

SYDNEY CENTRE
for REPRODUCTIVE
HEALTH RESEARCH

The Research Division of FPA Health

06 July, 2000

Dr. Graham Maynard
Chief Medical Officer
Conformity Assessment Branch
Therapeutic Goods Administration
136 Narrabundah Lane
Symeston, ACT, 2609

Dear Graham:

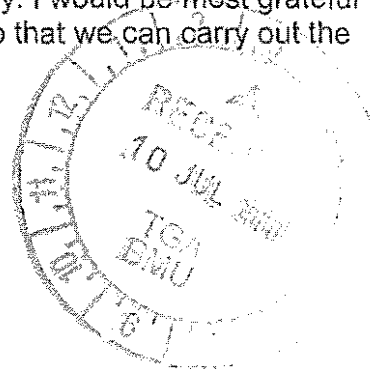
I am attaching two ethics approvals for the STOP Device placement feasibility study. This is basically a training study for the gynaecologists who will be undertaking the phase three study. Unfortunately, I do not yet have Ethics approval nor a signed CTN from the Central Sydney Area Health Ethics Committee for the training study. However, we need the clinical trial notification to be effective by the 12th of July, 2000 because the trainers from the United States are coming to Sydney on that date to supervise two of the gynaecologists who will be participating in the study. I would be most grateful if you could expedite this clinical trial notification so that we can carry out the training next week.

Many thanks for your help. With all best wishes.

Yours sincerely,



Edith Weisberg Director of research FPA Health



10 JUL 2000

Conformity Assessment Branch
Clinical Section

10 JUL 2000

Conformity Assessment Branch
Clinical Section

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18 May 2000

Dr Graham Maynard
Chief Medical Officer
Therapeutic Goods Administration
Conformity Assessment Branch
136 Narrabundah Lane
Symonston ACT 2609

Dear Dr Maynard,

RE: STOP Device

The Ethics Committee of FPA Health has approved the STOP Device placement feasibility study using hysteroscopic visualisation on women who are about to undergo a hysterectomy. We are notifying you under the CTN Scheme that this study is about to start.

The Chief Investigator is s47F [redacted] Other investigators in the study are Dr Edith Weisberg, s47F [redacted] and s47F [redacted]

Yours sincerely,

s47F [redacted]

Ethics Committee
FPA Health

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s47F [REDACTED]

Liverpool Hospital
Locked Bag 7103, Liverpool Business Centre
NSW 1871

Ph: [REDACTED] Fax: [REDACTED]

Dr Graham Maynard
Chief Medical Officer
Therapeutic Goods Administration
Conformity Assessment Branch
136 Narrabundah Lane
Symonston ACT 2609

Dear Dr Maynard,

Reference: STOP Device

The Ethics Review Committee of the South West Sydney Area Health Service, has approved the STOP Device placement feasibility study using hysteroscopic visualisation on women about to undergo a hysterectomy, subject to the following conditions:

- a. That the patient information sheet be amended.
- b. That proof of indemnity from Conceptus is forwarded.

Compliance with these issues has been addressed, and we are notifying you under the CTN Scheme that this study is about to start.

The Chief Investigator is s47F [REDACTED] Other investigators in the study are Dr E Weisberg, s47F [REDACTED]

Yours sincerely,

s47F [REDACTED]

SWSAHS Research Ethics Committee