# **HUMAN GENETICS SOCIETY OF AUSTRALASIA**



ARBN. 076 130 937 (Incorporated Under the Associations Incorporation Act)

The liability of members is limited

PO Box 6012, Alexandria, NSW 2015 ABN No. 17 076 130 937

Telephone: 02 9669 6602 Fax: 02 9669 6607 Email: secretariat@hgsa.org.au

**Policy** 

Title: Scope of Practice for Genetic Counsellors

Document Number: 2022GC01

Publication Date: 1 April 2022

Location: https://hgsa.org.au/Web/Web/Consumer-resources/Policies-Position-Statements.aspx

Replaces: 2018GC01; 2019GC09

Last Reviewed: August 2021

Review Date: September 2024

This document is published online, please access the most current version at the location above.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page 1 of 14

# Contents

Purp	oose	3
Figu	re: Code of Ethics, Competency Standards, and Scope of Practice	4
Area	as of Practice (listed in alphabetical order below)	5
1.	. Academic Genetic Counsellors	6
	Area of Practice	6
	Training/Qualifications/Experience	6
	Scope of Practice	6
2.	Clinical Genetic Counsellors	7
	Area of practice	7
	Training/Qualifications/Experience	7
	Scope of Practice	7
3.	Education Genetic Counsellors	8
	Area of Practice	8
	Training/Qualifications/Experience	8
	Scope of Practice	8
4.	Laboratory/Industry Genetic Counsellors	9
	Area of Practice	9
	Training/Qualifications/Experience	9
	Scope of Practice	9
5.	Policy Genetic Counsellors1	0
	Area of practice1	0
	Training/Qualifications/Experience	0
	Scope of Practice1	0
6.	. Research Genetic Counsellors1	1
	Area of Practice1	1
	Training/Qualifications/Experience1	1
	Scope of Practice1	1
Revi	iew Process	2
Refe	erences	2
Terr	ninology1	3

### **Purpose**

Genetic counselling is a rapidly evolving and dynamic profession. While the majority of genetic counsellors are engaged in clinical roles, genetic counsellors successfully engage in different areas of practice to advance the profession. For example, genetic counsellors also work in academic, education, research, and policy roles. The breadth and nature of genetic counsellors' professional practice will continue to expand. This document has been developed in consultation with genetic counsellors working in these areas of practice.

This Scope of Practice policy aims to represent the diverse roles of the profession, and the particular benefit that genetic counsellors in all areas of practice bring to the profession. Historically, in Australia, New Zealand and internationally, demonstration of advanced practice through Certification and/or Registration has been limited to genetic counsellors working in clinical practice. The hope is that a more diverse Scope of Practice document will provide a foundation for the development, assessment, and recognition of advanced skills across areas of practice, and more accurately reflect the varied career pathways available to genetic counsellors.

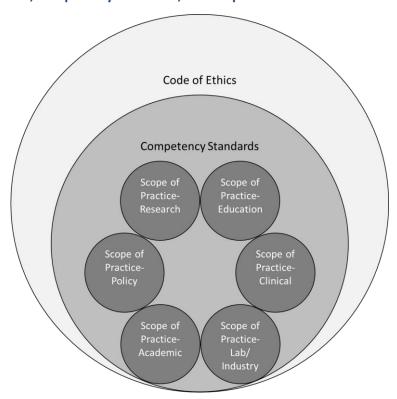
This policy is not exhaustive of all the possible activities genetic counsellors may undertake in the course of their practice, or of all of the diverse and emerging roles in which genetic counsellors may practice. However, as the roles of genetic counsellors continue to develop, their scope of practice should be underpinned by the Code of Ethics for Genetic Counsellors policy and the Competency Standards for Genetic Counsellors Policy, which are intended to apply to all areas of practice. An individual genetic counsellor's scope of practice may encompass more than one area of practice depending on their role.

The Scope of Practice addresses areas of professional practice, rather than the type of employer. Genetic Counsellors practice within scope in their area of practice regardless of whether their employer is a public or private institution, industry, or commercial company, or if they are in independent practice.

The Scope of Practice for Genetic Counsellors should be referred to in conjunction with the Code of Ethics for Genetic Counsellors document and the Competency Standards for Genetic Counsellors Policy. Scopes of Practice articulate how the Competency Standards for Genetic Counsellors are applied practically in and across different areas of genetic counselling practice. The Code of Ethics for Genetic Counsellors requires genetic counsellors to practice not only in accordance with the Scope of Practice for Genetic Counsellors, but also to recognise and practice within their individual scope of practice. A genetic counsellor's individual scope of practice may be broader or narrower, and will change over time depending on their knowledge, interests, experience, training, role, area of practice and/or specialisation, and their personal capacity and wellbeing (e.g., burnout, compassion fatigue).

Dated: 1 April 2022 Page **3** of **14** 

Figure: Code of Ethics, Competency Standards, and Scope of Practice



This figure shows the relationship between these three documents as defined below (based on the definitions in the National Alliance of Self Regulating Health Professions (NASRHP) Self Regulating Health Profession Peak Bodies Membership Standards, 2016).

A **Code of Ethics** expresses the overarching values and responsibilities which are integral to and characterise the profession, assist practitioners (collectively and individually) to act in ethically accountable ways in the pursuit of the profession's aims, and by which practitioners are held accountable for ethical practice.

**Competency Standards** are standards for professional practice that set out what individuals should know, understand and be able to do, in order to practice safely and effectively.

A **Scope of Practice** describes the area or areas of the profession in which a practitioner has the particular knowledge, skills, and experience to practise lawfully, safely, and effectively, in a way that meets professional standards and does not pose any danger to the public or themselves.

Dated: 1 April 2022 Page 4 of 14

# Areas of Practice (listed in alphabetical order below)

The Scope of Practice addresses areas of professional practice, rather than the type of employer.

This policy is not exhaustive of all the possible activities genetic counsellors may undertake in the course of their practice, or of all of the diverse and emerging roles in which genetic counsellors may practice.

An individual genetic counsellor's scope of practice may encompass more than one area of practice depending on their role.

This document has been developed in consultation with genetic counsellors working in the following areas of practice.

- 1. Academic Genetic Counsellors
- 2. Clinical Genetic Counsellors
- 3. Education Genetic Counsellors
- 4. Laboratory/Industry Genetic Counsellors
- 5. Policy Genetic Counsellors
- 6. Research Genetic Counsellors

Dated: 1 April 2022 Page **5** of **14** 

#### 1. Academic Genetic Counsellors

#### Area of Practice

Academic genetic counsellors work in hospitals, universities, and research institutes. They design, undertake, oversee, and lead research programs that generate empirical evidence relevant to genetic counselling and genomic healthcare. These may include (but are not limited to) genetic counselling processes, clients' experiences, familial implications, and social, ethical, legal, and practical implications arising from genomics. Genetic counsellors in this role work collaboratively with other health professionals, researchers from other disciplines, and in partnership with consumers to ensure representation in research. The pursuit of an Academic career trajectory is what differentiates Academic genetic counsellors from genetic counsellors in other areas of practice.

Academic Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. Please see the other Areas of Practice outlined in this document, including Section 6. Research Genetic Counsellors (page 11) that encompasses a range of research roles and Section 3. Education Genetic Counsellors (page 8) that encompasses genetic counsellors working in education. Academic Genetic Counsellors may also practice under the Scope of Practice for Clinical Genetic Counsellors (section 2, page 7) if they provide direct genetic counselling to clients in an Academic or Research setting.

# Training/Qualifications/Experience

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling, AND
- PhD (or equivalent) or PhD candidate specialising in research related to genetic counselling.
- Current Good Clinical Practice (GCP)\* certification for research.
- An established and maintained demonstrable academic track record in genetic counselling including publications, research presentations, and research funding.

\*The Guideline for Good Clinical Practice (GCP) is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials, and is incorporated in the Therapeutic Goods Regulations 1990. Compliance is a requirement for Human Research Ethics Committee (HREC) approved research protocols and GCP certification is a requirement for named investigators.

### **Scope of Practice**

- Takes a critical and analytical approach to identify existing and emerging gaps in genetic counselling and genomics practice, patients' and families' experiences, and healthcare, where genomics is relevant.
- Designs and oversees research that generates empirical evidence to address identified gaps in genetic counselling and genomics practice.
- Critically analyses scientific, social, ethical, legal, and practical implications of genomics in healthcare.
- Works towards the translation and implementation of research-generated evidence into practice.
- Builds research capacity within the genetic counselling and genomics community through the supervision, and/or promotion of research.
- Provides education and mentoring within the field of genomics in an academic institution and provides supervision to postgraduate research students.
- Sources, gains, and manages funding for research.
- Disseminates research generated evidence through publications and presentations.
- Represents and advocates for genetic counsellors and the genetic counselling profession within the academic community.
- Contributes academic expertise to the genetic counselling profession.
- Partners with consumers, and other stakeholders to inform the development, design, and conduct of research, where appropriate.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **6** of **14** 

### 2. Clinical Genetic Counsellors

### Area of practice

Clinical genetic counsellors work in hospitals and a range of other healthcare settings providing direct clinical care to clients. This may include academic, research, clinical, laboratory or commercial/industry settings. Clients include people and families who are impacted by, or at increased risk of having an inherited health condition. Clinical Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. See the other Areas of Practice outlined in this document.

Genetic counsellors bring to this role an integration of clinical genomic knowledge, health communication, and counselling skills to facilitate clients' informed choices about their healthcare. They focus on identifying and meeting clinical, informational, and psychosocial needs by providing client-centred counselling. Genetic counsellors in this role work collaboratively with other health professionals (clinical geneticists, other medical specialists, nursing, and allied health providers), to deliver comprehensive, multidisciplinary care to clients.

Genetic counsellors are allied health professionals and, unless they hold additional qualifications or appropriate registration, are not physicians or nurses. While clinical genetic counsellors are health care providers, they do not prescribe medication or undertake medical procedures. Genetic counsellors are expected to refer/defer to other genetic counsellors, clinical geneticists, laboratory scientists, or other medical or healthcare providers as appropriate, depending on the limits of their individual scope of practice.

## Training/Qualifications/Experience

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling.
- Has or is expected to achieve FHGSA according to the HGSA Clinical Certification Policy for Genetic Counsellors.
- Expected to maintain annual Registration with the HGSA while practicing.

# **Scope of Practice**

- Obtains and evaluates individual, family, and medical histories to determine likelihood of genetic/medical conditions in a client, their offspring, and other family members.
- Discusses the features, natural history, means of diagnosis, genetic and environmental factors, likelihood, and management of risk for genetic/medical conditions.
- Identifies, coordinates, and facilitates appropriate genetic tests and other investigations as appropriate for assessment, including obtaining/facilitating informed consent.
- Integrates clinical and psychosocial implications of genetic test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic/medical conditions.
- Explains and explores the clinical and psychosocial implications of genetic and other diagnostic tests and results.
- Provides client-centred counselling and anticipatory guidance; explores and evaluates the client's
  or family's responses to the information discussed; and assesses and supports their adjustment to
  this information.
- Identifies and makes use of community resources that provide medical, educational, financial, and psychosocial support and advocacy.
- Provides written documentation of medical, genetic, and counselling information for families and health care professionals.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **7** of **14** 

### 3. Education Genetic Counsellors

### **Area of Practice**

Genetic counsellors practicing in education roles focus on identifying and meeting educational requirements by developing and delivering targeted genetic counselling and genomics education to different groups. This will include genetic counsellors teaching in Masters programs and other University courses, as well as genetic counsellors creating and delivering educational resources. Education genetic counsellors work collaboratively with other health professionals including clinical genetics services, teaching and research academics and various other stakeholders to produce up-to-date genetic counselling and genomics education in a variety of written and oral formats. Clients include students and professional or patient/community groups receiving the education.

Education Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. See the other Areas of Practice outlined in this document. Education Genetic Counsellors may also practice under the Scope of Practice for Clinical Genetic Counsellors (Section 2, page 7) if they provide direct genetic counselling to clients in an educational setting.

Genetic counsellors bring to this role: comprehensive and up-to-date knowledge of genetic counselling and genomics; critical thinking skills for reviewing existing resources and relevant research; excellent verbal and written communication skills to enable effective collaboration with clients and stakeholders and delivery of education.

# Training/Qualifications/Experience

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling.
- Additional qualifications or training in education, health communication and research may be an asset in these roles.

### **Scope of Practice**

- Engages with clients, students, and stakeholders to understand educational needs and requests.
- Actively engages in understanding the growing landscape of genomics in healthcare, in order to understand and anticipate new educational requirements.
- Identifies gaps and opportunities for development of new educational resources.
- Interprets genetic counselling and genomic information within the literature and other resources to achieve a high personal level of knowledge and understanding in order to provide education.
- Works with relevant stakeholders and experts to develop educational resources.
- Facilitates education of clients (including students) or other stakeholders by teaching directly and/or developing content for lectures or workshops.
- Conveys relevant educational information in a variety of formats (including but not limited to oral, written, video, electronic, media releases, educational modules/courses, podcasts, etc.) to best meet the communication needs of the client or a given group.
- Tailors education to the capacity and learning needs of the client group, in a manner that is culturally and linguistically appropriate.
- Facilitates and supports dissemination of educational information to clients and stakeholders.
- Designs and perform evaluation of learning wherever possible following the education in order to assess and inform future use and/or modifications.
- Identifies and addresses barriers to providing genetic counselling and genomic education.
- Reflects on their own biases of practice preference when teaching.
- May be involved in genetic counselling and genomics research projects which have an education focus or component.
- May be involved in projects to educate health professionals with a genetic counselling and/or genomic education component.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **8** of **14** 

# 4. Laboratory/Industry Genetic Counsellors

#### Area of Practice

Genetic counsellors practicing in laboratory/industry roles focus on genomic testing and its associated processes. Genetic counsellors working in laboratory and/or industry roles have scope across various types of genomic tests that may range from traditional cytogenetic tests through to complex whole genome sequencing. They use their skills and training to contribute to the safe and effective and fiscally responsible delivery of genomic testing as a key component of the patient experience.

End-users/clients are those that engage with genomic testing in its many forms. This includes, but may not be limited to, referring clinicians and other healthcare providers from genetic and non-genetic specialties, general practitioners, patients accessing testing, and health consumers.

Laboratory/Industry Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. Laboratory/Industry Genetic Counsellors may also practice under the Scope of Practice for Clinical Genetic Counsellors (section 2, page 7) if they provide direct genetic counselling to clients in a Laboratory or Industry setting.

Skills that genetic counsellors bring to this role include but are not limited to; advanced communication skills; a sound clinical understanding of genetic diseases and/or patient phenotype; a sound understanding of genomic technologies; the ability to critically appraise evidence being used to interpret results/classify variants; experience in obtaining patient consent; familiarity with laboratory practices.

Laboratory and industry roles are new and evolving In Australia and New Zealand, therefore the scope described here is intended as a guide only and will develop over time.

# Training/Qualifications/Experience

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling.
- Further training may be provided on a laboratory/industry-specific basis. For example, formal training in variant curation may be an asset or requirement depending on the specifics of the role.

### **Scope of Practice**

- Acts as a liaison between the laboratory, patients, and/or clinicians including other genetic counsellors and clinical geneticists.
- Provides education to other health professionals about benefits and limitations of genetic/genomic testing and associated concepts.
- Collaborates effectively with members of the laboratory team, organisation, and other stakeholders.
- Ensures and educates about the appropriate ordering of genetic/genomic tests
- Recognises and manages the potential ethical issues that could arise from commercial interests.
- Facilitates understanding of the benefits and limitations of genetic/genomic testing.
- Provides education to health professionals in how to obtain appropriately informed consent.
- Assists with interpretation and relay of results to referring clinicians and/or patients, and ensures access to appropriate ongoing support.
- Contributes to the development, curation, and validation of genetic/genomic tests.
- Participates in decisions around the utility and appropriateness of offering new types of genetic/genomic testing.
- Contributes to educational material for clinicians and patients.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **9** of **14** 

# 5. Policy Genetic Counsellors

### Area of practice

Genetic counsellors practicing in policy roles focus on consultation, research and analysis of trends and issues, formulation of appropriate (public) policy responses relevant to human genomics, and/or genetic services. They play an active role in the articulation and/or implementation of policy positions by government or other relevant organisations.

Clients include the stakeholders in a policy, which may include, but not be limited to, national/state governments, patient/community groups, health organisations/services, health professionals and their professional bodies.

Policy Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. Although it would be unusual to provide direct genetic counselling to clients in a Policy setting, Policy Genetic Counsellors may practice under the Scope of Practice for Clinical Genetic Counsellors if they also provide direct genetic counselling in another clinical setting.

Genetic counsellors bring to this role: a knowledge of genomics; the impacts on individuals, families, and communities; genetic services and the health system; ability to critically assess empirical evidence; and communication skills, which enable elicitation of diverse perspectives and views, and communication of relevant issues and possible approaches.

### Training/Qualifications/Experience

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling.
- Additional professional development or training in law, public policy, public health or knowledge translation may be an asset in these roles.
- Professional experience, reputation, and strategic relationships will be an asset in these roles.

# **Scope of Practice**

- Evaluates/assesses the quality and outcomes of service delivery related to genetic conditions to
  identify opportunities for improvement and strengths upon which to build. {Amy wording
  intended to convey that it is not just genetic services, could be screening programs, genetics
  mainstreamed as part of other service's delivery etc)
- Encourages effective care of patients, identifying opportunities to improve care by integrating new and existing approaches into health care, determining barriers, and contributing to their resolution.
- Assesses research outcomes and evidence for their relevance to policy development.
- Promotes and may facilitate the implementation of projects to guide or evaluate relevant policy, in partnership with relevant stakeholders.
- Actively seeks to improve standards of service delivery of genetic/genomics in healthcare, for example, workforce development.
- Participates in, initiates, and/or supports strategic planning with the ultimate aim of improving the delivery of genetic services and genomic healthcare.
- Participates in the development and implementation of standards, guidelines, education, and/or research initiatives.
- Contributes to public health policy development and is aware of key issues that may influence wellbeing, clinical practices and/or health services.
- Recognises when a policy issue must be escalated within an organisation, or when additional stakeholders, expertise, or consumer consultation should be engaged.
- Maintains current knowledge of relevant regulatory and policy environments.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **10** of **14** 

#### 6. Research Genetic Counsellors

### **Area of Practice**

Research genetic counsellors work in roles that apply their genetic counselling skills, knowledge, and experience relevant to genomic practice/genetic counselling to the research setting. This may include (but is not limited to) aspects of genetic counselling processes or practice, clients' experiences, familial implications, clinical or laboratory genomics research (e.g. recruitment and data collection), the genomic aetiology of disease, and social, ethical, legal, and practical implications of genomics.

Research Genetic Counsellors may also practice in other Areas of Practice dependent on their role or practice setting. Research Genetic Counsellors may practice under the Scope of Practice for Clinical Genetic Counsellors if they also provide direct genetic counselling in a research or clinical setting.

Research genetic counsellors contribute to research programs in a variety of institutions including, but not limited to hospitals, universities, research institutes, or patient organisations, as well as industry, including commercial companies. They may work collaboratively with other health professionals, academics, researchers from other disciplines, patient-participants and their families, members of the general public, students, government/non-governmental agencies or departments and consumers.

# **Training/Qualifications/Experience**

- Master's level or recognised equivalent tertiary qualification in Genetic Counselling.
- Good Clinical Practice (GCP)\* training for research where applicable.
- Research genetic counsellors may benefit from acquiring additional skills or further training that contribute to practice within their specific role.

\*The Guideline for Good Clinical Practice (GCP) is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials, and is incorporated in the Therapeutic Goods Regulations 1990. Compliance is a requirement for Human Research Ethics Committee (HREC) approved research protocols and GCP certification is a requirement for named investigators.

### Scope of Practice

- Contributes to research and the application of emerging evidence relevant to genomics and/or genetic counselling.
- Provides genetic counselling expertise and perspective to existing and developing research endeavours.
- Represents and advocates for genetic counsellors/counselling within the research setting.
- Contributes to the development of research protocols and ethics and governance applications, and practises in accordance with them.
- Applies the principles of research design in developing research projects or protocols.
- Identifies the relevance and potential impacts of research to patients and/or their families and engages participants in the research process where appropriate.
- Explains the benefits, limitations, and potential outcomes of research.
- Facilitates and/or obtains informed consent from participants for research studies.
- Advocates for the safety and interests of patient-participants within research.
- Disseminates and communicates research outcomes by writing or assisting with publications and presenting their own and/or others' research to clients, collaborators, and academic audiences.
- Critically analyses, evaluates and translates current evidence and research findings.
- Identifies existing and emerging evidence gaps, and areas for future research in genetic counselling and genomics.
- Undertakes research that generates empirical evidence to address identified gaps and supports the translation of research findings into evidence-based practice.
- Identifies and addresses ethical and legal implications of genomics research and genomics in healthcare.

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **11** of **14** 

#### **Review Process**

The HGSA Code of Ethics (COE), Competency Standards, and Scope of Practice (SOP) for Genetic Counsellors will be reviewed together every three years, or sooner if necessary, to maintain consistency with current evidence-based best-practice guidelines. A working group will be formed by the HGSA Board of Censors (BOC) for Genetic Counselling Chairperson no later than six months before the end of the third year. The size and membership requirements of the working group will be determined by the BOC Chair.

The working group shall include, but not be limited to:

- 1. The members of the BOC. The Chair of the BOC will act as the Chair of the working group.
- 2. A genetic counsellor and/or academic member with an interest in the process of genetic counselling, and with training in medical ethics and/or law.
- 3. A member of the HGSA Education, Ethics and Social Issues Committee (EESIC).
- 4. A member of the Australasian Society of Genetic Counsellors (ASGC) Executive.
- 5. A Master of Genetic Counselling course convener/academic genetic counsellor.
- 6. Any other member representation deemed necessary for a thorough review, including additional legal or medical ethics experts. Representation from diverse areas of genetic counselling practice is necessary to ensure that the documents remain inclusive and applicable to all practicing genetic counsellors.

Any genetic counsellor members must be practising genetic counsellors in good standing on the HGSA Register of Genetic Counsellors with at least two years of professional experience in a genetic counselling role.

The working group will review the documents in light of the current and developing trends in the practice of genetic counselling and benchmark them internationally and against other allied health professions. A draft of the revised documents must be circulated to the ASGC Executive for comment and feedback before being circulated to the membership for a period of four weeks. Feedback will be considered and incorporated by the working group as appropriate. A final draft should be approved by the Board of Censors for Genetic Counselling and ratified by the HGSA Council. Final ratified versions of the revised documents are posted on the HGSA website.

# **References**

- National Alliance of Self Regulating Health Professions (NASRHP). (2016). Self Regulating Health Profession Peak Bodies Membership Standards. http://nasrhp.org.au/wpcontent/uploads/2018/01/SR\_Standards\_Full\_Dec\_2.pdf
- 2. National Society of Genetic Counselors (2018). National Society of Genetic Counselors Scope of Practice.

http://www.cap.org/apps/docs/statline/pdf/nsgc\_genetic\_counselor\_scope\_of\_practice.pdf

HGSA Scope of Practice Policy for Genetic Counsellors Policy Number 2022GC01

Dated: 1 April 2022 Page **12** of **14** 

# **Terminology**

consumer	Consumers are people, including family and carers, who currently use a particular service, have used the service in the past, or who may use the service in the future.
client	The term 'client' applies to any individual or organisation receiving services from a genetic counsellor, including patients and their families, the general public, students, other health care providers, and government/non-governmental agencies or departments. Clients are also consumers of genetic counselling services.
Good Clinical Practice (GCP)	With a foundation in the Declaration of Helsinki, the principles of Good Clinical Practice (GCP) provide guidance for the conduct of clinical research. The Guideline for Good Clinical Practice (GCP) is an internationally accepted standard for the designing, conducting, recording and reporting of clinical trials, and is incorporated in the Therapeutic Goods Regulations 1990. Designed for trials of clinical products, treatments, and interventions, GCP guidelines also apply to other clinical investigations that may have an impact on the safety and well-being of human participants. GCP is considered good research practice, and has relevant elements that apply to all research. Compliance is a requirement for Human Research Ethics Committee (HREC) approved research protocols and GCP certification is a requirement for named investigators.
genomic (genetic)	For the purpose of this document, the term 'genomic' is inclusive of single genes (genetics), multiple genes (genomics) and the interactions between genes and environmental or non-genetic factors that have health implications. These terms may be used interchangeably in this document.
patient	A 'patient' is a person receiving direct clinical care in the context of a health service. A patient is also a client of a healthcare provider(s) and a consumer of health services.
stakeholder	The term <i>stakeholder</i> refers to colleagues, other professionals, individuals, services, or organisations who are not clients, but who have a common interest in client-related goal, or with whom the genetic counsellor engages in the course of providing services.
practice	The term <i>practice</i> "indicates that an individual is drawing on their relevant professional skills and knowledge in the course of their work to contribute to safe and effective delivery of services within the profession It is not restricted to the provision of direct clinical care and may also include working in a direct non-clinical relationship with clients; working in management, administration, education, research, advisory, regulatory or policy development roles, for example. This work can be of a paid or formal volunteer nature on a full or part-time basis." <sup>2</sup> The term practice also includes staying informed of, and adhering to, evidence-

<sup>&</sup>lt;sup>1</sup> Commonwealth of Australia Department of Health. (2017). National Health Genomics Policy Framework.

<sup>&</sup>lt;sup>2</sup> National Alliance of Self Regulating Health Professions (NASRHP). (2016). Self Regulating Health Profession Peak Bodies Membership Standards.

	based professional guidelines.
MHGSA	The HGSA grants the title Member of the Human Genetics Society of Australasia (MHGSA) in recognition that a genetic counsellor meets the minimum educational requirements to practice as a genetic counsellor.
FHGSA	The HGSA grants the title Fellow of the Human Genetics Society of Australasia (FHGSA) to tertiary-qualified health professionals who have completed specialist practice training requirements in genetics and counselling, and are certified by the HGSA Board of Censors for Genetic Counselling.

Page **14** of **14**