

## Psycho Genomics Research Institute Inc

### Proposal for clinical trial Psychogenomics and cancer

It is noted from the article "[The future of genomics in pathology](http://f1000.com/reports/m/4/14/fig-001)" that the recent advances in technology and the promise of cheap and fast whole genomic data offer the possibility to revolutionize not only the discipline of pathology, but also can be an approach towards whole personalized medicine and care outcomes. Further it observes that whole genomic analysis approaches have the potential to replace 85% of the tests in this directory (<http://f1000.com/reports/m/4/14/fig-001> )".

These same recent advances in technology and the promise of cheap and fast whole genomic data offer the possibility of this clinical trial proposal. The opening paragraph reflects one of the significant areas that is actively being explored is the emerging field of psychogenomics. Most simply put, psychogenomics is the study of the effect of genetics on behavior and health. Recent studies in epigenetics imply that we could also define psychogenomics as the study of behavior and health on genetics.

#### **This Research Hypothesis**

*That there is a different and measurable genome RNA expression change and/or impact following a psychosocial/psychological intervention on a randomized group of cancer patients.*

#### **The research approach**

The research proposal is to add genomic array analysis in replicating the intervention of an earlier clinical trial reported under "[Efficacy and Costs of Two forms of Stress management for Cancer Patients Undergoing Chemotherapy](#)". The key to replicating this clinical trial is in its ability to provide a solid foundation for the research proposal and simply adding a genomic analysis. Adding this aligns with the ICGC Cancer Genome Consortium Goal "to obtain a comprehensive description of genomic, transcriptomic and epigenomic changes in 50 different tumor types and/or subtypes which are of clinical and societal importance across the globe".

The genomic array analysis procedure would include obtaining genomic samples at the time of the first Quality of Life Assessment and at the end of each series of chemotherapy. Alternatively the sampling could be taken at the first assessment and at the end of each of the 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> of the series of chemotherapy treatments. The samples be either through blood sampling and/or saliva sampling. Otherwise all other procedures would be replicated in line with the above mentioned trial.

Reporting and related procedures would follow the CONSORT 2010 Statement and guidelines for reporting randomized trials.

Taking on the above procedures would I feel greatly assist the obtaining of the required appropriate Ethics Committee approval

Future directions and opportunities could result from a positive outcome, from a neutral outcome or a negative outcome. These may include:

- (a) generate considerable further research opportunities,
- (b) join in genomics and pathology directions noted,
- (c) presents wholistic personalized medicine medical approaches and opportunities,
- (d) provide clearer evidence of the health mind body connection,

- (e) provide opportunities for wider approaches to incorporate health programs into more levels of society including education programs,
- (f) provide further direction for stress related interventions,
- (g) provide products and services to drive personalized medicine.

Consideration may be given, upon review, to further extend the clinical trial to include:

- costs analysis of the genomics in this environment and potentially towards personalised medicine and care, and/or
- extend the interventions for further out years, say twice per year, and/or
- it may be useful to run a parallel trial with cancer patients who are not undergoing chemotherapy or engage such patients as a comparative group,

Overall, human understanding, interest, attention and knowledge would be greatly enhanced regardless of the outcome of this proposed clinical trial.

### **Some background**

The abstract of the clinical trial to be used reported at [www.ncbi.nlm.nih.gov/pubmed/12065562](http://www.ncbi.nlm.nih.gov/pubmed/12065562) states:

#### **PURPOSE:**

*Professionally administered psychosocial interventions have been shown to improve the quality of life of cancer patients undergoing chemotherapy. The present study sought to improve access to psychosocial interventions during chemotherapy treatment by evaluating the efficacy and costs of a patient self-administered form of stress management training that requires limited professional time or experience to deliver.*

#### **PATIENTS AND METHODS:**

*Four hundred eleven patients about to start chemotherapy were randomly assigned to receive usual psychosocial care only, a professionally administered form of stress management training, or a patient self-administered form of stress management training. Quality-of-life assessments were conducted before randomization and before the second, third, and fourth treatment cycles. Intervention costs were estimated from both payer and societal perspectives.*

#### **RESULTS:**

*Compared with patients who received usual care only, patients receiving the self-administered intervention reported significantly ( $P < \text{ or } = .05$ ) better physical functioning, greater vitality, fewer role limitations because of emotional problems, and better mental health. In contrast, patients who received the professionally administered intervention fared no better in terms of quality of life than patients receiving usual care only. Costs of the self-administered intervention were estimated to be 66% (from a payer perspective) to 68% (from a societal perspective) less than the average costs of professionally administered psychosocial interventions for patients starting chemotherapy.*

#### **CONCLUSION:**

*Evidence regarding the efficacy and favourable costs of self-administered stress management training suggests that this intervention has the potential to greatly improve patient access to psychosocial intervention during chemotherapy treatment*

In The Principles of Psycho-Oncology, it expresses:

While the acute response to catastrophic news is similar in most patients at the time of diagnosis, individuals vary widely in how well or how poorly they adapt to illness over time. Therefore, it is important to recognize factors that predict good or poor adjustment,

enabling early identification of particularly vulnerable individuals. Factors that contribute to adaptation derive from three areas: (1) society-derived factors, which are the social attitudes and beliefs about cancer that impact on the patient; (2) patient-derived factors, which are the personal attributes the person brings to illness; and, (3) cancer-derived factors, which represent the clinical reality of the illness to which the patient must adapt (Table 69.3).

<b>Society-derived</b>
Open discussion of diagnosis versus unrelieved secret
Knowledge of treatment options, prognosis, and participation as partner in treatment
Popular beliefs (does cancer cause cancer)
<b>Patient-derived</b>
<b>Intrapersonal</b>
Developmental stage at time of cancer and meaning of curtailed goals (e.g., marriage, children)
Coping ability, emotional maturity at time of cancer, philosophic, spiritual, or religious beliefs that
<b>Interpersonal</b>
Spouse, family, friends (social support)
Socioeconomic/social class
<b>Cancer-derived</b>
Site, stage, symptoms (especially pain) and prognosis
Treatment required (surgery, radiation, chemotherapy) and sequence (immediate and delayed)
Altered body structure or function, rehabilitation/reconstruction available
Psychological management by the health staff

**Table 69.3**

### Factors that Determine Psychological Adjustment to Cancer.

Psychosocial problems of patients vary across the continuum of cancer. They can be considered in four broad categories: (1) those in patients receiving active treatment with cure as a goal; (2) psychosocial problems patients receiving palliative care, with the treatment of cancer aimed at control or comfort; (3) problems of patients who have completed active treatment and who are considered survivors; and (4) asymptomatic, healthy individuals who have a known enhanced genetic risk of cancer by family history.

[Citation - Holland JC, Gooen-Piels J. *Principles of Psycho-Oncology*. In: Bast RC Jr, Kufe DW, Pollock RE, et al., editors. *Holland-Frei Cancer Medicine*. 5th edition. Hamilton (ON): BC Decker; 2000. Chapter 69. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK20982/>]

Various experiments and clinical research have identified links between psychological, psychosocial, environmental factors and genes which may provide some bases for treatment and prevention of cancers. In psycho-genomics research we take a whole and an integrated approach to prevent and treat cancers offering personalized medicine outcome.

A stress hypothesis, including the epigenetic alterations, was investigated in a study that reported sustained stress environment (SSE) investigations, noted in the table below, by different natures of stress impacts (Karpinets, & Foy, 2005).

The following table shows some of the links between epigenetic alterations and the relationships with the nature of stress (environmental).

Epigenetic alterations	Nature of stress
Hypomethylation of genes known to be involved in cancer	Exposure to Phenobarbital and carcinogens such as cadmium, arsenite, dichloroacetic acid and trichloroacetic acid. Radiation
Damage to DNA structure and introduction of new elements into the DNA	Exposure with nickel, oxidative stress (free radicals), lack of oxygen
Hypermethylation of genes necessary for normal repair of DNA	Chronic inflammation (chronic ulcerative colitis)

Epigenetic silencing of genes	Proliferation under stress
Aberrant methylation	SV40 virus infection Epstein-Barr virus-associated gastric carcinoma

Various factors, including environmental dietary lifestyle and emotional factors can play a large role in the epigenetic control of various diseases. It is becoming apparent that not only —you are what you eat and —man does not live by bread alone, but we also are what we think and what we feel.

### Whole Genomics

Further in the article [“The future of genomics in pathology”](#) it expresses:

“The field of pathology cannot afford to ignore the next generation sequencing innovation because, in the hands of medical pathologists, it has the potential to reshape the fabric of healthcare and make personalized medicine a ubiquitous reality. Another reason is that unlike all others that have advanced the impact of pathology on healthcare, the practice of next generation whole genome analysis can, should, and will replace many current standard pathology practices of diagnosis and prognosis on which proper therapy and disease management rely today, the same best practice standards of pathology that drive considerable proportions of the clinical decision-making process.

The extent of genetic testing suggests that next generation sequencing and whole genomic analysis approaches have the potential to replace 85% of the tests found in this directory, greatly simplifying the network and having the potential to streamline the industry.

We have to train our future doctors to understand the whole genomics analysis pipeline and to be able to interpret medical impact reports that contain genomically informed diagnoses. Pathology programs have to embrace the innovation of next generation genomics by establishing residency training programs that provide all the skills necessary to interpret and act on whole genomic data. This is already happening now.. We are moving fast toward definitions of the core competencies in genomics and personalized medicine, and it is likely that, within two years, it will be required that all residents in pathology demonstrate proficiency in these areas.”

From the eBook [“Mind Body Medicine and cancer”](#):

It has been found that the environment, stress, disease and even the food we eat can change our DNA in measurable ways—and that these changes can be handed down to our children. Different genes that are known to be involved in the appearance and progression of cancers have been found to be affected by these types of epigenetic changes. Many of these changes have been related to environmental, foods and various lifestyle choices. Epigenetic research has also begun to focus on how it may be involved not only in the cancer itself, but how cancer begins<sup>38</sup> and is dependent on environmental and nutritional factors, how epigenetic factors can affect tumor spread and recurrence and how epigenetic factors can change the risk or likelihood of a particular disease or condition.

A recent paper —Beyond clinical phenotype: The biologic integratome stated —Beyond the clinical phenotype, the biological *integratome* theoretically has the potential to transform human disease classification, illuminate our understanding of drug action, and set a new dawn for personalized medicine The integratome refers to the complete set of genetic and epigenetic information about an individual combined with information about their responses to all forms of stressors. The idea is to personalize medicine and to

recognize that each individual responds differently to therapeutic interventions. Part of the response is genetic; part of it has to do with the total life experience of an individual incorporating all phases of experience—physical, mental, emotional and spiritual.

### **About Psycho Genomics Research Institute Inc**

Psycho Genomics Research Institute Inc, previously Power Thinking International Incorporated. We are a NSW registered charity, a registered Tax Concession Charity and Deductible Gift Recipient for Australian Tax purposes.

Consultants, sponsors and advisers have included Professor Avni Sali, MBBS PhD FRACS FACS FACNEM, *Dr Richard Eek*, Medical Oncologist / Conjoint Lecturer, Border Medical Oncology / University of New South Wales, MBCHB MMED FCP FRACP; *Professor David Bowtell PhD*, Director, Research. Research Division, Peter MacCallum Cancer Centre; *Susan Forrest (CEO)* and Melinda (Genotyping Manager); *Dr Debra Foley BSc PhD*, ORYGEN Research Centre, Head of Applied Genetics Research Unit, Australian Genome Research Facility Ltd; Roberts, Psychologist; Don Power, Power + Executive Coaching; Gayl Chivers Inspirational Life; Charles Sturt University; Gloria Jeans Albury Wodonga; Peard's Nursery, Albury; Peter Chandler, Chartered Accountant; Albury Wodonga Cancer Support Group; Just Foods Albury, Albury Apartments, Petrea King Quest For Life Centre, Canberra Plan Printing, and over 500 attendees at our workshops and discussion groups in and around Albury Wodonga.

We note that as almost all cancers are gene based, the evidence from earlier research indicates that there is potentially a very positive adjustment and/or survival outcome through psychological/ psychosocial interventions. Positive survival/adjustment outcome, therefore, may be reflective of changes in gene expression and/or gene mutation impacts that reflect on cancer prognosis and outcomes. Thus, in comparison to current cancer screening, identification of abnormalities and treatments, our research will focus on genomics. Our research will include aspects of the complete DNA material, including genes and their functions.

Our research findings are further explored in the research findings paper "[Stressors, psychogenomic pathways and cancer - Identifying psychological, psychosocial, physiological, environmental & genomic pathways to prevent and treat cancers](#)"

### **About Theo Richter**

I came to this research from several life experiences.

Firstly, my father had a double brain haemorrhage when he was around 92. After being taken off life support, he came back fully functional in all aspects with some minor loss of his native Dutch language. Then a few years later, after he took care of mum before she passed away, he passed away as peaceful as ever in front of me in hospital with rosary entwined in his crossed fingers. It registered, sent questions and a search going inside of me on the human potential. That human potential, in this case, showing up for me that we can come back from the brink of death and yet also call it a day so effortlessly.

Secondly, my brother-in-law to my youngest sister died of melanoma. They tried everything, they planted in me the question they often asked, there has to be another way out of this. Several members of my wife's family have died from cancer and other family members have been treated for different cancers.

I was the inaugural Chairperson of the Albury Wodonga Cancer Council Relay for Life. The team did a great and successful job in what were then some difficult circumstances. At the

end of it I asked if the Council were doing any research on the power of the mind and cancer. They said they didn't. So we started our research program. This continues and included setting up the charity, and tax deductible organization, set up the website (<http://psycho-genomics.com>), establish and undertake an online survey, conducting community workshops attended by over 500 people over 8 weeks, undertaking a review of cancer related clinical trials, reviews, and other material and write the research paper and author "Mind Body Medicine and cancer".

Billions of dollars have been spent on finding outcomes for cancer cures and treatments, yet none appear to have done this conclusively. More needs to be done and explored in areas not yet included. My drive continues towards finding how we can overtly and openly manage, manipulate, control or drive (or other appropriate human mechanisms) our own personalized health and wellbeing.

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**Current employment:** Executive Leader, Technical Leader and internal workplace and Executive Leadership Coach, Australian Taxation Office (20 years)

**Previous employment activities:** 20 years of previous commercial experiences include as a store manager, supervisor and franchisees leader in an international fast food chain; as operations and store manager with a large national retailer; as computer retailing, service and training franchisee owner operator.

**Qualifications and Education:**

- Associate Certified Coach (ACC ICF)
- Vocational Graduate Diploma of Ontological Coaching. (RTO)
- Certificate of Coaching Skills, Executive Coach, Intuitive Coach, Coaches Toolkit and Workplace Coach Training (Results Coaching System)
- Graduate Certificate in Leadership in Education and Training (RPL - Victoria University)
- Graduate Certificate in Management (RPL - Victoria University)
- Master of Taxation (University of NSW)
- NLP NS Trainer

**Associations**

- Member of International Coaching Federation (ICF)
- Fellow of the Institute of Public Accountants (FIPA)
- Corporate Tax Advisor - Australia Tax Institute (CTA)

Signed

Theo Richter