

# **RESEARCH ETHICS INFORMATION**

## **TITLE OF PROPOSED INVESTIGATION**

AUSTRALIAN NEUROENDOCRINE TUMOUR INTEREST GROUP and REGISTER (ANTIGR)

## **SUMMARY**

This application outlines a proposal to establish an Australian Neuroendocrine Tumour Register. The primary objectives of the Register are to promote national and international collaborative research in conjunction with optimal clinical management of rare neuroendocrine tumours (e.g. carcinoid, gastrinoma, insulinoma and VIPoma). The Register will provide a basis for establishing an Australian Neuroendocrine Tumour Interest Group for endocrinologists, gastroenterologists, oncologists, surgeons and other individuals involved in relevant clinical and research activities.

## **AIMS**

The proposed Register and interest group will have the following aims:

1. To establish a national neuroendocrine tumour register.
2. To support collaborative national and international studies into the pathogenesis, behaviour and clinical management of neuroendocrine tumours,
3. To promote appropriate investigation and management of neuroendocrine tumours.

## **SIGNIFICANCE**

Secretory neuroendocrine tumours comprise an anatomically diverse group of benign and malignant neoplasms. The management of these tumours often involves cross-disciplinary collaboration. Tumour rarity creates significant barriers to both the clinician and researcher. Individual and institutional experience with specific tumour species is often limited to fewer than one incident case per year. To assemble a sufficient number of cases to support effective clinical management and basic research will necessitate multidisciplinary cooperation at a national level.

To achieve these goals the Australian Neuroendocrine Tumour Interest Group and Register (ANTIGR) has been established. ANTIGR operates in multidisciplinary environment seeking the active participation of endocrinologists, gastroenterologists, oncologists and surgeons. Whilst it is proposed that ANTIGR focus on enteropancreatic neuroendocrine tumours (e.g. carcinoid, gastrinoma,

insulinoma, VIPoma) and extra-abdominal carcinoid tumours (e.g. bronchial and thymic carcinoid), the capacity will exist for ANTIGR to interact with, and support, related interest areas such as an acromegaly register.

During September of 1999 a feasibility survey was undertaken to determine the support for establishing ANTIGR. Specialists in key clinical areas have been surveyed to determine the level of support for establishing ANTIGR, the mode of incident case reporting, the preferred organisational structure and governance of the Register, and the ethical implications of the Register. It is concluded from this survey that ANTIGR is feasible and funding is sought in this application to establish ANTIGR.

### **PLAN**

Australian endocrinologists, gastroenterologists, oncologists and surgeons will be provided with a summary of the ANTIGR survey findings, an interest group registration form and a copy of the reporting proforma for submission of incident tumour cases to the Register. Case reporting will be based on provision to the Register (by the treating clinician) of deidentified demographic information, histological diagnosis and the submitting clinicians contact details. Once operational, the governance of the Register will be vested in a multidisciplinary management committee established under the auspices of a relevant specialist society such as the Endocrine Society of Australia. It is envisaged that the ANTIGR secretariate will initially (first 1-2 years) be located at the University of Tasmania (Hobart). The ANTIGR Management Committee will determine the best long term location for the Register as well as other operational issues.

<b>Ethical issues</b>	<b>YES</b>	<b>NO</b>
risk of physical, mental or social harm		<b>NO</b>
the collection of body tissues or fluid samples		<b>NO</b>
the administration of any substance or agent		<b>NO</b>
the possibility of physical harm, pain, or discomfort above the everyday norm		<b>NO</b>
the possibility of emotional distress, anxiety or embarrassment above the everyday norm in the subjects or others		<b>NO</b>
obtaining information which may be prejudicial to participants		<b>NO</b>
obtaining data containing personal information		<b>NO</b>
covert research techniques		<b>NO</b>
secondary use of human specimens		<b>NO</b>

The Register will receive and record de-identified patient demographic data, tumour histological and endocrine biochemical data. The data to be collected is: - tumour histopathological diagnosis, full pathology report excluding any patient identifying details, date at histological / hormonal diagnosis, a one sentence description of the patients presenting complaint, hormonal profile (relevant positive and negative results), patient full date of birth, patient residential post code, clinicians name and contact details and patient identifier code number. As the data does not identify the patient, it is requested that this data be routinely provided to the Register at the treating clinicians discretion without a specific requirement for patient consent. Patient identification will not be possible without contacting the clinician(s) responsible for submission of the de-identified data. Specific research initiatives requiring case identification / contact will require

1. submission to and approval by the Register Management Committee,
2. specific approval by the appropriate Institutional Research Ethics Committee(s),
3. contact with, and permission of the submitting clinician.