

A proposed methodology for engagement, informed consent, and governance for conducting genetic research with Indigenous communities: An Australian example

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BACKGROUND

Acute Rheumatic Fever (ARF) and its chronic manifestation Rheumatic heart disease (RHD) result from an autoimmune reaction to group A streptococcal infection. Despite decades of research, underlying genetic mechanisms for why RHD occurs are not well understood. Yet this remains critical to developing preventive and therapeutic interventions.

STUDY OBJECTIVE: to better understand the pathogenesis (development patterns) of Rheumatic Heart Disease (RHD)

Location: 18 consenting communities across the Northern Territory of Australia



Sample: 500 Aboriginal people with RHD and 1,000 community-matched controls



Past controversy in Indigenous genetic research has raised ethical concerns about the collection, use and storage of genetic samples.

An appropriately designed methodology with a focus on cultural and ethical processes for gaining informed consent for the collection and treatment of samples was therefore vital to guide the study.

METHOD

STUDY AIM: to establish a range of consultative, culturally aligned & community guided mechanisms to support & ensure a robust and ethically sound approach to genetic research with participating Aboriginal communities

An Aboriginal governance committee (AGC) guided and developed the study plan and led the engagement processes with communities

Community engagement involved relationship building through 'yarning', use of language and local cultural interpreters and guides

Community-based researchers shared local community protocols, knowledge and understanding of kinship systems

Long term governance of samples, overseen by the AGC will govern issues such as: future sample use requests, community engagement, publications, ensuring no misuse of data and overseeing benefit sharing

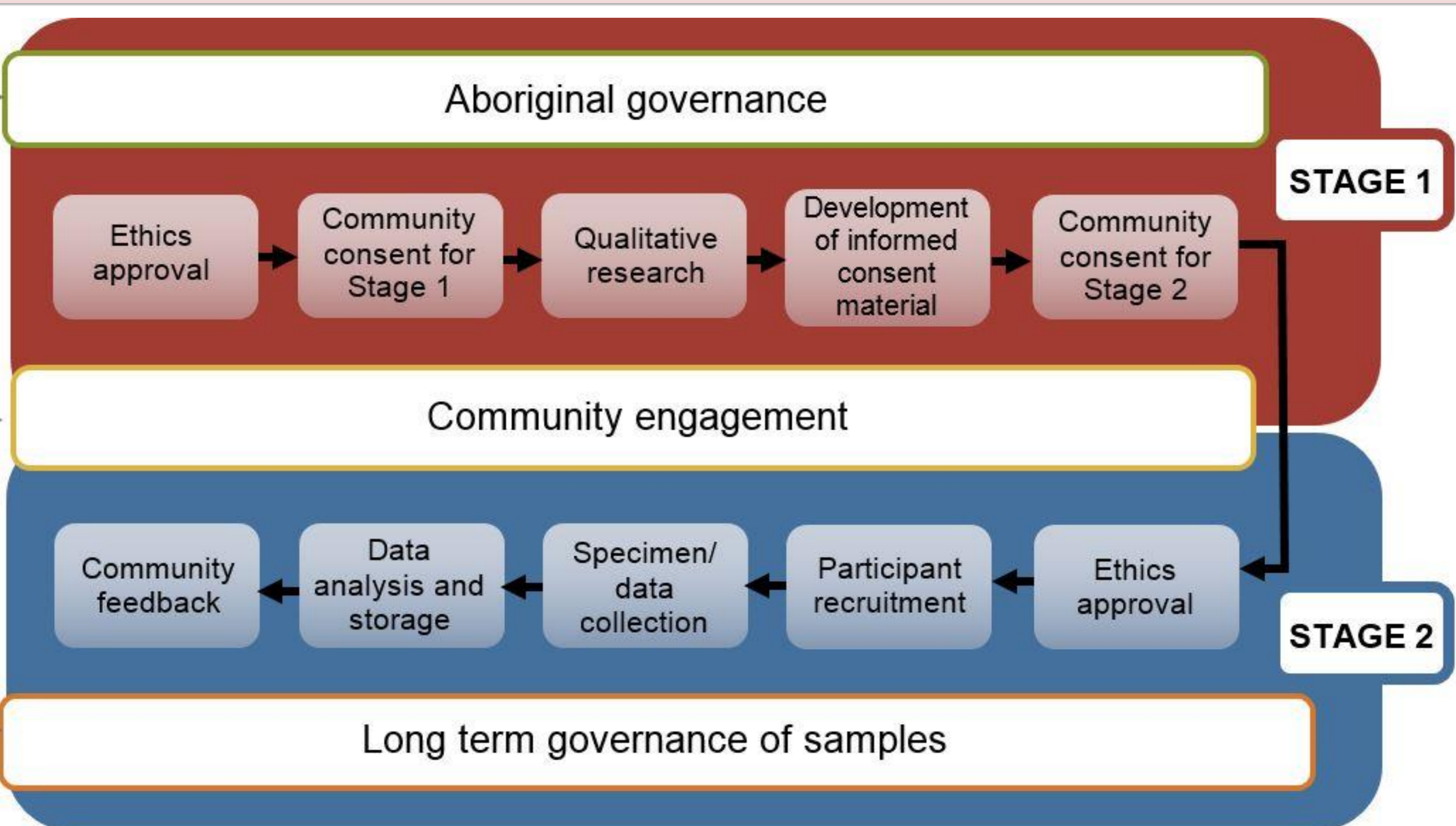
Ethics approval for the project was granted in February 2011

Consent was first sought by communities prior to seeking individual consent

Consenting communities were further engaged through local reference groups to:
i) conduct 'yarning circles' (focus groups) in selected communities, and
ii) ensure consent materials were suitable for use in their community

Genetic and health literacy material (flipchart), informed by communities, was produced to ensure consent for the collection, use and storage of samples was well informed and understood

Only after local reference groups deemed consent materials suitable did the study proceed within that community to stage 2



STAGE 1 AIM: Engage in culturally safe consultation and engagement with the Aboriginal community to ensure that issues associated with genetic research were thoroughly explored and discussed

STAGE 2 AIM: enrol 500 Aboriginal people with RHD and 1,000 community-matched controls across the NT

All communities received feedback on the research and will continue to be engaged into the future

The AGC directed and advised on consent, recruitment, handling and storage of specimens across Australia

An optional, opt-in style of consent was requested giving participants the option to have their sample and data stored and used in future research

The flipchart on the story of genetics and RHD was discussed with participants prior to recruitment, consent, and collection of sample



Letters of support from relevant community agencies were included in the ethics application for Stage 2

RESULTS & CONCLUSION

- This study demonstrates how preliminary efforts to address issues of relationship building and engagement assisted in developing community members' genetic literacy and ensured that members understood what they were consenting to when giving permission to informed consent in the context of genetic research.
- This was critical to clarifying researchers' responsibilities and obligations in relation to the future use of stored data and genetic samples for other research projects, and will more likely result in benefit sharing between community members and researchers.
- This study demonstrates that such sensitive research can be ethically and successfully conducted. It can inform a pathway for ongoing research in this field and contribute to the formation of guidelines for the conduct of genetic research with Aboriginal communities.

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END RHD Centre of Research Excellence