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ORYGEN
Youth Health

Dear Madam

Find enclosed
TN FORM
CHEQUE FOR $240.00

Kind Regards

[redacted]

Locked Bag 10 (35 Poplar Road)
Parkville Vic Australia 3052
Phone: +61 3 9342 2800
Fax: +61 3 9387 3003

BPREC 2004·026

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TGA THERAPEUTIC GOODS ADMINISTRATION

CLINICAL TRIAL NOTIFICATION SCHEME

Commonwealth Department of Health and Aged Care

Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme

Therapeutic Goods Act 1989

2004/306.

To be used for:

- **initial notifications of clinical trials involving medicines and/or medical devices under the Clinical Trial Notification (CTN) Scheme; or**
- **notification of one or more additional sites for a Clinical Trial previously reported under the Clinical Trial Notification (CTN) Scheme**

THIS IS THE FORM APPROVED BY THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGED CARE

On completion please send this form to the Therapeutic Goods Administration:

Courier address
The Business Manager
Business Management Unit
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

or

Postal address
The Business Manager
Business Management Unit
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Cheques should be made payable to "Therapeutic Goods Administration"

system down
Received EDS
08/07/2004

RECEIVED TGA/FSG
Ent 15314
5 - JUL 2004 A.M. P.M.
B/D 1313.2509
REC 14-58461
$ 240
CODE TA-070-100

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Total Fee Paid	$	Receipt Number	
Enterprise ID Code		TGAIN Number	205650

SECTION 1. TO BE COMPLETED BY THE SPONSOR OF THE TRIAL

1.1 Notification Type *Complete this section for all notifications. Select one box only. If multiple sites are being notified, complete a 'Trial Site Details' page for each site.*

Initial notification of a single CTN site (new trial) ☑ Subsequent notification of a single additional CTN site ☐

Initial notification of multiple CTN sites (new trial) ☐ Subsequent notification of multiple additional CTN sites ☐

1.2 Use of Restricted Goods *Complete this section for all notifications of medicines only.*

Does this trial involve the use of any medicine as an abortifacient or for "post-coital" or "emergency" contraception in women, or the use of a progesterone antagonist or a vaccine against human chorionic gonadotrophin for any purpose? Yes ☐ No ☑

1.3 Sponsor of the trial *Complete this section for all notifications. In cases where a trial is sponsored by an individual, that person's name may also be the enterprise business name. Business details can be provided to TGA via the Enterprise Details Form. If in doubt, contact the Experimental Drugs Section.*

Sponsor name (Enterprise Business Name): MELBOURNE HEALTH – Royal Melbourne Hospital

Enterprise ID Code (If known): RMH - 15314

1.4 Trial details

Protocol Number *(Complete for all notifications; maximum of 20 characters)*: 2004.026

If adding a site, Clinical Trial Number *(assigned by TGA; see acknowledgment letter for previously notified sites. Leave blank if unsure)*:

Title of study *Complete for all notifications. Maximum of 255 characters. Title should indicate the aim of the trial and give a broad description of the trial. Include, for example: phase, indication(s) being treated, main medicines and comparators, use of placebo-control, focus of the study, patient population and any other significant or novel aspects. "A Trial of X" is not adequate. Similar detail is required for device trials.*

A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL OF THE NEUROPROTECTIVE AND ENHANCING EFFECTS OF VITAMIN B12, B6 AND FOLIC ACID AUGMENTATION ON COGNITION AND SYMPTOMS IN EARLY PSYCHOSIS

Trial Type ***Complete for initial notification only of trials involving the use of medicines****; tick relevant box(es) or otherwise describe.*

Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☑ Bioavailability/bioequivalence ☐

Describe if necessary:

This trial

Complete for initial notification only; tick only those boxes which are applicable. Note: For the purpose of this document, gene therapy includes related therapies that overlap with the traditional concept of gene therapy by virtue of the fact that they introduce DNA into somatic cells. For example, modifications to immunisation strategies in which DNA, rather than protein, is used to generate an immune response for the purposes of prevention or treatment of chronic viral infection or as part of cancer treatment, would be considered a related therapy.

involves the use of a medicine ☐ involves the use of a device ☐

is placebo controlled ☑ Is comparator controlled ☐

is also being conducted in other countries ☐ involves gene therapy ☐

Expected trial start date *(Complete for initial notification)* 10 / 08 / 04

Expected trial completion date *(Complete for all notifications)* 10 / 01 / 06

Medicine details

see attached specification sheets.

Complete for all notifications of clinical trials involving medicines. Do not use for clinical trials involving the use of devices only. List the therapeutically active components in formulations being used in the trial. All medicines being trialed should be listed, including comparators. The form has space for four medicines. For more than four, attach details of additional medicines in the same format. For the Active Name, enter the active ingredient name using where possible, the Australian Approved Name (AAN). If no AAN, BAN or USAN has been assigned, a code name (see below) or chemical name must be given. For the Code Name, enter code name/s used currently or previously to identify the drug. For the Dosage Form, enter a primary descriptor for dosage form (eg. tablet, injection) and include a secondary descriptor (eg. sustained release, microsphere emulsion) where necessary, particularly if a new dosage form is the focus of the trial.

1 Active name: Folic acid.

Trade name: | Code name: | Dosage form: capsule | Strength: | Biological origin:

2 Active name:

Trade name: | Code name: | Dosage form: | Strength: | Biological origin:

3 Active name:

Trade name: | Code name: | Dosage form: | Strength: | Biological origin:

4 Active name:

Trade name: | Code name: | Dosage form: | Strength: | Biological origin:

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APPENDIX B1 Specificiation sheet for Vitamin

Customer: Orygen Research Centre

Code: ORCFAB

Product Name: Folic Acid Plus B Softgel Capsule 2004 (1)

Version: 11 March

Size: 4 Minim

Shape: Round

Print: Not Printed

Fill Colour: Yellow to Light Brown Susp.

Shell Colour: Opaque Brown (L40)

Weights (mg): Fill: 235

Shell (approx.): 103

Total: 338

Disintegration Time: Not More Than 30 Minutes

Uniformity of Mass: Complies to Current Therapeutic Goods Order

[redacted]

Regulatory Affairs Manager

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APPENDIX B2 Specification Sheet for Placebo
Customer: Orygen Research Centre

Code: PBOFAB

Product Name: Placebo for Folic Acid Plus B Softgel Capsule 2004 (1)

Version: 11 March

Size: 4 Minim

Shape: Round

Print: Not Printed

Fill Colour: Yellow to Light Brown Susp.

Shell Colour: Opaque Brown (L40)

Weights (mg): Fill: 194

Shell (approx.): 103

Total: 297

Disintegration Time: Not More Than 30 Minutes

Uniformity of Mass: Complies to Current Therapeutic Goods Order

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[redacted]

Regulatory Affairs Manager

Device details

Complete for all notifications of clinical trials involving devices. Do not use for clinical trials involving the use of medicines only. Provide: name (trade name(s), if applicable); description of the device; details of design, composition, specification, mode of action and application; and method of use.

1.5 Trial site details

Complete for all notifications. Submit a Trial Site Details page for each site at which the trial will be conducted. Enter the name and location of the site (eg. name and address of hospital, institution, clinic or practice). For large institutions, the address need not include specific department details unless essential to identify the location or unless the unit /body/practice operates as a separate entity within the campus. In some rare circumstances, it will be appropriate to notify a trial as a composite site trial. For example, a GP-based trial conducted by a general practice network may need to be notified as a composite site trial. The site details should indicate clearly that there are multiple sites involved and include the name, address and contact numbers for the principal investigator. ***A list of all practices (sites) involved should be submitted as an attachment. The ethics committee and approving authority for such a trial must have appropriate authority for all sites. A sponsor intending to notify a composite site for the first time should contact the Experimental Drugs Section if they have any questions regarding the use of composite sites.***

Site expected start: 10/08/04

Site: ORYGEN YOUTH HEALTH

Site address: 35 POPLAR ROAD, PARKVILLE

VICTORIA. Post code 3052.

1.6 Sponsor certification

Complete this section last for all notifications. In the Name field, print the name of the person signing the form on behalf of the company, organisation, institution, body or individual sponsoring the trial. (Do not enter a company or organisation name here - the entity name appears in Section 1.3) In the Position field, state the person's position within, or relationship to, the entity sponsoring the trial.

I, the undersigned, certify:

- all details contained in this form are true and accurate, and all required information and signatures have been included;
- the sponsor of the trial named in section 1.3 of this form is taking overall responsibility for the conduct of the trial;
- the sponsor of the trial has met or agrees to meet all Human Research Ethics Committee conditions of approval;
- the investigator(s) has/have training and experience relevant to the conduct of this trial;
- the participating institution has resources adequate for the proper conduct of the trial;
- the sponsor of the trial has received an undertaking from the investigator(s) to conduct the trial in accordance with the Guidelines for Good Clinical Practice as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations and the National Statement of Ethical Conduct in Research Involving Humans as described in regulation 12AD(c) of the Therapeutic Goods Regulations;
- the sponsor of the trial agrees to report all serious and unexpected adverse reactions to the Therapeutic Goods Administration;
- the sponsor of the trial agrees to conduct the trial in accordance with the Guidelines for Good Clinical Practice as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations and the National Statement of Ethical Conduct in Research Involving Humans as described in regulation 12AD(c) of the Therapeutic Goods Regulations;
- the sponsor of the trial agrees to comply with requests by an authorised person, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 47AA of the Therapeutic Goods Regulations) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations; and
- the sponsor of the trial accepts that information concerning the use of unregistered therapeutic goods may be released to State and Territory regulatory authorities.

Name (Print) [redacted]

Position Director Neurointervention

Signature [redacted] 25/6/14

Phone [redacted]

Fax

SECTION 2. TO BE COMPLETED BY THE PRINCIPAL INVESTIGATOR

The principal investigator is the person responsible for the conduct of the clinical trial at a trial site. In the case of a trial being conducted by a team of individuals at the site, the principal investigator is the responsible leader of the team.

Principal investigator certification

I, the undersigned:

- am the principal investigator at the site shown in section 1.5 of this form;
- agree to personally supervise the clinical trial at this site in accordance with the relevant current protocol(s) and will only make changes in a protocol after approval by the sponsor;
- have received and read the trial protocol and other relevant information;
- have met or agree to meet all Human Research Ethics Committee conditions of approval for this trial:
- acknowledge my obligations with respect to monitoring patient safety, record management and reporting requirements for adverse events;
- agree to ensure that all associates, colleagues and employees assisting in the conduct of the trial are informed of their obligations in meeting the above requirements;
- agree to promptly report to the Human Research Ethics Committee all unanticipated problems and will not make any changes to the trial without Human Research Ethics Committee and sponsor approval, except where necessary to eliminate apparent immediate hazards to subject safety;
- agree to conduct the clinical trial(s) in accordance with the Guidelines for Good Clinical Practice as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations and the National Statement of Ethical Conduct in Research Involving Humans as described in regulation 12AD(c) of the Therapeutic Goods Regulations;
- agree to comply with requests by an authorised person, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 47AA of the Therapeutic Goods Regulations) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations; and
- accept that information concerning the use of unregistered therapeutic goods may be released to State and Territory regulatory authorities.

Name (Print) [redacted]

Signature [redacted] 15/04/04

Phone [redacted]

Fax

SECTION 3. TO BE COMPLETED BY THE HUMAN RESEARCH ETHICS COMMITTEE RESPONSIBLE FOR MONITORING THE TRIAL

This section must be completed by a Human Research Ethics Committee (HREC) that satisfies the following definition of an ethics committee, as set out in the Therapeutic Goods Act 1989, otherwise the notification is invalid :

A committee constituted and operating in accordance with guidelines issued by the National Health and Medical Research Council as in force from time to time and which has notified its existence to the Australian Health Ethics Committee.

HREC certification should not be given until all conditions of approval of the protocol by that HREC have been met. Wherever possible, the certification should be completed by the Chair or Deputy Chair of the Human Research Ethics Committee. Guidelines for the approval of clinical trials by HRECs are located at Chapter 12, The National Statement on Ethical Conduct in Research Involving Humans, 1999 and in the TGA publication 'HRECs and the Therapeutic Goods Legislation'.

For trials of gene therapy and related therapies, the proposal must be approved by all relevant bodies as per the NHMRC Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies.

HREC name: Behavioural + Psychiatric Research Ethics Committee

HREC address: 8th Floor, The Charles Lawrence Building, Grattan Street, RMH, Parkville

Postcode: 3052

Protocol Number approved by HREC: 2004.026

Does the trial for which approval is being given involve the use of gene therapy or a related therapy? (See NHMRC Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies) — Yes ☐ No ☒

If the trial involves gene therapy or a related therapy, has the Gene and Related Therapies Research Advisory Panel (GTRAP) agreed that the trial can be conducted under the CTN Scheme? — Yes ☐ No ☒

Human Research Ethics Committee Certification

I, the undersigned, certify:

- I am a member of the above named Human Research Ethics Committee;
- the above named Human Research Ethics Committee is a properly constituted ethics committee and operates in accordance with the guidelines issued by the National Health and Medical Research Council and has notified its existence to the Australian Health Ethics Committee;
- the above named Human Research Ethics Committee, having regard to the guidance provided by the *National Statement on Ethical Conduct in Research Involving Humans* and, where applicable, the *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies*, has approved the clinical trial protocol identified above and has assumed responsibility for monitoring the conduct of the trial; and
- the above named Human Research Ethics Committee agrees to comply with requests by an authorised person, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 47AA of the Therapeutic Goods Regulations) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations.

Name (Print): [redacted]

Position: Chairperson

Signature: [redacted] 23/06/04

Phone: [redacted]

Fax: [redacted]

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SECTION 4. TO BE COMPLETED BY THE AUTHORITY APPROVING THE CONDUCT OF THE TRIAL

Complete for all notifications. In cases where the Human Research Ethics Committee or Approving Authority for more than one site is the same, it is still necessary to submit a Trial Site Details Page for ***each*** *site. The bodies approving the conduct of the trial at each site need to be declared individually. This requirement also still applies in cases where, for example, an Area Health Service or Hospitals Group may encompass several different institutions.*

The Approving Authority must appoint a person to be responsible for giving approval on its behalf. The terms of approval for the conduct of the trial must be consistent with the Human Research Ethics Committee's (HREC) recommendations and these terms must be no less restrictive than the HREC advice.

Approving Authority name: North Western Mental Health

Address: 7th Floor, Collins Caresse Building, Grattan Street, Parkville

Postcode: 3052

Approving Authority Certification

I, the undersigned

- am authorised to represent the body, organisation or institution at which the above mentioned clinical trial will be conducted and, having regard to the advice and approval of the trial protocol by the Human Research Ethics Committee responsible for monitoring the trial at this site, give approval for this trial to proceed;
- undertake that the use of the drug will comply with all relevant Commonwealth and State or Territory legislation; and
- undertake to comply with requests by an authorised person, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 47AA of the Therapeutic Goods Regulations) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations.

Name (Print): [redacted]

Position: [redacted]

Signature: [redacted]

23 / 06 / 04

Phone: [redacted]

Fax: [redacted]