



## FSC Standard No. 11 Genetic Testing Policy

<b>FSC Membership this Standard is most relevant to:</b>	This Standard is relevant to FSC Members broadly. However, it is of particular relevance and binding upon FSC Members who are <i>APRA</i> registered life insurance companies or have a subsidiary that is a registered life insurance company.
<b>Date of this version (and commencement):</b>	This Standard was issued on (7 December 2016), and commences from 7 December 2016.
<b>History (prior version) of this Standard:</b>	This Standard was first approved by the FSC Board on 13 December 2001 to take effect from 1 January 2002. The Standard was reviewed and approved by the FSC Board on 7 December 2016.
<b>Main Purpose of this Standard:</b>	The purpose of this Standard is to specify Standards relating to the handling of genetic test results to be adopted by a Member in the operation of its business.

## TABLE OF CONTENTS

1. Title.....	3
2. Standards and Commentary.....	3
3. Date of Issue .....	3
4. Effective Date .....	3
5. Application of Standard.....	3
6. Statement of Underlying Principles .....	3
7. Statement of Purpose .....	4
8. Application of Materiality .....	4
9. Definitions .....	5
10. Genetic Testing Policy.....	5

**1. Title**

**1.1 This Standard (The “Standard”) may be cited as FSC Standard No. 11 ‘Genetic Testing Policy’.**

**2. Standards and Commentary**

**2.1 The standards set out in this Standard are shown in bold print.**

**Explanatory commentary is provided in normal print immediately after the Standard to which it relates, as an aid to interpretation of that Standard.**

**3. Date of Issue**

**3.1 This Standard was first approved by the FSC Board on 13 December 2001 to take effect from 1 January 2002. The Standard was reviewed and approved by the FSC Board on 26 October 2005 and 7 December 2016.**

**As some of the content is inter-related, Standards No.11 and No.16 were reviewed concurrently and amended as necessary, to ensure consistency.**

**4. Effective Date**

**4.1 This revised Standard should be applied in relation to a Member’s life insurance operations on or after 7 December 2016. Earlier application if this standard is permitted and encouraged.**

**5. Application of Standard**

**5.1 This Standard applies to all Members who are a registered life insurance company or have a subsidiary that is a registered life insurance company.**

**5.2 All life insurance companies registered by APRA who are not FSC Members are also encouraged to follow this Standard.**

**5.3 Where there is a conflict between the requirements of this Standard and any relevant legislation or guidance issued by a statutory or regulatory agency, the requirements of this Standard should, having regard to the purpose of the Standard, be modified appropriately so that (as far as is practicable) the Member can comply with the requirements of this Standard.**

**5.4 This Standard should be read in conjunction with FSC Standard No.16 ‘Family Medical History Policy’ and FSC Standard No.1 ‘Code of Ethics & Code of Conduct’.**

**6. Statement of Underlying Principles**

**6.1 When developing this Standard, the FSC’s Members abided by the following underlying principles:**

- life insurance should remain available to the majority of the insurable population at standard premium rates;**

- risk classification should be allowed to evolve and reflect the continuous development of medical knowledge and technological advances;
- the average price point (relative to age and other key risk demographics) at which life insurance is offered at standard rates should be affordable for most insurable Australians;
- given the long term nature of life insurance contracts, the industry must remain sustainable into the future. Sustainability requires constant prudential management, effective management of insurance risks (including minimal cross-subsidisation between customer groups) and delivering viable investment returns to shareholders;
- all Members should maintain consumer confidence and remain accountable and transparent, to help ensure that current and potential customers are not dissuaded from taking a genetic test, undergoing appropriate medical intervention, or participating in medical research.

## **7. Statement of Purpose**

**7.1** The purpose of this Standard is to specify Standards and Policies for the handling of Genetic Test results. The Standards and Policies are to be adopted by a Member in the operation of its life insurance business;

**7.2** Because of the sensitive nature of Genetic Test results and the potentially significant impact on customers who receive adverse results, Members should meet the highest standards in relation to the handling of Genetic Test results and genetic information within their life insurance operations.

As existing legislation (e.g. The Privacy Act 1988) already requires Members to comply with specific privacy protection obligations deemed important to customers, Members should also ensure ongoing compliance with the relevant legislative requirements.

**7.3** In addition to ongoing compliance with legislative and regulatory requirements, there are ethical business principles and practices that should be followed to deliver high standards of individual and collective conduct in the operation and management of a Member's life insurance business.

**7.4** This Standard aims to facilitate an efficiently-functioning life insurance industry that remains sustainable in the long term, while also recognising the industry's social responsibility to not hinder the ongoing advancement and adoption of new medical knowledge and technologies that could potentially improve individual and public health outcomes.

## **8. Application of Materiality**

**8.1** The Standards and Policies described in this Standard apply to all FSC Members without exception. Failure by a Member to adopt or implement a Standard could be deemed 'material' if such failure adversely affects:

- an insured or potential insured person's confidence in the Member;
- another insured person's confidence in the Member or in the life insurance industry.

**9. Definitions**

**9.1** In this Standard:

- 'Applicant' means the person to be insured;
- 'APRA' means the Australian Prudential Regulation Authority;
- 'Authorised Representative' means any person or entity authorised by the Member to provide information or advice to customers in respect of the sale of a Member's life insurance products.
- 'Genetic Test' means a medical test that identifies changes in chromosomes and genes. These tests incorporate pathogenic variants in DNA. The results of a genetic test may confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder, or risk from that disorder.
- 'Insurer' means a member of the Financial Services Council (FSC), or any non-member operating a life insurance business;
- 'Member' means a member of the Financial Services Council (FSC).

**10. Genetic Testing Policy**

**10.1** Members should not initiate any Genetic Tests on Applicants for insurance.

10.1.1 Under no circumstances will a Member ask an Applicant to undergo a Genetic Test to support an application for insurance.

**10.2** Members may ask Applicants to provide existing Genetic Test results for the purposes of risk classification.

10.2.1 This requirement to disclose existing medical information is consistent with the Duty of Disclosure required by the Insurance Contracts Act 1984, which places Applicants under contractual and statutory duties to disclose all relevant information to an Insurer.

10.2.2 Genetic information, like other personal medical information, may influence a person's decision to seek life insurance.

10.2.3 If an Insurer is not made aware of the same medical information that an Applicant already has about his or her individual risk profile, the Insurer cannot determine the

most equitable premium rate. This inequity in access to relevant information could significantly increase the cost of claims, eventually leading to premium rate increases for all customers.

In certain circumstances, if an Applicant deliberately withholds significant information from an Insurer to the extent of material and/or fraudulent non-disclosure, this could result in serious consequences for the Applicant under existing legislation.

10.2.4 To maintain a sustainable voluntary life insurance industry in Australia, it is essential that Insurers can continue to assess individual applications for insurance, in order to apply the most appropriate risk classification and premium rate for each Applicant.

**10.3 Members should not ask Applicants to provide Genetic Test results for the purposes of risk classification in circumstances where an Applicant's genetic test results were solely used for the purpose of a medical research study conducted by an accredited university or medical research institution where;**

**(i) The test results are not known by an Applicant and will not be provided to the Applicant or**

**(ii) The Applicant has specifically requested not to receive the test results.**

10.3.1 Ongoing scientific research is essential for the development of future medical advances that have the potential to continue enhancing individual and public health outcomes in Australia and globally.

Accordingly, as underwriters of morbidity and mortality risks, the Australian life insurance industry has an inherent stake in the ongoing progress of scientific research in medical genetics and related fields.

10.3.2 In circumstances where an Applicant's Genetic Test results were used for other purposes such as for medical research purposes, to clarify an Applicant's individual risk of developing a disease due to a known family history, then the Applicant would still be required to disclose and provide relevant medical information to the Member-

It should be noted that in such cases, an Applicant would have been required to disclose the relevant medical information anyway when completing the Medical or Family History questionnaires typically included in insurance application forms, irrespective of his or her participation in scientific research.

**10.4 Members should provide appropriate training on this Standard to their relevant employees and Authorised Representatives, so they can effectively apply the Standard in the course of carrying out their duties.**

10.4.1 Members' Authorised Representatives should be aware of the requirement to obtain specialist underwriting advice before responding to an Applicant's query regarding the impact of a specific Genetic Test result on an insurance application, as the range of Genetic Tests and their potential underwriting implications can vary significantly.

- 10.5** When assessing the cumulative risk associated with an Applicant's Genetic Test result, Members should consider the potentially-beneficial effects of medical screening, early diagnosis and treatment on the Applicant's long-term health outlook.
- 10.5.1 Members should ensure that their underwriting staff can access a company-internal or external subject matter expert (for example, a Chief Medical Officer) to obtain expert input into cases where a Genetic Test result is deemed a relevant factor in the underwriting assessment.
- 10.5.2 Members should monitor ongoing medical genetics research to identify new advances with the potential to impact life insurance pricing, products and underwriting.
- 10.5.3 As quickly as is practicable, members should incorporate into their procedures new medical knowledge that alters the underwriting assessment of specific genetic diseases.
- 10.5.4 In instances where a dispute arises regarding the reliability of scientific evidence used to inform an underwriting assessment, where appropriate, Members may consult independent external experts appointed by Insurers to independently review the reliability of the relevant scientific evidence.
- 10.6** Members should ensure that existing Genetic Test results are only obtained with the informed written consent of the tested Applicant, or where applicable by law, the informed written consent of the Applicant's appointed legal guardian.
- 10.6.1 Members should not ask a third party to provide an Applicant's Genetic Test result before obtaining the Applicant's informed consent, or (where applicable by law) the informed consent of the Applicant's appointed legal guardian.
- 10.7** Members should only use a Genetic Test result for the underwriting assessment of the Applicant who actually underwent the test, or the 'tested Applicant'. The same Genetic Test result should not be used for the underwriting assessment of a second Applicant who is a relative of the tested Applicant, unless the second Applicant disclosed the Genetic Test result separately on his or her insurance application.
- 10.8** Members should apply strict standards of privacy, confidentiality and data security to the handling and storage of all personal and medical information, including Genetic Test results, in accordance with relevant legislation and regulations.
- 10.9** Access to Genetic Test results in a format identifiable to a specific individual should be restricted in accordance with the relevant privacy legislation requirements. The results may be made available to a third party only after a Member receives informed written authorisation from the relevant Applicant, or where relevant, his or her appointed legal guardian.
- 10.9.1 Members should preserve the privacy and confidentiality of an Applicant's Genetic Test results when dealing with any third party.
- 10.10** Members should ensure that all authorised employees have signed a confidentiality agreement confirming they understand that all personal and medical information of Applicants should be kept strictly confidential at all times.

- 10.11 Members should give consideration to the following uniform wording when developing wording in personal statements with regard to genetic tests**
- 10.11.1 Have you ever had or are you considering having a genetic test where you have received (or are currently awaiting) an individual result?
- 10.11.2 This question is intended to provide clarity to Applicants who may have undergone genetic testing as part of their participation in a medical research project or trial but will not receive an individual genetic test result.
- 10.12.1 **Unless 10.12.2 applies,** Members should inform applicants in a clear and meaningful manner of the rationale for an unfavourable underwriting decision, including reference to the evidence relied upon to reach that decision.
- 10.12.2 In circumstances where a Member determines that the underwriting rationale and supporting evidence would be better explained by an Applicant's treating doctor, where appropriate, the Member may consider contacting the Applicant's doctor to provide the relevant information. In such cases, the Member will only provide the underwriting decision to the Applicant and ask him or her to discuss the underwriting rationale and supporting evidence with the treating doctor.
- 10.12.3 When informing an Applicant of an unfavourable underwriting decision, a Member should provide information about avenues the Applicant can pursue if he or she decides to request a review of the decision, including the process to lodge a complaint with the Member or the Financial Ombudsman Service.
- 10.13 After assessing an application, a Member may conclude that the risk is too great and cannot result in a viable insurance offer. In such circumstances and where possible, Members should endeavour to offer alternative terms or products.**
- 10.14 In accordance with their obligations under the Life Insurance Code of Practice Standard, Members should provide a competent and efficient disputes resolution service to manage complaints resulting from adverse underwriting decisions involving a Genetic Test result. A Member's response to any complaint should always include information on the legal remedies available to the Applicant.**
- 10.15 Members' compliance with this Standard should be reviewed and certified annually according to the terms of FSC Standard No. 1 Code of Conduct and Code of Ethics.**
- 10.15.1 Members should regularly monitor compliance with this Standard by their authorised employees and representatives, and should take remedial action in cases where an employee or authorised representative does not comply with the Standard.
- 10.16 Subject to compliance with the Privacy Act, Members agree to participate in the FSC's regular collection of de-identified data on applications involving a Genetic Test result. Members also agree to allow the FSC to make such de-identified data publicly-available to support new research initiatives.**