Female Estradiol & Testosterone Hormone General Consent Form

General: Bio-identical hormone pellets are comprised of naturally derived concentrated hormones. These hormones are designed to be biologically identical to the hormones a woman makes in her own body prior to menopause, including estrogen and testosterone, which are made in the ovaries and adrenal glands. Bio-identical hormones have the same effects on the body as one's own estrogen and testosterone did when the woman was younger, without the monthly fluctuations of menstrual cycles.

<u>Birth Control</u>: Patient who are pre-menopausal are advised to continue using reliable birth control while receiving pellet hormone replacement therapy. Testosterone is listed as category X (will cause birth defects) and cannot be given to pregnant women.

Benefits and Risks: I have been told I may have testosterone inserted under my skin to achieve a steady delivery of natural testosterone hormone into my blood system. The potential benefits of testosterone include a possible increase in my bone density, short term memory, protection against Alzheimer's and Parkinson's, increase in energy, libido, and sense of well-being. Testosterone decrease the frequency and severity of my headaches.

I have also been told that I may have estradiol pellet(s) inserted under my skin to also achieve a steady state of estradiol in my body. The potential benefits of estradiol include possible elimination of my mood swings, anxiety, irritability, cardiovascular protection, sleep disturbance, and protection from developing colon cancer, improvement of bone density and brain dysfunction.

Side effects can occur with pellet therapy. In some cases, the body will convert a higher percentage of testosterone to Dihydrotestosterone (DHT). DHT can cause acne or hair loss. Both can be corrected by adjusting the testosterone dose in the subsequent visit and/or prescribing medication that blocks the conversion to DHT.

The estradiol can aggravate fibroids or polyps, if they exist, and cause bleeding. I understand that if I have a uterus and receive estradiol, I will be required to take oral progesterone. Progesterone will offset estrogen's effect on the uterus lining and reduce my risk of bleeding or having a period. *I also understand that it is not unusual to have breakthrough bleeding or spotting though it is a nuisance.* I am to call my provider at ALLURA if breakthrough bleeding or spotting occurs.

Side effects that can occur but are transient or reversible may include:

- bleeding, infection and pain at the insertion site
- lack of effect (from lack of absorption)
- breast tenderness and swelling especially in the first three weeks (estrogen effect)
- increase in hair growth on the face
- transient water retention
- change in voice
- clitoral enlargement

Potential side effects that are to be aware of include:

- increased growth of estrogen dependent tumors
- birth defects in babies exposed to testosterone during their gestation
- growth of liver tumors, if they are already present

Pellet Insertion:

Sterile surgical placement of Estradiol and Testosterone pellets for under the skin is performed by a designated medical professional (Physician or Physician Assistant). Insertion of pellets requires the use of local anesthesia consisting of 1% lidocaine and epinephrine which is deemed necessary by the treating providers. Lidocaine can cause a brief stinging or burning sensation for a few seconds Epinephrine can cause brief shakiness, jitteriness, and heart racing.

Insertion Risks:

I understand that the insertion site may be sore for 2-3 weeks. My level of activity must be minimized for 2-3 days following the pellet insertion. As with any form of implant, there is always the risk of infection, bruising, or bleeding at the insertion site. Certain medications and supplements can thin the blood which can increase bleeding or bruising at the insertion site. We have found that women who return to a *vigorous* exercise program 2-3 days after insertion experience soreness or discomfort for 2-3 weeks. We have also found that infection at the insertion site and/or pellet extrusion can occur when the insertion site is continually rubbed or irritated by the waistline or belt. Instructions on the post-pellet insertion sheet must be followed to avoid such risks and/or minimize discomfort.

Medications:

I understand that progesterone will be prescribed if I have an intact uterus. Progesterone is to prevent the uterus lining from thickening. A diuretic may be prescribed if swelling or breast tenderness should occur after my initial insertion.

Labs and Appointments:

I understand that lab work is required prior to my first appointment and if not available, then the appointment for appointment will be postponed.

I also understand that labs are necessary for management of my hormone replacement, especially during the initial 6-8 months of therapy. Labs are required prior to the initial insertion, 4 weeks after the initial insertion, and 2 weeks prior to each maintenance insertion.

Once my hormone levels are stable, labs will be drawn on a yearly basis. Additional labs may be drawn when deemed necessary by the treating provider or when requested by you, the patient. I understand that I am responsible for any lab charges that may not be covered by my insurance company.

I understand that a booster insertion is required 5-6 weeks after the first insertion. Routine or maintenance appointments are every 3-4 months.

<u>Charges:</u> Office visit charges include an insertion fee, provider fee and hormone pellet fees. The pellet fee varies and depends on the number of pellets I may receive. The precise amount is to be determined by the treating medical provider.

<u>Payments</u>: I understand payment is due in full at the time of services. I understand that the clinic does not accept insurance.

I have read and understand the above. I have been encouraged and have had the opportunity to ask any questions regarding pellet therapy. All of my questions have been answered to my satisfaction. I further acknowledge that the risks and benefits of this treatment have been explained to me and I have been informed that I may experience complications, including one or more of those listed above. I accept these risks and benefits and I consent to the insertion of hormone pellets under my skin. I understand that no guarantee or assurance has been made as to the results of the procedure and that it may not cure any condition that I may have.

Patient PRINTED Name:	
Signature:	
Date of Birth:	Date:
Provider Signature:	Date: