BOSTON IVF

CONSENT FORM FOR A GESTATIONAL CARRIER

INSTRUCTIONS:

This consent form provides a description of the treatment that you are undertaking.

- Read the consent completely. If you have any questions please speak with your doctor.
- Do not make any additions or deletions to the consent.
- Treatment **cannot** be started until all consents are signed.
- Consents must be signed in front of your nurse or physician.

INTRODUCTION

In Vitro Fertilization (IVF) is a treatment that helps an infertile patient achieve a pregnancy. The technique involves four main steps: 1) the development of eggs in the patient's ovaries; 2) the removal of eggs from their ovaries; 3) the placement of the eggs and sperm together in the laboratory to allow fertilization to occur, and; 4) the transfer of fertilized eggs (embryos) into the gestational carrier's uterus for the establishment of pregnancy.

The existence of the embryos outside of a patient's body creates the possibility of placement of these embryos into a second patient (gestational carrier) who then carries the pregnancy. **The intention following the delivery is to unite the baby or babies with the couple who will be the intended parents.**

This consent explains the IVF procedure and describes the major risks. In addition, the responsibilities of those who participate in this treatment are discussed. This consent is valid for a period of one calendar year after it has been signed. Please make a copy for your records. It is recommended that you review the consent prior to each treatment cycle. If you have any questions about your treatment then it is your responsibility to speak with your physician.

Pre-treatment Recommendations

During treatment a patient should avoid any activity, behavior and medications that could reduce their chance of conceiving and having a healthy baby. In addition, the recommendations listed below should be followed.

1. A prenatal vitamin should be taken on a daily basis before the treatment is begun. This will reduce the chance that a baby will be born with a neural tube defect (e.g. spina bifida), which is a birth defect that affects the development of the spine.
2. Smoking must be avoided before and during treatment. It is also contraindicated during pregnancy.
3. Recreational drugs are absolutely contraindicated.
4. Ingestion of aspirin or aspirin-like products (e.g. Motrin®, Advil®, Anaprox®, Naprosyn®, Aleve®, etc.) should be avoided during treatment. However, in certain circumstances your doctor may prescribe low dose aspirin (baby aspirin, 81 mg). Tylenol® is safe to take before and during pregnancy.

5. The use of alcohol should be avoided during treatment and after pregnancy is established.
6. The use of all prescription and over-the-counter medications (including herbal remedies) should be discussed with a physician before starting a treatment cycle.
7. Ingestion of some fish, which contain higher amounts of mercury, can affect the development of the nervous system of a fetus. During the treatment and after pregnancy is established you should avoid eating these fish-shark, swordfish, king mackerel, tilefish and canned tuna fish. You should limit the intake of all other fish to 12 oz. per week.

DESCRIPTION OF THE TREATMENT

Gestational carrier treatment is done in conjunction with IVF and involves several steps. Success cannot be guaranteed at any or all of these steps. If optimal results are not appreciated at any step, it may be recommended that treatment be stopped and the cycle cancelled. The steps of the treatment are discussed below.

I. **Ovulation Induction**: The intended parent or egg donor will take medications to stimulate the development of multiple ovarian follicles (the fluid-filled cysts in the ovary that contain the eggs).

II. **Egg Retrieval:** The intended parent or egg donor will have the eggs removed from their ovaries.

III. **Insemination of the Eggs:** The eggs and sperm will be placed together in the laboratory and incubated in an effort to achieve possible fertilization and growth of the embryos.

IV. **Preparation of the Endometrium:** The uterine cavity of the gestational carrier will be hormonally prepared prior to the embryo transfer to allow implantation to occur.

V. **Embryo Transfer:** One or more embryos will be transferred into the uterus of the gestational carrier.

VI. **Embryo Freezing:** Following the embryo transfer, any remaining embryos of suitable quality may be frozen (cryopreserved) and stored for future embryo transfer(s).

The gestational carrier participates in steps IV and V. The intended parent/s will participate in steps I, II, III and VI. The steps of the treatment are described in greater detail below.

I. Preparation of the Endometrium

In order to properly time the embryo transfer, the gestational carrier must have the endometrium (uterine lining) hormonally prepared to allow implantation to occur. Several medications will be administered to achieve this goal. The first medication that is administered is leuprolide acetate (Lupron®). This medication is injected subcutaneously on a daily basis. Initially, it stimulates the pituitary gland to release FSH and LH, which are the hormones that regulate ovarian function. With continued administration of Lupron®, the pituitary gland is temporarily depleted of these hormones, which essentially puts the ovaries to rest. After the medication is administered for 8-12 days, a menstrual period occurs. When the intended parent starts the ovulation induction medications to stimulate their ovaries, the gestational carrier will be started on estrogen, which stimulates the growth of the lining of the uterine cavity called the endometrium. Estrogen can be administered orally, by a patch placed on the skin or injection. To monitor the response to estrogen a vaginal ultrasound may be performed to measure the thickness of the uterine lining. The day before the intended parent undergoes the egg retrieval, the gestational carrier will stop the Lupron®, continue the estrogen and be started on progesterone which helps to prepare the endometrium for implantation. Progesterone can be administered by intramuscular injection and

vaginally. If pregnancy occurs, the estrogen and progesterone are continued until approximately the third month of pregnancy. The estrogen and progesterone medications that are prescribed are natural hormones and do not increase the risk of birth defects.

Lupron®, estrogen and progesterone are not FDA-approved for this purpose. These medications are approved for other indications. Lupron® has been approved for the treatment of endometriosis and uterine fibroids. Estrogen medications have been approved for hormonal replacement for menopausal patients.

Side Effects - The use of these medications can cause side effects such as nausea, vomiting, hot flashes, headaches, mood swings, joint pains and visual symptoms. A rare risk of estrogen administration is the formation of blood clots, which can compromise the blood supply to vital organs, causing serious problems that could include a stroke or heart attack. Any of these conditions may cause death or serious long-term disability. Most studies of low-dose estrogen usage by patients do not show an increased risk of these complications. Allergic reactions are always a possibility. Injections can result in local discomfort and, in rare cases, abscess formation.

II. Embryo Transfer

After fertilization has been confirmed, the development of the embryos is monitored in the laboratory. If the embryos continue their development then plans are made for the embryo transfer. The embryo transfer is performed 3 to 6 days following the egg retrieval. Embryos transferred 3 days after the egg retrieval are generally at the 4 to 8 cell stage. Embryos transferred on day 5 or 6 are at a more advanced stage and may have developed into a blastocyst, which is made up of over 50 cells. Your physician will discuss with you the optimal time of the transfer. In the event that the embryos stop their development the embryo transfer is not performed.

At the time of the embryo transfer, a physician will review the fertilization results and the development of the embryos. A decision will be made regarding the number of embryos that will be transferred. Increasing the number of embryos transferred will increase the chances of pregnancy, but will also increase the risk of a multiple pregnancy (e.g., twins, triplets, etc). Remaining embryos that are not transferred will be examined and, if they are of suitable quality, may be frozen, stored and transferred at a later date.

Embryos which result from abnormal fertilization (i.e., polyspermy -when more than one sperm fertilizes an egg) will be discarded because they have no chance of developing normally. In addition, embryos that fail to develop properly (e.g., fail to divide, demonstrate other significant abnormalities of development) will also be discarded. Eggs and/or embryos, which have failed to develop (not viable), will not be transferred and will be discarded.

In order to perform the embryo transfer the gestational carrier is placed in the same position as for a pelvic exam. A speculum is placed into the vagina and the cervix is visualized. The vagina and cervix are rinsed with a solution. The biologist loads the embryos into a catheter, which the physician inserts through the cervical canal and into the uterine cavity. After placement of the catheter the embryos are injected into the uterine cavity. The catheter is examined by the biologist to confirm that the embryos have been discharged. Following the procedure the gestational carrier will be sent home. Activity should be limited on the day of the embryo transfer. Thereafter, normal activity should be resumed.

Very rarely, a uterine infection may occur after embryo transfer. The most common symptoms associated with infection are pain and fever. If fever, vomiting, abdominal pain or any other symptoms develop following embryo transfer, you should contact your physician.

TREATMENT OUTCOMES

The average success rates (the delivery of a live born infant) following a cycle of IVF are between 10-40%. The development of a pregnancy following IVF treatment is dependent on many factors, some of which include: the age of the intended parent or egg donor (who donates the eggs), the diagnosis, the number of previous cycles of treatment, the number and quality of the eggs, the quality of the semen sample and the number and quality of the embryos that are transferred. Despite repeated attempts of this treatment, there is the possibility that pregnancy will not occur.

An overview of some of the more common risks of pregnancy is discussed below:

Miscarriage - The risk of miscarriage in the general population is 15-20%. The risk of miscarriage increases with the age of the intended parent or egg donor who donates the eggs. Most miscarriages are associated with lower abdominal cramping and bleeding, but do not necessarily require treatment. In some cases, however, complete removal of the pregnancy tissue must be accomplished by a surgical procedure called a dilatation and curettage (D&C). This procedure is usually performed under anesthesia in the operating room and involves placing a suction tube into the uterine cavity to remove the pregnancy tissue.

Tubal (Ectopic) Pregnancy - Approximately 3-5% of pregnancies that result from IVF treatment are located outside of the uterine cavity. The majority of ectopic pregnancies are present in the fallopian tube. The chance of tubal pregnancy is greater in patients with damaged tubes. If a patient has a tubal pregnancy, they may need surgical treatment, which may involve the removal of the involved tube. Medical treatment with Methotrexate may be an option in selected cases.

Multiple Pregnancy - The chance of a multiple pregnancy increases with the number of embryos that are transferred. Approximately 60% of pregnancies following the transfer of multiple embryos result in the birth of only one baby. Of the 40% of pregnancies that are multiple, approximately two-thirds are twins and one-third are triplets. The chance of a quadruplet pregnancy is 1-2%. Multiple pregnancies are associated with an increased risk of most complications of pregnancy including but not limited to miscarriage, toxemia, congenital anomalies, gestational diabetes in the gestational carrier and premature birth. Premature birth is the single greatest cause of death and disability in newborn infants. If a multiple pregnancy develops, an option is to proceed with a multi-fetal reduction procedure. This procedure, which is performed at approximately three months of pregnancy, reduces the number of fetuses to a lower and safer number. Although the success rate is 90-95% a miscarriage may result from the procedure.

Congenital Anomalies – Most infants who have been born following IVF are normal**.** The rate of major congenital anomalies (birth defects) in the general population is 2-3% and is no different in babies conceived with IVF. Some birth defects are identified at the time of an ultrasound performed around 16 weeks of pregnancy. If a congenital anomaly is identified, the option to terminate the pregnancy can be accomplished with medications to induce labor and/or a dilation and evacuation (D&E). The latter is performed in the operating room under anesthesia.

The risk of chromosomal abnormalities increases with the age of the intended parent or egg donor who provides the eggs. The chromosomal status of the fetus(es) can be assessed by a chorionic villous biopsy or a genetic amniocentesis. The former is performed at approximately 10 weeks of pregnancy and a small catheter is passed through the cervical canal or the abdominal wall into the uterine cavity and a biopsy is obtained for analysis. The genetic amniocentesis is usually performed at approximately 16 weeks of the pregnancy. Under ultrasound guidance a needle is passed through the abdominal wall and into the uterine cavity. Fluid is then aspirated and sent to a laboratory for analysis. If a chromosomal anomaly is identified, termination of the pregnancy may be considered. These procedures can result in infection and/or miscarriage.

Bleeding – Vaginal bleeding may occur at any time during the pregnancy. If it occurs early in the pregnancy it may be a sign of a miscarriage. The risk of a miscarriage in the general population is 20-30%. Most miscarriages are associated with lower abdominal cramping and bleeding. If a miscarriage occurs early in the pregnancy, no treatment may be necessary. In some cases, however, a surgical procedure called a dilatation and curettage (D&C) may be required to remove the pregnancy tissue. This procedure is performed in an operating room under anesthesia and involves placing a suction tube into the uterine cavity to remove the pregnancy tissue.

Bleeding can occur later in the pregnancy and can be a sign of a placenta previa, which is a low-lying placenta that covers the cervix or placental abruption, which is detachment of the placenta from the wall of the uterus. Both of these conditions may result in premature labor and delivery. Uterine bleeding can also occur following a delivery. Management of the bleeding during pregnancy could include bed rest, dilation and curettage, transfusion, emergency cesarean section and/or a possible hysterectomy depending on the circumstances.

Infection – Infections may occur in the bladder, kidneys, and the uterine cavity or at other sites during a pregnancy. Infections could necessitate the use of antibiotics. In some cases, a hospitalization may be necessary. In rare cases, an infection in the uterine cavity following a delivery could result in clot formation in the pelvic vessels that may require heparin treatment.

Diabetes – The hormones during pregnancy put a patient at risk for developing diabetes. It is estimated that 4-5% of women develop diabetes during pregnancy. The risk increases with a multiple pregnancy. Initial management may include an adjustment of the diet and possible insulin injections. Diabetes can have a detrimental effect on the fetus. Testing of the fetal well-being may be indicated and may include ultrasound examinations and recordings of the fetal heart rate.

Toxemia – Toxemia or pre-eclampsia is a condition that develops during pregnancy and results in high blood pressure, fluid retention and loss of protein in the urine. It complicates up to 10% of pregnancies. It occurs more frequently in patients during their first pregnancy. Other factors that put a pregnant patient at risk for the development of toxemia include a history of high blood pressure, kidney problems, diabetes or a multiple pregnancy. Initial treatment includes bed rest. In some cases, hospitalization and early delivery may be indicated. In rare cases convulsions may occur as a result of this problem.

Premature Labor – The initiation of labor with uterine contractions generally occurs between weeks 37-42 of the pregnancy. The onset of the labor may be considered premature if it occurs before the 37th week of pregnancy. Premature labor complicates approximately 10-12% of pregnancies. Its incidence is increased in multiple pregnancies. Premature labor can result in premature delivery of an infant unable to survive without some assistance. Premature birth is the single greatest cause of death or disability of newborns. Treatment of premature labor could include a hospitalization with extended bed rest and medical therapy.

Route of Delivery – Most deliveries can be accomplished via the vaginal route. However, approximately 25% of deliveries are accomplished by cesarean section. In cases of a multiple pregnancy there is an increased chance of a cesarean section. A cesarean section is performed by delivering the baby through incisions made in the lower abdomen and the uterus. It can be performed under general, epidural or spinal anesthesia. Following a cesarean section a 2-5 day hospitalization will be necessary. After discharge, recovery may take up to 4-6 weeks. Complications from delivery could include infection, hemorrhage, blood clots in the legs (deep vein thrombosis) or lungs (pulmonary emboli) and other complications that may necessitate additional surgery (i.e., dilatation and curettage, hysterectomy) and/or medical treatment.

Postpartum – Generally, it may take up to 1-2 months following a delivery before a patient is able to return to their

normal activities. The average weight gain during pregnancy is 25-30 pounds. Some women do not return to their pre-pregnancy weight. Some of the other physical changes of pregnancy that may not reverse themselves include the development of stretch marks in the abdomen, change in the shape and texture of the breasts and vaginal relaxation which can cause protrusion of the colon, bladder or intestines into the vagina that could produce symptoms and require surgery. Following the delivery of the infant you may also experience feelings of depression or anxiety.

General Well Being – Pregnancy affects pregnant patients in different ways. While some patients feel fine during the pregnancy, others have complaints of nausea, vomiting, fatigue, loss of energy and may develop various discomforts (i.e., lower abdominal aching, back pain). These symptoms and others may affect a patient's sense of well-being and ability to function at home or at work. Depending on the nature and degree of the symptoms patients may not be able to continue working and therefore experience lost income. Following a delivery, between 50-70% of patients experience the "post-partum blues" characterized by mood swings, depression, fatigue, anxiety, confusion and difficulty with concentration. Less than 10% of delivering patients experience the more severe symptoms of postpartum depression that may necessitate medical intervention.

Time Commitment – Pregnancy lasts an average of 280 days, but may be shorter or longer depending on the circumstances. During the pregnancy the patient will make frequent visits to their obstetrician to monitor the pregnancy. It may be necessary that she remain in the vicinity and accessible to medical care during all or part of the pregnancy.

Mortality Rate – The overall mortality rate associated with pregnancy is 0.01% (1 in 10,000). Some of the reasons for death include: pulmonary embolism, hypertensive disease, bleeding, ectopic pregnancy, infection, stroke and complications from anesthesia.

Psychological Risks - Undergoing this treatment is psychologically stressful. Anxiety and disappointment may occur at any of the phases described above. Gestational Carriers who participate in this treatment are encouraged to meet with a counselor before, during and after a treatment cycle.

There are many complex and sometimes unknown factors, which may prevent the establishment of pregnancy. Known factors, which may prevent the establishment of pregnancy, include, but are not limited to, the following:

1. The intended parent or egg donor's ovaries may not respond adequately to the medications.
2. Technical problems including inadequate visualization or the position of the ovaries may prevent retrieval of the eggs.
3. There may be failure to recover eggs because ovulation has occurred prior to the time of the egg retrieval.
4. Eggs may not be recovered.
5. The eggs may not be normal.
6. The intended parent may be unable to produce a semen sample or the semen sample may be of insufficient quantity or quality.
7. Fertilization of the eggs and sperm to form embryos may not occur.
8. Cell division of the embryos may not occur.
9. The embryos may not develop normally.
10. Embryo transfer into the uterus of the gestational carrier may be technically difficult or impossible.
11. If the transfer is performed, implantation may not result.
12. If implantation occurs, the embryo(s) may not grow or develop normally.
13. Equipment failure, infection, technical problems, human errors and/or other unforeseen factors may result in loss or damage to the eggs, semen sample and/or embryos.

The foregoing general information is based upon the experience and knowledge of the Boston IVF physicians. It is based, in part, upon a review of the literature pertaining to Reproductive Medicine. This information is generally accurate and comprehensive, however, medicine is a dynamic discipline and reproductive medicine in particular is constantly evolving. Estimates of risks factors and the relative benefits of alternative treatment that have been discussed with you represent the best professional judgment of the physicians and caregivers of Boston IVF taking into account your specific needs and circumstances.

PRIVACY

Data from your ART procedure will also be provided to the Centers for Disease Control and Prevention (CDC). The 1992 Fertility Clinic Success Rate and Certification Act requires that CDC collect data on all assisted reproductive technology cycles performed in the United States annually and report success rates using these data. Because sensitive information will be collected on you, CDC applied for and received an "assurance of confidentiality" for this project under the provisions of the Public Health Service Act, Section 308(d). This means that any information that CDC has that identifies you will not be disclosed to anyone else without your consent.

ACKNOWLEDGEMENT OF INFORMED CONSENT AND AUTHORIZATION

I acknowledge that I, the undersigned, am voluntarily participating in the Boston IVF in vitro fertilization and gestational carrier program in order to carry a pregnancy for another person or couple. **The intention following the delivery is to unite the baby or babies with the person or couple who will be the rearing parent/s.**

I have discussed this treatment in detail with the Boston IVF staff in language that I understand. I understand the purpose, risks and benefit of the treatment. **I acknowledge that I have read all pages of this consent form and all of my questions concerning the treatment have been fully answered to my satisfaction.**

It is mandatory that the gestational carrier meet with a lawyer to learn about their legal rights and responsibilities. In addition a contractual agreement between the intended parent/s and the gestational carrier must be in place before the treatment is begun.

I assert that I have answered all questions asked of me truthfully. I assert that I have not provided misleading information for the purpose of becoming a gestational carrier. I assert that I have not intentionally modified, omitted or altered in a misleading manner information that I have provided to Boston IVF, a third party agency, health professionals involved in the screening process or the intended parents. I believe that I am a low risk candidate for sexually transmitted diseases (STDs) such as hepatitis, genital herpes, Chlamydia, HIV (Human Immunodeficiency Virus), etc. I agree to be screened for STDs including HIV and understand that I will be informed of positive results. I agree to inform Boston IVF if I engage or have engaged in any activities that put me at risk for STDs (i.e. new or multiple sexual partners or sharing needles).

I understand that the intended parent person or couple has been screened for sexually transmitted diseases (STDs) such as hepatitis, genital herpes, Chlamydia, HIV (Human Immunodeficiency Virus), etc. Unfortunately, no test or screening process in medicine is perfect or 100% accurate. An infectious disease may escape detection during the screening process and be transmitted to the gestational carrier. Fortunately, it is estimated that such transmission is extremely rare.

During the treatment, I understand I must abstain from sexual intercourse to avoid becoming pregnant with my own eggs.

I realize that the couple also participating in the treatment has other alternatives including adoption or remaining childless.

I am aware that there are other centers in the area that offer this treatment and I have agreed to have the treatment at Boston IVF.

I acknowledge that I have undergone independent medical, psychological and legal counseling that has been met with my satisfaction.

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By consenting to treatment at Boston IVF I accept the responsibilities, conditions and risks involved as set out in this document and as explained by the staff of Boston IVF. In addition, I consent to the techniques and procedures used to accomplish this treatment described in this document and as explained by the physicians and staff of Boston IVF.

I understand and acknowledge that medicine is not an exact science and that in cases of doubt Boston IVF physicians and caregivers will exercise their best professional judgment.

I acknowledge and agree that acceptance into treatment and our continued participation is within the sole discretion of Boston IVF. I understand that should this cycle be unsuccessful, it may be determined that further treatment may not be indicated.

I understand that medical information concerning the treatment may be analyzed and could be used in a publication. In accordance with federal law, identifying information and information concerning the treatment and any pregnancy must be submitted to a national data registry that publishes statistics on treatment outcomes. In order to obtain this information I give Boston IVF consent to contact any physicians who provided care during and after a pregnancy.

In order to obtain required cycle outcome data I give Boston IVF consent to contact any physicians who provided care during and after a pregnancy.

By signing this document I acknowledge that I have had a thorough discussion with the Boston IVF staff. This discussion included information on the risks, benefits, side effects and complications of the treatment. Furthermore, I acknowledge that the discussion with our Boston IVF physician provided sufficient information to allow me to make an informed decision whether or not to proceed with treatment. The discussion with the Boston IVF staff included alternative of not pursuing the treatment.

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By signing this document I acknowledge that Boston IVF has obtained from me informed consent to be a gestational carrier and my partner if applicable is also in agreement.

Witness of Consent Form **(if this form is completed no need to complete notarization form)**

Patient Name (print) **Patient Signature** **Today's Date** (MM/DD/YYYY)

PATIENT- TYPE OF PICTURE IDENTIFICATION: ☐ Driver's License ☐ Passport ☐ Other: _____

ID NUMBER:_____ State/Country:_____ Expiration Date:_____ (MM/DD/YYYY)

Witness Name and Title (print) **Witness Signature** **Today's Date** (MM/DD/YYYY)

Partner Name (if applicable, print) **Partner Signature** **Today's Date** (MM/DD/YYYY)

PARTNER - TYPE OF PICTURE IDENTIFICATION: ☐ Driver's License ☐ Passport ☐ Other: _____

ID NUMBER:_____ State/Country:_____ Expiration Date:_____ Date (MM/DD/YYYY)

Witness Name and Title (print) **Witness Signature** **Today's Date** (MM/DD/YYYY)

Physician Attestation

The above mentioned patient and partner (if applicable) have been informed and counseled by me and other team members regarding the risks and benefits of the relevant treatment options, including non-treatment. The patient and partner (if applicable) expressed understanding of the information presented during the discussion.

Physician Name (print) **Physician signature**

Today's Date (MM/DD/YYYY)

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Notarization Form **(This form is only needed if not able to have witnessed at Boston IVF)**

_____

Patient name (print)

State of:_____ County of: _____

On this _____ day of _____ 20____, before me, the undersigned notary public, personally appeared

_____, proved to me through satisfactory evidence of identification,

which were_____, to be the person whose name is signed on the

proceeding or attached document in my presence.

ID NUMBER:_____ Expiration Date: _____/_____/_____
(MM/DD/YYYY)

_____/_____/_____
Today's Date (MM/DD/YYYY)

_____
Notary Signature

_____
Title

My appointment expires: _____/_____/_____
(MM/DD/YYYY)

_____

Partner name (if applicable, please print)

State of:_____ County of: _____

On this _____ day of _____ 20____, before me, the undersigned notary public, personally appeared

_____, proved to me through satisfactory evidence of identification,

which were_____, to be the person whose name is signed on the

proceeding or attached document in my presence.

ID NUMBER:_____ Expiration Date: _____/_____/_____
(MM/DD/YYYY)

_____/_____/_____
Today's Date (MM/DD/YYYY)

_____
Notary Signature

_____
Title

My appointment expires: _____/_____/_____
(MM/DD/YYYY)