Guidelines, Consent Instruments, Procedures and Protocols for DNA Sampling with San Traditional Communities in Namibia

This Guide was developed as part of the OSISA funded project:

Informed consent for Human Genetic Research Among San People

Implemented by:

Anthropos www.anthropos.org.uk
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Foreword

“The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.”

Article 1, Universal Declaration on the Human Genome and Human Rights

Scientific enquiry and the freedom to produce, pursue and access knowledge is one of the characteristics of an open, free and tolerant society. This is not only because advancing the frontiers of our knowledge of ourselves, our environment, and the universe is inherently good, but because addressing society’s ills - whether poverty and inequality, the threat of climate change, or the delivery of quality public health and education to under resourced communities - depends upon evidence-based public policy, informed and underpinned by sound research.

We know all too well, however, that the unfettered pursuit of science, unmoored from ethical and human rights concerns, can lead to large scale human rights abuses and atrocities, especially when the human subjects are on an unequal footing with those conducting the research. Under these circumstances, the potential harm to indigenous peoples can be extensive if their rights are not properly protected, and all indications are that they are not, not least amongst the Ju|’hoansi, one of the most studied communities in the world.

In common with a number of other communities of interest to geneticists, few Ju|’hoansi have any understanding of the risks and opportunities involved, and are vulnerable to exploitation in the absence of a clear mechanism, or a protective tool, that enforces their right to free, prior and informed consent.

While the right to Free, Prior and Informed Consent is deeply embedded in a number of international instruments, more often than not, it does not translate into policies at the national level, much less into a tangible enhancement of the rights of communities such the Ju|'hoansi.

It is our hope, as the Indigenous Peoples' Rights Programme of the Open Society Initiative for Southern Africa (OSISA), that these guidelines and procedures will serve as a resource for the Ju|'hoansi, as well as other indigenous communities in southern Africa and elsewhere, in their ongoing engagements with research organisations, national oversight bodies, policymakers, and other stakeholders.

We wish to thank our partners, the South African San Institute (SASI), Anthropos, and the Ju|'hoansi Traditional Authority, in particular, for their tireless work and their passionate commitment to this important work.

Delme Cupido, OSISA.

November 2016

Human genetic research has moved in leaps and bounds since the first full mapping of the human genome was completed early in the new millennium. This research has proved to be of extraordinary value both in terms of understanding our own species' origins, evolution, development and expansion across the globe but also in terms of our understanding and potentially the management of issues that impact on human health and well-being. Genetics is a new field in which technological developments are moving rapidly and which is likely to impact ever more directly on all of our lives. In doing so, it raises a number of complex ethical and human rights questions that need to be addressed head on to keep up with the pace of advances in the field. This is particularly true for communities such as Namibia's Ju|'hoansi, the descendants of southern Africa's last hunter-gatherer indigenous communities.

Introduction

Discussions concerning genetic rights issues relating to plant materials have formed part of the national dialogue in countries like Namibia, in respect of questions relating to access and benefit sharing of biological resources. By contrast debate and understanding of the use of human genetic material is significantly less mature. In part, this is a reflection of the novelty of the field.

Khoisan populations, indigenous to southern Africa, have proved of particular interest to geneticists - as many Khoisan communities in Namibia, Botswana and South Africa are aware. Many communities have contributed DNA samples to researchers from institutions across the globe. Yet few of the communities that have participated in this research have either understood even the rough outlines of the work they were participating in or, indeed, had the results of this work fed back to them. As a result, the work of genetic researchers has become a cause for concern and mistrust.

The aim of these guidelines is to redress this trust deficit by creating a transparent and mutually beneficial framework for genetic researchers and San communities to collaborate with one another in one of the most exciting scientific fields to have emerged

in recent years. As much as this guide has been developed specifically for the two Ju|'hoan speaking traditional authorities in Namibia it is intended for use by any other community that wishes. To this extent it is an "open-source" document and other communities are free to use, amend and refashion it to meet their own needs.

This is also not intended to be a static document and it may well be revised as the field and circumstances change. In terms of use it is also not a rigid guideline, but a flexible framework that serves as the basis for the negotiation of any research agreement. This noted the core-tenets of the research agreements and the process framework are "red lines" and therefore not negotiable.

These guidelines are the product of a collaboration between the Ju|'hoan Traditional Authority, the =Kxao||ei Traditional Authority, Anthropos and the South African San Institute. They were developed as part of a program funded by the Open Society Initiative in Southern Africa (OSISA) intended to empower vulnerable communities in their engagements with genetic researchers. The guidelines were reviewed and debated by stakeholders in a series of meetings and at a workshop with the two Ju|'hoan speaking Traditional Authorities in Tsumkwe in September 2016. Attendees of the Tsumkwe Workshop are listed in the annexes.

James Suzman
1 November 2016

Contents:

Procedure Framework

1. Proposals developed by Research Organisation (RO) submitted to NSCHR and to Traditional Authorities (TA).
2. NSCHR to inform researchers that Traditional Authority consent is a pre-requisite for working in Ju|'hoan San communities.
3. RO informed of the TA's guidelines and procedures and requested to approach TA directly. RO will be expected to follow the recommendations and guidance in Guide documentation.
4. In the event of the TA being approached vis-à-vis genetic sampling, the TA will review application and assess whether they wish additional legal or advisory support to assist them to manage any engagements or negotiations with the RO.
5. RO will be invited to present their research plans to the TA and its designated representatives. The RO will be expected bear all immediate costs in this respect.
6. RO to follow procedures outlined in Guidance for Researchers and utilize templates included in these guidelines.
7. The TA and its representatives will establish a broad heads of agreement with the research organisation. This heads of agreement will need to deal specifically with:
    a. Precise research objectives, methods and procedures of the research organisation including all processes and procedures undergone
    b. Any research objectives of particular interest to the TA and TC the RO has agreed to undertake as a condition for TA endorsement
    c. Any specific limitations on the use of the samples and specific requirements in terms of storage, disposal etc.
    d. Expected minimum requirements for direct consultation of community members that may participate in the research
    e. Commitments and timelines for community feedback
    f. Commitments regarding disclosure, publication and data management

g. Expected payments, gifts or honorariums to individuals or to community organisations and procedures and institutions involved
h. Clear expectations regarding feedback commitments
i. Expectation in respect of building community capacity in genetics and potential ambassadors
j. Employment of local community members as research assistants
k. Translation requirements
l. Management of expenses incurred by TA's or community members
m. Remedies for contractual breach

8. In the event of no head of agreement being established consent will not be given by the TA and the RO and NCSRT will be informed. The RO may resubmit application at their own cost where the TA consents to this.
9. Where heads of agreement are established TA will request legal advisers to ensure that this is reflected in any formal agreement between the RO and TA. The costs for this will normally be borne by the RO.

Guidance For
DESIGNATED COMMUNITY REPRESENTATIVES

GENERAL ASSUMPTIONS:

A fundamental premise of any research conducted amongst any community or group of people, including especially, indigenous peoples, and including particularly, in this instance, DNA research amongst a community of Ju|'hoansi San is that the researchers should conduct the research within an appropriate ethical, legal, and professional framework.

One of the main prerequisites of conducting the research within such a framework is to demonstrate respect for both the community and the individuals who become involved as participants or subjects of the research undertaking. This primarily entails recognizing the dignity and autonomy of the members of that community and the individuals within the community who are, or may become, either participants or subjects of the research.

The role of designated community representatives, then, is to assist researchers who either are not residents of or natives of the community or who, although part of the community, may have different backgrounds and interests from other participants and individuals from the community involved in the research, to conduct themselves in such a way that the dignity and autonomy of all potentially affected persons in the community, and the community as a whole, is respected throughout the research endeavor.

Designated community representatives presumably can be important components in facilitating researchers in this regard, because they presumably have both: (a) a relatively complete and sensitive grasp of how members of the community can be best treated respectfully, *i.e.* with dignity and respect for their autonomy; and (b) the ability to communicate how to best treat them in a particular context, such as a research context, to persons from outside the community. This is because applied ethnographers and designated community representatives usually are:

- much more familiar with local traditions and values; local history and

ecology, and, local and regional political and community structures, processes and organisations

- also are more accustomed to communicating with persons with the backgrounds and perspectives of outside researchers.

Designated community representatives are, then, in essence, potentially important cultural brokers in any research endeavor involving indigenous peoples.

With these general principles in mind, the following more specific guidelines have been designed for use by designated community representatives who are assisting in a DNA, or similar, research enterprise that involves a community of indigenous peoples, such as the Ju|'hoansi:

1. Obtain the trust and consent of the community to assist it in assuring that all phases of the research are conducted ethically, professionally, and legally, and, to the extent the community or representative community members request it, advocate for the community and its members in negotiations with the research team to assure that all phases of the research are conducted ethically, professionally, and legally and, in particular:

    a. are respectful at all times of the dignity and autonomy of the Ju|'hoan community and its members;

    b. comport with Ju|'hoan San community needs and values; and,

    c. are otherwise consonant with Ju\'hoan cultural traditions, including especially what they regard as sacred and what they may want to preserve as secret and not to be shared with non-Ju\'hoansi San absent specific assurances and conditions.

2. In consultation with and with the consent of authoritative Ju\'hoansi community representatives, prepare targeted, project-specific digestible written background documents for the use of the research team in order to assist the research team in gaining appropriate insights into the Ju|'hoansi community history, traditions, values, and politics.

3. In conjunction with the preparation of targeted information documents for the research team, prepare a list of recommended published documents for the research team members to review regarding the Ju|'hoansi and a supplemental list of related optional readings.

4. In consultation with and with the consent of authoritative Ju\'hoansi community representatives, help organize and participate in both formal and informal workshops or information exchanges with the research team regarding Ju|'hoansi community history, traditions, values, and politics.

5. Be prepared to alert researchers to any prospective research conduct that might offend community members' values or be contrary to either sacred or secular community traditions or might affect the willingness of any community member to participate in the research or be a research subject so that the research can be timely and appropriately modified to avoid offensive conduct.

6. Be prepared to alert researchers to any political issues that might affect the willingness of any community member to participate in the research or be a research subject so that the research can avoid creating unnecessary political problems for participants or community representatives who are assisting with the research.

7. Be prepared to serve as an ongoing resource for local Ju|'hoansi communities

involved in or potentially affected by the research to help “demystify” the research and make it as understandable as possible to local Ju\’hoansi San communities and members.

8. Monitor the mandated free, prior, fully-informed consent process and implementation to assure that:

    a. Consent is obtained, if at all, in a reasonably quiet, unhurried, and pressure-free environment;

    b. The consent process includes someone who can communicate meaningfully with and on behalf of the community members and persons whose consent is sought and also is reasonably knowledgeable of the goals of the research project and the means by which it will be implemented;

    c. Competent interpreters are available who can translate or interpret communications in the native language or languages of the research team and the native language or language of preference of the Ju|’hoansi and who reasonably understand the cultural context in which those communications will occur;

    d. Community members and research subjects are fully informed, to the extent feasible and in accordance with their expressed preferences, at all stages of the research, before, during, and after DNA samples are taken and related information is obtained from the research subjects, of the status of the research and how the research subjects are or might be affected by it.

9. Become familiar with the prospective research and assist community members and potential research subjects, to the extent they are agreeable to and comfortable with

such assistance, in evaluating the potential risks and benefits to the community and its members of the research.

10. Assist the community and potential or eventual research participants and subjects in obtaining a fair and just sharing of any and all benefits, including any monetary profits, derived from the research.

11. Assist the community members in optimizing ways that they can become empowered by the research enterprise, for example, by actively assisting the research in a way that might lead to future careers or complement formal education opportunities.

Guidance for

RESEARCHERS

Background:

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[1] outlines the three principles, respect for people, beneficence, and justice, that are now generally accepted as the three quintessential requirements for the ethical conduct of research involving humans.[2] These are:

- Respect for people involves a recognition of the personal dignity and autonomy of individuals, and special protection of those people with diminished autonomy.
- Beneficence entails an obligation to protect people from harm by maximizing anticipated benefits and minimizing possible risks of harm.
- Justice requires that the benefits and burdens of research be distributed fairly and in accordance with international norms of justice.

Specifically, the principle of respect for people underlies the need to obtain informed consent; the principle of beneficence underlies the need to engage in a risk-benefit analysis and to minimize risks; and the principle of justice requires that participants be fairly selected and that international norms of justice are followed, in particular, with respect to the Ju\'hoansi San, in accordance with The United Nations Declaration on the Rights of Indigenous Peoples ("UNDRIP")[3] and the principles set forth therein. All of these principles apply to individual participants as well as to communities.

Respect for People

[1] United States. 1978. *The Belmont report: ethical principles and guidelines for the protection of human subjects of research*. [Bethesda, Md.]: The Commission, available at: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (last visited May 29, 2016).

[2] These guidelines and protocols draw substantially on the *Guidelines for Researchers* developed by the Portland, Oregon, USA, Indian Health Service Institutional Review Board, first developed in August, 2002, available at: http://www.npaihb.org/images/epicenter_docs/irb/docs/guidelines.pdf (last visited May 29, 2016).

3 UN General Assembly Resolution 61/295 of 13 September 2007.

Required by the principle of respect for people, informed consent contains three elements: information, comprehension, and voluntariness.

First, participants must be given sufficient information on which to decide whether or not to participate, including the research procedures; their purpose, risks, and anticipated benefits; alternative procedures; and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Even when some direct benefit to the participants is anticipated, the participants should understand clearly the range of risk and the voluntary nature of participation. Incomplete disclosure of information is justified only if it is clear that: (1) the goals of the research cannot be accomplished if full disclosure is made; (2) the undisclosed risks are minimal; and (3) it is feasible for participants to later be debriefed and provided the research results.

Second, participants must be able to comprehend the information that is given to them. The presentation of information must be adapted to the participant's capacity to understand it; testing to ensure that the participants have understood may be warranted. Where persons with limited ability to comprehend are involved, they should be given the opportunity to choose whether or not to participate (to the extent that they are able to do so), and their objections should not be overridden. Each such class of people should be considered on its own terms (e.g., minors, people with impaired mental capacities, the terminally ill, and the comatose). Respect for people requires that the permission of a third party also be given in order to further protect them from harm.

Finally, consent to participate must be voluntarily given. The conditions under which an agreement to participate is made must be free from coercion and undue influence. The researcher should be especially sensitive to these factors when particularly vulnerable participants are involved.

Beneficence

Ensuring beneficence entails conducting risk-benefit analyses, which involve weighing the probability and magnitude of possible harms against the anticipated benefits. This further involves defining the nature and scope of the risks and benefits and systematically assessing the risks and benefits. All possible harms, not just physical or psychological pain or injury, should be considered.

The principle of beneficence requires protecting individual participants against risk of harm and consideration of not only the benefits for the individual, but also the societal and community benefits that might be gained from the research.

Justice

The principle of justice mandates that: the selection of research participants must be the result of fair selection procedures; the selection process must result in fair selection outcomes; and the research must otherwise be conducted in all respects so as to comport with principles justice under applicable standards of international law and the principles underpinning UNDRIP.[4]

The "justness" of participant selection relates both to the participant as an individual and to the participant as a member of a class or group, and should not discriminate on the basis of age, sex, gender, or social category, except as may absolutely be necessary to fulfill the purposes of the research.

With respect to their status as individuals, participants should not be selected either because they are favored by the researcher or because they are held in disdain (e.g., involving "undesirable" people in risky research). Furthermore, "social justice" indicates

[4] *See* Note 3 above.

an “order of preference in the selection of classes of participants (e.g., adults before children) and that some classes of potential participants (e.g., the institutionalized mentally infirm or prisoners) may be involved as research participants, if at all, only on certain conditions.”)

The researchers should consider principles of distributive justice to determine if the proposed methods of selecting research participants may result in unjust distributions of the burdens and benefits of research. Such considerations may be appropriate to avoid the injustice that “arises from social, racial, sexual, and cultural biases institutionalized in society.”

Researcher Sensitivity and Responsibility

Researchers must be sensitive to the local culture, values, traditions, research priorities, and lifestyle of the local Ju|’hoansi community. The research therefore should be conducted only after thorough consultation with both authentic community representatives and qualified ethnographers who have a thorough grounding in the local community history, culture, values, traditions, lifestyles, and political economy.

Furthermore, researchers must be responsible and accountable to the Ju|’hoansi local community where the research is being conducted.

The following is a partial checklist to consider for improving researcher sensitivity and responsibility:

Researcher Sensitivity

- Prioritize mutual understanding and good communication
- Develop respect for Ju|’hoansi culture and traditions

- Respect Ju|'hoansi group and community sovereignty, self-determination, and expressed concerns and opinions
- Respect Ju|'hoansi local community research priorities and needs
- Recognize Ju|'hoansi individuals as members of families and communities
- Respect Ju|'hoansi participants' rights and dignity throughout the research
- Strive to clarify and demystify the research
- Be accessible
- Attempt to provide feed-back and findings to the Ju|'hoansi community representatives in a timely manner
- Respect each participant's and each community's right to decline participation

Researcher Responsibilities

- Communicate and coordinate with community liaisons designated by the community
- Respectfully negotiate free, prior, fully-informed consent protocols to be used during the research in good faith
- Strive to maximize benefits and minimize risks to the participants and the community
- Do not begin research until both community approval and appropriate individual free, prior, fully-informed consent is obtained
- Share results of the research with the Ju|'hoansi San in accordance with their prior agreement and consent
- Work with the Ju|'hoansi San Community to build capacity within the community
- Fully comply at all times with the protocol specifications that authentic Ju\'hoansi San community representatives have approved

Detailed Research Protocol

The research protocol that the research team ultimately develops for approval by authentic Ju\'hoansi community representatives should discuss in detail: (a) how it plans to carry out the research; (b) how it will analyze the data that it collects; and, (c) what it plans to do with the results. It should comprise the following components:

Introduction and Background

- Provide relevant research background and explain why this activity is necessary or important.
- Explain why it is necessary to involve Ju|'hoansi San as participants in the research.
- Explain how the burdens and benefits of the research will be equitably distributed.
- Describe the potential impact of the proposed research on the Ju|'hoansi community.

Study Design

- Provide a complete description of the research design, sequence, and timing of all procedures that will be involved in a manner and in a language or languages that can be readily understood by the community representatives or ambassadors and likely participants.
- Describe all places where any and all phases of the research will likely take place, and, where necessary, obtain written approval and cooperation from each participating site.

Participants

- Explain how the nature of the research requires or justifies using the participant

population.

- Describe the criteria for selection for each participant.
- Describe any participant exclusion criteria.
- Explain who will be contacting the participants and how the participants will be approached. Explain what steps you will take to avoid coercion and protect privacy.

Risks and Benefits

- Describe the nature and amount of risk of injury, stress, discomfort, invasion of privacy, and other side effects to individual participants from all research procedures, and describe the kinds and extent of risks that the larger community may be subjected to.
- Describe how due care will be used to minimize risks and maximize benefits to individuals and the community.
- Describe the provisions for a continuing reassessment of the balance between risks and benefits.
- Describe the expected benefits for individual participants, the community, and society.

Adverse Effects

- Describe how undesired, adverse effects or consequences of the research will be handled by the research team
- Explain who will be financially responsible for any physical injuries resulting from the research procedures

Confidentiality of Research Data

- Explain if data will be anonymous (no possible link to identifiers).

- Explain if identifiable data will be coded and if the key to the code will be kept separate from the data
- Explain if any other agency or individual will have access to identifiable data and, if so, under what circumstances.
- Explain how data will be protected (e.g., computer with restricted access, locked file, etc.).

Consent Forms and Assent Forms

- Develop all consent forms in cooperation with and with the approval of designated Ju|'hoansi community representatives.
- Describe all medical, academic, or other personal records that likely will be used in the research.
- Describe any audio-visual recordings, tape recordings, photographs, or publications that may be made prior to, during, or after the research is conducted and explain to appropriately-designated Ju|'hoansi community representatives how and to what extent Ju|'hoansi community representatives may participate in the creation of, will be acknowledged in, given credit for, named as co-creators or authors of, or receive any benefits derived from any such audio-visual recordings, tape recordings, photographs, or publications.

Informed Consent

Informed consent is one of the primary ethical requirements underpinning research with human participants; it reflects the basic principle of respect for people. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or discrete moment of time. Informed consent ensures that prospective participants will understand the nature of the research and can knowledgably and voluntarily decide whether or not to participate. This protects both the participant, whose autonomy is respected, and the

researcher, who otherwise faces legal hazards.

The Nuremburg Code, developed by the International Military Tribunal that tried Nazi physicians for the "experiments" they performed on non-consenting inmates of concentration camps, was the first widely recognized document to deal explicitly with the issue of informed consent and experimentation on human participants. The first principle of the code states:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

All subsequent codes and regulations, insofar as they pertain to competent, adult participants, follow these principles closely.

Providing free, prior, fully-informed consent requires that certain information must be provided to each participant:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed, and identification of any procedures which are

experimental.

- A description of any reasonably foreseeable risks or discomforts to the participants.
- A description of any benefits to the participants or to others that may reasonably be expected from the research, and a description of any limitation on those benefits (such as the length of time it may take to realize the benefits) and a parallel description of benefits that the participants are not likely to receive, so that the participants will not be misled into having unrealistic expectations of benefits from participation in the study.
- A disclosure of appropriate alternative research procedures, if any, which might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

The researcher should seek consent only under circumstances that provide the prospective participant or his or her representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. Furthermore, the information must be communicated in language that is understandable to the participant or representative.

The consent process may not involve the use of exculpatory language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

The research protocol followed by the researcher should explain the process of administering consent and specifically should address the following questions:

- Is consent obtained in a reasonably quiet, unhurried setting?
- Is there a knowledgeable person present who can answer questions in a clear manner, using layman terms?
- Will this knowledgeable individual assess the participant's comprehension and will this person utilize translators or interpreters for those participants who are not fluent in the language of the researcher?
- Who will explain the research to the potential participants? Who else, in addition to or other than the researcher, will be present during explanations to the participants?
- Should participants be reeducated and their consent required periodically?
- If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver? Is more than minimal risk involved? Can the research design be modified to eliminate the need for deception or incomplete disclosure? Will participants be given more information after completing their participation? Would the information to be withheld be something prospective participants might reasonably want to know in making their decision about participation?

Template:

Agreement Between Research Organisation and San Traditional Community

Research Stakeholder Agreement

THIS AGREEMENT (“Agreement”) is entered into by and between the _____ Traditional Authority (hereinafter referred to as “TA”), located at _____ and representing the _____Traditional Community (hereinafter referred to as "TC"), and_____, whose principal office is located at _____

(hereinafter referred to as "the Research Organization”).

WHEREAS, the Research Organization has applied to the TC to do research, and agrees to the conditions placed upon the Research Organization in this Agreement and to comply with the intent of all international, national, local, and customary laws that recognize the rights of indigenous peoples in a research context, including, but not limited to, The United Nations Declaration on the Rights of Indigenous Peoples (“UNDRIP”),[5] and the principles set forth therein; and

WHEREAS, the TC agrees to permit the Research Organization to do such research providing it complies with the intent of all international, national, local, and customary laws that recognize the rights of indigenous peoples in a research context, including, but not limited to, UNDRIP, and the principles set forth therein;

NOW THEREFORE, in consideration of the mutual covenants and conditions contained herein, the parties hereto understand and agree as follows:

Section 1. Parties Bound.
The provisions of this Agreement shall apply to and be binding upon the TC and the

5 UN General Assembly Resolution 61/295 of 13 September 2007.

Research Organization and the Research Organization's officers, agents, successors, assigns and all persons acting on the Research Organization's behalf. Each party certifies that its undersigned representative is fully authorized by the party he or she represents to enter into the terms and conditions of this Agreement, to execute it on behalf of that party, and to legally bind the party on whose behalf he or she executes this Agreement.

Section 2. TC's Authorization

The TA hereby authorizes the Research Organization to undertake research work in _____(location)_____ on the subject of:

DNA Research (“the Research”)

with the communities of:

in the capacity of (if more than one Research Organization is involved):

for the period up until (specify if research will involve more than one visit):

Section 3. Responsibilities of the Research Organization.

3.1 The Research Organization shall pay an administrative fee of N$_____ to cover all administrative fees and costs incurred in the setting up and implementation of the research venture, unless, in the discretion of the TA, which is a committee formed by The TC who are potential subjects of the research that is the subject of this Agreement ("RRC"), the fee has been waived.

3.2 The Research Organization shall regularly, on at least a quarterly basis, keep the RRC meaningfully informed orally and in writing of any and all plans, actions, collections of tissue and information, research results, publications, and products derived from the subject research, including, but not limited to, films, videos, other audio or visual media, cell lines, data banks, and commercial products, and shall account to the RRC, and, where feasible, to the local community, for any and all uses and profits resulting therefrom. When requested by the RRC, copies of publications, reports, films, videos, or other audio or visual media are to be provided, for deposit in an RRC-controlled archive, library, or repository. The TC, individually and collectively, in conformity with local the TC's traditions and customs, shall retain ultimate ownership and control of all tissue samples and information collected from the Research and any and all products derived therefrom, absent any express agreements or contracts, such as license agreements or contracts, to the contrary.

3.3 The Research Organization agrees to involve Local San Community scholars, students, and members of the community in research, to provide full recognition of their collaboration, and to provide training to enable future contribution to the community.

3.4 The Research Organization agrees to promptly notify the RRC of any and all information or products derived from the Research that might benefit the Local San Community, and the Research Organization shall take all reasonable steps necessary to assist in facilitating the realization of such benefits by the Local San Community.

3.5 The Research Organization, in addition to the research work and as a service to the Local San Community, shall undertake to:

3.6 The Research Organization, in undertaking research, shall:

(a) recognize the rights of people being studied, including the rights not to be studied, to privacy, to anonymity, to confidentiality, and to fully informed consent, and specifically to utilize a Free, Prior, Informed Consent Form that is substantially similar to the draft Form attached hereto as Exhibit 1 for each and every person in the Local San Community who might potentially be subjected to any aspect of the Research;

(b) recognize the primary right of informants and suppliers of data and materials to the knowledge and use of that information and material;

(c) respect the traditional knowledge and intellectual property rights of the Local San Community;

(d) respect local customs and values, and carry out research in a manner consistent with this Agreement;

(e) assume a responsibility to make the subjects in the research fully aware of their rights and the nature of the research and their involvement in it;

(f) contribute to the interests of the Local San Community in whatever ways possible so

as to maximize the return to the community for their cooperation in the research work; and

(g) recognize their continuing obligations to the Local San Community after the completion of the research in the field, including providing support and continuing concern for the well-being of the local community.

3.7 The Research Organization shall enter into any and all agreements with any other organizations or persons who are assisting or sponsoring the Research as necessary to assure that the provisions of this Agreement are fully met. Any and all such subsidiary agreements shall be executed by the Research Organization, the other person or entity involved in the Research, and the RRC. The Research Organization has the responsibility to make sure that such consultants are fully aware of their obligations and those of the Research Organization under this Agreement.

3.8 The Research Organization shall maintain all information and data gathered in its Research and shall make such information and data available to the RRC upon request for inspection and review.

3.10 The Research Organization, and the Research Organization's employees, students, and agents, shall maintain confidentiality of any and all records, data, and information gathered relating to the TC which is in the Research Organization's possession and control. Such information shall only be released or disseminated pursuant to the strictest policies of confidentiality and privacy with the consent of the TC.

3.11 The Research Organization is an independent contractor and nothing contained in this Agreement shall be deemed, construed, or interpreted to constitute the Research Organization as a partner, agent, or employee of the TC, nor shall the Research

Organization have any authority to bind the TC.

3.12 A breach of any part of this Agreement by the Research Organization or a decision by the affected community that it no longer desires to be involved in the research will result in the termination of the research project.

Section 4. Responsibilities of the TC.

4.1 The TC are the owner of their communal cultural, natural, and biogenetic resources, and retain ultimate discretionary authority and final authority and responsibility for the approved Research.

Section 5. Noncommercial Purpose

5.1 The Research Organization hereby warrants that it will not use any research performed under this Agreement, research products derived from such research, or traditional or indigenous knowledge obtained from the research, for commercial purposes, unless otherwise provided for in this Agreement, or unless the TC provides its prior, express, written consent for such use, and that it will take reasonable steps within industry standards to assure that there is no third party commercial use of such research, research products, or traditional or indigenous knowledge.

Section 6. Termination of Agreement.

6.1 This Agreement may be terminated by:

(a) the mutual agreement of both parties in writing; or

(b) either party giving the other party not less than sixty (60) days advance notice of termination; or

(c) the non-breaching party in the event the breaching party fails to correct a material breach within fifteen (15) days of receiving written notification from the non-breaching party;

Section 7. Miscellaneous Provisions.

7.1 The TC do not assume any liability by entering into this Agreement.

7.2 The failure of the TC to require the strict performance of any provisions of this Agreement in any one or more instances, or to exercise rights hereunder or seek enforcement of such provisions or rights at law or equity, shall not be construed as and shall not constitute a waiver or relinquishment of such provision or rights, and such provisions and rights shall continue in full force and effect.

7.3 This Agreement, including all matters relating to the validity, construction, performance, and enforcement thereof, shall be governed by the applicable laws of jurisdictions recognized by the TC and international law. The Local San Community Court shall have jurisdiction to hear disputes under this Agreement, and the Research Organization and the TC shall be subject to the personal jurisdiction of the Local San Community Court and all court rules thereof, and shall accept venue in the Local San Community Court. The Research Organization agrees that any process served for any action or proceeding shall be valid if mailed by Certified Mail, return receipt requested, with delivery restricted to addressee, its registered agent, or any agent appointed in writing to accept service.

7.4 All notices required to be given under this Agreement shall be in writing and shall be

either (1) personally delivered to the party to whom addressed, or (2) sent by mail, postage prepaid, registered or certified mail, return receipt requested, addressed to the party at the address which follows or to such other address as the parties may hereafter designate in writing. Any such notice shall be deemed to have been given, if mailed as provided herein, as of the date mail stamped.

TA's Address:

Research Organization's Address:

7.5 If any provision of this Agreement is found unlawful, void, or unenforceable by a court having jurisdiction over the TC, that provision shall be deemed severed from this Agreement, and in no way shall affect the validity or enforceability of the remaining provisions of this Agreement.

7.6 Neither party shall assign, pledge, or transfer, in whole or in part, their rights, duties, responsibilities, or interests under this Agreement without the prior written consent of the other party. No assignment of this Agreement shall be made to an individual, organization, firm, or business entity that has been convicted of a criminal offense related to or involved in any research concerning research of any San community or indigenous community. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and each of their respective successors and permitted assigns.

7.7 This Agreement constitutes the entire agreement between the parties and no agreements or representations have been made or shall be binding upon either party unless set forth herein. This Agreement supersedes any prior oral or written statements made by either party, its employees, representatives or agents.

IN WITNESS WHEREOF, the TC and the Research Organization have executed this Agreement, in triplicate, individually or by signature of this duly authorized representative as of the date and year written below.

The Ju|'hoansi Traditional Authority (local community)

By: _____

Name and Title Authorized Signatory:

_____

Date: _____

The Research Organization

By: _____

Name and Title Authorized Signatory:

_____

Date: _____

Free Prior Informed Consent Questionnaire

STATEMENT OF PERSONAL AGREEMENT TO OR LACK OF AGREEMENT TO CONSENT TO PARTICIPATE IN OR BE SUBJECTED TO RESEARCH*

**Note: Although any part of this draft Statement is subject to future editing and revisions after further consultation with both researchers and community members, the words in brackets are highlighted as sample language that may be particularly subject to editing and revisions after such further consultation.*

A competent interpreter (oral translator) and should be present at all times during this interview, i.e., the transcription of this statement, unless the person from whom consent is sought is fluent in the first language of the researcher/interviewer.

A. *Information Concerning the Person Providing the Statement*

1. *Name of the Person Providing the Statement* [Reassure the person interviewed that the person's identity will be kept confidential by the interviewer and research team]*:*

2. *Residential Location or Living Situation of the Person Providing the Statement:*

_____

3. *Any other pertinent identifying information that the Researcher requests AND THE PERSON PROVIDING THE STATEMENT AGREES TO PROVIDE AFTER THIS STATEMENT REGARDING CONSENT IS COMPLETELY READ BY OR ORALLY TRANSMITTED TO THE PERSON PROVIDING THE STATEMENT (e.g., Gender, Age, Immediate Living Family Members, Immediate Deceased Family Members, Marital Status, Names of Spouse or Spouses, or, if and only if the interviewee provides his or consent to be contacted in the future, contact information, such as mailing address, telephone number, or e-mail address):*

Introduction

You are invited to take part in a research study by [insert researcher and institution]. This study is part of [insert consortium or initiative if applicable] and is sponsored by the [insert funder]. [Institution] is one of many institutions involved in this project.

The choice to participate in this research is completely up to you. No matter what you decide to do, your decision will not affect the medical care you would normally receive or any other benefits that you would otherwise receive.

You can learn more about the [initiative], including major findings resulting from this research ***[from a designated community representative or ambassador].***

YOU HAVE THE RIGHT TO REFUSE TO PARTICIPATE IN THIS STUDY. EVEN IF YOU AGREE AT FIRST TO PARTICIPATE IN THIS STUDY, YOU HAVE THE RIGHT TO WITHDRAW FROM PARTICIPATION AT ANY TIME.

THE [RESEARCHERS] ALSO HAVE AN OBLIGATION TO KEEP YOU INFORMED OF THE STATUS OF THE RESEARCH PROJECT AND THE USES BEING MADE OF THE INFORMATION ABOUT YOURSELF AND THE SAMPLES COLLECTED FROM YOUR BODY THAT YOU PROVIDE TO THEM.

THE [RESEARCHERS] SHOULD PROVIDE YOU WITH THE INFORMATION THAT YOU NEED SO THAT YOU CAN MAKE AN INFORMED DECISION ABOUT WHETHER YOU WANT TO CONTINUE TO PARTICIPATE IN THE STUDY OR ALLOW THE SAMPLES AND INFORMATION OBTAINED FROM YOU TO CONTINUE TO BE USED.

B. What is this study about?

Here the interviewer should attempt to explain what the study is about to the person interviewed by using words and concepts that the person interviewed can understand, *i.e.,* by using non-technical words and concepts that the average person in the community would understand, such as:

We are asking for your permission to collect samples of [your saliva, blood, or skin] and [obtain health information from you] in order to [learn more about human beings and human health so as to understand how you, your family, the people in your community, and all people in the world may be able to live healthier and happier lives.]

Your [saliva, blood, or skin] samples **[contain "cells." Those cells contain DNA. DNA contains "genes." Genes make up the "instruction book" for the cells in your body. A complete sequence, or string, of all the genes in your body is called a genome.]**

[At this point, the researcher/interviewer, *i.e.,* the person requesting the subject's consent, might want to use visual aids, unless visual aids are deemed by the ethnographers or community members as not likely to be helpful or advisable ways to facilitate the communication process.]

After the above explanation (as with each and every explanation in this questionnaire), ask the person whose consent is sought if he or she has any questions about the explanation. Then, if necessary, engage in a dialogue with that person to confirm that person reasonably understands the explanation before going forward.

IMPORTANT: If, at any point, the person whose consent is sought indicates a lack of understanding after further dialogue, then the person administering the consent questionnaire should stop and seek further instructions from the research team and authorized community representatives before continuing to administer the questionnaire.

C. Further Disclosures Regarding How the Samples and Information Collected from this Study May Be Used.

1. DNA Sequence Analysis

The researchers who collect samples of your DNA from your [saliva, blood, or skin] **intend to** study your entire genetic sequence, known as your genome. The genome sequence will be read, and this information will be stored.

The researchers intend to use your genetic data to find differences and similarities among people concerning disease or other health traits, your ancestry, and the history of your ancestors.

The researchers intend to study your genetic *data and health information along with information from other participants in this study, and,* ***if and only if you provide your consent, after first being fully informed, the researchers may store it*** *for future studies by* ***them*** *and other research teams.*

2. Coding of Tissue Samples and Medical Information

Your [saliva, blood, or skin] sample, genomic data and health information will be labeled with a code and your name and other information will be removed.

We will keep a master list that links those codes to your samples and data. Only certain project staff can access this master list. We will keep the samples in locked freezers. We will keep genomic data and health information on secure computers. These computers have many levels of protection.

Your [saliva, blood, or skin] samples and health information may help us better understand how human beings can live healthier and happier lives. We may gain this understanding, in part, by better understanding, for example, how genes and genomes play a role in human diseases such as, for example, [cancer, heart disease, diabetes, or glaucoma].

E. The Process of Collecting Samples and Related Medical Information

If you agree to participate in this study, the manner in which we will collect your [saliva blood, or skin] samples is as follows: [describe the collection process, preferably with videos or illustrations—possibly by showing how it is done with a consenting live person].

Sample Language

If you have seen a medical doctor or other researcher who has collected a [saliva, blood, or skin] sample as part of your medical care, we may request permission from you to examine and study a part of this sample (for example, any DNA obtained) that already may have been extracted from the sample by your doctor or other researcher.

If a [saliva, blood, or skin] sample is not already available for this project, we likely will use a needle to draw a small amount of blood from a vein in your arm. If you object to having blood drawn, we can instead swab cells from the inside of your cheeks to obtain a saliva sample.

We will also ask you for information related to your health and/or disease history [directly as part of the study/from your medical records.]

Possible insert if there is a data bank or other ongoing data collection: [We may also look at your medical records from time to time, ***after first obtaining your prior, informed consent in each instance,*** *to update the information we obtain from you and/or your doctors. This* ***may*** *take place indefinitely,* ***unless you tell us now that you do not want the researchers to look at your medical records***

after [insert a date], *for as long as your information and samples are stored for this study, or any related studies.]*

[Only add the following section if applicable.]

F. *Cell Line Disclosure*

As part of this project, your [saliva, blood, or skin] samples may be used to create what are called cell lines. Cell lines keep reproducing and can be used for many purposes. If we create cell lines, we will store the cell lines and other samples and data in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. The cell bank will only release cell lines to researchers and others under certain conditions and only with your express permission. Some of the conditions include: [Specify the terms of release established by the repositories, such as ***only with*** *IRB approval****,*** *or approval by a governance committee,* ***or only for not for profit uses, etc.****.]*

G. *Possible Risks of Participating in this Study*

Sample Language

There are possible risks that you, your family, or your community may suffer harm or loss from your participation in this study. These risks may include:

1. Physical Risks

    a. The most common risk of having blood drawn is mild pain, bleeding, bruising, and infection (rare).

    b. If your tissue is collected through a skin biopsy, you will experience some discomfort at the biopsy site, which is usually mild and goes away in a few minutes. It can be treated with minor pain relievers. Normally, the risks include a reaction to the local anesthetic (very rare), bleeding (occasional), infection (rare), and scarring at the biopsy site (always).

    c. The Research Team will transport you to the nearest private health clinic if you are injured in any way from your participation in this study and will see that you receive any and all medical care that you might require according to the prevailing international standards of medical care. We will also compensate you for any medical costs that you need to incur from your participation in this study, including the costs to you of

paying for a doctor or nurse, the costs of an extended stay in a medical facility, and the costs of any medications or medical supplies (such as bandages) that a doctor prescribes for you.

2. Invasion of Privacy and Re-Identification Risks

Through all stages of sample and data collection, storage, sharing, and analysis, your privacy and confidentiality will be protected. [However, the research team is required to report child abuse and neglect, or substantial risk of harm to self or others to authorities.]

While neither the public nor the restricted-access databases developed for this project will have information such as your name or address, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post on the Internet about yourself). The risk of this happening is currently very low.

Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them.

It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk.

If your genomic information is linked back to you, someone might use this information to learn something about your health and use that information against you.

There also may be other privacy risks that we have not foreseen, but we will try to let you know about other risks that we learn about as soon as we can after learning about them.

3. Psychological or Social Risks Associated with Disclosure to Third Parties

This study has been developed in consultation with [representatives of your community, describe]. These community representatives have been/are involved in [describe their involvement].

Although we will not give your name to the researchers who study the [saliva blood, or skin] samples and health information that you provide, we will give them basic information such as your race, ethnic group, geographic region, age range, and sex [specify demographic variables]. This information may help researchers study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you.

However, it is also possible that such research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of your extended family, community, race, or ethnic group.

The research results may also report secrets of your culture or community [such as how it cures certain diseases] or stories about your culture or community [such as how your culture or community was first created] that you would normally be unwilling to share with people outside your community or that are different from what you believe to be true. The researchers will take precautions to keep such secrets from being shared with outsiders and to assure that the stories shared with outsiders about your community are not ones you would mind sharing with others, but they may not always be able to do so.

If you learn that any such secrets or stories are being shared with others that you do not want to have shared, you have the right to both: a) contact [designate person or institution] and withdraw from participating in the study; and/or b) have [that person or institution] stop sharing such secrets or stories with outsiders.

[Add the following subsection only if applicable.]

4. *The Role of Your Children in the Study*

As a part of the study, your children's [saliva, blood, and skin] samples, genomic data, and health information may be stored and used for future research. When any of your children reach age 18, we will try to contact him or her to ask whether he or she wants to continue to participate in research. If we cannot find your child, we

will remove identifying information and will not continue to include his or her samples, genomic data and health information in the research.

We may learn information relevant to your children's or your family's health. [Tailor based on the plans for returning results, for example:] If this happens, we will tell you only information directly related to diseases and disorders that affect children. Your child can request additional information when he or she is 18.

5. *Your Legal Rights for Compensation or Remediation*

You, your family, and your community have the right to seek compensation, remediation, or other redress under any applicable law or under any other written agreement that might be negotiated between you, your family, or your community and [the designated representative or representatives of the research team] for any harm or loss that you, your family, or your community suffer from your participation in this study.

H. *Possible Benefits from Participating in this Study*

You may also receive benefits from participating in the study. These may include:

1. Your participation may help medical researchers better understand various diseases and develop better treatments, which may help others like you in the future. However, such understanding and treatments, if any, likely will not be realized for many years.

2. You, members of your family, or your community may also receive the following possible benefits from participating in this study:

   a. [an honorarium] for the time you are taking to participate in this study;

   b. We have offered to make to transport you to this interview, if it was necessary, from your home in order to participate in this study, however we have attempted to conduct the study close to your home, so that you have not had to travel far from your home;

c. We will use your [saliva, blood, or skin] samples and information that you provide us about yourself only for research and only as you and your community permit us to, because your community and you will retain ownership of it. We will not sell them without your prior informed consent.

However, the results of this research might someday lead to the development of products (such as a new medicine or other commercial products) that could be sold for profit. Your community will be negotiating an Agreement with [the Research Team] that recognizes this possibility and ways that your community, and possibly your family and you, can benefit from the development of such products.

If you wish to learn more about this the status of this Agreement and such benefits, you should contact [Name, title, and contact information of Community Representative to Contact].

I. Withdrawal from the Project

REMINDER: You may stop your participation in this study at any time. If you decide to withdraw from the study or part of the study, you can contact [Insert Name & Contact Information of Principal Investigator] at [Insert Name of Institution].

If you inform [person and/or institution named immediately above] that you want to stop your participation in this study, he/she/it will direct that any of your remaining tissue samples and any research data that is stored from samples collected from you be destroyed. The facility or facilities storing the samples and data collected or obtained from you will no longer send out your samples or data to other researchers.

If cell lines have been derived from your samples, we will destroy the remaining cell lines being stored that have been derive from your samples.

However, the samples, cells, and data generated from your samples that have already been sent to other researchers or placed in the research databases cannot be withdrawn.

[Only add the following section if applicable.]

We may learn information relevant to your children's or your family's health. [Tailor based on the plans for returning results, for example:] If this happens, we will tell you only information directly related to diseases and disorders that affect children. Your child can request additional information when he or she is 18.

J. *Consent Confirmation*

If you wish to participate in this study, please check your answers to the following questions.

1. May we collect your [saliva, blood, and skin] samples and health information?

Yes No

2. *Researchers might want to ask you to participate in additional studies. In some cases, you might be a particularly good candidate for a particular study because of your health history or information learned from the samples of [saliva, blood, and skin] that you provide.*

May we contact you in the future to get your permission to use your [saliva, blood, or skin] samples, the information learned from your [saliva, blood, or skin] samples, or from other health information that you provided for additional studies?

Yes No

3. *May we contact you in the future to ask your permission for additional [saliva, blood, and skin] samples or follow-up information about your health or medical care?*

Yes No

K. Power of Attorney or Legal Guardian

If, in the future, I become so disabled or incapacitated that I cannot answer questions about whether to participate in this study or let the researchers know that I no longer want to participate or allow the samples collected and information obtained from me to continue be used for research:

You may continue to use the samples and data you have already collected from me [Yes] or [No]

You may collect new samples or data from me, just as described in this consent form [Yes] or [No]

I designate _____ [OR a previously designated legal guardian/named power of attorney] to make decisions about my participation, consistent with what I have agreed to here.

DATE(S) THAT THIS STATEMENT WAS TAKEN:

_____

PLACE(S) WHERE THIS STATEMENT WAS TAKEN:

_____

NAMES AND ROLES OR TITLES OF ALL PERSONS PRESENT WHEN THE STATEMENT WAS TAKEN:

_____
_____
_____
_____

SIGNATURE OF THE PERSON PROVIDING THE STATEMENT OR OF THAT PERSON'S GUARDIAN OR DESIGNATED POWER OF ATTORNEY:

_____

PRINTED NAME AND AUTHORITY OF THE PERSON SIGNING ABOVE:

_____

SIGNATURE OF ANY TRANSLATOR(S) OR INTERPRETER(S):

_____
_____
_____
_____

PRINTED NAME(S) OF ANY TRANSLATOR(S) OR INTERPRETER(S):

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PRINTED NAME OF INTERVIEWER(S):

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SIGNATURE(S) OF INTERVIEWERS:

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_____
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_____

RESEARCH INSTITUTION(S) OR AFFILIATION(S) OF THE INTERVIEWERS:

_____
_____
_____
_____


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