Donated ovarian tissue in embryo research & assisted conception : report / Human Fertilisation & Embryology Authority.

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

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HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CONSULTATION ON DONATED OVARIAN TISSUE

REPORT

The ovary produces the hormones and eggs required for reproduction. The statements in this report relate only to the genetic material in ovarian tissue which might be used to treat women who are infertile or to produce embryos for research.

Introduction

1. On 7 January 1994 the Human Fertilisation & Embryology Authority (the Authority/HFEA) published a consultation document on the issues surrounding the use of donated ovarian tissue in embryo research or infertility treatment. The document discussed possible clinical, scientific, social and ethical implications of using ovarian tissue from three sources: live donors, women or girls who have died and aborted fetuses. The Authority's aim in carrying out the consultation was to inform, to stimulate debate on the issues and to obtain views from the wider public before it became necessary to consider any new question of licensing the use of tissue from these sources[1]. The possible uses of ovarian tissue are some years away but the issues they raise are complex and the opportunity is available to begin considering them now.

2. The Authority is a large body with a broadly-based membership. A number of its members have expertise in ethics and social policy. However, the Authority considers it important to consult the public when issues of particular social and ethical importance arise.

3. The degree of interest shown by respondents from a wide spectrum of the public confirms the HFEA's belief that consultation of this sort is a valuable exercise. (In response to requests, 25,000 copies of the document were distributed and some 9,000 replies have been received.) It is hoped that many more people have become aware of the scientific possibilities in assisted reproduction and the complex issues surrounding them. The Authority has greatly appreciated the high quality of many of the responses from organisations and individuals. These responses have significantly influenced the Authority in reaching its conclusions.

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[1] The use of mature eggs from live donors is already subject to licensing

The Authority's position

Infertility Treatment

4. In the case of infertility treatment, the Authority believes that different considerations apply to the use of ovarian tissue from the three sources discussed: live donors, cadavers and fetuses. Balancing benefits against risk of harm, the HFEA has concluded that in treatment it would be acceptable to use ovarian tissue only from live donors. Whilst the Authority has no objection in principle to the use in infertility treatment of cadaveric ovarian tissue from adult women, it will not currently approve its use. The Authority does not consider the use of fetal ovarian tissue in treatment to be acceptable.

Embryo research

5. In the case of embryo research, the Authority has concluded that, again balancing benefits against the risk of harm, the use of ovarian tissue from all three sources to produce embryos is acceptable. This would be subject to existing controls and provided that informed written consent specifically for the purpose had been obtained from the live donor, the woman who has died or the woman undergoing abortion. The process would require all relevant information and counselling to be available to the woman before she could give consent.

General considerations

6. It is in the nature of human beings to intervene to try to shape their world. Medical treatment is by definition interventionist and has been developed through research and practice to overcome problems which afflict and distress men and women. Few would argue against interfering in the natural order for the purpose of healing, but some people have reservations about intervention in order to relieve infertility. However, infertility can often be alleviated. Society through Parliament has permitted the possibility of producing embryos outside the body and the use of donated eggs and sperm for fertility treatment and embryo research. All are subject to specific controls. The use of fetal tissue is already permitted in research or in treatment under the Polkinghorne guidelines adopted by the Department of Health[2].

7. The Polkinghorne guidelines say that consent to use fetal tissue obtained from a woman undergoing an abortion should be general and that the woman should not know the use to which the fetal tissue may be put, or if it is used at all. The guidelines also say that the woman's decision to allow the fetal tissue to be used should be separated from her decision to undergo abortion, and they recommend that a third party should be interposed between the person wishing to use the tissue

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[2] Polkinghorne report - Full title: Review of the Guidance on the Research Use of Fetuses and Fetal Material 1989 Cm 762 HMSO

and the woman. These guidelines need to be reconciled with the requirement of the Human Fertilisation and Embryology Act 1990 (HFE Act) for informed specific consent from the woman providing eggs if fetal ovarian tissue is to be used in embryo research.

8. There is no question of the Authority issuing licences for any treatment procedures until they have been adequately proved through licensed research. The Authority must also be satisfied that they are necessary or desirable for the purpose of treatment. There is no question of the Authority issuing licences for research projects unless it is satisfied that the research is necessary or desirable and that the use of human embryos is essential.

9. The HFE Act sets out the conditions which must apply before licensed research or fertility treatment is undertaken. Information about the implications of the procedure to be undertaken must be given, and counselling must be offered before consent to use or store eggs or sperm is obtained. Before accepting a particular woman for treatment, clinics are required to take into consideration the welfare of any child who may be produced and the welfare of any other child who may be affected. These procedures are subject to close monitoring by the Authority.

10. In addition to taking account of the requirements of the HFE Act, the Authority bases its considerations on the principles underlying the HFEA Code of Practice:

- the respect which is due to human life at all stages in its development;
- the right of people who are or may be infertile to the proper consideration of their request for treatment;
- a concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and
- a recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.

The supply of eggs

11. The deep distress felt by people who are unable to have children in the normal way is widely acknowledged. In some cases this could be alleviated but for the fact that there is a shortage of donated eggs. The Authority therefore believes that it is acceptable to seek to increase the supply of eggs for infertility treatment.

12. Eggs are used to produce embryos for research for the purposes permitted in the HFE Act. These are promoting advances in the treatment of infertility; increasing knowledge about the causes of congenital disease and miscarriages; developing more effective contraception techniques;

detecting genetic or chromosomal abnormalities in embryos. The availability of eggs from all three sources mentioned earlier could therefore enable embryo research to increase understanding of the causes of infertility and of birth abnormalities. Techniques to improve the treatment of infertility may be developed through this research which could reduce the need for egg donation in the future. The Authority therefore considers that it is acceptable to seek to increase the supply of eggs for embryo research.

13. The ways sought to increase the supply of eggs should comply with HFEA directions, minimise risk to the donor and, in the case of infertility treatment, minimise risk to the recipient and to the potential child.

Embryo Research

14. The Authority considers that the moral difficulties presented by using tissue from any of the proposed sources for embryo research permitted by licence under the HFE Act are not new. Donation of eggs and sperm for the purpose of embryo research is already permitted under the HFE Act.

Live donors and cadavers

15. The special status accorded to the embryo in the HFE Act requires informed specific written consent by the person providing eggs to their use to produce embryos. This can be obtained from live donors. Written decisions made before death or donor cards would be needed in the case of post mortem donation. There is no provision for proxy consent to the use of eggs and embryos in the HFE Act, and the Authority does not consider that next-of-kin should be able to give consent on behalf of a woman who has died or to override her consent. However, the Authority believes that it should be possible to develop a system for written informed consent by the woman before death which did not impinge on the existing donor card system for organ donation.

Minors

16. The Authority is satisfied that at present 18 is the age at which it can be confident that the full implications of donating ovarian tissue for the purpose of embryo research can be understood. This is the age limit set in the Code of Practice for live donors. However, the Authority recognises the concept of a child's maturity and understanding in relation to consent and intends to explore this further in the context of the use of ovarian tissue, including issues relating to post mortem donation.

Fetuses

17. In the case of fetal tissue the woman undergoing an abortion is recognised in the Polkinghorne guidelines as having a special position with regard to the fetus so that her explicit consent should be obtained to the use of the fetus or fetal tissue for research[3]. The use of eggs was not considered separately in the Polkinghorne report but consent to their use in embryo research could be obtained by an additional consent option.

Infertility Treatment

Live donors

18. The Authority has concluded that it would be acceptable to use ovarian tissue in infertility treatment from adult live donors provided informed specific written consent has been given. This can be carried out in accordance with the current provisions of the HFE Act and Code of Practice, which sets an age limit of 18. The Authority is satisfied that it is possible to control the number of offspring from one donor. Only a limited amount of ovarian tissue would be available from a single donor. Control would be in line with the Authority's policy on gamete donors set out in its Code of Practice, ie the limit of 10 offspring.

Cadavers

19. In the case of the use of ovarian tissue in infertility treatment from females under 18 who have died, the same concerns about obtaining specific informed consent from minors mentioned in paragraph 16 lead the Authority to the view that tissue from this source should not currently be used. In the case of an adult woman who has died, there is no objection in principle. This is provided that the woman has given informed consent specifically to donate her tissue for the treatment of others, for example, by means of a special donor card or a will. However, more can and should be done to find out about the psychological consequences for the recipient couple and particularly for the prospective child. The Authority will then reconsider licensing treatment using ovarian tissue from women or girls who have died.

Fetuses

20. The use of fetal ovarian tissue raises difficult social, medical, scientific and legal concerns. No arguments emerging from the consultation have convinced the Authority that these can be put aside. The Authority considers that the issue of the possible psychological consequences for the offspring is most difficult. There is widespread and fundamental objection to using fetal tissue in this way. Accordingly, it would be particularly difficult for a child to come to terms with being produced from a fetus because of prevailing social attitudes. The HFEA, therefore, does not

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[3] See Polkinghorne report, chapter 6

consider the use of tissue from this source to be acceptable in infertility treatment. Other developments are taking place involving ovarian tissue from adults which look likely to reduce the need to consider the use of fetal ovarian tissue in infertility treatment.

Conclusion

21. The Authority does not expect the debate on assisted conception to end with its present decisions. The debate will carry on as medical and scientific advances continue to present society with new and difficult issues. However, the Authority believes that the process of public debate helps to clarify the arguments and looks forward to future discussions on the matters which it has been set up to regulate.

PUBLIC RESPONSE TO THE CONSULTATION

General comment

22. Many respondents suggested that the consultation offered an opportunity for a fundamental review of the availability of abortion, of whether embryos should be made in vitro for research or treatment, and of whether donation of eggs and sperm should be permitted. The Authority acknowledges the strength of feeling on these sensitive issues expressed in replies from people who consider that all the possibilities mentioned in the consultation document are "against nature" and therefore abhorrent. However, in reaching conclusions, the Authority starts from the position in which society and Parliament has placed it. It has no remit to discuss abortion. The responses have been considered against a background of existing law and the ethical premises underpinning the Human Fertilisation & Embryology Act 1990 (HFE Act), the HFEA Code of Practice and the guidelines of the Polkinghorne report.

23. The scale of the consultation has greatly exceeded the expectations of the Authority. The number and strength of the arguments presented in many of the replies have been striking. Many groups and individuals have clearly taken great trouble to produce detailed and thoughtful replies. A notable feature has been the very large number of respondents who have said how pleased they are to have the opportunity to contribute their views in this way before decisions are made on sensitive public policy. Responses have been received from a very wide range of groups, including sixth-form classes, religious groups, village meetings, women's groups, professional scientific, medical and nursing organisations and the education department of one of HM prisons. The Authority recognises nonetheless that it has heard only from those people who were aware of the consultation and who have felt moved to write.

24. The Authority has taken account of all the views and representations it received and has analysed them with care. The consultation was not simply about numbers of responses. Its purpose was to gather arguments and views on the use of three potential sources of ovarian tissue. The Authority would like to thank all those who have contributed their views.

Numbers of responses received

25. The total number of responses received was 9,248. Of these, 299 were petitions, 3 were surveys and 8,946 were replies in letter or questionnaire form which addressed questions proposed in the consultation document.

Who said what

26. The 299 petitions contained 10,764 signatures. The petitions expressed disapproval of the use of fetal eggs and ovarian tissue to help infertile women produce children. They appeared to be primarily in response to a campaign of those opposed to abortion and the law as it stands rather than to the issues in the HFEA document.

27. The surveys based on the questions in the consultation document were carried out independently by three institutions and submitted to the Authority. Four groups of women took part: 870 women attending Family Planning Clinics, 100 pregnant women attending antenatal clinics, 335 women attending infertility clinics and 221 women presenting for termination of pregnancy. An overwhelming majority (approx 80%) of women from each of these groups considered that ways should be sought to increase the supply of eggs for donation. Over half were in favour of using the tissue from all three sources in embryo research. For infertility treatment, the majority approved of using ovarian tissue from live donors. The majority of the women, with the exception of those presenting for termination (43%), approved the use of cadaveric tissue in infertility treatment. Between one third and a half of all the women approved the use of fetal tissue in infertility treatment.

28. Analysis of the remaining 8,946 responses to the HFEA document shows the following: 8,409 (94%) came from individuals and 537 (6%) came from organisations or groups. Of the individuals, 58% came from women and 18% from men; 9% came from couples and the remainder did not specify. Fifty-six MPs and peers have commented or forwarded constituents' views.

29. The 8,946 replies to the particular questions posed in the consultation document have been analysed. The number of questions answered by each respondent varied. Of these replies, 28% stated opposition to egg or sperm donation and 24% stated that they were opposed to abortion. The pro-forma letters and questionnaires, numbering 1,467 (16%), all opposed the use of fetal tissue. As with the petitions, the standard letters appeared to be in response to the campaign of those opposed to abortion.

30. The following are the results of the analysis of the 8,946 responses to the questions raised in the document:

	Yes	No	No opinion
Increase supply:			
for embryo research	8.0%	29.9%	62.1%
for infertility treatment	7.5%	34.6%	57.9%

On the supply of eggs, a number of respondents suggested that women who were going to have hysterectomies could be approached and asked if they would be willing to donate ovarian tissue or eggs. Others suggested that publicity should be improved to increase awareness of the need for donors.

	Yes	No	No opinion
Embryo research:			
from live donors	14.3%	24.0%	61.7%
cadavers	10.7%	29.2%	60.1%
fetuses	7.1%	58.1%	34.8%

	Yes	No	No opinion
Infertility treatment:			
from live donors	12.5%	26.0%	61.5%
cadavers	5.4%	35.3%	59.3%
fetuses	2.8%	83.2%	14.0%

Reasons given in favour

31. Many of those who expressed approval of using donated ovarian tissue in embryo research and infertility treatment were sympathetic to the distress of infertility and believed progress to relieve infertility and genetic disease to be of benefit to mankind.

32. Some people who approved embryo research and infertility treatment using tissue from all sources said that a child was a gift from God however it was achieved and that medical and scientific advances were evidence of God working through humankind.

33. Some respondents were in favour of using ovarian tissue from all sources because they concluded that the benefits of using it outweighed the risks. Some people took the view that it would be preferable to use material from cadavers or fetuses rather than from live donors because of the risk involved for live donors.

34. Some respondents considered that concern about psychological difficulties for offspring was exaggerated. They considered that the situation of such children would be not unlike that of other children who did not know anything about one of their genetic parents. They would have the advantage of knowing that they had been a desperately wanted child. Their mother would provide the flesh and bone for their development, if not part of the genetic blueprint, and would give birth to them in the normal way. The children would be unlikely to have such difficulty coming to terms with their origins that they would rather not have been born. These respondents made the point that the effects on the child would depend on society's attitude. An example quoted was of the early fears about the psychological effects on children of being born from IVF which had proved groundless as society's acceptance of these procedures had grown.

35. Some respondents took the view that it was better in principle to do good than not to do good and that the opportunity to make purposeful use of fetal or cadaveric material which would otherwise be discarded should be taken unless there were overwhelming reasons for not doing so.

36. Many respondents and commentators argued that society should not interfere where there was no evidence that a development which might benefit the individual would harm others.

Reasons given for objecting

37. The premise that there is a shortage of eggs for donation to be remedied did not go unchallenged. Some respondents considered that the present self-limiting position was fair since the risks to live donors were balanced against the needs of infertile women. Others said that resources should be directed towards other medical needs and that the world was already overpopulated.

38. Concern about the likely adverse effect on a child of finding out that its mother had never lived was the reason most often given by respondents for objecting to the use of fetal tissue in fertility treatment. The respondents who sent standard letters or signed petitions gave the following three reasons, expressed in slightly varying terms, for objecting to the use of fetal ovarian tissue:

i. it requires the deliberate killing of a fetus;
ii. it will create psychological/identity problems for the child born;
iii. it is a step towards designer babies.

These three reasons were proposed in campaign material produced by groups opposed to abortion.

39. Many other people, who gave the above three reasons against using fetal tissue but wrote in more detail, were opposed in principle to any assisted conception for infertile people. They did not agree with producing embryos outside the body for research or treatment. They considered that donated eggs or sperm introduced a third "adulterous" party to a marriage and that children had a right to know their genetic inheritance. They argued that women did not have a right to have a child, that children were a gift from God and producing children by assisted means was "against nature". A number said that they were opposed to assisted conception because of religious beliefs which required no reason. Many stated that infertile women seeking treatment were selfishly pursuing their wish for a child to the detriment of society.

40. Respondents who took this line often said that the possibilities discussed in the consultation showed evidence of moral decline in society. Many said they were reminiscent of Nazi practices and showed lack of respect for the dead. They believed that allowing the use of fetal tissue would lead to increased numbers of later abortions, "fetus farming" for commercial gain and coercion of possible donors. Some expressed concern for the psychological well-being of the woman who had consented to the use of fetal tissue and others were worried about inadvertent incest between offspring. Many argued that if what they called "social abortions" were stopped, the children born could be made available for adoption by childless couples. Some commented on the social pressure on women to become mothers and considered that with counselling, women would realise that happiness did not depend on having children.

41. The link between a comprehensive abhorrence, or "yuk factor", and abortion was suggested to be because many, while accepting legal abortion, considered the product of abortion to be a "tainted source". This contrasts with the view expressed in the Polkinghorne report[4] which said that no moral taint should be attributed to fetal tissue from elective abortion.

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[4] See Polkinghorne report, chapter 2

42. Some respondents also foresaw legal difficulties relating to parentage and inheritance in using fetal or cadaveric tissue to help produce children[5]. Some respondents considered that since no consent could be obtained from a fetus, fetal ovarian tissue should not be used and that it was impossible to resolve the incompatibility between the Polkinghorne guidelines and the consent requirements of the Human Fertilisation & Embryology Act 1990.

43. A few respondents expressed the view that assisted conception should be resisted because it was an example of the medicalisation of childbearing and of the male dominated medical profession seeking to manipulate women's bodies.

44. Among the scientific concerns raised about using tissue from all three sources for infertility treatment was the risk of transmitting genetic diseases, and in the case of fetal and cadaveric tissue, the risk of transmitting Creuzfeldt-Jacob disease (CJD)[6].

45. Many scientists and clinicians urged caution in considering the use of fetal ovarian tissue in infertility treatment for safety reasons. This is because it is not known whether the steep fall in numbers of immature eggs during the gestation period and the early part of a girl's life is a "quality control" mechanism. Another point made by some clinicians is that grafting of fetal ovarian tissue is such a distant prospect that it need not be decided at present. They suggested that overcoming rejection by the recipient woman of foreign tissue without damage to the transferred germ cells was not a foreseeable possibility.

Consent

46. Most people who believed that ovarian tissue from live donors should be used in embryo research or infertility treatment considered that this was little different from egg donation and should be subject to the same informed written consent. Some people thought counselling should be obligatory before consent was given.

47. Most people who thought that ovarian tissue from cadavers could be used in embryo research or infertility treatment thought that the woman concerned should have given specific consent while alive, for example, by means of a donor card or a will. Some people said that in the absence of prior consent, the woman's next-of-kin should be able to give consent. Many people

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[5] These concerns were misplaced because the child and the donor have no legal relationship following licensed treatment

[6] CJD is the human version of "mad cow" disease, a degenerative brain disorder which has in the past been transmitted, outside the UK, through nervous system tissue. It is extremely unlikely to be transmitted through ovarian tissue

made an exception in the case of girls under the age of sixteen. A few people thought that consent should not be necessary in the case of cadaveric ovarian tissue because the material was from "dead bodies".

48. Most people who thought that it would be proper to use fetal ovarian tissue considered that since it was genetic material, it differed from other fetal tissue and the woman undergoing abortion should therefore give specific consent to its use. Some people thought that the man and woman concerned should give consent as the fetus contained genetic material from both. Others suggested that it would be more compatible with the Polkinghorne guidelines to have a system of general consent to use fetal tissue with an option to exclude the use of ovarian tissue for embryo research or infertility treatment. A few people thought that consent to use fetal tissue was unnecessary because it was discarded material.

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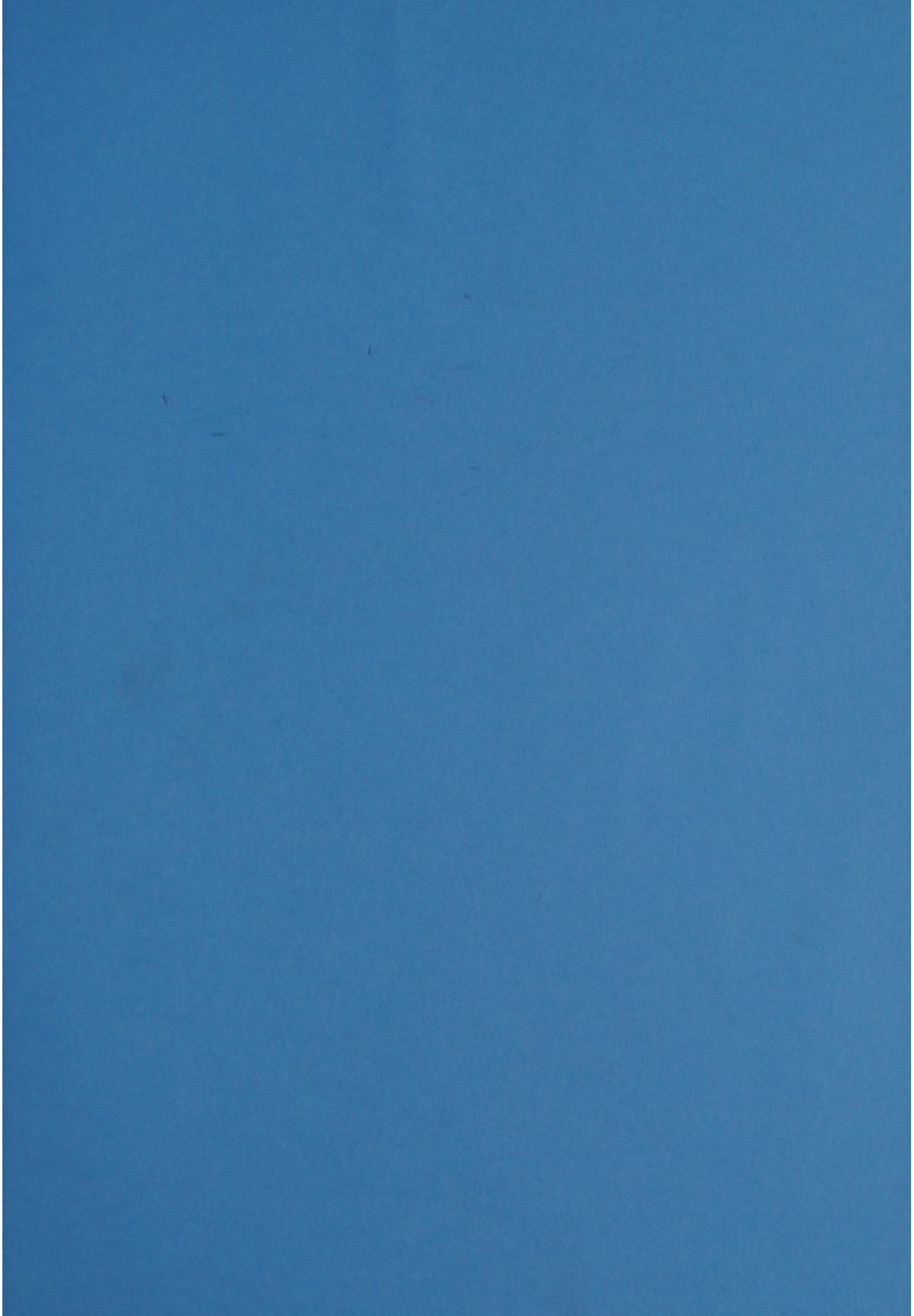

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