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Genetics and insurance in Australia: Concerns around a self-regulated industry

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Abstract

Background: Regulating the use of genetic information in insurance is an issue of ongoing international debate. In Australia, providers of life and other mutually rated insurance products can request applicants to disclose all results from any genetic test. Insurers can then use this information to adjust premiums and make policy decisions. The Australian Financial Services Council (FSC; an industry body) developed and maintains the relevant industry standard, which was updated in late 2016. **Aims/Objective:** To review the 2016 FSC Standard in light of relevant research and determine the legitimacy of the Australian regulatory environment regarding use of genetic information by insurers. **Results:** We identified five concerns arising from the 2016 FSC Standard: (1) use of results obtained from research; (2) the requirement for an applicant to disclose whether they are "considering" a genetic test; (3) failure to account for genome sequencing and other technology developments; (4) limited evidence regarding adverse selection; and (5) the inappropriateness of industry self-regulation. **Conclusion:** Industry self-regulation of the use of genetic information by life insurers, combined with a lack of government oversight, is inappropriate and threatens to impede the progress of genomic medicine in Australia. At this critical time, Australia requires closer government oversight of the use of genetic information in insurance.

Introduction

Predicting an individual's future health or illness has long been of interest to insurers. A consumer seeking to obtain a product such as life, critical care, or income protection insurance is asked to provide a medical history as part of the risk assessment or underwriting process, and genetic information may inform this. Yet whether and (if so) how such information should be used to influence insurance premiums has led to debates over issues such as genetic exceptionalism [1, 2], adverse selection [3-6], and genetic discrimination [7-11].

Traditionally, genetic testing has comprised single-gene tests conducted in clinical settings. However, whole exome or whole genome sequencing to identify thousands of genetic variants simultaneously has now become possible in both research and clinical settings. While clinical interpretation of the information generated is still being refined and population-wide genomic screening programmes are not yet feasible, policymakers are increasingly focusing on a healthcare future that incorporates precision medicine informed by genomic sequencing.

One potential barrier to implementing genomic testing is how information provided to those tested will be utilised by insurers. While health insurance in Australia is community risk rated[1], a significant proportion of premiums sold for life, critical care, and income protection insurance are mutually rated, meaning that insurers classify an individual according to their personal risk. Under Australian insurance law, an individual and insurer require symmetry of information – insurance contracts must be made *uberrima fidei*, i.e., in utmost good faith. Discrimination based on genetic status is prohibited under the *Disability Discrimination Act 1992* (Cth) (DDA). However, an exception in Section 46 of this Act means that insurers are exempt from this prohibition when underwriting if they can substantiate decisions based on actuarial, statistical, or other data on which it is reasonable to rely.

Fear around the insurance implications of genetic test results, whether perceived or real, continues to be one of the most commonly stated concerns preventing the uptake of clinical genetic testing in Australia, especially for predictive testing in families [10]. Insurance implications are also a concern for many individuals considering participating in medical research involving return of genetic findings, and can be a significant reason for declining to participate [12-15].

In this paper, we review the recently revised industry standard related to the use of genetic information in the provision of certain insurance products in Australia: the Financial Services Council's 2016 Standard No. 11 Genetic Testing Policy (the "2016 FSC Standard") [16]. We first synthesise the recent policy landscape in this area. Then, we raise five concerns with the 2016 FSC Standard: (1) use of results obtained from research; (2) the requirement for an applicant to disclose whether they are "considering" a genetic test; (3) failure to account for genome sequencing and other technology developments; (4) limited evidence regarding adverse selection; and (5) the inappropriateness of industry self-regulation. We conclude that Australia requires closer government oversight to ensure transparency and consumer confidence in the use of genetic and genomic information in insurance.

The Policy Landscape of Genetics and Insurance in Australia

Unlike jurisdictions such as the UK [17] and several European nations [18], Australia has not instituted a moratorium on the use of genetic test results by insurers. There is also no government regulatory mechanism in place to ensure that any discrimination is in accordance with the DDA. The type of genetic information that may be used and the way in which it may be used has been left entirely to industry self-regulation, with the only relevant policy document published by an industry body: the FSC (previously the Investment and Financial Services Authority [IFSA]). This policy is not legally binding.

IFSA's first Genetic Testing Policy took effect from 1 January 2002, around the same time as the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) undertook an inquiry into "Protecting Human Genetic Information" [19]. The inquiry's terms of reference included consideration of how best to protect against unfair discrimination with respect to human genetic information. The inquiry, which involved extensive public consultation, resulted in a Final Report which was tabled in Federal Parliament in 2003 and included four chapters addressing genetic discrimination, underwriting, and privacy issues in insurance [20; Ch. 25-28]. We explain below that many of these recommendations have not been implemented effectively.

Table 1 details several relevant recommendations from the ALRC's report. An overarching recommendation was the formation of a Human Genetics Commission of Australia (HGCA) [20; Ch. 5]. Its tasks were to include monitoring developments in insurance with respect to genetics (Recommendation 26-2) and establishing procedures to enable it to make recommendations for the insurance industry regarding whether particular genetic tests should be used in underwriting insurance (Recommendation 27-1). The report also made

recommendations for improved consumer protection with respect to genetics and insurance, including strengthening legislative protection and requiring insurers to inform consumers of a right to receive written explanations of underwriting decisions (Recommendation 27-6), and establishing effective review mechanisms for consumers aggrieved with underwriting decisions involving use of genetic test information (Recommendation 27-9).

In response to the ALRC's Final Report, the Australian (Federal) Government recognised that a body like the proposed HGCA was required to consider and advise the government on the complex and rapidly developing area of human genetic technology [21]. It established a Human Genetics Advisory Committee (HGAC)[2], which commenced work in 2009 [22]. Although genetic discrimination in insurance was on the HGAC's agenda for a number of years, the committee lacked a clear mandate to implement the report's key recommendations. The government's reliance on an industry body to implement the recommended changes also made it difficult for the HGAC to effect change [21]. The HGAC was disbanded in 2015.

While the government agreed in principle with the thrust of ALRC Recommendations 27-2, 27-4, and 27-6, it did not agree they required legislative change. Instead, it asserted that these recommendations could be met via industry bodies making regulations to bind their members [21]. IFSA subsequently modified its Genetic Testing Policy [23] (and the related Family History Policy) in 2005.

A Revised Industry Genetic Testing Policy Standard

The FSC is an industry body that represents and (to a degree) regulates companies providing products including investment portfolios and insurance. It is an independent commercial body, unconnected with the government. In late 2016, the FSC revised its Standard No. 11 Genetic Testing Policy [16] and Standard No. 16 Family History Policy [24], formally launching them in March 2017. As with previous iterations, the 2016 FSC Standard offers some protection to consumers:

- A "Member" of the FSC should not initiate a genetic test on an Applicant seeking insurance [16; at 10.1]. That is, no consumer should be required to undergo a genetic test when applying for insurance

- Assessments of cumulative risk associated with a Genetic Test result should "consider the potentially beneficial effects of medical Screening, early diagnosis and treatment" [16; at 10.5]
- A test result should not be used to assess risk in the relatives of the person tested [16; at 10.7 and 10.9]
- Members should be clear and meaningful in their reasoning given for underwriting assessments [16; at 10.12.1]. While rejecting an application for insurance is permitted, the Member should "endeavour to offer alternative terms or products" [16; at 10.13]

The 2016 FSC Standard introduces several subtle but important changes, summarised in Table 2. Below, we discuss the potential effects of these changes. It is also important to note that the 2016 FSC Standard does not mention *genomic* as opposed to *genetic* testing. We discuss this issue further below.

Concerns around the Current Policy Climate

While we applaud the FSC's recognition of the need for a clear and transparent policy, we consider that an industry standard alone does not meet the recommendations of the ALRC's Final Report. We here detail five concerns arising from the 2016 FSC standard.

1. Requesting Results Obtained from Research Participation

Although the previous 2005 IFSA Standard noted that the industry did not wish to negatively impact individual decisions to participate in genetic research, it did not distinguish between results obtained from research and clinical settings [23]. This meant that if asked, applicants were required to disclose any genetic test result, however obtained. The 2016 FSC Standard has introduced a clause that specifically considers research participation. Clause 10.3 reads as follows (with emphases added):

> 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.

While specifically recognising research participation is laudable, this clause does not add anything. First, Clause 10.3(i) states the obvious: applicants cannot disclose information they do not know and will not receive. Second, an applicant who has elected not to receive genetic test results (per Clause 10.3(ii)) would also not know any information that would require disclosure.[3] This new clause therefore does not provide research participants with any additional protection over the 2005 IFSA Standard: known research genetic findings still need to be disclosed.

The use of the term "Genetic Test results" is also problematic, as the 2016 FSC Standard does not specifically clarify whether results from genomic analyses would fall under this term. The standard defines a "Genetic Test" as meaning "a medical test that identifies changes in chromosomes and genes…" [16; at 9.1], but whether this is also meant to include the detection of multiple changes of potentially variable significance across the genome is unclear.

It is also unlikely that potential research participants will be reassured by these new research-specific clauses. While returning actionable results from genetic research is currently rare, the fear of adverse loading on insurance has already been observed to discourage research participation [14]. We have also observed that due to concerns about the potentially negative impact of genetic test results arising from research on insurance, some research ethics committees have imposed impractical conditions on research approvals, such as a requirement for prospective participants to obtain their own legal advice.[4]

The 2016 FSC Standard also fails to appreciate differing research practices. While gene discovery research is ongoing, translational research is the next necessary step in determining the utility of genomics. Translational studies are now demonstrating the cost-effectiveness and utility of exome sequencing as a first-line diagnostic test for eligible families [26, 27]. Not all results are returned, but of those that are, not all will be validated in an accredited laboratory. This reflects the fact that the purpose of much research is to gain population-level knowledge. Nevertheless, the ability to benefit individuals via returning actionable findings (with appropriate consent) is relevant too.

Integration of genomic technology into clinical management is an ongoing effort. This novel information can sometimes be critical for the diagnosis or management of rare genetic diseases. Therefore, there is slippage between clinical testing and research paradigms [28]. At this crucial early stage of genomic research and clinical implementation, actual or perceived barriers to the conduct of, and participation in, research should be minimised. To maximise research participation (and thus advance both basic and translational research), it is arguable that all genetic research results should be excluded from insurance underwriting. Ideally, it would be possible to distinguish genetic research findings and clinical test results for the purposes of risk assessment; however, this is difficult in translational research. The exclusion of all research findings is thus supported by the Human Genetics Society of Australasia [29] and an international body of experts [15]. It also reflects international practice, such as arrangements for participants in the UK's 100,000 Genomes project [17, 30].

2. "Considering" a Genetic Test

The 2005 IFSA Standard provided suggested wording as to how a member should respond if an applicant for insurance actively chose to disclose that they were considering a genetic test [23]. A significant change in the 2016 FSC Standard is the encouragement of uniform wording for all applicants to use in their personal statements regarding whether they are considering genetic tests. Specifically, it states:

> Members should give consideration to the following uniform wording when developing wording in personal statements with regard to genetic tests. "Have you ever had *or are you considering* having a genetic test where you have received (or are currently awaiting) an individual result?" [16; at 10.11.1; emphasis added]

In the commentary to this section, the FSC states that the question is included to provide clarity to participants who are involved in a research project, but who will not receive a result [16; at 10.11.2].

There are several issues with this new clause, and with the FSC's explanatory commentary. First, as discussed above, there is now a separate section in the 2016 FSC Standard that deals specifically with research [16; at 10.3]. Clause 10.11.1 does not cross-refer to the research clause and appears to be justifying a much wider (and in our view inappropriate) information gathering exercise by insurers.

Further, the wording of the clause is confusing.[5] How can an individual have received or be awaiting a result when she is only "considering" a genetic test? What does "considering" mean in this context? If the aim of the FSC was indeed to provide clarity to research participants, this question should have been included in the section dedicated to research results.

Section 21 of the *Insurance Contracts Act 1984* (Cth) states that an insured has a duty to disclose to the insurer every matter known to the insured that is relevant to the insurer's decision whether to accept the risk. However, we contend that the inclusion of this question about considering testing in insurance application personal statement forms exceeds what can reasonably be justified under the duty to disclose. It is also difficult to understand how insurers could reasonably use this information, or what they are entitled to do. It would be very unlikely to legally justify deferral of consideration of an application for life insurance.[6]

Finally, research participants especially may simply not know whether they will receive an individual genetic (or genomic) result. For example, a person might have provided a sample to a large biobank project which included broad consent to receive findings of interest in the future. They are not "awaiting" a result, as it is unclear whether there will ever be any findings of interest to return. Further, the individual may not even recall that they are a research participant [31]. None of these issues are adequately addressed by the 2016 FSC Standard.

3. A Narrow Focus on the Clinical Genetics Paradigm

While we are not taking a position on the exceptionalism of genetic or genomic information, we contend that several features of *genomics* can be considered as distinguishing it from *genetics*: (1) the volume of information that a single test can generate; (2) the dynamic and (3) uncertain meaning of much of that information, including the increased propensity for discovery of novel variants or variants of uncertain significance; (4) the increased likelihood that secondary or incidental findings may be identified; and (5) the blurring of the dichotomy between clinical practice and research [32].

The 2016 FSC Standard appears to focus on a single-gene test paradigm of clinical provision of genetic testing; one that is rapidly becoming unrecognisable. Genomic tests do not necessarily obtain a discrete piece of information in the way that single-gene tests do. Rather, genomic testing produces significant amounts of information that take time, knowledge (which

may not yet be acquired), and technology (which may not yet be developed) to interpret and meaningfully understand.

The FSC Standard also does not discuss that individuals can now obtain personal genomic information via direct-to-consumer testing companies, sometimes of questionable quality. Many direct-to-consumer tests are routinely returning genetic variants that are not supported by robust clinical data to calculate medical risks. Yet these results would need to be disclosed to insurers if requested.

It is also vague as to the checks that need to be in place to ensure that underwriting using genetic or genomic information is evidence based and actuarially or otherwise sound within the meaning of Section 46 of the DDA. The FSC Standard only mentions looking to the evidence when an applicant is given an unfavourable underwriting decision (Clause 10.12.1) and raises the option of consulting external experts when a dispute arises (Clause 10.5.4) [16]. There is nothing else to suggest how genomic evidence from research studies or direct-to-consumer tests should be assessed, and on what level of data or evidence underwriting decisions about genomic test results should be based.

The FSC Standard also fails to assist underwriters by providing guidance regarding current limitations in the interpretation of genomic information. Genomic information risk predictions are not yet uniformly supported by representative and robust population data, especially data from individuals of non-European ethnicity [33]. Studies in healthy individuals are suggesting that genetic variations previously thought to be strongly indicative of disease development may not carry such a high risk or may even be benign [34-39]. Predicting disease risk based on genomic information is difficult, even for genomic experts. Insurance underwriters may lack sufficient expertise or resources to understand and interpret genomic information, and there is little guidance on how to do so.

Further, individuals often seek genetic or genomic information so they can take steps to mitigate their risk, such as undertaking more regular screening for some cancers or changing simple health behaviours [40]. We are disappointed not to see a clearer recognition of these health behaviours in the 2016 FSC Standard, which is weaker in this respect than the preceding version (see Table 2).

4. Limited Evidence regarding Adverse Selection

Adverse selection (also termed “anti-selection”) is said to occur when a consumer either increases their insurance cover because they know that they are likely to develop a genetic condition [3], or ceases their cover in light of a reassuring genetic test result [4]. With respect to the former, the FSC maintains that allowing consumers the right not to disclose genetic test results when applying for life insurance will lead to adverse selection. This is implied in the 2016 FSC Standard, where it is stated that:

> Genetic information, like other personal medical information, may influence a person’s decision to seek life insurance. [16; 10.2.2]

The FSC also maintains that if adverse selection were to occur, it could lead to larger payouts, which will increase the cost of insurance for everyone [16; 10.2.3].

In May 2017, a paper presented at the Actuaries Australia Summit provided the first hypothetical modelling of the potential impact of wider population genetic testing on the Australian insurance market [4]. The report takes the most significant causes of claims on insurance and models what might happen to the insurance market if genetic testing to inform the risk of developing these conditions became more widespread. The authors suggest that “if genetic tests were to become more widespread [based on a rise from 0.5% to 2% of the population having tests], the potential impact on claim costs … could be material” and that “anti-selection risk would significantly increase” [4; pp 22-23].

Yet, as recognised in the report itself, the modelling contains a series of assumptions that are unlikely to materialise, in that they represent a worst-case scenario. These assumptions include that a relative risk is uniform across the lifespan, that no applicants for insurance will have exclusions or loadings applied to their premiums following genetic testing, that everyone not currently insured will apply for insurance prior to genetic testing, and that almost everyone who obtains lower-risk information will cancel their policies.

Additionally, in 2011, the Canadian Government commissioned two subject matter experts to prepare reports which considered the likely impact of a ban on insurers’ use of genetic test results in a reasonably sized insurance market [41, 42]. Both reports agreed that “at the present time and in the near future, the impact of a ban on the use of genetic test results by the life and health insurance industry would not have a significant impact on insurers or the efficient operation of insurance markets” [43].

Further, to our knowledge there has been no published evidence of adverse selection in markets where a moratorium or limited moratorium exists on the use of genetic information in insurance. Several of these markets serve populations smaller than Australia's. To this end, we contend that the FSC's claims regarding adverse selection are not yet supported by sound evidence.

5. Industry Self-Regulation

The Australian status quo of self-regulation for the insurance industry's use of genetic test information is at the extreme laissez-faire end of the regulatory spectrum. This is in contrast to the growing number of countries internationally with state-led regulation or co-regulation [11, 44]. While we accept that companies offering life insurance are for-profit entities, we claim that a self-regulating industry body as the sole overseer for this complex area arguably represents a conflict of interest and does not protect consumers, especially as the role of genomics in the healthcare system continues to expand. The FSC represents a wide range of financial entities, including superannuation funds, life insurers, funds management providers, and financial advisers. While their mission statement mentions "clients" and "customers" [45], their advocacy work focuses on the interests of its members. This leaves no independent entity to assess the robustness of evidence used in underwriting, nor to consider the interests of consumers.

While self-regulation and other forms of private regulation in the financial services sector have some benefits [46], they are also subject to criticism [47]. There can be problems with accountability, transparency, conflict of interest, and mandating compliance. Oversight can lack enforceability. Indeed, several of the clauses of the 2016 FSC Standard have been edited to use "should" (recommending language) rather than "will" or "must" (mandating language) (see Table 2).

In the UK, the Government entered into a moratorium and concordat with the Association of British Insurers (ABI) in 2001. This agreement, which has been renewed a number of times since, offers an appropriate balance of protecting commercial and consumer interests and presents an alternative model to both pure self-regulation and centralised command and control oversight. However, insurers in the UK do not have to be ABI members, just as insurers in Australia do not have to be members of the FSC.[7] This may impact compliance.

We therefore advocate that the Australian Government needs to introduce independent oversight mechanisms regarding the use of genetic information in insurance. However, such oversight needs to be flexible and responsive to this rapidly changing area. This oversight should also establish a government body (with clear terms of reference) to independently oversee the use of genetic and genomic information in insurance. Reflecting the recommendations of the ALRC's 2003 Report, this body will have the responsibility to (1) determine which genetic or genomic tests or results can be used in underwriting; (2) mandate and enforce the compliance of all insurers with its determinations; and (3) provide a clear and accessible avenue for independent dispute resolution should an adverse decision regarding insurance occur. This body should also be responsible for undertaking regular audits on the use of genetic information by insurers. It is logical that this body should be a government entity with the necessary authority to implement regulation that is more robust. In the absence of such a body currently being in place, a moratorium on the use of genomic information should also be considered.[8]

Conclusion

This paper has discussed the failure of the Australian Government to ensure ongoing implementation of previous recommendations regarding the use of genetic information in insurance. We have raised concerns about not only the substance of the 2016 FSC Standard but also the broader regulatory landscape in Australia.

In a climate of rapidly emerging genomic technologies, a status quo based on industry self-regulation is insufficient to permit the level of consumer protection necessary to facilitate wider use of genomic testing, as and when it is appropriate to do so. The Australian Government needs to play a larger role than it currently does in ensuring that Australians will be motivated to obtain genomic information (when indicated), without fear of how that information will be used.

As the benefits of genomic research and medicine begin to be realised, maintaining trust among the Australian public will require consumer confidence in both the technology itself and the impact of testing on individuals. Genetic discrimination in access to insurance has occurred [9, 48-51] and will likely continue to occur without a more robust approach to governance that also explicitly accounts for genomic testing [52]. At a broader level, the *perception* of genetic discrimination in insurance is also already having an adverse impact [8, 12, 13].

While the effect of the 2016 FSC Standard is yet to be seen, and we acknowledge the efforts made by the industry to address this complex issue, the standard contains many subtle but important changes. It provides consumers with *less* certainty, *fewer* rights, and *fewer* reasons to participate in research, undertake genetic testing, and access appropriate and potentially life-saving interventions. It also demonstrates how easily a self-regulated industry can gradually erode consumer rights, necessitating independent regulatory oversight. Transparency of insurance practices and an assurance for consumers that inappropriate genetic discrimination will not occur are critical. Independent oversight of the use of genetic and genomic information by insurers in Australia is well overdue.

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Footnotes

1. This means that premiums are not loaded on the basis of individual risk information.
2. Note the different name. In its response the Commonwealth Government did not account for this.
3. An interesting issue might arise in circumstances where a research participant can still be told about certain research findings despite having previously expressed a preference not to know. Such a policy is currently being considered in New South Wales with respect to certain high-risk, high-penetrance actionable findings [25].
4. Based on author experience.
5. Preliminary findings from survey research being undertaken by authors JT and PL indicate that genetics professionals find it hard to determine when an individual "is considering" a test.
6. There is a need for empirical research to determine whether insurers are in fact delaying issuing a premium until a finding has been returned to an applicant.
7. The 2016 FSC Standard specifies in Clause 5 that the standard applies to all members who are a registered life insurance company or have a subsidiary that is a registered life insurance company (Clause 5.1) and further that "[a]ll life insurance companies registered by APRA who are not FSC Members are also *encouraged* to follow this Standard" [16; Clause 5.2; emphasis added].
8. A paper arguing in support of a moratorium on the use of genetic information in Australia, written by authors JT, MO and PL, is under review.

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Table 1. Selected recommendations from the Australian Law Reform Commission's 2003 Report: *Essentially Yours: The Protection of Human Genetic Information in Australia*

Number	**Recommendation text** (all emphases added)	**Government Response**
26-2	"The Human Genetics Commission of Australia, in consultation with peak industry bodies and regulators, should *keep a watching brief* on developments in the insurance industry in relation to the use of human genetic information...."	Agreed
27-1	"The Human Genetics Commission of Australia (HGCA) should, ... establish *procedures to assess and make recommendations on whether particular genetic tests should be used in underwriting* mutually rated insurance, having regard to their scientific reliability, actuarial relevance and reasonableness."	Supported the proposals but claimed they were directed at industry bodies rather than Government. (Note 27-1 specifically related to the HGCA)
27-2	"[Relevant industry bodies] should *develop mandatory policies* for their members to ensure that, once the HGCA has made a recommendation in relation to the use of a particular genetic test in underwriting, that test is used only in conformity with the recommendation. ...."	
27-3	"[Relevant industry bodies] should require their members to state, on relevant insurance application forms, that not all genetic test results have to be disclosed and that applicants may obtain further information about this from the insurer….."	
27-5	"The Commonwealth should amend the Insurance Contracts Act 1984 (Cth) to clarify the nature of the obligation of an insurer to provide written reasons for an unfavourable underwriting decision upon the request of an applicant. Where such a decision is based on genetic information, including family medical history, the *insurer should be required to give reasons that are clear and meaningful and that explain the actuarial, statistical or other basis* for the decision."	Supported need for clear reasons, but asserted any change should be to industry policy not legislation.
27-6	"[Relevant industry bodies] should *require* their members to *inform applicants* of their statutory *entitlement to reasons for an adverse underwriting decision based on genetic information*, including family medical history. …"	

Table 2. Key changes introduced by the 2016 FSC Standard No. 11 Genetic Testing Policy

The changes soften the meaning of terms, reduce industry obligations towards applicants, and relax implications of non-adherence.

2005 IFSA Standard	**2016 FSC Standard**
Clause 7.4: Balancing industry's functioning with its "social responsibility to **support**… medical technologies" to "**improve** [community] health outcomes"	*Clause 7.4:* Balancing industry's functioning with both long-term sustainability and its "social responsibility to **not hinder**… medical knowledge and technologies" to "**potentially improve**… health outcomes"
Clause 8.1: Failure of an IFSA(FSC) member to adopt standard deemed **material** if it has the **potential to adversely affect** an applicant or customer	*Clause 8.1:* Failure of an FSC member to adopt standard **could be deemed material** if it **adversely effects** an applicant or customer
Clause 10.3.3: Advised Members what to do **if an applicant discloses that they were considering** taking a genetic test. Members were not advised to routinely ask applicants whether they were considering testing	*Clauses 10.11 and 10.11.1:* Members should consider **including "uniform wording"** for personal statements regarding genetic tests. The suggested wording (see in-text section) explicitly asks applicants whether they are **considering** having a genetic test.
	Clause 10.3: New clause relating to **research** – see main text for discussion.
Clause 10.5: "Insurers **will** take into account the **benefits** of special medical surveillance, early medical intervention and… likelihood of successful treatment."	*Clause 10.5:* "Members **should** consider the **potentially beneficial effects** of medical screening, early diagnosis and treatment…"
Clause 10.5.3: "Members **must** incorporate… new information, which affects the way certain genetic diseases are underwritten…."	*Clause 10.5.3:* "Members **should** incorporate… new medical knowledge that alters the underwriting assessment…"
Clause 10.6: "Insurers **will** ensure that results of existing genetic tests are only obtained with the written consent…"	*Clause 10.6:* "Members **should** ensure that existing… results are only obtained with the **informed** written consent… "
Changes from 'will' or 'must' to 'should' also appear in Clauses: • 10.6.1: asking a third party for a result; • 10.7: using an individuals' risk to assess relatives; • 10.12: providing information regarding unfavourable/adverse underwriting decisions and subsequent options available; • 10.14: members having internal dispute resolution services available and including reference to legal remedies in responses; and • 10.15 & 10.15.1: reviewing and certifying members' compliance with the Standard, monitoring compliance and taking action when there is a breach (termed non-compliance in 2016)	