APPENDIX 1

INTERIM REPORT OF THE IN VITRO FERTILISATION ETHICS COMMITTEE OF WESTERN AUSTRALIA

4276c - 6 - 16.8.84

INTERIM REPORT OF THE IN VITRO FERTILISATION ETHICS COMMITTEE OF WESTERN AUSTRALIA

1. Formation of the Committee

The Committee was formed in June 1983. The Honourable the Minister for Health called for nominations for membership of the Committee from various bodies and in turn nominated four members himself.

The Committee is chaired by Mr Robert Meadows - barrister and solicitor - Chairman of the Ethics Committee of the Law Society of Western Australia - nominated by the Law Society of Western Australia.

The members of the Committee in alphabetical order are:

Associate Professor R.A. Barter - Director of Laboratory Services, King Edward Memorial Hospital for Women - nominated by The Board of Management, King Edward Memorial Hospital for Women.

Doctor Peter Brine - President of the Medical Board of Western Australia - nominated by the Australian Medical Association.

4276c - 6 - 16.8.84

The Most Reverend P.F. Carnley - Anglican Archbishop of Perth - nominated by the Anglican Church.

Miss Rosalind J. Denny - Director of Nursing, King Edward Memorial Hospital for Women - nominated by the Minister.

Doctor Athel Hockey - Senior Medical Officer Irrabeena and Geneticist, and King Edward Memorial Hospital for Women and Princess Margaret Hospital for Children - nominated by the Minister.

The Reverend Colin Honey - Master of Kingswood College at the University of Western Australia - nominated by the Minister.

Doctor Geoffrey Lilburne - Obstetrician and Gynaecologist - nominated by the Royal Australian College of Obstetricians and Gynaecologists.

Associate Professor C.A. Michael - Department of Obstetrics and Gynaecology at the University of Western Australia - nominated by the Vice Chancellor, University of Western Australia.

Mrs. Margaret Papaelias - President of "Concern for the Infertile" - nominated by the Minister.

The Reverend W. Uren - Rector of Saint Thomas More College, University of Western Australia - nominated by the Most Reverend Sir Launcelot Goody - Catholic Archbishop of Perth.

The Executive Secretary of the Committee is Mrs J.M. Anstead - Principal Staff Development Officer, Education Services Branch, Department of Public Health. The Committee is indebted to Mrs Anstead for her invaluable assistance in arranging meetings, keeping minutes and her efficiency in co-ordinating the affairs of the Committee.

2. The Committee's Terms of Reference

In appointing the Committee the Minister stated its terms of reference to be:

"To consider the social ethical and legal issues arising from in vitro fertilisation, to advise on the relevance of any recommendations from similar committees both in Australia and overseas and to supervise the practice of in vitro fertilisation in Western Australia."

The Committee was informed that its responsibilities were on-going and that it had a relatively free hand to determine its operating procedures and the extent to which it wished to involve itself in any aspect of the terms of the reference.

Although it was not asked to report to the Minister within any specified time the Committee took the view that it should prepare an interim report to appraise the Minister of the work it had been doing and of what recommendations it had to make at this stage. The Committee perceives that it will make reports to the Minister from time to time. It is envisaged by the Committee that the Minister would make its reports public.

3. Work of the Committee

The work of the Committee is still in its preliminary stages.

The Committee has met on ten occasions and in summary:-

(a) has discussed at length the broad issues relating to IVF;

(b) has interviewed Dr. J.L. Yovich and Dr. T. Thomas, two medical practitioners practising IVF;

(c) considered reports and other literature relating to IVF, in particular the reports of the Royal College of Obstetricians and Gynaecologists published in March 1983 and the reports published by its Victorian

counterpart which is generally known as the Waller Committee and more recently the report of the Demack Committee in Queensland;

(d) defined the questions which it considered required the attention of the Committee and established a priority list in relation to those questions;

(e) considered a number of those questions and formulated recommendations to the Minsiter;

(f) prepared this interim report.

4. <u>The Practice of In Vitro Fertilisation in Western Australia</u>

Before dealing with this question specifically it is necessary to describe what is meant by In Vitro Fertilisation. It is the process whereby an egg recovered from the ovary by laparoscopy is fertilised by sperm in the laboratory. The resultant embryo is then transferred to the uterus.

The collection of eggs normally takes place after a series of tests have been undergone by the woman and after the administration of drugs to stimulate the production of more than one egg in each cycle. The menstrual cycle is monitored to determine how the eggs

are ripening and this is followed by further tests. Collection is sometimes preceded by a hormone injection that triggers off ovulation a day and a half later. The woman is taken to the operating theatre and under general anaesthetic her peritoneal cavity is filled with carbon dioxide. A small hole is made in the umbilicus through which a viewing instrument is passed. Another small hole is made for the needle to pass into the cyst which forms on the ovary immediately prior to expelling a ripe egg. Through this needle the fluid from the ovary is aspirated into a glass tube. The fluid is taken into a laboratory for identification of eggs.

Sperm are then provided by the intending father. These are centrifuged and washed prior to being used for fertilisation.

Fertilisation is attempted after the egg has been held in an incubator for 5-6 hours. The egg and sperm are brought together in a culture medium. Once fertilisation has occurred this is confirmed microscopically by the presence of two nuclei in the embryo(s).

Depending upon the team performing the procedure one or more embryos is transferred to the mother usually at the 4 or 8 cell stage. The transfer is effected by a fine

bore tube which is passed into the uterus and the embryo is injected in a drop of fluid.

The mother remains in hospital for about 36 hours and then rests at home for several days. Weekly blood hormone tests are then conducted for the first 12 weeks for the purpose of diagnosing and monitoring pregnancy.

As indicated earlier in this report the Committee interviewed Dr. J.L. Yovich and he informed the Committee that initially he had commenced the practice of IVF in the Department of Obstetrics and Gynaecology of the University of Western Australia at the King Edward Memorial Hospital for Women, but this had discontinued in 1981 because financial and other support was not available at the hospital. Accordingly he and his team had gone out on their own and set up an IVF clinic at Avro Hospital. Subsequently the team had split up and he had gone his separate way and formed a new team.

Dr. Yovich was currently actively engaged in the practice of IVF.

As indicated the Committee also interviewed Dr. T. Thomas who informed the Committee that when Dr. Yovich left the team operating at the Avro Hospital he was asked to replace him. This was in mid-1982 although it was not

until November 1982 that the first patients under his team were admitted.

Reference will be made to various aspects of the information obtained from Doctors Yovich and Thomas in the course of considering the various questions relating to IVF which are considered in this report.

5. <u>The process of IVF in which the gametes are obtained from husband and wife and the embryos are transferred into the uterus of the wife.</u>

This was the first question considered by the Committee.

This is the normal situation. The Committee was informed that in the case of one team 90% of cases involved husband and wife. In the case of the other team the great majority of cases involved husband and wife.

Whilst some reservations were expressed by some members of the Committee regarding IVF in principle, the Committee came to the majority view that IVF in such circumstances was ethically acceptable and recommended that it be so recognised.

<u>Recommendation</u>. The process of IVF in which the gametes are obtained from husband and wife and the resulting

embryos are transferred into the uterus of the wife be regarded as ethically acceptable.

The Committee emphasises that this recommendation was subject to the adoption of the Committee's remaining recommendations outlined in this report.

6. De facto Relationships

As previously indicated, both of the teams engaged in the practice of IVF had treated couples who were not husband and wife. It is therefore necessary for the Committee to form a view as to whether this is ethically acceptable and if so under what conditions.

The Committee discussed at length the question of whether IVF should be made available to couples who were living in a de facto relationship. There were differing views amongst the Committee members.

The Committee regarded this as an area in which it should receive submissions from the community before taking a final position. The Committee also considered that it should take into account the public debate which is current on this issue and moves contemplated by the legislature regarding de facto relationships.

The Committee seeks the consent of the Minister to call for submissions on this and other issues referred to later in this report and, depending upon the response received, to hold public hearings.

Accordingly, at this stage the Committee is not prepared to make a recommendation to the Minister on this question.

7. <u>To what extent should couples who wish to participate in IVF have exhausted other medical procedures to overcome their infertility before being permitted to undertake IVF.</u>

The Committee noted the Waller Committee's recommendation:-

"When infertility has proven unresponsive to other means of treatment or the couple has sought alternative treatment for a period in excess of 12 months then such couple shall be entitled to be selected to join in the in vitro fertilisation programme if they are otherwise suitable candidates for treatment."

The Committee regarded the requirement for alternative treatment as arbitrary. It did not take account of the case where it was apparent from the outset that no alternative treatment was possible or was likely to be as successful as IVF. The Committee considered that if it be the case that IVF is to be regarded as ethically acceptable if it be the most efficacious treatment then it should be offered. In deciding whether IVF was appropriate, the high cost of that treatment was a factor to be considered.

Recommendation. The Committee recommends that a couple should be eligible for IVF if this is in all the circumstances the most appropriate means of treatment to overcome their infertility.

8. Counselling and Information

A number of things emerged from the Committee's inquiry.

(a) Participation in the IVF programme is particularly arduous for the woman.

(b) In spite of media publicity the full extent of the procedure is not widely understood.

(c) It is important for participants to be fully informed of the nature and implications of the procedure.

(d) Participants require counselling and support, both before, during and after the procedure.

(e) Counsel and support are particularly necessary where the procedure had been unsuccessful.

The Committee noted the recommendations of the Waller Committee regarding the dissemination of information which was in the following terms:-

> "The Committee believes that each couple seeking admission to an IVF programme must be provided with clear and comprehensive information about the programme. Each couple must be advised of any risks involved in the programme, and of its likely duration, and given the most accurate information about the prospects of success. This will then permit each couple to express in writing their free and informed consent to participate in the programme."

The Committee was concerned about the apparent lack of understanding in the community as to the relatively low success rate with IVF. The best reported results to the Committee were to the effect that in only 1 in 12 patients was a diagnosed pregnancy achieved and that live births occur in perhaps as few as 1 in 20 patients.

Appended to the report are details of the results of IVF treatment carried out by the two teams practising IVF in Western Australia - Appendix 1.

The results appear to be consistent with those achieved in other programmes and it is evident that the rate of success is increasing.

In order to monitor the IVF programme in Western Australia the Committee believes that a confidential register should be established in which a record of each IVF attempt is kept. The form of the register and how it is to be maintained should be the subject of further determination.

The Committee considers that potential participants in the programme should be given the fullest of information regarding all aspects of the programme and endorses the recommendation of the Waller Committee.

Furthermore, the Committee is of the view that the counselling of participants is of considerable importance.

Recommendation. The Committee recommends that all persons proposing to undertake IVF be provided with comprehensive information about all aspects of the programme and in particular about the prospects of success. This information should be provided in a written form to enable mature consideration of the information.

Counselling should be provided to participants in IVF both before, during and after participation. Such counselling should be provided by appropriately trained counsellors.

A register be established to record all IVF attempts.

9. Consent

It seems that doctors rely on both oral and written consent. The Committee considered that a written form of consent was essential.

This Committee has examined the form of consent used by Dr. Thomas and the Monash University team. The Committee considers that a written form of consent should be given by both intending participants substantially in the form used by the Monash University team. A copy of that form of consent is appended to this report - Appendix 2.

Recommendation. Both intending participants in IVF should sign a written form of consent substantially in the form appended to this report. Such consent form should only be signed after mature consideration of information regarding IVF and after counselling.

10. In What Hospitals Should IVF be Practised

It will have been noted that initially the practice of IVF was carried out at the King Edward Memorial Hospital for Women. For reasons which have been briefly indicated earlier in this report those who were involved in the practice of IVF were constrained to set up a clinic at a private hospital if they were to continue. It has now evolved that there are two clinics in Western Australia where IVF is practised and both these clinics are conducted at private hospitals.

It was considered by the Committee that it was not desirable that such an innovative procedure should at this stage be undertaken other than under the auspices of a major teaching hospital. This is not to say that the IVF clinic need be within the precincts of the teaching hopsital itself, although this would be more desirable. The Committee recognised that there were unusual problems in the practice of IVF, such as the availability of operating theatres and other facilities, which must necessarily be available on short notice, and these may not be available when required in the context of the administration of a teaching hospital. However if the practice of IVF was conducted at locations where it was possible to provide these facilities as and when required, but under the umbrella of a major teaching hospital, the most desirable situation could be achieved.

The Committee saw the association with a major teaching hospital as desirable for a number of reasons including:

(a) IVF would be accessible to a wider section of the community and not just those who could afford treatment at a private hospital.

(b) Those practising IVF would be subject to the overview of their peers.

(c) The practice of IVF would be governed by existing ethics committees within teaching hospitals.

(d) The availability of counselling by trained counsellors.

The Committee considered that the King Edward Memorial Hopsital for Women was the hospital under which auspices the practice of IVF should be conducted.

Recommendation. The Committee recommends that the practice of IVF in Western Australia be conducted either at or under the auspices of the King Edward Memorial Hospital for Women.

11. Under What Criteria should IVF be available to Intending Participants

This was another question in respect of which the Committee considered it would like to have the advantage of input from the community. It is a question which raises fundamental issues in circumstances where the number of patients to whom the treatment can be offered is limited. The Committee was firmly of the view that financial ability to pay for the cost of the treatment should not be regarded as an acceptable basis for selection. However as to the other issues raised by this question the Committee reserves its position until it has examined submissions received from the community and the other materials available to it.

Accordingly the Committee makes no recommendation on this issue at this stage.

As indicated earlier in this report there are a number of issues which the Committee has yet to address. Not necessarily in order of priority these issues are:-

(a) Should the use of donor sperm be permitted and if so in what circumstances and subject to what conditions?

(b) Should the use of donor ova be permitted and if so in what circumstances and subject to what conditions?

(c) Should donor embryo be permitted and if so in what circumstances and subject to what conditions?

(d) Should cryo preservation of sperm, ova and embryos be permitted and if so in what circumstances and subject to what conditions?

(e) Should all embryos be transferred and if not what should be done with excess embryos?

(f) Should experimentation on embryos be permitted and if so in what circumstances and subject to what conditions?

(g) What legislative changes (if any) are required in order to render lawful the practice and procedures of IVF?

(h) What legislative changes are required in order to protect the status of children born as a result of IVF?

In order to assist it in the consideration of the final two questions the Committee requested the Minister to appoint Dr Anthony Dickey of the Law School of Western Australia to the Committee because of his special knowledge and expertise in relation to these issues. The Committee is pleased to note that the Minister has acceded to its request.

In conclusion the Committee requests of the Minister that he appoint a research officer to devise and conduct an evaluation of IVF in Western Australia in co-operation with the medical practitioners who are working in this area and that this evaluation be proceeded with while this Committee continues its deliberations.

This request is made on the grounds that as is the case with all medico social procedures where the immediate and long term outcome is uncertain they require evaluation. The Committee lacks answers to many of the questions asked by its members and

the community with regard to IVF. An evaluation such as that proposed should be an integral part of the IVF procedure.

The design of the evaluation should be prepared under the direction of a member of the National Health and Medical Research Council Epidemiology Research Unit. It would be necessary for the unit to be reimbursed for these services and funding of the evaluation project generally will be required.

In the Committee's view the design of the evaluation should provide for immediate and long term follow up of:-

(a) children born as a result of IVF;

(b) the effect on the marriages and de facto relationships as the case may be of the parents;

(c) the costs associated with the procedure and any changes in costs;

(d) any differences observed between those in whom the procedure has been used as a treatment for infertililty and those for whom the procedure has been used because of risks of transmitting a serious genetic disorder;

(e) the outcome for those parents where IVF treatment has proved unsuccessful;

(f) in instances where disclosure of the mode of conception is made to the child or other family members the effect that this disclosure has.

The study should consist of a case control design with at least two control groups:-

(1) parents where conception occurs naturally;

(2) parents where conception is achieved by using other methods of treatment for infertility.

The Committee would see itself as receiving regular reports under these research arrangments and this will allow the Committee to continue to deliberate on the issues involved in the knowledge that some attempt is being made to measure the results and the effect of IVF from which the Committee can make a considered and informed judgment on these issues. It would also allow the Committee to follow through the recommendations already made in this report and to suggest modifications where necessary. In the absence of such research the Committee is concerned that it will become increasingly difficult to control the situation.

APPENDIX I

DR. JOHN YOVICH

RESULTS TO 30 JUNE 1984

Number of patients treated (i.e. have reached the stage of laparoscopy to collect oocytes)	330
Number of IVF attempts	465
Number of diagnosed pregnancies	46
Number of live births (including 1 set of non-identical twins, 1 set of identical twins and 1 set of non-identical triplets)	24

AVRO HOSPITAL

SUMMARY OF PATIENTS 1.1.84 - 30.6.84

Patients commenced treatment (c)		77	
(ET84/76 collected in July)			
" " cancelled		11	
" " underwent follicle aspiration		63	
Total follicles aspirated			
Large	2.0 cm	165	
Medium	1.5 - 2.0 cm	42	
Small	1.5cm	15	
		94	316 (4.8/asp)
Total oocytes collected			
Immature		39	
Slightly immature		117	
Mature		60	
Slightly atretic		30	
Atretic		11	
Damaged		2	
(including 3 collected from P.O.D.)			259 (3.9/asp)

Patients with oocytes fertilised	63	
Total oocytes fertilised		193
Patients re-implanted	62	
Total embryos re-implanted		161

(balance of fertilised oocytes either:

1: polyspermic

2: did not cleave

3: badly fragmented (non-viable)

No. Embryos transferred	1	2	3	4
No. Transfers	13	16	16	17
(a)				
No. of Pregnancies (Chemical)	2	2	5	12
(b)				
No. of Pregnancies (Clinical)	1		3	6

Patients showing chemical pregnancy	a)	21	(33.9%/transfer)
Patients showing clinical pregnancy	b)	10	(19.2%/transfer to 8/6/84)

(one patient has since delivered @ 21 weeks a male infant due to cervical incompetence)

Addendum:

(a) Chemical pregnancy evidenced by a significant rise in endogenous BHCG over 2 consecutive samples taken 2/3 days apart.

(b) Clinical pregnancy evidenced by presence of foetal heart on ultrasound.

(c) Number allocated at commencement of programme.

Births:

No. live births - 4 (2 male and 2 female)
(including 1 set of male infant twins)

APPENDIX 2

PATIENT CONSENT FORM FOR IN VITRO FERTILIZATION

We agree to the procedure of in vitro fertilization and embryo transfer and understand the following:-

(1) There is no guarantee of success.

(2) The risk of laparoscopy as done for oocyte pick-up.

(3) The possible risk of foetal malformation.

(4) The availability of tests to detect foetal malformation during pregnancy.

Witness: .....

Signed : Husband..... Wife.....

Date : .....