RACGP
Royal Australian College *of* General Practitioners

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29 June 2020

Ms Vanessa Clements
Director, Speciality Service and Technology Evaluation Unit
NSW Ministry of Health
Tower B, Level 8, Zenith Centre
821 Pacific Highway
Chatswood NSW 2067

Via email: vanessa.fitzgerald@health.nsw.gov.au

Dear Ms Clements,

**Re: National Model for Clinical Consent to Genomic Testing (Draft final report)**

The Royal Australian College of General Practitioners (RACGP) thanks the NSW Ministry of Health for the invitation to respond to the consultation for the draft *National Model for Clinical Consent to Genomic Testing*.

The RACGP does not support the use of this form as a compulsory checklist prior to every genetic test undertaken by patients. The RACGP believes the consent form would be useful only as a reference checklist for general practitioner (GPs).

We provide the following comments for your consideration.

1. **The utility of a genomic consent form in general practice**

GPs regularly order tests for patients and are skilled in having informative discussions, in a way that meets the individual needs of the patient and in the context of the patient's medical history, to gain informed consent. GPs keep clinical notes to document such discussions and consent.

The form is a useful aid to support such discussions. However, if it is part of a compulsory process it will most likely hinder these discussions and create unnecessary bureaucracy.

The RACGP is also concerned that although the form is designed to meet the needs of patients, many will not fully understand its intent. It is unclear whether the consent form was developed in consultation with patients and consumers from different language abilities, educational levels, cultures and disability. The form appears to have a high language level, which will significantly impact patients from culturally and linguistically diverse backgrounds, patients with disability, and patients of lower educational level. For example, the term 'uncertain significance' is a complex concept that includes the limitations of current knowledge, technology and testing procedures.

2. **Use in electronic records and privacy concerns**

If these forms were to be used, the RACGP seeks clarification on what will happen to the forms once completed. If the intention is that general practices save these to a patient's electronic medical record, the future purpose for doing so should be clarified. Alternatively, if the intention is for the form to be submitted to a national collection centre, who will be required to do this and the steps taken to maintain patient confidentiality and privacy need to be clearly outlined.

It is also unclear what level of consent is required if other family members request the documented information.

**3. Form content**

Patients may have family members with them in a consultation, for cultural reasons or if the presenting patient is a child and/or has a disability. There is no place to provide parental or guardian consent on the form.

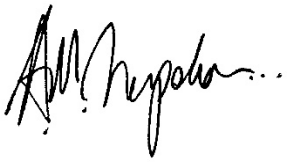
The form needs to clearly indicate that the patient's sample will not be used for research purposes. Patients may also have questions about how samples could be retained for future testing when technology has improved.

**4. Financial and future implications of genomic testing for patients and their families**

Several new Medicare item numbers for genomic testing have recently been introduced. It is important to note, however, that not all genetic tests are currently subsidised. The economic consequences of genomic testing should be clearly articulated. This includes the initial cost of genetic testing and the potential impact on insurance of a 'positive' test, as both of these issues are important considerations for many patients.

We thank the NSW Ministry of Health again for inviting the RACGP to provide a submission. Please contact Mr Stephan Groombridge, Manager, e-Health and Quality Care on (03) 8699 0544 or at stephan.groombridge@racgp.org.au if you have any further queries.

Yours sincerely



**Dr Harry Nespolon**
President