Access and Benefit Sharing

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Towards Access and Benefit-Sharing Best Practice

Pacific Case Studies

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Cover photos

The photos are of a Raui marine protected area in the Cook Islands. One of the roles of the Koutu Nui is to educate and enforce the respect of Raui areas.

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The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (hereafter Nagoya Protocol) to the Convention on Biological Diversity (CBD) was adopted in Nagoya, Japan on 29 October 2010. The Nagoya Protocol supplements the CBD and supports the further implementation of one of its three main objectives: the fair and equitable sharing of benefits arising out of the utilization of genetic resources for the purposes of research and development. The Protocol will enter into force 90 days after the deposit of the 50th instrument of ratification or accession by a Party to the CBD.

The Nagoya Protocol is intended to create greater legal certainty and transparency for both providers and users of genetic resources by establishing core obligations for its contracting parties, including:

- Providing fair and non-arbitrary rules and procedures.
- Domestic measures for prior informed consent and mutually agreed terms.
- Provisions for issuance of a permit or equivalent when access is granted
- Establishment of an international ABS Clearing-House Mechanism which registers national permits and converts them into internationally recognised Certificates of Compliance.
- Taking legislative, administrative or policy measures to ensure that benefits arising from the utilization of genetic resources and/or traditional knowledge associated with genetic resources (and subsequent applications and commercialization) are shared in a fair and equitable way with the Party providing such resources (and with indigenous and local communities where appropriate).
- Creating conditions to promote and encourage research contributing to biodiversity conservation and sustainable use (representing the other two main objectives of the CBD).
- Taking compliance measures to ensure that users are meeting the regulatory requirements of provider countries when accessing genetic resources for their utilization (adapted from CBD Secretariat, 2011).

Importantly, the Nagoya Protocol also addresses traditional knowledge associated with genetic resources with provisions on access, benefit-sharing and compliance. Parties to the Protocol are to take into consideration indigenous and local communities' customary laws, protocols and procedures with respect to traditional knowledge associated with genetic resources.

The Nagoya Protocol will require a number of mechanisms to assist with implementation, including the establishment of national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points for information, grant of access, or cooperation on issues of compliance. The Access and Benefit-Sharing Clearing House Mechanism (CHM) also provides a platform to share information such as domestic regulatory ABS requirements, to display permits issued at the time of access as evidence of prior informed consent and the establishment of mutually agreed terms, or to share information on NFPs and CNAs.

This report is intended to support implementation of the Nagoya Protocol, by highlighting the experiences of a number of biological research activities in the Pacific, the permissions sought by the researchers, and any agreements established for the sharing of benefits relating to the utilization of genetic resources and associated traditional knowledge (where relevant).

Pacific Case Studies

Four case studies from the Pacific were selected to demonstrate some of the attributes that would be expected of 'best practice' biological research (often broadly described as 'biodiscovery') access and benefit-sharing agreements, as well as the challenges that stakeholders face in seeking to achieve the fair and equitable sharing of benefits. Information was collected from publicly available sources, websites, requested from the researchers or parties to the agreement, government authorities and in some cases through the conduct of interviews with key stakeholders. Field trips were also conducted to a number of countries to verify the existence of benefit-sharing agreements, specific tangible benefits (e.g. facilities and technologies), and compliance with permits and laws where they exist. An examination of alignments between the ABS agreement in each case study and the main principles of the Nagoya Protocol is made. Comparisons can also be made between the benefits decided or provided, and the monetary and non-monetary benefits listed in the Annex of the Nagoya Protocol. Each case study is structured such that different elements can be compared and contrasted between cases. Key challenges and lessons are provided in summary to each case study.

From the demonstration of these case studies it is hoped that lessons will be derived that can be applied to the development of national systems for ABS. Any issues identified are also highlighted such that Pacific countries considering implementing the Nagoya Protocol can be mindful of potential implementation challenges and also benefits that an international regime on ABS would provide. Last, the case studies may be useful as a reference for biodiscovery researchers seeking to comply with the principles and terms of the Nagoya Protocol.

Case 1: The International Cooperative Biodiversity Group (ICBG) 'Sustainable Use of Biodiversity in Papua New Guinea' Project

The International Cooperative Biodiversity Groups (ICBG) are managed by the John E. Fogarty International Centre of the US National Institutes of Health (NIH). They represent a "unique effort that addresses interdependent issues of biological exploration and discovery, socioeconomic benefits, and biodiversity conservation" (NIH, 2012). The ICBG have provided grant funding for a collaboration between the University of Papua New Guinea (UPNG), the University of Utah and University of Minnesota, on the conservation and sustainable use of biodiversity in Papua New Guinea. The overarching goal of the ICBG project is to improve human health and well-being through a set of programs dedicated to the description, assessment, utilization and conservation of biodiversity in PNG. This project has been running for 8 years and is in its second cycle of grant funding from the Fogarty International Centre.

The biodiscovery and research activities

The biodiscovery activities are broad in scope and are described in the memoranda between the partners as 'a scientific research collaboration to investigate the biological chemical and medicinal properties of the biodiversity of Papua New Guinea and to establish economic value thereof.' The primary activity of drug discovery focuses on HIV and tuberculosis, with source organisms sought from terrestrial endophytic microbes and marine invertebrates. The project seeks to identify new therapeutic medicines from either validated traditional medicines or developed traditional medicines.

The project also has a secondary emphasis on documentation and preservation of traditional medicinal plant knowledge in PNG. Towards this, the ICBG supports the PNG Ministry of Health's Traditional Medicines Taskforce and student theses to provide pharmacologic validation and chemical standardisation of medicinal plants, and the identification of novel bioactive molecules (University of Utah, 2010).

A third area of research activity focuses on conservation and biodiversity in a forest dynamics plot established in Wanang, PNG. The plot has been used by the collaborators for analysis of forest dynamics, carbon sequestration, climate effects, botanical surveys, ecosystem studies including analysis of soil microbes and small plants.

Conformance with ABS legislation and permits

In 1998, the PNG Department of Environment and Conservation (DEC) established the PNG BioNET (initially called the PNG Biodiversity Institute): an organisation of PNG scientists and government officials advisory to the DEC on assessment, use, and development of PNG biological resources. The ICBG collaboration was influential in bringing together stakeholders in workshops to discuss issues relating to access and benefit-sharing, and the role of the PNG BioNET (Matainaho, Pers. Comm, 15/12/11).

The Draft PINBio Act seeks to establish PNG BioNET as the national clearinghouse for all research permits and access to PNG's genetic resources. Despite being a draft law, there is a formal permit procedure in place through PNG BioNET and DEC.

Permit procedures followed by the ICBG include the following:

- A research proposal is submitted to DEC (by both PNG and foreign researchers).
- Proposal is registered with the Wildlife Enforcement Branch of DEC and the PNG BioNET Technical steering committee (made up of several relevant government department representatives) reviews the proposal and endorses or denies it.

- Considerations include that the proposal must be consistent with the CBD and develop an MOU fostering scientific collaboration to build PNG's scientific and research capacity. The MOU should specify joint patents/publications, recognize PNG's sovereignty over natural resources, consider local values and practices.
- Recommendation by PNG BioNET then is submitted to DEC for approval. This is subject to DEC obtaining approval from research committees at the relevant provincial government level and consultation with local government.
- Approved biological research activities are registered by PNG BioNET Secretariat and DEC who then issue permits.
- Export permits are also required from Agriculture/Quarantine for plants, and from DEC for marine samples.
- Where samples are sought from locally owned land, PIC must be sought from the owners/Chiefs. If they approve the research they should be involved in their activities. This might include payments for local guides and research assistants and basic taxonomic training. Further to this, the ICBG has a standard operating procedure for local PIC and benefit-sharing when conducting collecting activities (described below).

Access/prior informed consent procedure followed
For obtaining local prior informed consent (and sharing benefits with local people), the ICBG project has a standard operating procedure including the following steps:

- Reconnaissance visits are conducted and permission sought in advance of collection activities. Translators are used where relevant to discuss the potential research and collection activities in local dialects.
- Villagers are hired as research assistants (approximately K10/day or $4.70 USD)[1] and fees paid to stay in the village accommodation (often with families, approximately K35/day or $16.45 USD per person). Food supplies are donated to feed families and field assistants. Sometimes medicines are also donated.
- An appreciation fee can be paid to the chief, community leaders or land owners of approximately 1500 USD per trip. This can be given as cash or (preferably) through the purchase of supplies (e.g. water tanks, building materials).
- A list and numbers of plants collected are provided to community. An explanation of potential direct and indirect benefits (education, royalty payments to people or conservation trust, global health/conservation understanding) is made.
- Community leaders informed of risks (e.g. community conflict or discord, cultural erosion through infusion of money, unrealistic expectations of rewards that do not arise, violation of spiritual values of plants or traditional knowledge).
- Offer of preventative medicine workshop to community and assessment of health needs of the community.
- Offer of economic valuation of their forest area.
- May inform communities of potential royalty benefits – 25% of those received by UPNG to the community where the 'hit' arises (discussed in more detail below).
- Local villages are provided with conservation outreach material and possible workshops run by partner NGOs.
- When permission granted a $300 USD donation made to school fund of the village, including support for school costs to financially disadvantaged children of approximately K50-100 per child (or from $23.50 to 47 USD).
- Prompt feedback should be provided to the collection areas, including plant survey data, economic valuation results, and assay data if anything significant is identified

[1] 1 PNG Kina is worth 0.47 US dollars (3/9/2012). Weekly minimum wage is 37.4 Kina per week (approximately $17.50 USD). Therefore the rate paid to research assistants by the researchers is at or above the minimum wage, which is rarely achieved in practice in PNG particularly in rural areas (US State Department, 2009).

which may lead to development. Community representatives are invited to ICBG annual meetings with assistance for travel and lodging provided.

- A record of the dates and locations of visits, permission granted, people hired, services paid for, gifts and donations made (i.e. all above activities) should be kept, dated and signed by the ICBG team leaders. Procedures not achieved should also be noted. These records are reported to the Fogarty International Centre annually.

Consultation with relevant parties

The ICBG researchers have had several years of collaboration with a wide range of relevant stakeholders, going back prior to the 8 years of research activity in the recent ICBG project phases. Initially the ICBG funded workshops helped draw together various government and non-government actors from DEC, the Attorney General's Office, the Forest Research Institute (FRI), UPNG, NGO partners, and others towards the development of what is now the PINBio Act. This demonstrates that from the beginning the ICBG partners have made considerable effort towards ensuring there are transparent access and benefit-sharing procedures in place in PNG and that they comply.

Through their PIC standard operating procedure the researchers engage directly with indigenous and local communities prior to, during, and after collection activities (noted above). Two NGOs, The Nature Conservancy and Conservation Melanesia have been involved in the collaborations of the ICBG and provide outreach to communities. The ICBG also provides medical outreach as described above.

The ICBG research team have also worked together with the Smithsonian Tropical Research Institute (STRI) towards the establishment of a 50 hectare nature plot in Wanang, PNG in 2008 (involving the New Guinea Binatang Research Centre, the PNG Forest Research Institute, the University of Minnesota, Harvard, the Smithsonian Institution Global Earth Observatories – SIGEO, the Smithsonian Centre for Tropical Forest Science - CTFS, and several PNG government agencies). The research team has been working in partnership with the Wanang community landowners towards the long-term protection of the forest and maintenance of subsistence livelihoods. The research represents the first large-scale study of biodiversity and carbon dynamics in PNG, fostering collaborations with local communities and PNG scientists (STRI, 2008).

Terms of benefit-sharing agreements

There are memoranda of understanding dating to 2002, renewed in 2008, between the University of Utah, University of Minnesota and the University of PNG, establishing terms of research collaboration between these parties. The memoranda make commitments towards compliance with the CBD and UN Convention on the Law of the Sea, notably that it is recognised that PNG has jurisdiction over its biological resources. The agreement describes commitments towards improving education and scientific infrastructure in PNG; contributions towards the conservation and sustainable use of biodiversity; transfer of knowledge, expertise and technology related to the collection, storage bioassay-guided isolation and characterisation of natural products and therapeutic agents.

In the event of commercialisation, the agreement specifies joint-promotion of intellectual property and a percentage of total income derived from the commercialisation of transferred biological resources (including income derived from use of resources by third parties under license arrangements).

The terms of collaboration are divided into two phases. The first phase deals with initial collection activities and investigations. This phase specifies joint research applications between Utah (and collaborative partners) with UPNG, encouragement of joint fieldwork, analysis by bioassay at both Utah and UPNG, and co-authored publications. When

conducting taxonomic identification of species, duplicate plant vouchers are deposited with UPNG and the FRI for their own scientific use.

Phase two refers to the development of lead compounds and materials identified in phase one towards commercial products. The trigger point for phase two is the application for patent coverage by Utah and UPNG on compounds or genetic constructs from PNG genetic resources. Separate agreements are made for each product entering phase two development, and even for synthetic materials for which the natural product provided a key development lead. The agreement notes that all scientists and individuals who contribute to the identification and discovery of new therapeutics, molecular probes, genetic constructs or pharmaceuticals will be compensated in terms of royalty proceeds arising from patent agreements. Compensation also includes milestone payments at key stages of clinical development. If a natural product is required for sourcing towards commercial agents, then PNG will be the first source of the raw material. Also, if indigenous knowledge is involved in the collection of samples or development of commercial agents, then suitable recognition would be given to their intellectual property, including suitable recompense and patent inventorship where appropriate. The memoranda specify that any licenses granted to agents or companies on any patents arising from this collaboration must abide by the terms of the agreement (University of Utah-UPNG, c2002; University of Utah, University of Minnesota and UPNG, c2010).

Summary of monetary and non-monetary benefits
The following table summarises some of the monetary and non-monetary benefits derived from the ICBG collaboration so far.

Monetary	**Non-monetary**
Sustaining contributions to the UPNG herpetarium and National Forest Research Institute herbarium in Lae.	Education and training: 65 UPNG student projects, 39 of them resulting in completion of degrees or certificates (undergraduate, honours, masters).
Supported collection expeditions, travel costs and field supplies, infrastructure (air conditioning, computers etc).	Workshops and support towards development and implementation of research permits, PIC and benefit-sharing procedures in PNG.
In the past 8 years of activity approximately $350,000 USD has gone to herbaria activities, students and infrastructure (most to UPNG). Has provided equipment and supplies for the bioassay lab for Honours and Masters students at UPNG pursuing diverse topics.	Expanded opportunities for PNG researchers through access to grants, fieldwork, updated laboratories and equipment.
Considerable milestone payments have been made to UPNG under the MOU (>$100,000 USD) with the most substantial payments made in 2004	17 co-authored publications (UPNG-Utah/Minnesota), and three patents (1 current, 2 pending).
The Wanang nature plot activities provides opportunity for development of PNGs scientific capacity through postgraduate fellowships (funded by an external philanthropic donation of USD $250,000).	Biodiversity conservation related scientific knowledge as described below.

Tangible impacts derived from these benefits
Apart from the tangible impacts described above for UPNG student completions and support for UPNG laboratories and herbariums, there are considerable scientific achievements from research conducted at the Wanang nature plot. The pilot Wanang study resulted in 12136 herbarium specimens deposited in local herbariums representing 5519 plants and at least 536 species collected and identified. An online checklist of New Guinea woody plant genera has been produced including 1073 taxa, their respective families, growth habits, and status as endemic, native, introduced, or cultivated plants (STRI, 2008). Related to these have been a number of ICBG-funded student training/projects on woody plant identification and enumeration, and herbivorous insects, as well as data collection on forest carbon dynamics. Other important medical discoveries of benefit to PNG are described below.

Products of the research and development
There have been a number of products of the many R&D projects undertaken in this ICBG. These include:

1) A predecessor collaboration, between UPNG and a research consortium headed by the University of Utah, funded by the US National Cancer Institute, helped lay the foundation for the ICBG and demonstrated good partner intentions of the University of Utah for the ICBG collaboration (Barrows, Pers. Comm, 8/6/12). This antecedent work led to the discovery of HTI-286. HTI-286 is a synthetic experimental anticancer drug recently in phase II clinical trials for the treatment of lung cancer (and with potential prostate cancer application). The lead structure for the development of HTI-286 was the sponge tripeptide hemiasterlin, which was collected in PNG under the auspices of the ICBG collaboration (Andersen and Roberge, 2005). Considerable milestone payments have been made to UPNG under the MOU (>100,000 USD) with the most substantial payments made in 2004. This money was used to build laboratory space on the main Waigani campus of UPNG. HTI-286 has not yet completed clinical trials.

2) A project conducted at the ICBG supported UPNG BioAssay lab and Herpetarium has led to the development of new antivenoms for the lethal Papuan taipan snake (*Oxyuranus scutellatus*) (see figure 1). The research was conducted by Mr David Williams from the Australian Venom Research Unit and Mr Owen Paiva, a UPNG student studying his masters. The antivenom has passed pre-clinical toxicity testing, is under GMP production at an institute in Costa Rica, and is ready for clinical trials. The new antivenom is reputed to have superior stability, shelf life, and is considerably cheaper to produce than existing taipan antivenoms. Following this success, the researchers are working on another antivenom for the Small Eyed snake (*Micropechis ikaheka*) which will soon be ready for production (University of Utah, 2010).

3) A traditional medicine selected for assessment and development by the Traditional Medicines Taskforce, headed by UPNG researchers, was a topical analgesic and anti-inflammatory preparation manufactured by a Papua New Guinean woman, Minnie Bate (see figure 2). Ms Bate uses a vegetable oil extract and a species of fresh or dried/stored lichen (subsequently identified as *Parmotrema saccatiboum* and *Pyxine cocoes*) which was pharmacologically examined by UPNG and Utah researchers. The data collected chemically validated Ms Bates' traditional medicine and has supported her marketing and product distribution to other countries such as Japan. Additionally, the empirical results of the study have led to adjustments in the strength of the preparations to improve efficacy, and reformulation to use coconut oil instead of vegetable oil (University of Utah, 2010).

Figure 1: The UPNG Herpetarium.[2]

Figure 2: Ms Minnie Bate formulating Traditional Medicines[3]

Challenges and lessons

The permitting procedures for access and prior informed consent are extensive and intended to ensure that informed permission is obtained by as many stakeholders as possible. This decreases the likelihood that there will be parties that are excluded or that have objections to the research activities once they have begun. The only evident drawback relating to these access procedures are that they may be quite time consuming.

According to the researchers involved (Prof. Matainaho and Prof. Barrows), and reports in response to queries by the Fogarty International Centre, there have been few issues related to access and prior informed consent. Occasionally documentation of activities in the field has been limited (e.g. missing dates, names of people involved, amounts paid), and on occasions there has been limited information exchange (e.g. explanation of taxonomic findings or similar). These are likely affected by the challenges of working for prolonged periods in remote areas through translators, while trying to meet multiple objectives.

The project takes a comprehensive approach to benefit-sharing at all stages of the research and development process (from access to potential commercialisation). This ensures that there are tangible benefits in terms of training (at UPNG and in communities), small

[2] Source: http://www.pharmacy.utah.edu/ICBG/pdf/student_achieve.pdf (Acc. 6/6/12, used with permission).
[3] Source: http://www.pharmacy.utah.edu/ICBG/news.html (Acc. 6/6/12, used with permission).

monetary benefits for communities, joint publications, and educational opportunities for PNG researchers, amongst other things. The agreements and procedures ensure benefits for UPNG as the main collaborating institution in PNG, but also local people who are involved in the project. By ensuring benefits are shared at multiple stages of the R&D activities, stakeholder satisfaction is likely to be higher than if the project had adopted solely an 'end product' benefit flow (e.g. a royalty upon commercialisation). Royalties upon commercialisation often do not eventuate unless the bioactive molecules identified as useful are also found to be safe. This can take decades of analysis through clinical trials and considerable investment – often millions of dollars.

Case 2: The Cook Islands CIMTECH – Koutu Nui Agreement

Dr Graham Matheson, a medical researcher brought up in the Cook Islands, observed the traditional application of plant-based extracts for treatment of bone fractures and other medical and therapeutic applications, by members of his community, friends and family. Matheson later trained as a medical practitioner and in 2000 undertook research towards his PhD at the Orthopaedic Research Laboratories at UNSW. In 2003 he developed a proposal for the investigation and potential commercialisation of medical and therapeutic remedies based on plant extracts and associated traditional knowledge and took it to the Cook Islands. Dr Matheson reached a benefit-sharing agreement with the Koutu Nui – a lawfully recognised assemblage of chiefs charged with overseeing the cultural impacts of modern lawmaking (Sissons, 1998). Dr Matheson's research led to the establishment of the company 'CIMTECH' which incorporates the Koutu Nui as a shareholder.

The biodiscovery and research activities

Dr Matheson undertook a study of pharmacological effects of traditional Cook Islands methods of bone healing at the UNSW Orthopaedic Research Laboratories. He conducting cell culture experiments, testing on small mammals, fractionation and isolation of active ingredients, and quantification of the effects.

This research, which initially focused solely on bone and wound healing, has also led to a number of practical cosmetic applications. Consequently, Matheson and CIMTECH have filed for a number of patents[4] covering three distinct areas: bone and cartilage treatment, wound healing, and skin care treatments. For the promotion of wound healing and the treatment of skin disorders, the CIMTECH patents list bio-active extracts of one or more of *Vigna marina* (Burm.) Merr., *Cocos nucifera* L., or *Terminalia catappa* L. in compositions and extracts providing therapeutic and cosmetic uses. For the promotion of healing of bone and cartilage injuries, the patents claim a bioactive extract of *Hibiscus tiliaceus* L. and therapeutic compositions related to this.

Conformance with ABS principles, legislation and permits

Initial engagement for 'research access' with the Cook Islands government began in 2003. Pilot study funding was sought from the Ministry of Health (Peri Vaevae, Roro Daniel and Denise Rairi) in March 2003. They advised that Dr. Matheson seek aid funding for the project from other sources. Representatives of the Ministry of Culture, the Aid Coordinating Committee (Edwin Pitman) and the Ministry of Finance and Economic Development were also approached by Dr Matheson and Dorice Reid (cMay 2003). Having no objections to the research and expressing no interest in involvement in the research, they also suggested external grant funding to support it. No regulations, permissions or permits were advised for the project – A National Research Policy and process for obtaining research permits was established later in 2006. With no other options, Dr Matheson personally funded the pilot studies with some resourcing from UNSW (Matheson, pers. comm. 2012). While the Cook Islands have since established a research permit requirement for foreigners, Dr Matheson would also be exempt from this, given that he is a Cook Islander.

[4] Filed in Australia in May 2009 (and with the PCT in November) "Methods and compositions for the promotion of wound healing" AU 2009901952; Filed in Australia in December 2009 (and the PCT in May) "Methods and composition for bone and cartilage repair" AU 2009906034; Filed in Australia in November 2010 "Methods and compositions for the maintaining and improving the health of skin" Australian Provisional Patent No. 2010904905; and filed in Australia in November 2010 "Methods and compositions for the treatment and prevention of skin disorders" Australian Provisional Patent No. 2010904906

Access/prior informed consent procedure followed
Matheson also sought prior informed consent from an appropriate and lawfully recognized indigenous representative body – the Koutu Nui (established in written law in 1972 under an amendment to the 1968 House of Ariki Act) – prior to any research activity. The intended research was informed in detail in submissions to the Koutu Nui. In (cMarch) 2003 the Koutu Nui executive met, returned with questions, and then reconvened at an annual general meeting in June 2003 to unanimously approve the project.

The Koutu Nui provided a bottle of Vairakau Ati prepared by Taunga Ngateina Ngapare and handed to Dr Matheson by Dorice Reid (cMay 2003). This arrived too late to be used in the pilot research, but was felt to be extremely important to the Koutu Nui that they hand over the Vairakau Ati as proof of their commitment. This is also reflected in the wording of the Deed of Confirmation and Assurance, the Koutu Nui shareholding, and share in ownership of IP (CIMTECH is the patent assignee, of which the Koutu Nui are a shareholder).

The Taunga of the Koutu Nui did not provide the TK/GRs used, but rather Graham developed his own formula based on various pieces of information from family and friends, with their approval. Graham obtained plants from within 100m of his home. A solution derived from the plants was carried to Australia for testing (in order to avoid issues relating to the importation of plant materials through customs and quarantine into Australia) (Matheson, pers. comm, 7/3/12).

Consultation with relevant parties
As noted in the above sections, Dr Graham Matheson consulted both government and the Koutu Nui as deemed to be the primary stakeholders to engage. Notably, Dr Matheson's submissions to the Koutu Nui were also communicated to a number of Taunga (traditional healers) who were members of the Koutu Nui, prior to establishment of an agreement.

Terms of benefit-sharing agreements
Matheson reached a benefit-sharing agreement with the Koutu Nui under mutually agreed terms. A company: Cook Islands Medical Research and Development (CIMRAD) was incorporated with Matheson and the Koutu Nui equal share-holders. This was agreed to be the vehicle through which the R&D would be commercialized, with the Koutu Nui agreeing to take responsibility for the allocation of monies it received, as a shareholder, for the benefit of the Indigenous inhabitants of the Cook Islands (Matheson-Koutu Nui Deed, 2003).

An Australian company, CIMTECH, was also subsequently established to take advantage of grant opportunities, for tax reasons, and for the protection of intellectual property (Australia is a signatory to World Intellectual Property Organization agreements allowing the filing of international patents). The new company incorporated the Koutu Nui and UNSW (which provided financial and institutional support towards the development of intellectual property) as shareholders: CIMTECH is owned by an Australian trust whose beneficiaries include the Koutu Nui and Matheson family, with no royalties owed, but rather their interests represented by a shareholding in CIMTECH and the potential for dividend payments upon the sale of products by CIMTECH. The Koutu Nui were informed that further investment required for R&D and commercialization of CIMTECH's products would dilute their shareholding and they agreed to these terms (Matheson-Koutu Nui Deed, 2003). This was confirmed in a meeting with the current President of the Koutu Nui, Turi Maria Henderson (Henderson, pers. comm. 6/3/12).

Summary of monetary and non-monetary benefits

Monetary (USD)	Non-monetary
Koutu Nui shareholding value estimated to be worth at least $150,000 (after personal investment by Matheson of $300,000).	Expected contributions to the local economy through the laboratory and processing facility in Raratonga, sales, marketing and tourism (use of product in spas and hotels).
Anticipated dividend payments to the Koutu Nui via the shareholding in CIMTECH.	Research directed towards priority health care needs – bone and wound healing.
Research income to CIMTECH: $264,000 in grants received from the Australian Government, and $74,000 from UNSW.	Physical technology transfer of machinery to the processing facility and laboratory.
Employment of 12 people on a part time basis in the Cook Islands (expected to expand upon launch of the cosmetic product)	Joint ownership of patents assigned to CIMTECH (of which the Koutu Nui are shareholders)
Investment in CIMTECH: $560,000 in pre-seed investment in 2010 and a further $800,000 in 2011 for further R&D.	Improved livelihood security for staff (through employment).
	Social recognition regarding Cook Islands traditional medicine, and particularly for recognition of the role of the Koutu Nui as a cultural authority involved in conservation-oriented practices like Raui.

Tangible impacts derived from these benefits

Although further testing and analysis is required to determine the therapeutic effects and safety of the treatments for wound and bone healing (requiring significant external funding), CIMTECH is on the verge of launching their skincare line in 2012. CIMTECH has now completed construction of a processing facility and laboratory on Rarotonga (Figures 3 and 4). The facility includes equipment for shredding the plants, pressing and extracting the infused oil, filtering/separating the oil solution, and has systems in place for quality control. The preparation of skincare products is currently providing some part time employment for 12 people and this is expected to grow as the product comes to market. The processing facility in Raratonga has the potential to be also used to process other plant products to derive essential oils, thus providing for other spin-off products (Romagnino, pers. comm. 5/3/12).

It is anticipated that the Koutu Nui (which currently has a limited budget of approximately $10,000 NZD/$8000 USD per year for its activities) will derive monetary benefits that will further its work promoting and educating about Raui (customary no-take marine conservation zones, see front cover images). The Koutu Nui is also involved in aged care and other charitable activities that could be expanded with further income. In addition, the Koutu Nui have been involved in the primary, secondary, retail and knowledge aspects of the production and revenue chain to date (confirmed by Henderson, pers. comm, 6/3/12). All agricultural production and supply is agreed to be undertaken by Cook Islanders in the Cook Islands. To date, preliminary production and processing of the essential oil solution for pre-launch sample products and gifts has occurred (see figure 4).

Figure 3: The CIMTECH Facility in Avarua, Rarotonga[5]

Figure 4: Bottles of cosmetic active ingredient solution produced in the CIMTECH Lab

Products of the research and development

CIMTECH is preparing to launch a skincare line entitled 'Te Tika' which has the literal meaning of 'truth and integrity'. As noted on CIMTECH's website: "TeTika skin care range has been developed with CIMTECH's BioActive Cook Islands oil. This natural product is based on Australian scientific research and incorporates traditional Cook Islands medicines to create a unique skin care range that has regenerative and anti-aging effects." (CIMTECH, accessed 14/5/2012). The launch of the Te Tika range by the company occurred on 8th August at the Pacific Resort in Rarotonga, Cook Islands. Samples of the skincare products have also been prepared as a gift from the Cook Islands to the Queen of England for her Diamond Jubilee (Romagnino, pers. comm. 5/3/12).

[5] Robinson, D. Both photos taken 6th March 2012.

Challenges and lessons

The CIMTECH-Koutu Nui agreement provides an example of the importance of engagement with Indigenous groups prior to research, sufficiently informed about intent and risks, with an up-front agreement on the terms of benefit-sharing. The former Koutu Nui President, Ruby Dorice Reid, was quoted saying that the research was a first for the Cook Islands and would provide a new industry: “It is such an important venture for us. We are really proud and excited that this traditional medicine can help people throughout the world. And the people of the Cook Islands will also receive a great deal of benefit from it” (Reid, cited by Smith, April 2011).

Through the ability to diversify their R&D, CIMTECH have been able to bring a product to market quicker than they would if solely focused on pharmaceutical therapeutics (and thus share benefits earlier). The establishment of processing facilities, laboratories and investment in the Cook Islands demonstrates willingness to ensure inclusion of Cook Islanders in the value chain of the skincare products. This should provide a broader range of longer term (monetary and non-monetary) benefits than through a narrower royalty-sharing model.

The case also highlights the possibility of ‘home-grown’ R&D by Pacific island nationals. This needs to be considered when drafting conditions of research permits – countries must decide if they want to regulate only foreign biodiscovery activities (as per the current conditions of the Cook Islands permit system) of if they should require permits for all biodiscovery research (as per the permit system in PNG).

A number of the plants used are found in different parts of the Pacific and there are likely to be different traditional uses of them, particularly common plants like coconut. However, the traditional knowledge related to wound and especially bone healing in this case appears to be unique to the Cook Islands, as ethnobotanist Art Whistler (1994, p157) notes:

> In Tahiti, the Cook Islands, and the Marquesas, the flowers, either fresh or boiled into a paste, are used as a poultice for sores, cuts, boils and swellings. The Cook Island Maoris use the bark, together with coconut bark or crushed husk, to make an infusion for bathing fractures.

Last, the case study raised a question about who represents ‘traditional knowledge-holders’ in the Cook Islands. This is a complex question in many Pacific nations. Within the Koutu Nui are a number of Taunga who ultimately endorsed the agreement with Dr Matheson. Some discussions in the first Pacific ABS workshop organized by the ABS Capacity Development Initiative and DSEWPaC from 19 to 22 March 2012 in Nadi, Fiji have suggested that it may also be useful for a formalisation of Taunga networks to represent traditional medicinal practitioners, such that there is a clear consultation framework for PIC relating to traditional medicines in the future.

Case 3: The Falealupo Covenant and R&D on Mamala, Samoa

This case study examines the discovery of an anti-viral phorbol (prostratin) from ethnobotanical study of Samoan remedies in the late 1980s, and the agreements put in place to benefit the community of Falealupo and the people of Samoa. Prostratin was identified by Dr Paul Cox of the Institute for Ethnobotany as an isolated extract from traditional healer remedies that used the rainforest tree 'Mamala' (*Homalanthus nutans*). Three agreements are relevant:

- The Falealupo Covenant which allowed Dr Paul Cox to access a community-held rainforest area for biodiscovery purposes (1989).
- An AIDS Research Alliance (ARA) agreement with the Government of Samoa (2001).
- A University of California, Berkeley agreement with the Government of Samoa (2004).

The biodiscovery and research activities
Dr Paul Cox conducted ethnobotanical studies in the Falealupo rainforest, reputedly collecting many plants. Mamala was identified as a plant of interest during discussions between Dr Cox and some of the village healers (see Figure 5). According to Dr Cox's field notes:

> Several healers, including Epenesa Mauigoa, Pela Lilo, and Seumantufa's wife Lemau, told me that water infusions of *Homalanthus* are used to treat yellow fever[6] and intestinal complaints... (Cox, 2001, p35)

Cox found that although there was broad knowledge in Samoa of the use of *Homalanthus* to treat intestinal complaints (the use indicated by Lemau Seumantufa), that only two healers, e.g. Epenesa Mauigoa and Pela Lilo, knew of the use of the plant to treat acute viral infection (pers. comm, 6/6/12). Interviews with a number of members of the community confirmed Dr Cox's ethnobotanical activities in the late 1980s, including an interview with Lemau (noted above, interview 23/5/12).

Subsequently, Dr Cox received an invitation from the US National Cancer Institute (NCI) in 1986 to collaborate in screening the plants for anti-cancer activity. While they did not identify activity against cancer, subsequent testing by the NCI identified the prostratin molecule displayed 'potent cytoprotective activity' – the capacity to protect healthy cells from a range of pathogens. In vivo studies with mice also showed that, despite being a phorbol (which often promote tumor growth), prostratin did not promote tumours (Cox, 2001).

[6] This was incorrectly understood by the healers or translated by Dr Cox – the treatment was in fact for hepatitis as evidenced by jaundiced yellow skin.

Figure 5: The 'Mamala' tree.

Conformance with ABS principles, legislation and permits

Dr Cox (2001) explains that, having previously spent considerable time living in Samoa (and having learnt the language); he returned with funding from the US National Science Foundation to conduct an ethnobotanical study in the mid 1980s and settled in the village of Falealupo on Savaii. Dr Cox indicates that he initially obtained verbal prior informed consent for his ethnobotanical studies:

> My first introduction to the village was a kava ceremony with the village chiefs where I explained the purpose of my research, and asked their permission to study with the village healers and to collect their medicinal plants for laboratory analysis. I also told them that there was a slight chance that a discovery could result in a commercial interest, and pledged to do my best to ensure a return to the village from any discovery. The village chiefs unanimously agreed to grant me permission to conduct the research and to assist me in any way that they could (Cox, 2001, p35).

This research was prior to the CBD, and therefore ABS principles had not yet been developed. There does not appear to have been a specific research permit requirement in Samoa at the time – many countries have implemented such requirements following ratification or accession to the CBD.

Access/prior informed consent procedure followed

Following the verbal admission of consent from the Falealupo chiefs, Dr Cox continued his research in the Falealupo forest from c1985 to 1988. In 1988 the Samoan Government required the Falealupo community to build a primary school for the community, which had led to a deal with a logging company which began felling trees in the local forest to raise sufficient income for the school construction. In late 1988/early 1989, Dr Paul Cox met with the community to negotiate a covenant for the protection of the forest and repayment of the community's $85,000 USD debt, in exchange for continued ethnobotanical research access (Cox, 2001). Several interviews confirmed this agreement was made, that the community was happy with the payment of the debts and establishment of the rainforest reserve (Fuiono Patolo, interview, 23/5/12; Seumantufa Fale mai, interview, 23/5/12; Manu Toifotino, interview, 24/5/2012; Taii Tulai, interview, 24/5/2012) (figure 6 is a photo of the rainforest preserve). Dr Cox was subsequently titled 'Nafanua', which is an honorary title named after a goddess warrior from Falealupo who conquered and united Samoa.

Consultation with relevant parties

The Falealupo Covenant described briefly above was signed by every chief in Falealupo in a kava ceremony attended by the village (with the exception of one 'banished' family, as noted by several current chiefs).[7] Dr Cox also met with the Samoan Prime Minister Tofilau Eti, the Samoan Minister of Agriculture Solia Papu Va'ai (confirmed by interview in March 2012), and a number of members of parliament to notify them of the preliminary research findings and the NCI's commitment to both honour the Falealupo Covenant and to require any licensee to negotiate fair and equitable terms of benefit-sharing of any proceeds arising from a patent (issued later in 1996) (Cox, 2001). Dr Cox later was involved in the negotiation of two memoranda of understanding establishing terms for potential benefit-sharing between the Samoan Government, the AIDS Research Alliance, and University of California Berkeley. These negotiations involved Mr Solia Papu Va'ai, who was the Member of Parliament for Falealupo at the time. It is unclear to what extent the Falealupo community was involved in negotiation of these two agreements. According to Cox, he took representatives from both the AIDS Research Alliance and the University of California to Falealupo where the village chiefs reviewed and signed the respective benefit-sharing agreements (Cox, pers. comm. 6/6/2012).

Figure 6: The Falealupo Rainforest[8]

Terms of benefit-sharing agreements

Falealupo Covenant: the main terms in summary include:

- The payment of a debt of $77000 WST to the Bank and $31,000 WST to Samoa Forest Products for the construction of the school (total of approximately $85,000 USD at the time),
- An acknowledgement of the perpetual sovereignty of the Falealupo community over the rainforest,
- A commitment by the community to preserve the rainforest for 50 years, including limitations on hunting and allowance for traditional uses,
- Allowance for Dr Paul Cox and his associates to access the rainforest for scientific research in perpetuity, as long as they do not damage the rainforest. If Dr Cox is successful in finding new drugs, he will return to the village 33% of the income received.

[7] Fuiono Aleki, Taii Tapana, Tapua Tamasi, Manutuaifo, Kelemete, Gaga Sanele, Ulufanua Aleuna, Kolone Va'ai, (pers. comm 15/3/12) and Solia Papu Va'ai (pers. comm. 13/3/12).

[8] Robinson, D. Photo taken 15/3/12, in Falealupo, Samoa.

It is worth also noting that Dr Cox and his associates subsequently established the NGO Seacology which has provided a number of benefits to the Falealupo community including:

- The construction and maintenance (costing over $100,000 USD) of a rainforest walkway which generates ecotourism income for the community,
- The re-construction of the school, water tanks and a clinic, plus emergency supplies after hurricanes Ofa and Val (costing over $160,000 USD),
- Plus subsequent personal contributions by Dr Cox to a perpetual endowment fund and village retirement funds.

Dr Cox estimates that over $480,000 USD in contributions have been made to Falealupo village by himself, his associates and Seacology (Cox, 2001). Interviews with some members of the community in May 2012 confirmed the approximate individual costs of specific contributions would tally to this approximately amount (Seaumantufa Falemai, interview, 23/5/12; Manu Toifotino, interview 23/5/12). Cox donated his share of the 1997 Goldman Environmental Prize to Seacology to create an endowment for benefit of the Falealupo Forest. These funds have been used to pay for annual maintenance on the Falealupo Rainforest Canopy Walkway, and, prior to the stock market collapse in 2008, annual payments to the village (Cox, Pers. Comm., 6/6/2012). From the interviews conducted there was little knowledge about the way the perpetual fund operates, and a number of community members noted that annual payments had recently stopped (Taii Tulei, interview, 23/5/12; Fuiono Patolo, interview, 23/5/12).

<u>The ARA – Government of Samoa Agreement</u>

Subject to a number of qualifications such as the passing of three phases of testing and USFDA approval, and the capacity for ARA (a not for profit) to partner with a company and generate surplus revenue net of expenses for ARA, the ARA agreed to pay the following to the Samoan Government:

- USD $5000 as a good faith payment,
- $10,000 as a milestone payment for the passing of phase 1 trials,
- $20,000 for passing phase 2 trials,
- $40,000 for passing of phase 3 clinical trials, and
- Once passed USDA approval if ARA realises revenues that exceed costs, they agree to pay royalties of this revenue at:
  - 12.5% to the Samoan Government;
  - 6.7% to Falealupo village;
  - 0.4% to the lineal descendants of Epenesa Mauigoa, late of Pesaga village (being the first healer to identify for Dr Paul Cox ‘mamala’ as having potential anti-viral qualities); and
  - 0.4% to the lineal descendants of Pela Lilo, late of Falealupo village (who shared ethnobotanical knowledge concerning formulation and use of mamala as a treatment for illness).

While interviewed members of the community had some knowledge of this agreement, noting that Dr Cox had visited and discussed it in 2001, they only had basic knowledge of the division of potential royalties (Taii Tulei, 23/5/12; Fuiono Patolo, 23/5/12; Manu Toifotino, 23/5/12). Seaumantufa Falemai and his mother Lemau were surprised that they were not listed as direct beneficiaries in this agreement (interviews, 23/5/12 and 24/5/12). However Cox indicates that although Lemau taught him many things about Samoan healing plants, she did not teach him about the use of *Homalanthus* to treat viral illness and only used it to treat intestinal complaints (Cox, Pers. Comm. 6/6/12).

The UC Berkeley – Government of Samoa Agreement:

Subject to a number of terms, 50% of the net revenue proceeds (after reimbursing costs and legal fees) that arise from UC Berkeley's licensing of intellectual property directly from this research on *Homolanthus nutans* will go to the NGO Seacology to be distributed as follows:

- 50% to the Samoan Government
- 33% to Falealupo village
- 2% to Saipipi village
- 2% to Tafua village
- 8% to other villages that participate in the research or allow collection of mamala, grow crops of mamala at the time of FDA approval of prostratin or its analogues as a drug in a reasonable and equitable manner as decided by Seacology.
- 2% to the lineal descendants of Epenesa Mauigoa.
- 2% to the lineal descendants of Pela Lilo.
- 1% to Seacology for handling the royalty payments.

Several interviewed members of the community had only limited awareness of this agreement, and very little knowledge of the terms or progress of the R&D.

Summary of monetary and non-monetary benefits
The community has received considerable monetary benefits from the initial Falealupo Covenant, the subsequent philanthropic contributions made by Dr Cox and Seacology, and there are considerable terms of royalties and milestone payments established in the subsequent agreements (although almost entirely contingent upon successful commercialisation).

Monetary (USD)	Non-monetary
$85,000 to pay for the school in return for agreed access for R&D (Falealupo Covenant).	Conservation of the rainforest area in Falealupo.
Over $100,000 for construction and maintenance of a rainforest walkway[9]	Community benefits including the schools and health care clinics.
Several other charitable donations to the community from Seacology and Dr Cox (approximately another $300,000).	Social recognition for the healers who have provided the knowledge about mamala.
Up to $70,000 in milestone payments under the ARA agreement if clinical trials are passed (ARA Agreement)	Opportunity for Samoan farmers to provide extract from the mamala plant (employment in biotrade activities) for further testing (although this case study could identify no evidence of this occurring in practice – synthetic analogs of prostratin appear have been used recently in the US instead of sourcing from Samoa).[10]
6.7% royalties of revenues to Falealupo (net of expenses) if the ARA is able to license and commercialise a drug. Total returns to Samoa will be 20% of profits.	
16.6% royalties of revenues to Falealupo (net of expenses) if UC Berkeley is able to license and commercialise a drug of a total of 50% of royalties to be returned to Samoa.	

Tangible impacts derived from these benefits

Although royalty payments 'arising from the utilisation of genetic resources' have not yet been made, a number of benefits for Falealupo community are visible. These have been made under the Falealupo Covenant (much like an 'upfront/access fee') and through philanthropic donations made by Dr Cox and Seacology.

From several interviews, every respondent indicated that they were happy that the community has been receiving benefits to the village fund through ticket sales for the rainforest canopy walkway (see figure 7). Several of the Falealupo Chiefs[11] explained that ticket sales are distributed to the community under a split as follows: 10% to the individual collecting ticket revenue, 45% to his/her family, and 45% to the village fund. The Chiefs estimated that 800-1000 WST ($342-428 USD) in fees are collected in average weeks in the high season and weekly collections are more like 200 WST ($85 USD) at the bottom of the low season.

Other benefits do not appear to have arisen directly from the R&D, with the exception of an upfront milestone payment by the ARA to the Government of Samoa.

[9] Although this is a philanthropic contribution, rather than a benefit arising from access to genetic resources, it has been included here because it demonstrates a subsequent commitment to the community post-access and during R&D.

[10] See Wender et al. (2008).

[11] Fuiono Aleki, Taii Tapana, Tapua Tamasi, Manutuaifo, Kelemete, Gaga Sanele, Ulufanua Aleuna, Kolone Va'ai, (Pers. Comm 15/3/12).

Products of the research and development

Research on anti-retroviral applications of prostratin has not yet passed phase 1 clinical trials in the US. Pre-clinical studies are still being conducted by ARA. Given that a patent relating to prostration was filed in 1996, it appears likely that this patent will lapse prior to commercialisation of an anti-viral drug. Recently, the ARA have filed additional patent applications in 2009 on 'Methods of administering Prostratin and Structural Analogs Thereof' (US Application no. 12/937364; EPO Application No. 09730430.7; ARA accessed 5/6/12). As Dr Cox and associates have noted:

> Synthesis of analogs... raises interesting issues concerning indigenous intellectual property rights. Because knowledge of prostratin's antiviral activity originated from ethnobotanical studies with Samoan healers, the AIDS Research Alliance (ARA) and the Government of Samoa agreed that 20 percent of ARA's profit from prostratin will be returned to the Samoan people. Similarly, Samoa and the University of California, Berkeley, agreed to share equally in commercialization of the prostratin gene sequences. In the spirit of these previous agreements, we encourage future developers of prostratin analogs for antiviral therapy to negotiate fair and equitable benefits with the Samoan people (Cox, et al. 2008, p1589).

It is yet to be seen if the future users of synthetics analogs of prostratin will share benefits upon commercialisation of any drugs.

Figure 7: The Rainforest Canopy Walkway Ecotourism Attraction in Falealupo[12]

Challenges and lessons

Although there have been few benefits provided to Falealupo directly 'arising from' the utilisation of genetic resources and traditional knowledge (taking a narrow view of the wording of the CBD and Nagoya Protocol), there have been considerable monetary and non-monetary contributions made to the conservation of the Falealupo rainforest, and to the Falealupo community. These reflect an acknowledgement of the contributions made by traditional knowledge holders to the potential development of a useful medicine, and the provision of access to genetic resources in the Falealupo rainforest. The establishment of a rainforest preserve directly responds to the first objective of the CBD, with caveats for traditional and sustainable use activities. Also, the related charitable contribution of the rainforest walkway provides a perpetual income for the village to be utilised for community activities, projects or infrastructure.

[12] Robinson, D. Photo taken 15/3/12, in Falealupo, Samoa.

While some in the Samoan press have been critical of the ARA and UC Berkeley agreements, the royalty rates are quite high in comparison to many other negotiated figures for use of natural products in drug development. One issue that some interviewees raised was that expectations of short term royalties were quite high following a visit from Dr Cox in approximately 2001, when he explained the ARA agreement (Fuiono Patolo, interview 23/5/12; Seaumantufa Falemai, interview 23/5/12; Manu Toifotino, 24/5/12; Lemau Seaumantufa, interview, 24/5/12; Taii Tulei, interview, 24/5/12). Subsequently, interviewees and Chiefs indicated they had not heard about recent progress by the ARA and other researchers.[13] This highlights that it is important that the risks involved and long timelines for pharmaceutical R&D are clearly communicated to potential beneficiary communities with regular updates on progress.

Some other members of the public have also highlighted that prostratin was identified by researchers in New Zealand, some time prior to 1986. However, it does not appear to have been screened for anti-viral qualities until sent to the NCI and then subsequently patented for this intended use. Others have pointed out that the *Homolanthus nutans* tree is found across the South Pacific from approximately New Caledonia to French Polynesia (Whistler, 2004). Article 11 of the Nagoya Protocol highlights that in such circumstances; those Party to the Protocol should 'endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.' The extent to which cooperation and transboundary benefit-sharing will occur is likely to be something that the Parties will resolve amongst themselves, through regional agreements, or through further negotiations at the Intergovernmental Committees of the Nagoya Protocol (ICNP).

The case study also raises an interesting question about requirements for benefit-sharing relating to R&D towards synthetic analogs that are based on a naturally occurring compound. The Nagoya Protocol definition of 'utilization of genetic resources' includes derivatives, meaning 'naturally occurring biochemical compounds'. Because analogs are synthetically produced, they probably do not fall under the scope of the Nagoya Protocol. However, this does not preclude Governments from specifying in benefit-sharing agreements that synthetic analogs utilised by the researchers involved must also share benefits (see Article 5.1 of the Nagoya Protocol on 'subsequent applications'). Enforcing third party benefit-sharing upon the development of synthetic analogs would be complex.

[13] Fuiono Aleki, Taii Tapana, Tapua Tamasi, Manutuaifo, Kelemete, Gaga Sanele, Ulufanua Aleuna, Kolone Va'ai (Pers. Comm 15/3/12) and Fuiono Patolo, Seumanu Tafa Faaolo, Seumanu Tafa Falemai, Manu Toifotino, Lemau Seaumantafa, Taii Tulei, Marianive Fuiono (interviews, 23-24/5/12).

Case 4: The Santo 2006 Global Biodiversity Survey, Vanuatu

Santo 2006 was a scientific expedition to document the flora and fauna, both marine and terrestrial on the Island of Espiritu Santo in Vanuatu. The expedition involved a natural history inventory, and also a taxonomic inventory (including alien species), intended to provide a baseline of biodiversity for scientists to monitor on the island due to impacts such as climate change (Nari, interview, 12/6/12). The expedition involved collaboration between the French National Museum of Natural History (MNHN), the French Institute for Research for Development (IRD), Pro-Natura International, and involved the Ministry of Lands of the Government of Vanuatu as the umbrella organisation in Vanuatu. Over 100 participants from 15 countries were involved in fieldwork focused primarily between August and December 2006 (Bouchet et al. 2006).

The biodiscovery and research activities

The expedition was primarily a taxonomic inventory of species on the island of Santo, intended to answer academic and practical environmental change questions. Bouchet et al. (2008, p404) explain that it was the 'gap between taxonomy and conservation that the SANTO expedition has attempted to bridge.' The scientific program consisted of four major themes centred on their major sampling facilities and intended to investigate all habitats of the island (deep offshore, coral reefs, continental and marine caves, lowland and highland forests, and rivers). The main questions posed by the project leaders included: what is the real magnitude of biodiversity when the richest habitats and most diverse taxa are considered? What is the share of rare species and species assemblages? What is the spatial distribution of biodiversity, and how do we evaluate site representativeness at an 'ecoregional scale' (Bouchet et al. 2006)? The project involved sampling of species, but this sampling was not apparently conducted for commercial purposes. The project leaders note that during negotiations and consultations with government agencies in Vanuatu prior to the expedition, "reservations arose on some of the objectives of the expedition in the field of ethnobotany – especially ethnopharmacology. Given that this was a very minor part of our project... and to avoid being suspected of biopiracy, we decided to remove this component" (Bouchet et al. 2011). The agreement terms respond to some of these concerns as further discussed below.

Conformance with ABS principles, legislation and permits

The expedition team and a number of authorities in Vanuatu reached a Memorandum of Understanding in November 2005. This was circulated to various government departments and the Luganville Provincial Secretary for comment (Path, interview, 13/6/12). The agreement was ultimately signed on 24 March 2006 by the then Minister of Lands, Maxime Carlot, and the then director of the Paris Museum, Bertrand-Pierre Galey, who represented the Santo 2006 expedition team. This agreement then provided the underpinning for a research permit issued collectively to all members of the expedition, signed on 2 June 2006 by Ernest Bani, director of Vanuatu's Department of Environmental Protection (Bouchet et al. 2011). The agreement signed between the Government and MNHN asserts that the expedition 'commits to collect information and specimens for academic and management purposes only' and committed to the Vanuatu Cultural Centre giving its prior informed consent to any publication that might contain elements of indigenous or traditional knowledge gathered by the project (Bouchet et al. 2011, p545).

The agreement also commits to the following terms, amongst others:

- 'taking steps to prevent the use of this information and specimen for commercial purposes after the end of the period of the present agreement'
- the housing biological samples collected during the expedition at the Forest Department (plants), Fisheries (fish), Cultural Centre (fossil vertebrates), and insects and other biota of quarantine interest at the Quarantine Department.
- The assertion of intellectual property rights of the Government of Vanuatu over any data created from the expedition, except for indigenous or traditional knowledge which belongs to the person providing it. The parties to the agreement are free to use the data for academic research.
- The agreement was signed for effect over a period of 3 years from March 2006 (MNHN – Vanuatu Agreement, 2006).

Access/prior informed consent procedure followed and consultation with relevant parties

After government permits were issued and agreements made in Port Vila, the expedition team also sought permissions from leaders on the island of Santo. As described by the project leaders:

> In Santo, as in the rest of Vanuatu, the real power to accept visitors comes from the communities themselves, at the level of customary chiefs and villages. We therefore had to contact all members of these communities and inform them about our projects with the support of the traditional chiefs, as well as the field workers of the Vanuatu Kaljarol Senta (Cultural Centre – VKS) and the members of parliament for West Santo, Sela Molissa, who personally took part in informing the people of "his" constituency (Bouchet et al. 2011, p532).

A large meeting was held in Luganville with the chiefs of the province with many people coming to hear about the objectives of the expedition in English and Bislama. Specific activities in villages required prior informed consent from village leaders (Nari, interview, 12/6/12; Path, interview, 13/6/12; MNHN – Vanuatu Agreement, 2006). Rufino Pineda, the national coordinator for the expeditions, indicates that he has digital copies of the PIC agreements signed by local chiefs but could not locate them at the time of interview (Pineda, 12/6/12). Interviews in Butmas village and Matantas/Vatthe village confirmed that local permissions were obtained (Serei Maliu, interview, 14/6/12; Chief Solomon, interview 14/6/12; Purity Solomon, interview, 14/6/12; Bill Tavine, interview, 14/6/12).

Terms of benefit-sharing agreements

From the outset it was made clear that the project had non-commercial scientific aims. Therefore the primary benefits directed towards Vanuatu were indirect monetary benefits, or non-monetary benefits including the exchange of scientific information, provision of training and similar. The agreement specified that:

> The Museum [MNHN] commits to involve Vanuatu Cultural Centre Fieldworkers and community workers for data collection, as well as, to the largest extent possible, ni-Vanuatu biodiversity officers, technicians, and students. It commits to do its best to continue after the field season the training of ni-Vanuatu biodiversity officers, technicians, and students, by facilitating their access to grants and training in institutions in France and New Caledonia (MNHN – Vanuatu Agreement, 2006, p2).

In Butmas and Matantas villages, from which researchers based themselves and went out into surrounding areas for their surveying, there does not appear to have been much training of local people and guides (Serei Maliu, interview, 14/6/12; Chief Solomon, interview 14/6/12; Purity Solomon, interview, 14/6/12; Bill Tavine, interview, 14/6/12). In Matantas

village the community has received a copy of the Natural History of Santo book and some illustrative posters of local biodiversity for their school as supplied by Mr Rufino Pineda (Chief Solomon, interview 14/6/12; Purity Solomon, interview, 14/6/12; Bill Tavine, interview, 14/6/12). Butmas village, a remote village in the mountains, was a research site that was occupied for only approximately 1 week by the researchers (Figure 8). The village Chief indicated he had not received the posters and post-expedition information (Serei Maliu, interview, 14/6/12).

Figure 8: One of the research camps in 2006 was based at Butmas Village, Santo[14]

It was also agreed that biological sample duplicates (where they were collected – sometimes only individual specimens could be found) would be housed in Vanuatu at the Cultural Centre in a wing focusing on natural history that is yet to be built, and at other relevant departments including Fisheries and Forestry. To date, many of these samples are still housed in foreign facilities, including the Museum in Paris, because the facilities in Vanuatu are not yet established and taxonomic work is still being undertaken (Nari, interview, 12/6/12). Duplicate samples were also sent to the University of South Pacific, and a US-based institute (Pineda, interview, 12/6/12).[15]

The project team has not yet passed on scientific literature based on the expedition to the Vanuatu Cultural Centre/National Library or the Department of Environmental Protection, as was originally agreed (Kalfatak, interview, 11/6/12; Hickey, pers. comm, 11/6/12; Norman, pers. comm. 11/6/12). The agreement specifies a website to be established to allow free access to articles produced as an outcome of the research. A website containing many freely accessible photos and limited explanatory documents related to the expedition is still available (www.santo2006.org). The French IRD website still contains some content on the research activities. Bibliographies are provided but not the actual scientific publications.

Russell Nari, formerly the Director-General of the Department of Lands (interview, 12/6/12), noted that many copies (approximately 400) of the book have been supplied to the Vanuatu Government, schools and stakeholders and some scientific papers, but not many yet. He notes that these were recently published and there are still many publications being produced.

[14] Robinson, D. Taken 14/6/12.
[15] Rufino Pineda indicated that he believed this was the Smithsonian.

Payment of local communities, guides and assistants occurred during the expedition (Serei Maliu, interview, 14/6/12; Chief Solomon, interview 14/6/12; Purity Solomon, interview, 14/6/12; Bill Tavine, interview, 14/6/12). There were sometimes issues over the amounts paid or the work expected (Kalfatak, 11/6/12). One of the participants anonymously complained about the low wage paid for their research assistant work (anonymous, interview, 12/6/12). In the Vatthe conservation area (see figure 9), researchers paid 600 Vatu (approximately $6 USD) to be used for community conservation as a one-off fee for entry. Purity Solomon from Matantas village noted that this was the only payment or contributions made to the community – other payments were made to individuals (interview, 14/6/12).

Figure 9: Vatthe Conservation Area and Big Bay in the Background, Santo.[16]

Summary of monetary and non-monetary benefits

Monetary	**Non-monetary**
Payment of local communities, guides and assistants for accommodation and assistance.	Inclusion of 10 Ni-Vanuatu participants in the expedition with the scientific team and related training.
Restoration of a boat *Euphrosyne* which was used to transport people from Luganville to the western side of Santo (worth an estimated $125,000 USD), which was until recently the property of the Vanuatu Maritime College and provided transport services to the island.	Production and distribution of approximately 400 copies of the 'Natural History of Santo' book (in French and English) to authorities in Santo, in Port Vila, and to schools.
Direct injection of and estimated 2.4 million Vatu or $26,000 USD into the economy of Penaoru and villages surrounding it on the west coast of Santo (camp construction, portering, supplies, guides etc).	Contributions to understandings of the local taxonomy of Santo and its surrounding marine areas.
	10 educational posters created on various biodiversity themes, printed as 500 copies, disseminated to every school in the country in the three main languages of Vanuatu with EU funding.

[16] Robinson, D. Taken 14/6/12.

Tangible impacts derived from these benefits
The Expedition claims to have identified 650 species of plants (higher plants, ferns, mosses and liverworts), 350 species of fungi, 1700 species of terrestrial animals, 1100 species of decapods crustaceans, 4000 species of molluscs, and 650 species of fish, of which hundreds of new species have been collected and are being described (Waiwo, 2011). Details of the entire expedition have been published as a book *The Natural History of Santo*, of which many copies have been provided to relevant authorities in Santo and Vanuatu, as well as to schools to 'increase the awareness of schoolchildren on the diversity of life and to introduce them to "science in action"' (Waiwo, 2011). Mr Joel Path, the Secretary General of Sanma Province (including Santo), noted that the book, documentaries and publicity created from the expedition had been good for Santo. He indicated that it had boosted interest in the local environment and had an impact on tourism, particularly ecotourism (interview, 13/6/12).

In addition, EU funding was received for the preparation and publication of 500 copies of posters featuring the biodiversity of the island of Santo to be distributed to schools in Vanuatu. These were both provided to the Ministry of Education for distribution and some were distributed to individual schools by the National Coordinator of the expedition (Pineda, interview, 12/6/12).

While the team was able to include 10 Ni-Vanuatu participants in the expedition with the scientific team, they noted the lack of local academic institutions in the field of biodiversity. Philippe Bouchet, a project leader for the Santo Expedition notes that:

> 'Vanuatu is a small country and, overall, we found that the one difficulty in following the spirit and letter of the CBD for the Santo 2006 project was the scarcity of in-country partners. We proactively searched for students, technical officers etc. to take part in the expedition, but were only moderately successful' (Pers. Comm. 4/6/12).

Although local field guides were used and paid, there was minimal training of local people, except for some training of the 10 ni-Vanuatu scientists or participants (generally from government or universities). In terms of training, the project leaders note that following the expedition, one of the participants (Samson Vilvil-Fare) received a grant from the Territory of New Caledonia to do a Masters degree at the Pierre and Marie Curie University in Paris, in fulfilment of one of the commitments made under the agreement (Bouchet et al. 2011, p545).

There was also some investment in infrastructure such as water supplies in the west coast camp site at Penaoru, plus the refurbishment of a boat to be used in the expedition (then given to the Maritime College of Santo) (Pineda, interview, 12/6/12; Path, interview, 13/6/12).

Products of the research and development
The main 'products' of the R&D are scientific papers and *The Natural History of Santo* book. Several papers have been recently published including Gerstmeier & Schmidl (2007), Jaume and Queinnec (2007), Malzacher & Staniczek (2007), Pyle et al. (2008), Golovatch et al. (2008), Ng & Naruse (2007), Kantor et al. (2008), Terryn & Holford (2008), and Bouchet et al. (2008) amongst others. Most of these have been written as taxonomic descriptions of newly identified species, many of which are named after the island of Santo or the country, Vanuatu. Notably there is little co-authorship of the papers by Ni-Vanuatu people, which the project leaders acknowledge was an unfortunate outcome resulting from limited human capacity in the biological sciences in Vanuatu. Only two of the chapters in the *Natural History of Santo* book appear to have been authored or co-authored by Ni-Vanuatu.

Challenges and lessons

The case highlights some of the differences between R&D intended towards commercialization, and research intended towards academic or scientific discovery. When establishing their project, the leaders met some concerns from individuals about whether they had intentions of conducting 'bioprospecting' type activities. As a result, the project was altered so that ethnobotanical aspects were no longer included, and terms were included in the agreement to ensure prior informed consent from the Vanuatu Cultural Centre before any publication related to the traditional knowledge of Vanuatu. Several commitments were made in the agreement with the Government of Vanuatu, including sharing of data and intellectual property, sharing of published documents and photography, provision of duplicate samples to be housed with relevant government agencies, and the provision of training to Ni-Vanuatu. These commitments have been at least partially achieved to date and others are pending (e.g. repatriation of specimens upon completion of the additions to the Cultural Centre; further provision of publications from subsequent examination of collected species overseas). There appear to have been other indirect benefits to Santo and Vanuatu (although difficult to quantity), including tourist interest in the biodiversity of the island and some of the sites (such as Millennium Cave), as well as the provision of some infrastructure and a refurbished boat to the Maritime College.

The project leaders also seem to have intended to involve greater collaboration from local scientists and technical staff, but due to a lack of human capacity in the biological sciences in Vanuatu, this was limited during the expedition. Instead, the results of the research – largely published taxonomic works – will hopefully provide benefits towards conservation of species and ecosystems in Vanuatu. In order to successfully utilise this data towards conservation and sustainable use, further training and building of human capacity relating to biodiversity must take place.

Summary and Comparisons:

Access is sought to conduct R&D on genetic resources for commercial reasons (as evident in the PNG, Samoan and Cook Islands case studies), but also for academic and environmental management purposes (as in the Vanuatu case). In both circumstances there is an expectation under the Nagoya Protocol that access permission is sought. When implementing the Nagoya Protocol, countries may make provisions for streamlined access for academic research, and require more detailed information from those with commercial intent. While many countries now have research permit procedures, these may need some amendment to take into account the different types of research 'utilizing genetic resources' (including biochemical extracts) and associated traditional knowledge. Procedures for access should be fair and non-arbitrary, transparent and easily accessible (e.g. on a relevant government website with contact details of the NFP and CNA). In some of the Pacific cases discussed, there were no procedures or relatively unclear research access procedures in place at the time. Related to this, some countries delegate responsibilities for different types of research access permit to different departments (e.g. the Vanuatu Department of Environmental Protection handles permits for access to biological resources, and the Vanuatu Cultural Centre also requires permits for access to traditional knowledge and cultural information). Roles of departments need to be clear and mechanisms or rules for consultation/ communication between departments needs to be established (e.g. research advisory committees can be established to meet at regular intervals, representing relevant departments such as environment, agriculture, fisheries and marine, forestry, health and culture, amongst potentially others).

In the past, the degree to which PIC has been obtained (e.g. not at all, verbally, written, signed and witnessed) has varied considerably in biodiscovery research, as noted in the different Pacific case studies. Gradually we have seen a formalisation of PIC requirements in most countries and the implementation of the Nagoya Protocol provides an opportunity for countries to make clear procedures for obtaining PIC from providers of genetic resources and associated traditional knowledge (where relevant). The Nagoya Protocol also asks Parties to consider appropriate solutions for situations where it is not possible to obtain PIC from traditional-knowledge holders (e.g. when traditional knowledge is widely held public domain knowledge). In some cases, such as the CIMTECH case, the researchers have been able to identify an Indigenous representative body through which to establish mutually agreed terms and a benefit-sharing agreement. Local customs of traditional knowledge holders should be respected by researchers, and where possible, governments should support the development of community protocols and/or raise awareness about existing customary laws, and relevant Indigenous representative organisations.

When obtaining PIC and negotiating mutually agreed terms with a provider of genetic resources (and associated traditional knowledge), it is important that the providers are sufficiently informed of the intent of the research, the likely timeline of the R&D, the likelihood of a commercial product resulting, potential future uses or transfer to third parties, and the terms of intellectual property rights sought (for example, some public concerns have arisen in the Mamala case due to high local expectations). Timelines for pharmaceutical R&D and clinical trials can be very long, with low odds of a resultant commercial product. Timelines for other R&D, such as for cosmetics, may be shorter than for pharmaceuticals, and there is still no guarantee of commercial success. Thus it is important not to raise overly high expectations amongst the providers if royalty rates are decided to be a vehicle for benefit-sharing.

Besides royalties, other forms of benefit-sharing may make important contributions to local communities, conservation and sustainable use of biodiversity. These might be monetary (e.g. upfront payments or access fees similar to what has been described in the Mamala

case; or milestone payments as delivered upon for one of the products of the PNG project) or non-monetary (as seen in all of the cases, including for example, the dissemination of educational materials in the Santo Expedition). Although the language of the Nagoya Protocol is framed in terms of 'benefits arising from utilization', benefit-sharing may occur at different stages of the R&D. As noted in the PNG project, a range of benefits provided to various stakeholders at different stages of access and R&D has meant that stakeholder satisfaction from their project is relatively high.

The establishment of value chains for the supply of biological products from within provider countries can also result in sustained benefits for providers and provider countries (e.g. income and employment). This has been established in the CIMTECH case and was included as a 'best endeavours' clause in the UC Berkeley agreement from the Mamala case. Supply should be under 'sustainable use' conditions to align with the CBD objectives.

It is important to ensure timely reporting to countries and providers on the outcomes of R&D, any changes of intent by the researchers, or transfers to third parties (some concerns from interviews in the Samoan and Vanuatu cases appear to have arisen due to delays in reporting the outcomes of R&D). Where possible, joint intellectual property rights (as per the CIMTECH case) and joint publications (as per the PNG-ICBG case) should be encouraged as they represent a shared allocation of rights (e.g. patent rights, moral rights) and can benefit individuals in the provider countries and Indigenous and local communities.

One aspect of Nagoya Protocol alignment and implementation that has not really been addressed in the case studies is in relation to 'user measures' and compliance. Although some of the Pacific Island delegates in the ABS workshops in 2012 perceived their countries largely as provider countries, the CIMTECH and PNG cases also demonstrate that researchers based in those countries may also be users of genetic resources and associated traditional knowledge. This highlights that Pacific countries will need to also establish checkpoints and mechanisms to ensure that users within their countries, from universities, companies or otherwise, are acting in compliance with the access and benefit-sharing requirements of the countries that they seek genetic resources and associated traditional knowledge from. They will also need to put in place non-compliance measures.

Guidelines for Best Practice ABS.

Based on the case studies, a number of lessons regarding 'best practice' in access and benefit-sharing are described so as to provide guidance to researchers. Following this, some basic lessons for governments are highlighted.

Basic guidelines for researchers seeking to be complaint with the principles of the Nagoya Protocol

- Ensure appropriate research permits are obtained prior to the conduct of research from the government in question. If in doubt, contact the CNA or NFP for the CBD. Researchers must work within the specified terms and limits of the permits.
- Obtain prior informed consent (PIC) from the providers of genetic resources (and associated traditional knowledge-holders where relevant) in accordance with research permit or access conditions in the country.
- Establish mutually agreed terms as part of the PIC process – negotiate fair and equitable benefit-sharing with the providers, in accordance with local legal requirements, and establish a signed contractual agreement.
- The terms of benefit-sharing can include monetary and non-monetary benefits. Many developing countries lack scientific capacity and basic technologies. Helping build these capacities and transferring technologies to host country institutions can be important non-monetary benefits. Where possible, benefits should be directed towards the conservation of biodiversity and its sustainable use.
- Upfront benefits provided when access is granted can demonstrate goodwill on the part of the researchers. Royalties and milestone payments are just two possible benefit-sharing options. Others are provided in the Annex to the Nagoya Protocol.
- Researchers should negotiate with providers clear provisions on dispute settlement, third party uses, changes of intent (e.g. changing from an academic study to development of a commercial product), and intellectual property rights.
- Researchers need to ensure that they do not unnecessarily raise undue expectations of large royalty or milestone payments. Local providers should be made aware of the time required to conduct R&D, to pass clinical trials, and to reach commercialisation. They should be made aware that only rarely are useful and safe biochemical compounds or genes isolated for use in drugs, cosmetics, biotechnology or otherwise.
- Engagement of traditional knowledge-holders can be complex due to the way knowledge is distributed, transmitted (often orally), and due to customs associated with the knowledge or genetic resource. At a minimum, PIC should be sought from the providers of traditional knowledge associated with genetic resources. Countries may specify that PIC should also be sought from a body that represents traditional knowledge-holders (e.g. a traditional medicines forum).
- Researchers should respect customary norms, protocols or laws of traditional knowledge-holders.

Basic guidelines for governments adopting the Nagoya Protocol

Below are some basic guidelines for government implementation of ABS systems, providing lessons from the case studies.

- Governments need to establish national focal points (NFPs) for the provision of information on access procedures such as obtaining prior informed consent for the utilisation of genetic resources and associated traditional knowledge. They also need to establish competent national authorities (CNAs) responsible for granting access.
- Governments may take legislative, policy or administrative measures, with the aim of ensuring that benefits arising from the utilisation of genetic resources (as well as subsequent applications and commercialisation) and associated traditional knowledge (where relevant), are shared in a fair and equitable way with the Party providing such resources, and with indigenous and local communities where relevant.
- Governments that have existing research permit systems in place may be able to utilise these, with amendments as necessary, to comply with the access provisions of the Nagoya Protocol.
- Governments will need to establish a mechanism for forwarding approved permits to the Access and Benefit-Sharing Clearing House of the Nagoya Protocol.
- Governments should consider whether only foreign nationals are required to obtain such a permit, or if all people conducting R&D, including citizens and residents, must also obtain a permit. Article 6 of the Nagoya Protocol makes mention of 'fair and non-arbitrary rules and procedures on accessing genetic resources.'
- Governments should provide clear guidance on how to apply for prior informed consent of local providers of genetic resources and associated traditional knowledge (whee relevant).
- Governments may wish to establish criterion for establishing mutually agreed terms including possible clear provisions on dispute settlement, third party uses, changes of intent (e.g. changing from an academic study to development of a commercial product), and intellectual property rights. In addition, governments may wish to make clear provisions on benefit-sharing for 'subsequent applications and commercialization' (as discussed in this report in relation to synthetic analogs of naturally occurring compounds discovered through R&D).
- The Nagoya Protocol stipulates that Parties shall take into consideration indigenous and local communities' customary laws, community protocols and procedures, with respect to traditional knowledge associated with genetic resources. Parties are also encouraged to support the development of community protocols by indigenous and local communities, including minimum requirements for mutually agreed terms, and model clauses for benefit-sharing.
- Governments will need to establish one or more checkpoints for the monitoring of the utilisation of genetic resources (Article 17 of the Nagoya Protocol).
- Governments will need to take appropriate legislative, administrative or policy measures to ensure that genetic resources and associated traditional knowledge utilised within its jurisdiction have been accessed legally (in accordance with prior informed consent and mutually agreed terms), as required by other parties. In addition, measures to address situations of non-compliance must be put into place (see Articles 15 and 16 of the Nagoya Protocol).

References:

Andersen, R.J. and Roberge, M. (2005) 'HTI-286, A Synthetic Analog of the Antimitotic Natural Product Hemiasterlin' in Kingston, D.I., Cragg, G.M., Newman, D.J. (eds) *Anticancer Agents from Natural Products*. CRC Press, Florida.

ARA 'Prostration: A Potential Cure Strategy' http://aidsresearch.org/cure-research/prostratin/ Accessed 5/6/12.

Bouchet P., Le Guyader H. & Pascal O. (c2011) *The Natural History of Santo*. National Museum of Natural History, France, IRD, Pro-Natura, Paris, and Government of Vanuatu.

Bouchet P., Le Guyader H. & Pascal O. 2009. — The SANTO 2006 Global Biodiversity Survey: an attempt to reconcile the pace of taxonomy and conservation. *Zoosystema* 31 (3) : 401-406.

CIMTECH, 'News and Events' http://www.cimtech.com.au/ Accessed 14/5/2012

Cox, P. (2001) 'Ensuring Equitable Benefits: The Falealupo Covenant and the Isolation of Anti-Viral Drug Prostratin from a Samoan Medicinal Plant.' *Pharmaceutical Biology*. 39 (supplement): 33-40.

Cox, P. Johnson, H.E. Tavana, G. (2008) 'Giving Samoan Healers Credit for Prostratin' *Science* 20 June, 320(5883): 1589.

Gerstmeier, R. & Schmidl, J. (2007) '*Omadius santo* sp. nov. from Espiritu Santo, Vanuatu (Coleoptera, Cleridae, Clerinae)'. *Entomologische Zeitschrift*, 117 (2): 85-87.

Golovatch, S., Geoffroy, J.-J., Mauries, J.-P. & Vandenspiegel, D. (2008) 'The first, new species of the millipede family Pyrgodesmidae to be recorded in Vanuatu, Melanesia, southwestern Pacific (Diplopoda: Polydesmida)'. *Arthropoda Selecta* 17 (3-4): 145-151.

Jaume, D. & Queinnec, E. (2007) 'A new species of freshwater isopod (Sphaeromatidea: Sphaeromatidae) from an inland karstic stream on Espiritu Santo Island, Vanuatu, southwestern Pacific'. *Zootaxa* 1653: 41-55.

Kantor, Y., Puillandre, N., Olivera, B. & Bouchet, P. (2008) 'Morphological proxies for taxonomic decision in turrids (Mollusca, Neogastropoda): a test of the value of shell and radula characters using molecular data'. *Zoological Science* 25: 1156-1170.

Malzacher, P. & Staniczek, A. (2007) '*Caenis vanuatensis*, a new species of mayflies (Ephemeroptera: Caenidae) from Vanuatu.' *Aquatic Insects* 29 (4): 285-295.

MNHN (French National Museum of Natural History) – Government of Vanuatu Agreement for the Santo 2006 Global Biodiversity Survey Expedition.

Ng, P. K. L. & Naruse, T. (2007) '*Liagore pulchella*, a new species of xanthid crab (Crustacea: Decapoda: Brachyura) from Vanuatu.' *Zootaxa* 1665: 53-60.

NIH, (2012) 'Our Mission and Vision' http://www.fic.nih.gov/About/Pages/mission-vision.aspx Acc: 6/6/12.

Pyle, R. L., Earle, J. L. & Greene, B. D. (2008) 'Five new species of the damselfish genus *Chromis* (Perciformes: Labroidei: Pomacentridae) from deep coral reefs in the tropical western Pacific'. *Zootaxa* 1671: 3-31.

Terryn, Y. & Holford, M. (2008) 'The Terebridae of Vanuatu with a revision of the genus *Granuliterebra* Oyama 1961'. *Visaya* Supplement 3: 1-96.

Secretariat of the CBD, (2011) *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, to the Convention on Biological Diversity. Text and Annex*. Montreal.

Secretariat of the CBD, (2011) 'The Nagoya Protocol on Access and Benefit-Sharing, Information Pack.' CBD Secretariat, Montreal.

Sissons, J. (1998) 'Conspiracy, Class and Culture in Oceania: A View from the Cook Islands' *The Contemporary Pacific,* Spring 1998, pp164-178.

Smith, D. (2011) 'Medicine Man makes no Bones about Paying Dues' *Sydney Morning Herald,* 9 April.

STRI, (2008) 'Establishment of the Wanang CTFS/SIGEO Plot. CTFS/SIGEO to study forests of Papua New Guinea' October 20, http://www.stri.org/english/about_stri/headline_news/news/article.php?id=884 Acc: 6/6/12.

University of Utah, University of Minnesota and UPNG, (c2010), Memorandum of Understanding. Focus: A Scientific Research Collaboration to Investigate the Biological, Chemical, and Medicinal Properties of the Biodiversity of Papua, New Guinea and to Establish Economic Value Thereof.

University of Utah, (2010) ICBG PNG: Conservation and Sustainable Use of Biodiversity in PNG http://www.pharmacy.utah.edu/ICBG/ Acc 9/5/12

University of Utah and UPNG, (c2002), Memorandum of Understanding. Focus: A Scientific Research Collaboration to Investigate the Biological, Chemical, and Medicinal Properties of the Biodiversity of Papua, New Guinea and to Establish Economic Value Thereof.

US State Department, (2009) '2008 Human Rights Report: Papua New Guinea.' Accessed 3/9/2012 from: http://www.state.gov/j/drl/rls/hrrpt/2008/eap/119053.htm.

Waiwo, E. (2011) 'The Natural History of Santo book Released to Sanma Authorities' *Vanuatu Daily Post*. 6/13/2011.

Wender, P.A., Kee, J.M and J.M. Warrington (2008) 'Practical Synthesis of Prostratin, DPP, and Their Analogs, Adjuvant Leads Against Latent HIV' *Science,* 2 May 320(5878): 649-652.

Whistler, A. (2004) *Plants in Samoan Culture: The Ethnobotany of Samoa*. Isle Botanica, Honolulu.

Whistler, A. (1994) *Polynesian Herbal Medicine*. Pacific Tropical Botanical, Hawaii.

Interviews (in Chronological order)

Samoa

Fuiono Patolo, Chief from Falealupo, 23/5/12

Seumanu Tafa Faaolo, Chief from Falealupo, 23/5/12

Seumanu Tafa Falemai, Chief and healer from Falealupo, 23/5/12

Manu Toifotino, Elder from Falealupo, 24/5/12

Lemau Seaumantafa, Elder/healer from Falealupo, 24/5/12

Taii Tulei, Chief from Falealupo, 24/5/12

Marianive Fuiono, Elder from Falealupo, 24/5/12

Aeau P. Leavai, Member of Parliament for Falealupo (current and past), Apia, 25/5/12.

Tima Leavai, Lawyer from Falealupo, Apia, 25/5/12.

Vanuatu:

Donna Kalfatak, Department of Environmental Protection (Biodiversity Unit), Port Vila, 11/6/12.

Anonymous, former research/field assistant for the Santo project, 12/6/12.

Rufino Pineda, Former National Coordinator for the Santo Expedition, Port Vila, 12/6/12.

Russell Nari, Former Director General of the Department of Lands, Port Vila, 12/6/12.

Joel Path, Secretary General of Sanma Province (Santo), Luganville, 13/6/12.

Serei Maliu, Chief of Butmas Village, Santo, 14/6/12.

Chief Solomon, Chief of Matantas/Vatthe, Santo, 14/6/12.

Purity Solomon, Matantas/Vatthe, 14/6/12.

Bill Tavine, Matantas/Vatthe, 14/6/12.

Personal Communications

Bouchet, P. French National Museum of Natural History, Paris. Email. 4/6/12

Cox, P. Director, Institute for Ethnomedicine, Email. 5/6/12/

Hickey, F. Vanuatu Cultural Centre. Phone, 11/6/12.

Matainaho, L. Professor, University of Papua New Guinea. Email.15/12/11

Matheson, G. Doctor and biomedical researcher. Email. 6/6/2012

Norman, J. Head Librarian, Vanuatu Cultural Centre. In person, 11/6/12.

Obeid, A. Director of Fisheries Office in Santo. In person, 13/6/12.

Va'ai, Solia Papu. Former Minister of Agriculture for Samoa, and former MP of Falealupo, Meeting in Apia, Samoa. In person, Apia. 13/3/2012.

Chiefs Fuiono Aleki, Taii Tapana, Tapua Tamasi, Manutuaifo, Kelemete, Gaga Sanele, Ulufanua Aleuna, Kolone Va'ai. Meeting in Falealupo, Samoa. 15/3/12.