Appendix 1

Patient

Addressograph

Label

Consent for Use of Micronised Vaginal Progesterone Treatment in Women with Early Pregnancy Bleeding and Previous Miscarriage 1/3

◯ I am aware of the recent NICE guideline [NICE] produced by NHS England recommending vaginal progesterone pessary treatment to reduce risk of further miscarriage in women with early pregnancy bleeding ***and*** one or more previous miscarriage.

◯ I am aware this recommendation was based on a large UK-wide medical research trial called the PRISM trial [PRISM].

◯ I am aware the trial showed in women with bleeding in early pregnancy and ***no*** previous miscarriage, progesterone treatment had **no** benefit

◯ I am aware the trial showed in women with bleeding in early pregnancy ***and*** previous miscarriage, progesterone treatment increased the chances of a successful pregnancy. An increase of 2% after one previous miscarriage; 6.6% after two previous miscarriages; and up to 14% after three or more previous miscarriages.

◯ I am aware, overall the study showed, the chances of a successful pregnancy without using progesterone were 72% and with progesterone treatment were 75%.

◯ I am aware that any recommendation from the Scottish Government on the use of progesterones is awaited.

◯ I am aware that the progesterone recommended by NICE and used in the PRISM trial was a micronised (natural) progesterone called Utrogestan®. It is not currently licensed for use in pregnancy.

◯ I am aware that the dose recommended by NICE is 400 mg twice a day, as vaginal pessaries, from the time an intrauterine pregnancy is confirmed by ultrasound scan to 16 weeks of gestation. The manufacturer's recommended dose of Utrogestan® is 200mg three times day.

◯ I am aware this unit can use other micronised vaginal progesterone preparations, such as Cyclogest 400 mg twice a day. The manufacturer's recommended dose is 200mg twice a day.

Patient

Addressograph

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Consent for Use of Micronised Vaginal Progesterone Treatment in Women with Early Pregnancy Bleeding and Previous Miscarriage 2/3

- ◯ I am aware the use of progesterone was considered safe by the PRISM trial as there was no increase in harmful effects for mothers or babies in the womb nor any increase in congenital abnormalities recorded in the babies born to mothers in the trial.
- ◯ I am aware the longer term safety data on the health of the children and subsequently adults exposed to progesterone treatment in the womb will not be known for several years.
- ◯ I am aware the NICE recommendation is to continue the progesterone to 16 weeks of gestation.
- ◯ I am aware all beneficial effects of progesterone treatment were seen by 12 weeks of gestation.
- ◯ I am aware progesterone treatment had no effect when started after 9 weeks of gestation.
- ◯ I am aware there is little data from the trial on the effects, beneficial or harmful, of progesterone treatment between 12-16weeks of gestation.
- ◯ I am aware there are animal studies showing harmful effects on male babies' testes, and other hormones glands (pituitary and adrenal) as well as an effect on brain development with progesterone use between 12-16 weeks. As these effects were seen in animals it is unknown whether this would be seen in human boys.
- ◯ I have none of the following: a history of liver tumours; severe kidney disease; current genital or breast cancer; severe arterial disease (angina or high blood pressure, previous heart attack or stroke); previous or increased risk of blood clots; jaundice related to pregnancy; severe itch related to pregnancy; pemphigoid gestationis; acute porphyria; diabetes; epilepsy; moderate to severe asthma; severe migraines; depression requiring medication; previous reaction to progesterone.
- ◯ I understand some of the side effects include: headache; dizziness; mood change; breast pain; constipation; vaginal soreness; oily discharge from the pessary.

Patient
Addressograph
Label

Consent for Use of Micronised Vaginal Progesterone Treatment in Women with Early Pregnancy Bleeding and Previous Miscarriage 2/3

◯ I am aware smoking and a high BMI (>30) will increase my risks during progesterone treatment.

◯ I am aware that should the pregnancy stop growing once I start taking Progesterone the natural process of miscarrying will be delayed. This may not be diagnosed until the booking scan, around 12 weeks.

◯ I am aware if a miscarriage is diagnosed, that I would need to stop progesterone treatment for 4 days to allow for a natural miscarriage to take place or prior to active management of miscarriage being offered.

◯ My questions about this consent form have been answered.

◯ Gestation by Ultrasound Scan, TV or TA (circle) ……

◯ Number of previous pregnancy losses …….

◯ Bleeding in this pregnancy …….

◯ Name of Micronised progesterone given …….

◯ Dose …….

◯ Duration (ie to 12 weeks or 16weeks) …….

Patient Name: Patient Signature: Date:

Staff Name: Staff Signature: Date: