

# IMAP Statement

## on human reproductive tissue donation for research

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### Introduction

This Statement has been prepared by the International Medical Advisory Panel (IMAP) and was approved in November 2016.

Research involving human subjects – including the study of human reproductive tissues, cells and fluids – has been and will continue to be essential for scientific advancement. For example, organ biopsies (such as cervix, ovary, uterus, testes, prostate, placenta and so on), cell lines developed and maintained in laboratories derived from both normal and abnormal reproductive tissues, and sampling of reproductive fluids (such as semen, cervical mucus, uterine and amniotic fluid) have contributed to both the understanding of normal reproductive physiology and pregnancy as well as the pathogenesis of disease. Modern contraceptive methods, the human papillomavirus vaccine, the Papanicolaou test, amniocentesis, regimens for the treatment of reproductive cancers and advanced reproductive technologies for infertility are examples of the diverse preventive, diagnostic and therapeutic innovations resulting from studies of human reproductive tissues.

Protecting participants, particularly those most vulnerable, from any potential exploitation in research is paramount in the course of pursuing scientific enquiry and its many benefits. International guidelines have been developed to inform the ethical conduct

of biomedical research involving humans (including reproductive tissues, cells and fluids), emphasizing meaningful attention to three principles – respect for persons, beneficence (balancing the benefits and risks) and justice – in the conscientious preparation for and operationalization of research.<sup>1,2</sup> Governments, responsive to both public and scientific opinion, regulate aspects of research as well, ideally to prevent harm to the well-being and interests of their constituencies while supporting quality science and innovation in health delivery.

In contrast to ethical guidelines and legislation dictating best practices for collecting and donating most human reproductive tissues for science, special attention is given to the permission for and conduct of research with the use of products of conception, including fetal tissue derived from aborted pregnancies.<sup>3,4</sup> Concerns are complex and reflect diverse attitudes about the moral and legal status of procedures for using the products of conception, the politicization of abortion, and public anxiety about rapidly changing technologies and their impact, all grounded in significant cultural, social and religious differences and firmly held beliefs.<sup>5</sup> However, research using donated aborted pregnancy tissue is considered legal and is conducted ethically in many countries around the world.<sup>6</sup>

Fetal tissue research is vital to the development of vaccines and other treatments for a variety of infectious diseases including Zika, Ebola, HIV and influenza.

## The purpose of this Statement

IPPF Member Associations that offer safe and legal abortion services may be requested to participate in programmes to donate human reproductive tissues, including aborted pregnancy tissue, to research programmes. It is critical that Member Associations understand the ethical and legal dimensions of this practice and communicate their commitment to the highest standards of practice to the communities they serve, including to the women granting permission for the donation of aborted pregnancy tissue for research.

This IMAP Statement provides essential information concerning the donation of human reproductive tissues, particularly aborted pregnancy tissue, for research. It also summarizes some history of research using aborted pregnancy tissue, its public health impact and regulation for Member Associations engaging in research partnerships. Finally, it offers succinct recommendations for how best to proceed with the acquisition and donation of aborted pregnancy tissue for research.

## Intended audience

This IMAP Statement is aimed primarily at all Member Associations, but particularly those interested in or involved in programmes to donate human reproductive tissues, including aborted pregnancy tissue, for research. It is also highly relevant for other audiences such as:

- individual investigators
- academic institutions
- tissue bank repositories
- others involved in scientific enquiry and seeking donations of human reproductive tissues, especially aborted pregnancy tissue, for research purposes
- policy and decision makers who regulate the use of human reproductive tissues for research
- other organizations and advocates dedicated to the ethical conduct of research while ensuring that the humanitarian benefits of medical science and technology may be shared justly by all

## Why is aborted pregnancy tissue important for research?

Fetal tissue research is vital to the development of vaccines and other treatments for a variety of infectious diseases including Zika, Ebola, HIV and influenza.<sup>7</sup> It is also critical to the study of human development, particularly neurodevelopment, and treatments for neurodegenerative diseases like Parkinson's disease, among many other conditions of public health concern.<sup>8</sup>

Unlike adult tissues, cells contained in aborted pregnancy tissue, or fetal tissue, have particular characteristics that allow them to divide rapidly, grow and adapt to new environments.<sup>9</sup> These attributes make them important to the study of diverse biological processes and diseases. Since the 1930s, the results of fetal tissue research have not only included achievement of key milestones in scientific understanding, but also development of treatments that have improved the quality of life for millions of people around the world.<sup>10</sup> Historically, fetal tissue research has led to the development of vaccines for polio, measles and rubella, contributing to the virtual eradication of these viral illnesses in many parts of the world.<sup>11</sup>

These same tissues can potentially be derived from spontaneous abortions or ectopic pregnancy. However, there are several reasons why tissue from these processes may not be as suitable for donation for research. The timing and recognition of these conditions can be unpredictable, they may result in serious health emergencies for women, and tissue may be affected by chromosomal abnormalities.<sup>12,13</sup> Newer alternatives to fetal tissue include the use of induced pluripotent cells, or cells derived from somatic adult tissues that are genetically reprogrammed to behave like cells found in fetal tissue. This technique was first described in 2007, but still requires additional research.<sup>14,15,16,17</sup> In the near future, fetal tissue derived from aborted pregnancies will remain a crucial resource for science.

Protecting participants, particularly those most vulnerable, from any potential exploitation in research is paramount in the course of pursuing scientific enquiry and its many benefits.

## Ethical and legal considerations for research with aborted pregnancy tissue

In countries where research using fetal tissue is legal, numerous medical associations, government advisory bodies and policy makers have considered what may be needed to rigorously ensure fairness and respect.<sup>18,19,20,21,22,23,24,25</sup> It is important to have clear guidelines to use these tissues for specific research purposes along with evidence of adherence to legal and ethical principles during the conduct of

biomedical research. In addition, a woman's decision making process to undergo an abortion, as well as whether or not to donate aborted pregnancy tissue to research, must be free of any and all inducements, incentives or coercion. Finally, maintaining the woman's informed consent, well-being and safety during the collection and donation of any aborted pregnancy tissue to research is absolutely necessary.

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### CASE STUDY: UNITED STATES

Research using fetal tissue has been performed in the United States since early in the 20th century. In 1954, American immunologists were awarded the Nobel Prize in Medicine for developing the polio vaccine using a culture of fetal kidney cells.<sup>26</sup> The donation of fetal tissue to research was only formally legalized several decades later. In 1974, Congress passed the National Research Act that led to the creation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This body was responsible for generating guidelines for the ethical conduct of research involving human subjects and included recommendations for research involving fetuses or fetal tissue.<sup>27</sup>

In 1988, the federal government issued a moratorium on federal funding for fetal tissue research that was to last for five years.<sup>28</sup> Scientists from the National Institutes of Health proposed research into novel treatments for Parkinson's disease that involved transplantation of fetal cells and tissue into the brains of persons living with this condition; the use of these tissues for transplantation and not merely as a substrate for experimentation in the laboratory clashed with the political environment, precipitating the moratorium.<sup>29</sup>

In 1993, the moratorium was lifted by executive order, and new legislation was passed later in the same year. The National Institutes of Health Revitalization Act of 1993 banned the buying and selling of fetal tissues for profit, but makes allowances for clinics to recover 'reasonable payments' to offset costs associated with the donation of tissue. Separately, the Act imposed additional requirements applicable whenever fetal tissue would be used in federally funded research involving the human transplantation of the donated tissue. These requirements prohibited alterations to the timing or method used to terminate a pregnancy when those alterations were solely for the purpose of procuring the tissue, and they also added specific standards for informed consent.<sup>30</sup>

### CASE STUDY: UNITED KINGDOM

The Abortion Act 1967 legalized abortion in the United Kingdom, and fetal tissue research has been permitted formally for decades. In 1972, the Department of Health and Social Security issued the Peel report, outlining conditions to use fetuses and fetal material in research.<sup>31</sup>

Some years later, in the wake of the first operations to transplant fetal tissue to the brains of people affected by Parkinson's disease, the Department of Health generated the Polkinghorne Guidelines.<sup>32</sup> These updated guidelines, published in 1989, included a number of additional recommendations for investigators, clinicians and research review bodies to consider for the ethical conduct of fetal tissue research. Notably, the Polkinghorne Guidelines emphasize the concept of separation: decisions to terminate a pregnancy and whether to donate aborted fetal tissue to research must be made sequentially and separately. Consent should be broad such that the woman cannot specify how or where the tissue should be used, to avoid any possibility that she might derive personal benefit.<sup>33</sup> While these guidelines are not legally binding, elements have been widely influential and enshrined in law and policy around the world.

In the 2000s, the European Union Tissues and Cells Directives established a uniform approach to the regulation of human tissues and cells across Europe.<sup>34</sup> In the UK, the regulatory authorities carrying out standards set out by the European Union Tissues and Cells Directives include the Human Tissue Authority and the Human Fertilisation and Embryology Authority. The Human Tissue Authority regulates organizations that remove, store or use human tissue, including fetal tissue, for research,<sup>35</sup> and the Human Fertilisation and Embryology Authority regulates use of gametes and embryos for human application.<sup>36</sup>

It should be made explicit that regardless of a woman's decision to donate human reproductive tissue, including aborted pregnancy tissue, she will receive routine high quality care and experience no adverse consequences, such as the denial of a service or stigma, should she decline to participate.

### CASE STUDY: SWEDEN

Research using fetal tissue has led to important scientific findings such as the Maternal Fetal Unit research on stem cells, environmental disruptors, congenital heart conditions and treatment of Parkinson's disease.<sup>37,38,39</sup> Good clinical practice and research ethics were formally regulated and legalized more recently, including donation of fetal tissue. Abortion was legalized in the 1974 Abortion Act that came into practice in 1975 (SFS 1974:595, amended SFS 2013:271). The basic principles and rights to autonomy and respect for human equality (equal rights for all) is regulated by law and is the basis of all health care (SFS 1982:763).

The ethical conduct of research involving human subjects is regulated by law (SFS 2003:460) and ethical evaluation is carried out by a regional ethics committee. Permission also has to be obtained from the National Board of Health and Welfare for research on fetal tissue. Tissue from an aborted fetus can only be used for medical purposes after informed consent is obtained from the woman and only in special conditions (11 § SFS 1995:831, 4 kap. 18–22 §§) (SOSF 2009:30).

All research must be approved by the regional (or national) ethics committee and the clinic where the research takes place. In addition, biobank permission is needed for any sampling or collection of tissue (even if it is only a blood sample that is not stored) in a patient participating in a clinical trial (SFS 2002:297). These requirements apply to all research, including research using human reproductive tissue. Further permission is required for genetic analysis and from the Medical Products Agency for any clinical trial involving an investigational drug.

Women must give their consent to participate in research, including any donation of tissue. The consent should be in writing, but can be verbal if approved by the ethics committee. The woman should always be informed of the purpose of the research; her alternatives if she does not participate; an assurance that donation of tissue or participation in a clinical trial is voluntary; and an assurance that choosing not to participate will not affect her current and/or future treatment or access to care. There is usually no financial compensation associated with donation of tissue or participation in research. For women undergoing an abortion, donation of reproductive tissue must not affect the evidence-based standard care (abortion method, timing of treatment, access to post-abortion contraception and other related issues).

## Recommendations for Member Associations

- IPPF supports the value of research using human reproductive tissues, including aborted pregnancy tissue, recognizing its contribution to scientific advancement and development of life-saving therapies around the world. Participation of Member Associations in any research or donation programme is entirely voluntary.
- For those Member Associations choosing to participate in human tissue donation for research, it is critical that all parties – Member Association and any collaborating partners – are knowledgeable about and adhere to both national and local legal regulations and policies governing practices for human reproductive tissues (including aborted pregnancy tissue) and research (collection, transfer, storage, labelling, among others) as well as guidelines for its ethical conduct. Necessary steps should be taken to ensure that any engagement in these activities is exemplary and above reproach in all respects.
- The following points cover special considerations for Member Associations to ensure ethical conduct of on-site activities associated with the donation of human reproductive tissues, including aborted pregnancy tissue for research:
  - A woman's decision to undergo an abortion and the informed consent process for any procedure should be separate from and precede any informed consent process for donation of tissue to research. In addition, it should be made explicit that regardless of a woman's decision to donate human reproductive tissue, including aborted pregnancy tissue, she will receive routine high quality care and experience no adverse consequences, such as the denial of a service or stigma, should she decline to participate.
  - While adolescents seeking abortion should be able to access safe services without routine notification or consent from a parent or guardian when not mandated, informed consent for participation in any

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research, including donation of aborted pregnancy tissue to research, might subject adolescents to such requirements separate from the abortion procedure. It is important that Member Associations understand the implications for adolescents in these circumstances and communicate with them accordingly; adolescents' privacy and confidentiality should not be compromised inadvertently.

- Donated human reproductive tissues, including aborted pregnancy tissue, should only be used for the purposes described during the informed consent process agreed to by the woman. If new research is being proposed to use the tissue beyond the scope originally agreed on, additional consent is required. If consent cannot be obtained or is not granted, the tissue should not be used for additional purposes.
- In cases where human reproductive tissues, including aborted pregnancy tissue, will be donated to a tissue bank repository for unspecified medical research, women should understand that the tissue from the abortion may be used to make stem cell lines for medical research and possibly used in human or animal transplantation or genetic research. These cells could be kept for many years, and it is possible that products developed from this tissue might have commercial value; women will not be paid at the time of donation or at any time in the future.
- Women who provide informed consent to donate tissue should not be subject to any alterations in the timing or performance of the abortion procedure or provision of usual care (including post-abortion contraception) such that the collection of tissue for research is prioritized over the woman's safety.
- No payment or incentive of any kind should be made to women who decide to donate aborted pregnancy tissue to research.
- Member Associations, both the organization as well as individual health care personnel they employ, should receive no direct benefit, financial or otherwise, from contributing aborted pregnancy tissue to research. However, it may be necessary for the Member Association to collect reasonable fees to offset costs for on-site supplies, processing, storage and transfer logistics related to the collection and donation of aborted pregnancy tissue to research.

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## WHO WE ARE

The International Planned Parenthood Federation (IPPF) is a global service provider and a leading advocate of sexual and reproductive health and rights for all. We are a worldwide movement of national organizations working with and for communities and individuals.



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