?

By S. Aparna and G. Sridhaya Iyer
From SASTRA Deemed to be University, Thanjavur, Tamil Nadu

ABSTRACT

A fetus grown in an extracorporeal environment – a thought that cannot be comprehended by a layman, whereas the 21st-century technology repeatedly proves to be ahead of perceived reality. It is depressing to acknowledge the fact that India, a developing country, has the highest number of premature deaths and such deaths in the NICUs - Neonatal Intensive Care Units are predominantly due to infections affecting the underdeveloped immune system of the premature babies. Thus, AWT - Artificial Womb Technology can be a robust pinch hitter for NICUs a few decades from now. Hitherto, India has not been vocal about research on AWT. For serving this purpose, this paper contributes a Model Act to regulate research on AWT with the cardinal aim of saving the lives of premature babies. To further research, the paper suggests aborted fetuses as the research subjects. The researchers of this paper have provided categorical reasons as to why aborted fetuses are preferred as the research subjects. The researchers of this paper have provided categorical reasons as to why aborted fetuses are preferred as the research subjects. AWT research is indeed a double-edged sword but the fact that India has to mitigate the death rate of premature babies cannot be ignored. Medico-legal experts have critically opined that partial ectogenesis has potentiality in the artificial womb. In light of this statement, the Model Act provided in this paper envelops partial ectogenesis.

Keywords: AWT, NICU, premature deaths, aborted fetuses, partial ectogenesis.

1. INTRODUCTION

The “Artificial Womb” is a replica of the female uterus in an extracorporeal environment and is designed for “Ectogenesis” - the growth of the fetus outside the mother’s body. It is an invention in progress that does not construe a founder and acknowledges the cumulative efforts of many minds that have led to the present developmental stage. It is a concept that Emanuel M. Greenberg had solidified into research and futuristic writing in the 1920s. The artificial womb is still a concept that is foreign to a common man and will still be reciprocated the same, ten years from now. Hope always floats among the researchers indulging in AWT research, an invention that is positively looked forwarded to be used as a savior for struggling human fetuses that are on the brink of death due to lack of peak technology like the artificial womb. Research that has taken so many decades and is yet in the development stage might prove to be a costly affair but belief exists that it may become affordable – a few years down the lane.
Figure 1: Depicting the design of an artificial womb.\(^1\)

The existence of artificial wombs in the Hindu mythological times like the *Mahabharata*, where the flesh from the womb of the female was divided into sections to result in hundred fetuses and was successfully grown into well-developed babies, is a well-known incident among the Hindu religious community. The idea of artificial womb design has been portrayed in many works of fiction.

Figure 2: Blueprint of the 1955 EUFI.\(^2\)

Emmanuel M. Greenberg had acquired a patent in 1955 for the design of an artificial womb. The design portrays an amniotic fluid-filled tank to host the fetus connected via the umbilical cord to a machine that facilitates the circulation of blood, a heater to regulate the tank, and an artificial kidney for waste regulation.\(^3\)

Yoshinori Kuwabara led a project in 1996, Juntendo University, Tokyo, for the development of premature goat fetuses. Fourteen goat fetuses were nurtured in an artificial amniotic fluid sac called the **EUF** - Extra Uterine Fetal Incubation, similar to the mother goat’s uterus.\(^4\) The project succeeded to sustain the fetuses for three weeks but it sadly was not compatible to test human fetuses, though it later proved to be a spark model for the present research.

The EUFI was further developed in 2017 by the researchers in Children’s Hospital, Philadelphia. The improved EUFI additionally incorporated an interface that acts as the placenta, supplying nutrients, oxygen, removing waste, and the design resonates with the simulated sound of the mother’s heartbeat.\(^5\) Though the lamb fetuses were successfully sustained for a month, noticeable progress from the 1996 EUFI, testing on premature human fetuses is a reality yet to be realized. Researchers in that


\(^5\) Emily A.Patridge,*An extra-uterine system to physiologically support the extreme premature lamb*, NAT COMMUN. (Apr. 2017).
project hints the non-viability of the development of the artificial womb to sustain a full pregnancy – complete ectogenesis. “Complete ectogenesis” starts from IVF-In Vitro Fertilization to the delivery of the fetus in an extracorporeal environment. IVF is the external procedure where sperm and unfertilized eggs are induced to fertilize in an external medium. Complete ectogenesis is predominantly not been supported yet by researchers and bioethics experts.

On the progressive side, “Partial Ectogenesis” is the growth of an immature fetus, the age ranging from 8 weeks (considering the viability of AWT development hitherto) to 40 weeks outside the mother’s womb. This paper will only focus on partial ectogenesis, the latter being a reality-come-true in a few decades and also holding the support of experts in the field.

2. DESIGN OF ARTIFICIAL WOMB TECHNOLOGY (AWT)

2.1. THE 1996 EXTRA UTERINE FETAL INCUBATION (EUFII)

EUFII for 14 goat fetuses was developed in 1996 by Yoshinori Kuwabara and his team. The goat fetuses were surrounded by artificial amniotic fluid in a sustainable equipment that was connected to Extracorporeal Membrane Oxygenation (ECMO) – which is a pump system that circulates blood in the bloodstream of the pre-term baby, via an artificial lung. ECMO is an extracorporeal life support system that supports a person whose heart and lung are unable to function at the optimum level required to sustain life. The circulated blood is drained at systematic intervals from the umbilical arteries and is streamed into the umbilical veins. This blood is in turn recirculated and ventilation of a mixture of optimum amounts of oxygen, nitrogen, and carbon-dioxide is infused into the blood to produce the required natural chemical compounds in the blood.

The heart rate, blood pressure, and movements of the fetus were continuously being recorded by the polygraph systems. This ensures that the fetus is always kept in a stable favorable environment at its best physiological conditions to sustain the fetus. But the 1996 EUFI could ensure this stability only for a limited period. The team succeeded in sustaining the ill newborns in the EUFI for three weeks. So the 1996 EUFI could be used only for sustaining the goat fetuses that were ill newborns requiring critical intensive care. The research on human fetuses was not undertaken owing to the necessity of a more sustainable equipment.

---


2.2. THE 2017 IMPROVED EUFI

Figure 3: The 2017 improved EUFI.

The fetus of a lamb was sustained in a device for 4 weeks, an appreciable improvement from the 1996 project. A closed tank of amniotic fluid, where the umbilical cord of the fetus was connected to a pumpless oxygenation system was designed. A new technique of umbilical vascular access was incorporated. Also, the mother’s heartbeat was echoed in the artificial womb to ensure that the fetus is completely supported physiologically. Any medical access involving physical contact, that is required to be done for fulfilling the duty of a caregiver, need not be performed because AWT owes to no-external contact. The AWT system design promises constant monitoring by ultrasound machines. And the external interface can be used for all the vascular needs like drawing blood, providing nutrition support, etc., without disturbing the internal fetal environment.

Hitherto, the artificial womb research is carried out by the scientists with the prime aim that AWT should be used for saving babies that are born preterm – somewhere around 24 weeks of pregnancy. The 2017 EUFI could successfully prove that the fetal lambs that were extremely premature could be developed normally for 4 weeks. Again, the EUFI developed till then was not viable for research on human fetuses.

3. CURRENT DESIGN OF ARTIFICIAL WOMB AND DEVELOPMENTAL CONSIDERATIONS

The artificial womb is amniotic fluid-filled equipment with optimum temperature and humidity regulators, an artificial placenta – a simulation of the human female placenta, in the amniotic sac, and an umbilical cord interface for the artificial supply of blood, nutrients, and disposal of waste.

Artificial supply and disposal confirm that AWT is highly immune to infections. The similar possibility of cases wherein the mother experiences gestational immune intolerance - the unfortunate situation wherein the immune system of the mother rejects any foreign matter in her body, including the fetus in the placenta, is ruled m/2017/04/27/insights-daily-current-affairs-27-april-2017-2/artificial-womb/.

8 supra note 5.
9 artificial womb, INSIGHTS ON INDIA (Apr. 27, 2017), https://www.insightsonindia.co
out in AWT, proving that it shows complete inclination towards the protection of the fetus in the artificial womb under any circumstance.

There is an ongoing discussion on the possibility of connecting the birth mother to the fetus in the artificial womb to provide Immunoglobulins antibodies – an indispensable antibody for the immune system to be working at the optimum level for the growth and development of the fetus.

Concerning expulsion of the fetus – otherwise named ‘delivery’ - at the end of pregnancy, the artificial womb is suggested to be provided with an external circulation mechanism wherein the expelled fetus will be directed, just like how natural delivery works. Also, the artificial womb will be developed to an extent that is a replica of the female uterus and will accommodate the periodical growths of the cell linings in the placenta to provide the most optimum environment for the fetus.

4. PRETERM BIRTH (PTB)

Any birth that occurs before the gestation period of 40 weeks is said to be preterm birth. Such babies are underdeveloped and are called as ‘premature babies’. Preterm birth is the dominant cause of death among children below five years of age. Preterm birth has three significant periods;

a. Extremely preterm – less than 28 weeks,

b. Very preterm – ranging from 28 to 32 weeks and

c. Moderate to late preterm – 32 to 37 weeks.\(^{10}\)

It is a grave concern that India has the greatest number of preterm births and also the highest number of preterm deaths across the world.\(^{11}\)

Figure 4: Preterm births and neonatal deaths - A comparison between India and the world. It can be inferred that AWT may be hope for 75% of premature babies.\(^{12}\)

Because India still is an LMI (Low and Middle Income) developing country and all the hospitals in India are not endowed with NICUs- Advanced Neonatal Intensive Care


\(^{11}\) *Id.* at note 10.

Units that host the premature babies to sustain their lives, numerous deaths of premature babies can be attributed to this fact of lack of accessibility of NICUs.

Adding to this predicament, ‘golden hour’ – the time of transition when the PTB baby is transferred from the mother’s womb to the NICU care, there is an undeniably high susceptibility of such babies to suffer from IVH (Intra Ventricular Hemorrhage) during this period of ‘golden hour’. The lesser the birth weight of the PTB baby and the earlier the PTB baby is born, the longer will be its stay in the NICU and the higher will be the possibilities of complications. So, utmost care is to be given, to ensure that such PTB babies survive. Also, the care taken in the golden hour day is directly influential to the baby’s health in the future and whether the baby will survive the optimum gestation period in this extracorporeal NICU.

5. AWT - A HEALTHY SUBSTITUTE FOR NICU(s)

PTB babies are always at the risk of respiratory issues due to their underdeveloped respiratory system, hypothermia (inability to stay warm), hypoglycemia (low blood sugar), jaundice, etc.

Most importantly, the immune systems of such premature babies are not fully developed, so there is a very high risk of such babies being prone to even the least harmful of infections.


predominantly due to infections that affect the underdeveloped immune system of the PTB babies.

The incubation methods that are currently in use in the NICUs are bound to involve physical human interactions with the preterm baby inside the incubator. The preterm baby is prone to all the infections in the NICU and the current NICU facilities still prove to be inadequate to control the humidity in the NICU. Most importantly, any medical procedure or immediate care requires the preterm baby to be accessed physically by the responsible hospital staff, since the baby is placed under a closed hood incubator that needs to be opened by physical interference.

Figure 6: Causes of neonatal deaths.\textsuperscript{15}

AWT hosts the fetus in a completely closed artificially simulated environment that eliminates any kind of human interaction and shuts off even the least possibility of infection. It is completely supported by ultrasound machines making it superior to any physical examination that may be required. It incorporates an anticoagulation interface, without ventilators and pressors, thereby eliminating the likelihood of IVH. Thus, the high risk of IVH during the golden hour, as discussed earlier, is nullified in AWT. The fact that the primary aim of AWT is to save the lives of preterm babies that are on the brink of a life-death situation, is always to be reflected upon.

Babies in the NICUs are likely to suffer retinal damage and NICUs have to be lighted to monitor the baby. The use of fluorescent tube lights has not served the purpose to the extent as expected, so they were replaced in multiple incubators by UV lights, but this also poses a great danger of UV exposure to the premature baby. Though partly effective measures have been taken to protect them against such complications, eliminating the scope for such complications is always better than risking the same.

Parents of the PTB baby visit the NICU, though there is hope that the cleaning procedures are thoroughly followed, there is always the risk of spreading infection to the PTB baby in the NICU. Adding to this, a single NICU hosts multiple incubators.

Never can any legal instrument not allow the parents to visit the NICU, but this risk can be mitigated and nullified if AWT is adopted. Because the artificial womb is completely monitored and is a high-end technology-assisted equipment, so parents of the PTB

baby can view the fetus through visual instruments that are being essentially incorporated into the artificial womb system design.

Though there can be an argument that the baby in the NICUs can be open to the mother’s physical touch and care, with medical approval, and in the artificial womb it is not possible; such an argument can be defied by being attentive to the fact that artificial womb incorporates a simulation environment of the mother’s womb resonated with the constant sound of the heartbeat of the mother. In partial ectogenesis the fetus remains in the mother’s womb for the first few weeks and then it is immediately transferred to the artificial womb which is an exact simulation of the mother’s womb. So, the fetus will feel that it is in the mother’s womb for the full gestation period. In the artificial womb, the golden hour is minimized to the least possible, to avoid all the complications that arise in the NICU incubators during the golden hour day.

It is easy to notice that artificial womb provides a highly protective environment to the fetus as the monitoring of the health of the fetus and supply and extraction of nutrients and waste respectively is being done in a machine-medium that has no contact with the external environment. If proving a high success rate in the future, artificial womb, can be substituted for NICUs because of the primitive indispensable fact that it provides an extracorporeal environment that is highly immune to infections and thus protects the fetus sustaining inside the artificial womb.

Though NICU is almost similar to AWT techniques, it cannot provide the fully immune, strictly no-external contact environment that AWT can offer.

6. SHORTCOMINGS OF AWT

Though AWT poses a lot of benefits in addition to the main cause – saving the lives of premature babies, there are detriments to every invention in this world. Otherwise, it would be named as God’s creation. The artificial womb is a far-fetched reality that will spring decades down the lane. The research is still in the infant stage and requires lots more to consider. Though AWT has reached a stage of belief more than hope, with assured viability in the initial stages of commercial release, AWT will not be affordable by the needy. The natural milk production of the birth mother is a problem that will be unsolved even if AWT becomes a reality because the presence of the growing fetus in the mother’s womb is a necessary prerequisite for the mother to produce milk naturally, which sadly would not be the case in the artificial womb.

7. INDIAN BACKDROP

7.1. AWT IN INDIA

Hitherto, separate legislation for research on AWT has not been passed. Though there may have been private research works conducted towards AWT, it has not come to public notice. Nevertheless, most of the researchers are inclined towards the adoption of AWT for partial ectogenesis to save the lives of premature babies.

Considering the infamous fact that India has the highest number of premature deaths, the main reason for this zeroes down to iatrogenic factors and failure of being immune to the infections in the NICUs; it
would be most favorable if India could adopt AWT when it becomes a reality. Not only will this make India more public health-oriented, but it will also be on par with the countries across the world that will realize the beneficial effects of such technology in the future.

7.2. ABORTION

7.2.1. ABORTED FETUSES AS RESEARCH SUBJECTS FOR AWT?

The 2015 study on “The Incidence of Abortion and Unintended Pregnancy in India” - quoted in figures “We estimated 48.1 million pregnancies, a rate of 144.7 pregnancies per 1000 women aged 15-49 years, and a rate of 70.1 unintended pregnancies per 1000 women aged 15-49 years”\(^{16}\). Abortions accounted for one-third of all pregnancies, and nearly half of the pregnancies were unintended.\(^{17}\) Such aborted fetuses are cast off as biomedical waste. This can be productively used for furthering the research on AWT.

Figure 7: Data depicting - out of 48% unintended pregnancies, 33% end in abortion.\(^{18}\)

7.2.2. SCOPE IN INDIA FOR LIVE ABORTED FETUSES

Even though the usage of a live fetus for research is non-licet as per the ICMR (Indian Council of Medical Research) guidelines, there arises a grave need to use the same due to lack of other alternatives.

7.2.3. REGULATIONS THAT REQUIRE ADOPTION IN INDIA


\(^{17}\) Id. at note 16.

In the “Protection of Human Subjects of Biomedical and Behavioral Research” report published by the National Commission, the commission concludes “some information which is in the public interest and which provides significant advances in health care can be attained only through the use of the human fetus as a research subject.”19. The objective of AWT is to save the lives of premature babies, for which research on the human fetus is indispensable.

Under Section 46.204 of the United States “Code of Federal Regulations”, if there is no direct benefit to the fetus from the research, the occurrence of any risk undertaken should be minimized to the highest extent possible, to accomplish the research’s objective. In such cases, the purpose of the research should be towards realizing crucial areas of biomedical knowledge that cannot be achieved by any other means.20 As previously stated, owing to the lack of alternatives, research on fetuses is imperative.

Section 46. 207 of the Code, states that the secretary shall fund the research if it is satisfied that “The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonate; the research will be conducted in accord with sound ethical principles; and that, informed consent will be obtained”.21 Research on AWT satisfies all the above prerequisites to obtain funding. Hence, research on fetuses should be allowed in India for the sake of public welfare.

8. RESEARCH ON AWT

As stated already that AWT can be a healthy substitute for NICUs, there is an imperative necessity to further research on AWT so that it is a near reality that can be used to save the lives of premature babies. Since India is still in its initial stage concerning AWT there is a need for regulating the current research on AWT. Since R&D on AWT is ongoing across the world, the researchers of this paper would like to contribute a Model Act for regulating research on AWT.

8.1. EMBRYO AND FETUS

Embryo refers to that stage of growth from fertilization, resulting in a zygote, to the end of 4 weeks22 whereas ‘Fetus’ refers to the growth of the unborn child from 8 weeks until birth.23 This paper emphasizes that Partial


23 William C. Shiel, Medical Definition of Fetus, MEDICINE NET(Dec. 12,2018)
ectogenesis involves the growth of a fetus and not an embryo, thus partial ectogenesis is implied to start from 8 weeks of growth.

8.2. ABORTED FETUSES

This paper proposes to research on aborted fetuses since there is no alternative for such research. Researching on aborted fetuses is more favorable ethically than research on PTB babies that are expelled naturally during delivery.

8.3. ABORTED FETUSES FROM THREE TO FOUR MONTHS SUITABLE FOR RESEARCH

Before 3-4 months, the aborted fetuses are very underdeveloped and post 3-4 months the mother undergoing such abortion would have a higher emotional attachment with the fetus and the researchers of this paper do not prefer to add to the mental agony of such mothers, hence research on the period of 12 weeks to 16 weeks (3 – 4 months) is suitable.

8.4. NEED FOR SETTING ASIDE THE 14 DAY RULE

As per the ICMR Guidelines, any research on embryo shall not be carried out beyond a period of 14 days -the period when primitive streak appears. Primitive streak refers to the phase in which an embryo can no longer split into two, or where two embryos can no longer fuse into one. Thus it marks the origin of one’s individuality. Research on embryo beyond 14 days is a human right issue but the viability of AWT cannot be gauged if the 14-day limit is not relaxed. Since Partial ectogenesis in AWT requires research on fetuses that are 3 to 4 months old, thus the 14-day rule should be set aside.

9. MODEL ACT

This paper contributes a rough draft of regulations to research on AWT. The Transplantation of Human Organs and Tissues Act, 1994, and the ICMR Guidelines are the base materials for the construction of this draft.

A. The following Model Act concerns only aborted fetuses that are 12 weeks to 16 weeks for the reasons stated under the title - 8.3. Aborted fetuses from three to four months - suitable for research.

B. Since the researchers of this paper do not possess the requisite knowledge and expertise in the scientific field, details about the following aspects are not provided in the draft-

1. The expertise that the AWT researchers should possess for carrying out the research.
2. Scientific details.
3. Criteria for selection of research sites.
4. Other miscellaneous matters.

B. A rough idea is provided with respect to the following, and such proposals are not exhaustive -

1. Technical details on the composition of committees, Appropriate Authorities, etc.

24 Ethical Guidelines For Biomedical Research On Human Participants, October 2006, pg.101.
25 supra note 12.

27 Ethical Guidelines For Biomedical Research On Human Participants, October 2006.
2. Infrastructural and other requirements of the research site.
3. Documents to be filed by the AWT center etc.
4. Details on quorum and inspection are only illustrative.

C. Penalties and Miscellaneous are not elaborated in this draft.

ARTIFICIAL WOMB [TECHNIQUES AND REGULATIONS] MODEL ACT, 2020

An Act to provide for regulating the research on Artificial Wombs with the aim to save the lives of premature babies and for matters connected therewith or incidental thereto.

“Be it enacted by Parliament in the Seventy-third Year of the Republic of India as follows:"

CHAPTER I
PRELIMINARY

1. Short title, application, and commencement-

(1) This Act may be called the Artificial Womb [Techniques and Regulations] Model Act, 2020.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may by notification in the Official Gazette, appoint.

2. Definitions- In this Act, unless the context otherwise requires-

a) “Appropriate Authorities” means the Appropriate Authorities appointed under Sec 14;

b) “Artificial Womb” is an equipment where the natural processes of pregnancy are sustained in an extracorporeal environment;

c) “Artificial Womb Technology Center” means a center registered under the Act that undertakes AWT research;

d) “Authorization Committee” means the committee formed under Sec 8.

e) donor means any person as specified under Sec 4;

f) “fetus” is the unborn child from the end of the eighth week of pregnancy until birth. Provided that, for the purpose of this Act “fetus” all refer to fetuses that are twelve weeks to sixteen weeks old;

g) “hospital” means any approved center for abortion under the MTP (The Medical Termination of Pregnancy) Act, 1971;

h) “registered medical practitioner” means a medical practitioner as defined under Sec 2(h) of the Indian Medical Council Act, 1956. Such person should be enrolled under the State Medical Register as required under Sec 2(k) of the Indian Medical Councils Act, 1956;

i) “Sexually Transmitted Diseases” means disease spread by sexual contact.

CHAPTER II
DONATION OF FETUS FOR AWT RESEARCH

3. Donation of a fetus for AWT research-

(1) A pregnant woman who has decided to undergo abortion under the MTP Act, 1971,
may consent for donating her fetus for the purpose of research on AWT.

   i. It shall be the duty of the registered medical practitioner to obtain the consent of the pregnant woman for donating her fetus for research;

   ii. Provided that, For the purpose of subsection (1),
    a) Such consent should be an informed consent, as lawful under The Indian Contract Act, 1872;
    b) Such consent has to be taken before the fetus is expelled out of her womb.

   (2) A donor giving consent under subsection (1) is required to produce the same in writing in the presence of two or more witnesses (at least one should be the near relative of such person).

   (3) Such consent shall not be taken from a pregnant woman who is carrying a child such that,

   i. If the child were born, it would suffer from physical or mental abnormalities or

   ii. Such pregnancy is alleged (by the pregnant woman) to have been caused by rape,

   iii. The pregnant woman is a minor.

Note: Provisions under subsection (3) have been included to reflect the intention that consent from such pregnant woman would only subject them to further agony.

4. Donations can be accepted only in the following circumstances;-

   (1) Cases in which abortion is intended to restore the deteriorating physical or mental health of the pregnant woman;
   (2) Cases in which the life of the pregnant woman is in danger and thus abortion is intended;
   (3) Cases in which abortion is intended due to failure of contraceptive thus resulting in an unwanted pregnancy.

In all the above cases;

   a) The woman should not suffer from Sexually Transmitted Diseases.
   b) The woman should have decided to undergo abortion of fetus that is twelve weeks to sixteen weeks old as stated in section 2(f) of this Act.

5. A donor who consents has to be medically examined by –

   (1) The registered medical practitioner in charge of the hospital in which the abortion is to be effected;
   (2) Two independent registered medical practitioners authorized by the Appropriate Authorities.

6. Preservation of the fetus-

   (1) After the removal of the fetus from the pregnant mother’s womb, the registered medical practitioner shall take all necessary steps for the safe preservation of the fetus.
   (2) The hospital shall inform in writing to the Artificial Womb Technology Center for removal and storage of the fetus of the donor, as may be prescribed.

7. Restriction on donations-

   No donations shall be taken for commercial purposes. Donations shall be purely altruistic.

8. Authorization Committee-

   (1) An Authorization Committee shall be constituted by the Central Government by notification in the Official Gazette. An application has to be made before the
committee by the registered hospital where abortion is to be effected. On application, the committee, if satisfied that the consent for donation is not furthered by coercion and that the conditions of this Act are satisfied, then the committee shall allow for such donation.

(2) The committee should notify the order of acceptance, as may be prescribed, within a week from the date of such application.

CHAPTER III
REGULATION OF HOSPITALS

9. Regulation of hospitals which donate fetuses to AWT centers -

On and from the commencement of this Act,

(1) Any hospital under the MTP Act, which is not registered under this Act, shall not conduct, or associate, or assist in the donation of the fetus for AWT purposes.
(2) A medical practitioner / any other person shall not conduct or aid directly or indirectly, either through themselves or through any other person, any activity relating to the donation of the fetus at a place other than a place registered under this Act.

10. Explaining effects, etc. of donation - A registered medical practitioner shall explain the purpose of such donation to the pregnant woman. Such person shall explain all possible effects, complications, and hazards associated with AWT research, as may be prescribed.

11. No Objection Certificate -

(1) A Certificate of No Objection has to be acquired from the pregnant woman and her spouse if alive, close relatives if the spouse is not alive.
Provided that; Such No Objection Certificate shall state that-

i. They shall not question if the AWT research results in failure;
ii. Once the fetus is implanted all their parental rights stand extinguished.

(2) However, such certificate can be revoked before the implantation of the fetus in AWT.
(3) The pregnant woman must give written consent on behalf of the fetus as well.

12. Letter of Confidentiality -

A Letter of Confidentiality has to be given to the pregnant woman by the registered hospital concerned, and the AWT Center, since abortion, is a question of her privacy.

13. Contact details of the donor -

The registered hospital where such abortion cases have come up, has to maintain a record of the contact details of the donor, to contact him in case of necessity. Such records are to be kept confidential.

CHAPTER IV
APPROPRIATE AUTHORITIES


14 A. Functions of Appropriate Authorities -

The Appropriate Authorities shall deal with registration and its related affairs, holding meetings, inspection of registered hospitals and AWT Centers, setting standards for registered hospitals and AWT Centers, and such other functions as may be prescribed.

14 B. Advisory Committee -

An Advisory Committee shall be set up for aiding Appropriate Authorities. It shall have such powers and functions as may be prescribed.
14 C. Powers of Appropriate Authorities - The Appropriate Authorities shall have all the powers of the civil court.

14 D. National Registry - A national registry shall be maintained to record the list of donors, AWT Centers, registered hospitals, etc.

CHAPTER V

REGISTRATION OF HOSPITALS, ARTIFICIAL WOMB TECHNOLOGY RESEARCH CENTERS

15. Registration of hospitals engaged in the donation of fetuses to AWT Centers -

(1) No other hospital other than those hospitals under the MTP Act, 1971 that are proximate to the registered AWT centers can register under this Act for donation.

(2) Application for registration shall be made by the hospital to the Appropriate Authorities in such form and manner, as may be prescribed.

(3) Hospitals that are not in a position to provide specialized skills, services, and medical instruments shall not be eligible for registration.

16. Registration of Artificial Womb Technology Centers -

(1) No center that is not registered under the Act for undertaking research on AWT shall deal with any matter concerning the research.

(2) Those centers which have the necessary expertise, skilled manpower, latest technology, etc., required for the research may apply to the Appropriate Authorities for the certificate of registration. The application shall be made in such form and manner along with the fees as may be prescribed. Such application shall contain the following -

i. Full Name and Full address of the research site;

ii. Site-related documents (land acquisition approval, location, infrastructure, safety, etc.);

iii. Complete Details and a signed declaration of each of the members of the research team;

iv. The methodology of research, duration of the study, sample size, study design, etc.;

v. Details of risk involved, if any;

vi. Alternatives available, if any;

vii. Statement of ethical issues involved and the measures to tackle the same;

viii. Checklist of the equipments and devices;

ix. Checklist of drugs and chemical substances used;

x. Details with respect to quality assurance;

xi. Details with respect to the declaration signed by them;

xii. Certificates of Compliance as necessary;

xiii. Letter of approval from various concerned departments;

xiv. All other documents related to the research.

(3) The Appropriate Authorities shall inspect the site with his team consisting of -

i. Qualified scientists specialized in AWT research;

ii. Bioethics lawyers and experts;

iii. A social activist etc.

(4) The site should mandatorily consist of the following -

i. Favorable infrastructure for research;

ii. The site should be spacious enough to conduct the research;

iii. The center must have well-trained researchers with expertise in AWT research;

iv. High safety and surveillance measures must be installed;

v. Provision for favorable transportation of fetus;
vi. Proper storage inventories for fetuses before implantation in AWT;
vii. Provision for disposal of biological waste in accordance with Good Dispensing Practices;
viii. Necessary apparatuses for carrying out the research;
ix. Provision for record maintenance for each research subject daily;
x. Provision for training staff periodically in Good Clinical Practices;
xi. Other required infrastructure.

(5) After such inspection, a meeting shall be conducted for passing a resolution to grant registration. The quorum shall consist of-

i. A Chairman;
ii. Medical experts;
iii. Clinical experts;
iv. Biomedical laws experts;
v. A social activist;
vi. Educated Commoner from the general public who can comprehend AWT research;
vii. Other members as may be prescribed.

A special resolution is to be passed for approving the registration. Any conflict of interest shall also be recorded. In case of tie of votes, the chairman holds the deciding vote.

17. Certificate of registration-
(1) The Appropriate Authorities shall after inquiring into the application for registration, if satisfied that the applicant has met out with all the requisites of this Act, and a resolution of approval has been passed, shall grant the certificate of registration in such form and manner for such period, subject to such conditions as may be prescribed.

(2) Otherwise, the Appropriate Authorities shall give an opportunity to be heard to the applicant. Further, if he is satisfied that the conditions of the Act are still not met with, he shall reject the application for registration.

(3) Such certificate of registration must be renewed once every six months, failure of which results in cancellation of registration.

18. Restrictions on research-
(1) Minutes and records of the research must be kept confidential;
(2) The AWT Center shall not publish any report regarding the research without the approval of the committee.

19. Suspension or cancellation of registration-
(1) The Appropriate Authorities may suo moto or on the receipt of any complaint may investigate into issues relating to compliance of the provisions of the Act. After offering an opportunity of being heard to the registered center (Hospital or AWT), if it is satisfied that there has been a breach of provisions of this Act, it may suspend its registration for such period till the same is rectified or may cancel the registration depending on the degree of deviation from the Act.

(2) Such cancellation or suspension shall not affect criminal liability, if any.

20. Appeals-
Any person aggrieved by the suspension or cancellation of registration may prefer an appeal within thirty days from the date of the order of suspension or cancellation, to the Appropriate Authorities.

CHAPTER VI
ALLIED MATTERS

21. Information on further matters to be given by AWT Center-
(1) The AWT Center shall immediately inform the committee,

i. If the research plan has been altered;
ii. If the research has been dropped, the reasons for the same should be recorded. Details of
the research conducted hitherto are to be filed;

iii. The details of accident(s), if any;

iv. The emergence of factors that might impact the research.

22. Submission of progress report- The progress report of the research shall be submitted once in a month to the Appropriate Authorities.

23. Meeting of the Quorum - There shall be a periodic review of the research once every two months in a meeting by the quorum as mentioned in Section 16(5).

24. Inspection of research site- The site shall be inspected periodically by the team consisting of inspectors as mentioned in Section 16(3).

CHAPTER VII
OFFENCES AND PENALTIES

25. Offenses and penalties- Any contravention of this Act shall be duly punished with imprisonment or fine or both.

CHAPTER VIII
MISCELLANEOUS

26. Power to make rules- The Central Government shall have powers to make rules under this Act.

10. CONCLUSION
Concluding with the words of Plato that “Necessity is the mother of invention”, this paper proposes a Model Act that is envisioned to be implemented in India to support AWT research so that AWT can become a reality in a few decades.

Incorporating AWT as a healthy substitute for NICUs is indispensable for two reasons:

a) The rate of survival of premature babies will increase, due to reasons stated in this paper.

b) India has the highest number of premature deaths in the world and AWT will aid India to be relieved from this nightmarish ranking.

*****