Consent for In Vitro Fertilization/Assisted Reproduction

I / we, ________________________ and ___________________, desire to participate in the Assisted Reproduction Program at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. We understand that there are a number of steps to this procedure and that starting this process does not guarantee that we will complete the process, achieve pregnancy or delivery of a healthy child. One of the physicians has discussed with us the etiology of our condition, and alternative therapies, if any, that are available. We understand that the female partner will receive medication to induce the maturation of several eggs and during this period she will undergo a surgical procedure to retrieve her eggs. We realize that this consent form pertains to the laboratory portion of the procedures. We understand that the eggs will be prepared and inseminated in marked dishes with a sample of the male partner’s sperm after preparation, which removes the sperm from the seminal fluid. The embryos, which may result from fertilization, will be placed into the female partner’s uterus by means of a small catheter, which passes through her cervix under ultrasound guidance. Following this transfer, blood hormone levels will be monitored in the female partner to make sure that there are adequate hormonal levels to support a developing pregnancy and then to determine if a pregnancy has resulted. We understand that each of these steps may fail and carries known risks as well as theoretical concerns as detailed in the following paragraphs.

A - Preparations

We understand that a variety of medications are available for the induction of ovulation. We understand that some of these medications must be given by intra-muscular or by subcutaneous injection, which may cause bruising or discomfort at the injection site. These medications may cause the ovaries to become over stimulated, leading to a condition called ovarian hyperstimulation syndrome (OHSS). We understand that in its most severe form this condition might require hospitalization for intravenous fluids and monitoring until the syndrome resolves. Worldwide there have been rare reports of death following severe OHSS. We therefore understand the importance of maintaining close contact with the IVF team during the time that these medications are being used and for two weeks afterwards.

We understand that before the start of a cycle, the male partner will be asked to supply a semen sample for analysis by the andrology laboratory. In certain cases, semen may also be frozen in advance to be certain of its availability at the time of egg retrieval.

We understand that while receiving the medications listed above, the female partner will be closely monitored by the IVF team. We understand that this monitoring will include frequent blood drawing, which can cause mild discomfort and bruising at the puncture site. We understand that ultrasound examination of the ovarian follicles and the uterus will be performed frequently. These examinations may be uncomfortable, but have no known risks of any kind. We understand that if monitoring suggests a low probability for successful egg retrieval that the stimulation cycle will be stopped and no egg retrieval will occur. We also understand that we may be given the option of starting the ovarian stimulation procedure again in a subsequent cycle.

B - Egg retrieval

We understand that, at a time determined by the IVF team, the female partner will be admitted for the egg retrieval procedure. We understand that in the vast majority of cases, ultrasound directed needle puncture of the follicles will be done. Rarely, the retrieval may be done by laparoscopy under general anesthesia. We understand that the procedure involves the small risk of anesthesia as well as injury to bowel, bladder, or blood vessels, which might require a large incision (laparotomy) to repair. We understand that a separate informed consent will be obtained for a laparoscopic retrieval if it becomes necessary. With either type of egg retrieval, we understand that in rare cases there could be bleeding from the site where the ovaries were punctured. This may require laparotomy (an incision in the abdomen) if the bleeding cannot be controlled through the laparoscope. The risks of the procedure are similar to the risks of laparoscopy.

We understand that we cannot be guaranteed that the number of eggs predicted prior to retrieval will indeed be recovered or that any of the eggs will be normal or mature. Some follicles may not yield eggs and rarely
none of the follicles will yield eggs. The egg retrieval involves equipment such as incubators, suction apparatuses and ultrasound machines that may fail because of technical malfunction. We also understand that once the eggs are isolated in the laboratory, that blood and abnormal nursing cells are removed from around the egg using dissection needles and that although unlikely, some or all of the eggs may be damaged in the process. Eggs may also be damaged because of shock due to differences in conditions.

Initial egg yield numbers are counted once and rapidly in order to place the eggs inside the incubators and stabilize conditions as soon as possible. Eggs themselves are not visualized during egg retrieval, but only the nursing cells surrounding the eggs. The normality of the eggs cannot be assessed at egg retrieval. The exact number of eggs is only determined later on at insemination or ICSI.

C - Insemination, fertilization and embryo growth

Once retrieved, the eggs will be incubated in a special solution (culture medium) and evaluated for timing of insemination by the embryology team of the IVF program. We understand that a sample of semen from the male partner, obtained by masturbation in a private collection room near the laboratory, will be evaluated, prepared, and used for insemination. Semen collection in this way can be unsuccessful and if there are any doubts, a sample can be prepared and frozen in advance for thawing at this time. However, in case of unexpected failure it is possible to obtain spermatozoa from a testicle using a minor operative procedure (testicular sperm retrieval). Separate consent is needed for this procedure.

The seminal fluid that surrounds the spermatozoa must be removed prior to insemination. Sperm processing involves high centrifugal force, washing with artificial colloidal suspensions called Puresperm, Isolate or Percoll or by swim-up. We understand that the consistency of highly viscous semen may be reduced by an enzyme. The prepared semen may be exposed to substances intended to promote sperm movement or materials intended to remove toxic substances. The zygotes or fertilized eggs are changed over into a culture solution. This solution may be changed every 48 hours or more frequently. Solutions may be specially tailored to embryonic stage. The embryos are checked at least once daily and their development is determined. Embryos will remain in the solution(s) for 48-120 hours and then transferred.

Should a pregnancy occur, we understand that no risk to the fetus is presently known to medical science arising from the materials and methods used in the preparation and handling of eggs, semen and embryos. We understand that not all eggs recovered may be fertilized, and that it is possible that none of the eggs may fertilize. We also understand that not all eggs may be mature and that mature eggs may be fertilized multiple times by sperm or even self-fertilize without the sperm participating. Zygotes and later stage embryos may develop abnormally at any time.

D - Blastocyst culture and embryo transfer

We understand that 3 days after egg retrieval our embryo(s) will be placed into the uterine cavity of the female partner. Alternatively, we may recommend to you to consider having embryos transferred at the blastocyst stage five or six days after egg retrieval, using commercial culture solutions that support growth for a longer period. This protocol may be especially advantageous to couples who are at risk of multiple pregnancy, since the extended culture increases the opportunity for embryologists to select the highest quality embryos. A potential disadvantage is that some embryos may be more sensitive to prolonged presence in the laboratory with the result that cryopreservation and/or embryo transfer may not occur.

For any embryo transfer, a thin catheter will be passed through the cervix and into the uterus so the embryo may be deposited there. We understand that this may involve some cramping and discomfort, and possibly a small amount of bleeding. Infection could be introduced at the time of the catheter insertion into the uterus, requiring antibiotic therapy. We understand there is no guarantee that any of the embryos thus transferred will result in a pregnancy.

We understand that the success of IVF can often relate directly with the number of embryos transferred to the uterus. We also understand that IVF significantly increases the risk for multiple gestation (more than one baby), and that this risk also correlates directly with either the number of embryos transferred, their
development, the age of the female partner (or egg donor), the number of prior attempts and other unknown factors. We also understand that in rare cases, embryos may split in two or three, resulting in multiple fetuses; on occasion this can mean that there are more fetuses than embryos transferred. There are distinct obstetric risks to multiple gestations, the most serious of which is preterm delivery of infants who require intensive care. It is the policy of this program to replace anywhere from one to five embryos in a given cycle all depending on availability and factors such as your age, cycle attempt and embryonic parameters and the national guidelines published by the American Society for Reproductive Medicine (ASRM). Any additional viable embryos may be cryopreserved (frozen) for possible replacement in a subsequent cycle. We understand that a separate consent for the cryopreservation must be completed if the embryos are to be cryopreserved.

E - Disposition of unwanted or unsuitable cells, fluids, spermatozoa, eggs and embryos
Blood, blood products and cells as well as follicular and seminal fluids and cells contained therein obtained during follicular monitoring, egg or sperm retrieval, will be disposed of. In the event that we have unused or immature spermatozoa, these may be subjected to handling and further observations to assess their potential for fertilization. Under no circumstances will these spermatozoa be used for fertilization purposes or donation to other individuals, couples, corporations or institutions. In the event that we have immature, unfertilized or abnormally fertilized eggs, these may be subjected to further observations and handling. We understand that these eggs will never be used for fertilization purposes or donation to other individuals, couples, corporations or institutions and that further growth of them will be ceased immediately after the observation when the cells will be appropriately discarded. We also understand that these eggs are considered abnormal. Embryos that arrest 1-6 days after egg retrieval, that are partially degenerate or for any other reasons considered unsuitable for embryo transfer or cryopreservation may be observed to determine microscopically visible abnormalities. No research will be done on these cells. We understand that these embryos or their cells will never be used for purposes other than those described and will never be offered to other individuals, couples, corporations or institutions. We also understand that these embryos or their cells are unwanted and considered abnormal.

F - Use of blood products
Human serum albumin, a commercially prepared blood product for clinical laboratory use, is added to the egg collection fluid, micromanipulation, and semen preparation fluids. It is considered necessary for successful culture. Careful screening is done by the manufacturers to reduce the likelihood of transmission of infectious diseases such as HIV, Hepatitis B and C. To date there have been no documented cases of disease transmission linked to human serum albumin usage in our Center. We understand and accept the risk that use of these blood products could result in the transmission of HIV, Hepatitis and/or other viral or possibly as yet unknown non-viral diseases.

G - Use of chemical substances, disposable items and mechanical devices during the procedures
A large number of chemical substances (sugars, salts, enzymes, proteins), mechanical devices (incubator chambers, microscopes, air handling systems, filters, standard laboratory equipment) and disposable items (pipettes, petri dishes, flasks, microtools) are used during the laboratory procedures. There may be unknown risks associated with the use of any of these items that cause your procedure to fail, even though checks and quality control measures are performed on a regular basis. Thus far we do not know of any association between the use of these materials and anomalies of pregnancy and fetal development, but underlying unidentified problems may nevertheless exist. An enzyme made from cow testis called hyaluronidase is routinely used to remove nursing cells from around the eggs, and there is a chance that this enzyme may inadvertently remove the zona pellucida (the layer surrounding eggs) and cause your procedure to fail. We understand that this enzyme may have to be used in our case and we accept the risk associated with its use. Another enzyme called chymotrypsin made from cow pancreas may be used to reduce the viscosity of seminal fluid. This enzyme may also in very rare instances inadvertently remove the zona pellucida and also may cause your procedure to fail.
H - Risks associated with procedures
Based on current medical knowledge, we understand there does not appear to be a higher incidence of birth defects associated with IVF procedures. However, there is not at present sufficient statistical data available to definitively conclude that this is so. Therefore, we understand that IVF may impose risks to the fetus during development. We also understand that because more than one embryo or egg may be transferred, there may be a higher incidence of multiple births. An embryo may split when inside the uterus, forming identical twins and there may be other associated anomalies. In certain cases, fetal reduction may be considered if more embryos implant that can be medically (or personally) deemed advisable to carry through a pregnancy. We also understand that ectopic or tubal pregnancies may occur in the procedure. These associated procedures can also produce increased emotional burdens.

We understand and accept that the use of ovarian fertility drugs may be associated with an increased risk of ovarian diseases in later life, including cancer. We recognize that the exact risk, if any, has yet to be established and may not be known for many years.

I - Financial responsibility
Financial responsibility for all services and medical treatments given by and for the A.R.T. Institute of Washington, Inc., staff services, laboratory services and hospital costs associated with medical care are the sole responsibility of the couple receiving these treatments. The couple desirous of having children from donor sperm bear the responsibility for the purchase and shipment of the sperm to the facility. Responsibility for the pregnancy and any pregnancy related complications and delivery are the responsibility of the couple and their obstetrician.

J - Success rate and outcome
We understand that failure to obtain a pregnancy may result from many reasons, including:

- Maturation of the egg(s) may not occur, or the time of the egg maturation may be misjudged, may not be predictable or may not take place in the monitored cycle.
- Pelvic adhesions may prevent access to the ovary with the follicles, thus causing the procedure to obtain the egg from the ovary to fail.
- The egg(s) obtained may be abnormal.
- Normal spermatozoa may not be available.
- Normal fertilization of the egg(s) by the sperm may not occur.
- Cleavage or growth of the embryo(s) may not occur at any day of development or the embryo(s) may not develop normally.
- The embryo(s) may become infected in the laboratory or an unforeseen laboratory accident may result in loss or damage to the eggs, sperm, or embryo(s).
- The embryo(s) may become contaminated by infection in the semen or bacteria from the vagina.
- Some embryos may not develop well in approved commercial culture medium despite standard testing.
- Implantation of the embryo(s) in the uterus after embryo transfer may not occur or an early pregnancy may be lost after an initial positive result
- Even if a pregnancy is established, we understand that delivery of a child may not occur due to miscarriage, ectopic pregnancy (outside the uterus), stillbirth, or other complications associated with pregnancy and delivery.
- There may be unknown side-effects from any of the procedures used resulting in abnormal pregnancy or abnormal fetal development.

We understand that the members of the IVF team cannot guarantee that a pregnancy will result from this procedure. Even in normally fertile couples, the chance of pregnancy is approximately 25% in a given natural cycle. If no pregnancy occurs, we may be offered participation in future cycles when assessment by the IVF team reveals no contraindications. We understand that the IVF team cannot guarantee the normality of any infant that results from this procedure.
We understand that we may at any time decide to withdraw from participation in this program without prejudice. Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publication resulting from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC), The Society for Assisted Reproductive Technology (SART) and The Departments of Health of Washington may inspect the records.

We have been encouraged to ask questions and any that we have asked have been answered to our satisfaction. A member of the IVF team will answer future questions.

Initials

__/___
The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center

Consent form for Intracytoplasmic Sperm Injection (ICSI)

A - We understand that the purpose of this document is to give our consent to the embryology team at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center (WRNMMC) to perform intracytoplasmic sperm injection (ICSI) using the sperm and eggs of our IVF procedure.

B - We understand that the ICSI procedure is performed when the sperm may not be judged adequate to achieve fertilization using conventional insemination (putting the eggs and sperm closely together). It is also used to increase the chances of fertilization in those cases where fertilization has failed or was substantially reduced in a prior IVF cycle. ICSI is also used in cases where sperm has to be retrieved from the epididymis or testicle because spermatozoa are not present in the semen (ejaculate). Occasionally, it is decided to do ICSI because it allows for closer observation of the eggs compared to standard insemination.

C - We understand that physicians and scientists of The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center believe that the ICSI procedure will be beneficial to us because the chances of successful fertilization will improve, and thereby increase our chances of pregnancy. However, we understand that there is no guarantee that we will achieve fertilization or that any embryos which are transferred will implant and result in a pregnancy.

D - Other consent agreements for IVF, cryopreservation and assisted hatching are not altered by this consent form. Our decision to request the ICSI procedure in no way affects our ability to complete any other component of an IVF cycle.

E - We understand that ICSI involves the following:
- Obtaining the male specimen that contains the sperm by masturbation, from frozen samples, or through surgical aspiration.
- Preparation of the sperm to purify the sample and obtain the optimal number of sperm for the micro-injection procedure.
- After egg retrieval, enzymes will be used to remove the granulosa cells surrounding the eggs. This enzyme has been used in a large number of studies and has very rarely been known to cause removal of the zona pellucida (outside layer) from some eggs that are unusually sensitive to the enzyme. Inadvertent zona removal at this stage is likely to be detrimental.
- Only mature eggs that are suitable for ICSI, so they will be separated from the other eggs. Normally, three quarters or less of the eggs are mature. In rare cases, none are mature. The mature eggs will then be stabilized with a holding pipette using a micromanipulator.
- A single sperm will be picked up with a small injection pipette from a droplet containing a highly viscous fluid made with a substance called PVP. Hypothetical problems have been described in the medical literature about the use of PVP, including the potential for reduced fertilization and/or increased chromosomal abnormalities. In general, these risks are considered small.
- With the narrow injection pipette, one sperm will be inserted into each egg.
- The egg(s) will be returned to the incubator, and will be examined 14 to 18 hours later to determine if fertilization has occurred.

F - We understand that the female partner will receive antibiotics for three days. This medication is to protect the embryos from bacterial contamination and attack by immune cells. There will be no other differences from the standard IVF protocol, when embryo replacement typically occurs three or 5 days after retrieval.

G - We understand that ICSI may involve the following risks or disadvantages:
- The eggs may be damaged during the ICSI procedure. Serious damage that threatens egg viability actually occurs in less than 10% of the eggs. Some batches of eggs may be over-sensitive resulting in higher damage rates.
The exact likelihood of fertilization for any single egg or individual patient cannot be accurately predicted. However, fertilization rates currently exceed 65% per egg and over 95% of couples usually have some embryos to transfer. Nevertheless, failure of fertilization or embryo transfer may occur.

- Even when embryos are transferred, there is no guarantee that pregnancy will occur.
- This technology is relatively new (started 1992), and there may be unknown risks to the baby or mother.
- Patients with very low sperm counts or without spermatozoa in their semen may transmit similar fertility problems to the male fetus and male babies born. In some groups this occurs in up to 10% of patients. Genetic transmission of abnormal gene(s) occurring on the Y chromosome and their anomalies are known as Y micro-deletions. The highest risk of infertility transmission is in certain men with very low sperm counts and in others where there are no spermatozoa present in the semen sample and who require testicular sperm retrieval.

- While there seems to be no higher overall incidence of congenital malformations in children born after ICSI with using either regular sperm or epididymal or testicular spermatozoa, the risk cannot be totally ruled out.

H - Disposition of unwanted or unsuitable spermatozoa and eggs

In the event that we have unused spermatozoa, we understand that these may be subjected to further observation and appropriately discarded. Under no circumstances will these spermatozoa be used for fertilization purposes or donation to other individuals, couples, corporations or institutions. In the event that we have immature, unfertilized or abnormally fertilized eggs, we understand that these may be subjected to further observation and appropriately discarded. We understand that these eggs will never be used in part or whole for fertilization purposes or donation to other individuals, couples, corporations or institutions and that any further culture will be ceased immediately after observation. We also understand that these eggs are unwanted and considered abnormal.

I - At any time prior to egg retrieval, we understand that we may cancel our consent for performance of the ICSI procedure; however, once egg retrieval has taken place, irrevocable steps for the performance of ICSI will occur. Any information obtained during this procedure and identified with us will remain confidential and will be disclosed only with our permission. Any publication resulting from this procedure will not identify us individually. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC) and The Departments of Health of Washington DC may inspect the records.

J - We hereby attest that we have read this entire consent form, or that it has been read to us, so that we understand it completely. We further attest that any and all questions of ours regarding this procedure have been answered to our complete satisfaction.

Initials

____/____
Consent for Assisted Hatching and Fragment Removal

I / We, ________________________ and _____________________, understand that this consent gives the embryology team at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center permission to assess our embryos microscopically and determine whether assisted hatching with/without fragment removal will be performed.

A – Initial studies and inclusion criteria
We understand that the embryologists have performed assisted hatching and fragment removal in scientific studies involving infertile couples and have found this micromanipulation technique to be advantageous for some of the embryos, by promoting attachment to the uterus. It was found that certain patients and embryos benefited from the procedure, whereas others did not. We agree that the embryologists will assess the embryos and determine the speed of their development. Some embryos may be selected for the procedure, whereas others will be left as is. We agree that the embryologists may remove debris and/or fragments (blebs released from the embryonic cells) from underneath the zona pellucida (clear layer of membrane surrounding the egg), which may otherwise interfere with the development of the embryo. We understand that this is only done when there are many fragments present or when their appearance suggests that they could interfere with normal growth. We understand that there are embryonic characteristics, which are used to determine whether assisted hatching can be safely applied to those embryos selected for transfer. We also understand that certain aspects of the female partner’s history, such as age, basal FSH levels, previous IVF history and prior medical history may also be used to determine whether the embryos should undergo selective assisted hatching. Further experiences beyond those initial studies have confirmed the results of the published studies, which indicate enhanced pregnancy rates. We understand that the magnitude of the anticipated result varies from patient to patient and will depend on our specific circumstances.

B – Description of procedure
We understand that the procedure involves the use of the micromanipulator (a delicate instrument that holds the egg) to pick up the embryo and another micromanipulator to deposit minute amounts of acidic solution onto a small area of the zona pellucida to create an opening. We also understand that by consenting to have selective assisted hatching performed, that our physicians will prescribe an oral antibiotic (usually doxycycline) and an oral corticosteroid (methylprednisolone) for the female partner, both beginning on the day of retrieval. These drugs are administered to protect the embryos from bacterial contamination and attack by immune cells. The role of these corticosteroids is not determined at this time and is considered optional. The IVF procedure will otherwise not deviate from the standard protocol. Embryo transfer may occur anywhere between three to five days after retrieval. If for any reason our embryos need to be replaced prior to day three, the selective assisted hatching procedure cannot be performed.

C – Potential drawbacks and risks
The procedure may also involve the following risks or disadvantages as is only recommended in specific instances which will be discussed with us prior to the procedure being offered:

1. There is potential for harm to occur to our embryos during the hatching process. Although damage to the embryos is exceedingly rare, single cells within the embryo may be damaged in less than 1% of cases. Information available at this time indicates that this does not appear to affect the overall developmental potential of the embryo.
2. The exact likelihood of success for a given embryo or patient cannot be predicted. However, the implantation rate per embryo may rise. This rise in implantation rate raises the risk for a multiple gestation pregnancy.
3. Although unlikely, this technique may yield unknown risks to the baby or mother. The holes in the zona may decrease its protective effect for the embryo. The higher implantation rates found in
appropriately selected embryos which undergo selective assisted hatching indicate that the net effect is likely beneficial.

4. The micromanipulation itself may produce abnormal embryos or rarely, may cause immediate degeneration of the embryos.

5. The corticosteroids given to the female partner are considered low dose. Over five thousand patients have now been treated with this regimen in cycles where there was some zona manipulation. The only notable side effect has been the rare occurrence of vaginal yeast infection. Though none of the following effects have been reported to date in these thousands of cases, we nevertheless understand that these drugs may: mask signs of infection and new infections may occur during use; increase blood pressure, salt and water retention, and excretion of potassium and calcium, cause mood swings, insomnia, depression, psychotic manifestations, muscle weakness, impair wound healing, increase sweating, headache, vertigo, allergic reaction, loss of muscle mass, osteoporosis and abdominal distention, cause nausea, vomiting, diarrhea, loss of appetite, rashes, increase sensitivity to the sun, hypersensitivity reactions resulting in shock, blood disease including reduced platelets or fractured red cells which occur with anemia or bleeding.

6. The chances of having identical twins may be increased. Identical twins carry all the risks of any multiple pregnancies, but may also have special risks. These include an increased risk for pre-term labor, small-for-gestational-age babies, and umbilical cord accidents, which may lead to the demise of the developing fetus. Conjoined twins or triplets, also known as Siamese twins, are abnormal identical fetuses that can occur rarely after IVF and assisted hatching. In such cases, fetal reduction may be considered. This associated procedure can produce increased financial and emotional burdens.

7. Fragment removal may cause damage of one or two cells in less than 5% of cases. The damage is usually done in embryos with very poor growth and excessive fragmentation or where the fragments are closely associated with the cells.

We understand that our decision to have selective assisted hatching may be beneficial as the chance of pregnancy may increase. In our particular case, however, we understand that there is no guarantee that our embryos will receive any benefits from the procedure, or even that the procedure will be performed on any of our embryos.

D – General policies

The consents of the IVF, cryopreservation, and ICSI consent forms apply to this consent as well. This consent form is being offered to all couples treated with IVF at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. Any information obtained during this study and identified with you will remain confidential. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC) and The Departments of Health of Washington DC may inspect the records. Your decision whether or not to have assisted hatching of your embryos will not prejudice your future relations and/or treatments with The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. If you decide to participate, you are free to discontinue participation at any time. Your participation is voluntary and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. In any event, it is understood that the Institute and its staff, as well as the partners must abide by any applicable federal, state, or local laws or regulations.

E - We hereby attest that we have read this entire consent form, or that it has been read to us, so that we understand it completely. We further attest that any and all questions of ours regarding this procedure have been answered to our complete satisfaction.

Initials

____/____
Consent for Embryo Cryopreservation (Freezing/Storage)

A – Cryopreservation policies

I / We, _______________________ and ______________________, understand that this consent gives
the embryology team at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical
Center permission to cryopreserve (freeze and store) any suitable embryos which are not transferred during
the original assisted reproduction cycle. We understand that only those embryos with quality presumed
adequate to survive the cryopreservation process will be cryopreserved.

We understand that it is the general policy of this program to transfer no more than a certain number of
embryos, in order to minimize the risk of multiple gestation while maximizing the per cycle success rates of
the procedure. We also understand that where more morphologically normal embryos are obtained, any
additional embryos will be cryopreserved (frozen).

We also understand the possibility that a proportion or all of the embryos may not continue to grow in the
laboratory and reach the stage of development where they can be cryopreserved. A proportion or even all of
the embryos, which are cryopreserved, may not survive or resume normal growth when they are thawed, nor
successfully implant when they are replaced into the uterine cavity. There may not be any viable embryos for
transfer after thaw. We also understand that although to date, in the children born, there have been no
observed detrimental effects arising from the cryopreservation procedure; there can be no guarantee as to the
normality of any pregnancy that develops following the transfer of a cryopreserved embryo.

B – Property and disposition

We agree that any resulting cryopreserved embryos are joint property of both the male and female partner as
signed below. No use can be made of these embryos without joint consent. If both partners do not agree in
writing to a disposition of these embryos by ____/____/____ (the 50th birthday of the female partner), the
embryos shall become the sole and exclusive property of The A.R.T. Institute of Washington, Inc. at Walter
Reed National Military Medical Center at which time they will be discarded. We understand that all
shipping and storage costs are our responsibility. Both partners shall waive any and all interest in said
embryos following this date. We understand that a yearly storage fee shall be charged starting 12 months
after the procedure, and that any such embryos shall be stored in special containers in an inert gas called
nitrogen and frozen. The straws, ampules and containers may ultimately fail to function correctly at these
low temperatures because of structural, mechanical or electrical failure. We understand that such failure may
happen despite extensive supervision and maintenance by laboratory staff. All or some of the embryos may
be lost during storage due to technical malfunction or because of operational hazards associated with any
kind of storage facility.

Before the above said date, the couple may decide on the disposition of the embryos. Since this is a
rapidly evolving field both medically and legally, one cannot be certain what the available or acceptable
avenues of disposition will be at that time. However, at present, the alternatives are shipping the embryos to
another facility, discarding the embryos or donation of embryos to another couple.

Subject to the above, we understand that:

I. In the event of divorce or dissolution of the marriage, the ownership and/or rights in and to the
   embryos will be as directed by the divorce decree.

II. In the event of the death of one of the undersigned partners, the ownership and/or other rights in
    and to the embryos shall revert to the surviving partner.

III. On the death of the survivor, the ownership of and/or rights to the embryos shall revert to The
    A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. We agree
    that in this event, our embryos are to be disposed of.
C – Other storage policies
We understand that we are at all times permitted to remove the frozen embryos and that we may ship and store them elsewhere. The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center will not be responsible for any costs associated with shipment and storage elsewhere. We also understand that The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center cannot guarantee the state of the embryos after shipment and transfer to another facility. Shipment and storage elsewhere may effect the survival of the embryos and their ability to implant and develop normally. We understand that we have to remove all embryos from storage at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center, once we end or discontinue service in the United States military. We also understand that we have to give notice to The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center, once we change our address or telephone number. We understand and concur that we will at all times be available to staff members of the The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center, so that they may verify ownership of the frozen embryos.

D – General policies
This consent form is being offered to all couples treated with IVF at The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. Any information obtained during this study and identified with you will remain confidential. Representatives of The Food and Drug Administration (FDA), The Center for Disease Control (CDC) and The Departments of Health of Washington DC may inspect the records. Your decision whether or not to have embryos frozen will not prejudice your current or future relations and/or treatments with The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center. If you decide to participate, you are free to discontinue participation at any time. Your participation is voluntary and your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. In any event, it is understood that the Institute and its staff, as well as the partners must abide by any applicable federal, state, or local laws or regulations.

We hereby attest that we have read this entire consent form, or that it has been read to us, so that we understand it completely. We further attest that any and all questions of ours regarding this procedure have been answered to our complete satisfaction.

Initials

____/____
The A.R.T. Institute of Washington, Inc. at Walter Reed National Military Medical Center

Signature page

- Consent for Embryo Cryopreservation (Freezing/Storage)
- Consent for Assisted Hatching and Fragment Removal
- Consent form for Intracytoplasmic Sperm Injection (ICSI)
- Consent for In Vitro Fertilization/Assisted Reproduction

We hereby attest that we have read the above referenced consent forms, or that they have been read to us, so that we understand it completely. We further attest that any and all questions of ours regarding all procedures have been answered to our complete satisfaction.

Name female partner ____________________  Signature _____________________

Name male partner ____________________  Signature _____________________

Name physician ____________________  Signature _____________________

Name witness___________________  Signature _____________________

Date: _________________________