



GMG Terms and Conditions for Genetic Testing

Document 20.4



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Title: **GMG Terms and Conditions for Genetic Testing**

Document Number: 20.4
Document pages: 15

Document Version Details		
	Name/ Date	Title
Originally Created by	Pavel Bitter	Facility Manager
Date created	04.12.2015	
Current version	2	
Edited by		
Date edited		
Description of changes		
Date reviewed	07.12.2016	Quality Manager
Date authorized	09.12.2016	Quality Manager

Quality Control Document – GMG Terms and Conditions for Genetic Testing Document 20.4

This cover sheet controls the layout and components of the entire document.

Issued Date: 11.12.2016
Effective Date: 15.01.2017

Department Approval:

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Garvan Molecular Genetics Manager

QA Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the document control SOP to verify the current revision.

1. Purpose

This document describes the Terms and Conditions in place for all services of Garvan Molecular Genetics (**GMG**).

2. Introduction

These Terms and Conditions state the legal obligations and conditions as to how GMG provides its research and clinical diagnostic services.

3. About these Terms and Conditions

- 3.1. These Terms and Conditions apply to Services provided by GMG on request from Clients.
- 3.2. The obligation of GMG to perform Services is conditional on acceptance of a Request under clause 4 of these Terms and Conditions.

4. Request and Acceptance

- 4.1. A Client may submit a Request by completing an Online Sample Submission Manifest via GMG's secure Sample Submission Portal.
- 4.2. For all clinical genetic diagnostic requests, a completed GMG Patient Consent Form must be included with the Specimen sent to GMG.
- 4.3. If the Request is:
 - 4.3.1. a clinical diagnostic test, the Client must include a completed GMG Patient Consent Form with the Specimen;
 - 4.3.2. a research test, the Client must include confirmation that the requirements of clause 8 have been satisfied.
- 4.4. The Client must arrange for the Specimen to be delivered to GMG at:

Garvan Molecular Genetics
Garvan Institute of Medical Research
384 Victoria Street, Darlinghurst, NSW 2010
- 4.5. The Client must ensure the Specimen is prepared, transported and delivered in accordance with the technical instructions and specifications of GMG prescribed for this purpose from time to time.
- 4.6. GMG will inspect the Specimen in accordance with the Specimen Acceptance Policy applicable to the specific service requested. GMG may request additional information about a Request and/or request a replacement

Specimen if the Specimen does not comply with the Specimen Acceptance Policy applicable to the specific service requested.

- 4.7. GMG may decline a Request on the basis of the Specimen Acceptance Policy applicable to the specific service requested or for any other lawful reason.
- 4.8. If GMG declines a Request, GMG will:
 - 4.8.1. offer the Client the opportunity to transfer the Specimen to another laboratory or service or, if that offer is declined, destroy the Specimen; and
 - 4.8.2. de-identify or destroy any Personal Information received from the Client (if it is lawful and reasonable to do so).
- 4.9. If GMG declines a Request on the basis of its service specific Specimen Acceptance Policy, the Client must pay GMG's costs and expenses in accordance with clause 11.1.

5. Services

- 5.1. On acceptance of the Request under clause 4, GMG will perform the Services in accordance with these Terms and Conditions.
- 5.2. The Services will be:
 - 5.2.1. provided with due care and skill; and
 - 5.2.2. fit for the purpose specified in the Request.
- 5.3. GMG may at any time decline to provide, or cease to provide, the Services where providing the Services:
 - 5.3.1. would be unlawful;
 - 5.3.2. may infringe the intellectual property rights of any person; or
 - 5.3.3. would be unethical or may otherwise damage the reputation of GMG or Garvan.
- 5.4. GMG may subcontract performance of any part of the Services where permitted by the terms of GMG's NATA Accreditation.

6. Turnaround time

- 6.1. GMG will use reasonable endeavours to complete the Services and provide the Report within the number of Business Days outlined in Table 1 upon acceptance of the Request under clause 4.

Table 1

Fragment Analysis	3 days
Premix Sequencing	3 days
Other Sequencing	7 days
Clinical Diagnostic Sequencing	30 days
RNA Extraction (standard)	3 days
RNA Extraction (special)	10 days
DNA Extraction (standard)	3 days
DNA Extraction (special)	10 days

- 6.2. A Report is taken to be delivered when the Report is emailed, faxed or posted to the Client.

7. Patient Consent (Clinical Services)

- 7.1. If a Request is a clinical diagnostic test, the Client must ensure that:
- 7.1.1. each Specimen has been obtained in compliance with all applicable laws (including laws applicable to the donation and removal of human tissue); and
 - 7.1.2. the consent of the Patient for a clinical genetic test has been obtained.

8. Ethics Approval and Consent

- 8.1. If the Request is a research test, the Client must ensure that if the research to which the Request relates:
- 8.1.1. is required by law to be approved by a HREC; or
 - 8.1.2. in accordance with generally accepted standards of research or clinical practice, would be required to be approved by a HREC,
- the Client has obtained approval of a HREC for the research (and that approval is valid and subsisting and has not been revoked).
- 8.2. If the Request is a research test, the Client must ensure that if the consent of the participant from whom the Specimen has been derived:
- 8.2.1. is required by law;

- 8.2.2. is required as a condition of approval by a HREC; or
- 8.2.3. is required in accordance with generally accepted standards of research or clinical practice for the research to which the Request relates,

the Client has obtained that consent (and that consent is valid and subsisting and has not been revoked).

- 8.3. If the Request is a research test, the Client must ensure that each Specimen has been obtained in compliance with all applicable laws (including laws applicable to the donation and removal of human tissue).

9. Privacy

- 9.1. The Client must:
 - 9.1.1. collect Personal Information in accordance with Privacy Laws; and
 - 9.1.2. ensure that the Patient or Participant (as applicable) and each other relevant individual whose Personal Information will be disclosed to GMG has been provided a copy of the GMG Privacy Collection Statement and consents to the disclosure of his or her Personal Information to GMG.
- 9.2. GMG will:
 - 9.2.1. take such steps as are reasonable in the circumstances to protect Personal Information from misuse, interference and loss and from unauthorised access, modification or disclosure; and
 - 9.2.2. otherwise comply with Privacy Laws in respect of Personal Information it collects, holds, uses or discloses in connection with providing the Services.

10. Communication with Patients and Participants

The Client is responsible for communicating clinical results and interpretations to the Patient or Participant (as applicable to the Request). GMG is under no obligation to directly communicate with the Patient or Participant (or any other person) any clinical result or observation arising from or in connection with the Services.

11. Fees

- 11.1. GMG will issue a tax invoice on delivery of the Report for:
 - 11.1.1. the Fee; and

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- 11.1.2. such other expenses incurred by GMG in performing the Services (including the cost of transit of Specimens, expedited Services, Specimen and data retention or destruction, and any reasonable associated expense).
- 11.2. The Client must pay the tax invoice within 30 days of the date of invoice. If the tax invoice is not paid in accordance with its terms, GMG may charge interest on the unpaid amount, accrued each day at the rate equal to the sum of the official cash rate quoted by the Reserve Bank of Australia on that day plus 2% per annum, and is capitalised (if not paid) every 30 days.

12. GST

- 12.1. In this clause words and expressions that are not defined in these Terms and Conditions but which have a defined meaning in the GST Law have the same meaning as in the GST Law.
- 12.2. Except as otherwise provided in these Terms and Conditions, all consideration payable under these Terms and Conditions in relation to any supply is exclusive of GST.
- 12.3. If GST is payable in respect of any supply made by a supplier under these Terms and Conditions, subject to clause 12.4 the recipient will pay to the supplier an amount equal to the GST payable on the supply at the same time and in the same manner as the consideration for the supply is to be provided under these Terms and Conditions.
- 12.4. The supplier must provide a tax invoice to the recipient before the supplier will be entitled to payment of the GST payable under clause 12.3.

13. Retention of Specimens

- 13.1. GMG may retain Specimens at the completion of the Services for the purposes of:
 - 13.1.1. meeting legal obligations and/or NATA Accreditation requirements;
 - 13.1.2. identification and internal audit (e.g. to confirm correctness of Specimen identity); and
 - 13.1.3. quality assurance.

14. Intellectual Property Rights

- 14.1. Title to and ownership of all intellectual property rights in the Report vest upon its creation in GMG.

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- 14.2. GMG grants to the Client a perpetual, worldwide, irrevocable, royalty-free licence to use the Report for the purpose described in clause 14.
- 14.3. If the Request is a clinical diagnostic test, the Client must not:
 - 14.3.1. use the Report for any purpose other than for the care of the Patient to whom the Report relates; or
 - 14.3.2. authorise any other person to use the Report for any purpose.
- 14.4. If the Request is a research test, the Client must not:
 - 14.4.1. use the Report for any purpose other than the research to which the Request relates; or
 - 14.4.2. authorise any other person to use the Report for any purpose.
- 14.5. The Client must indemnify GMG against all Claims incurred or suffered by GMG in connection with the use of the Report in breach of this clause 14.
- 14.6. As between GMG and the Client, the title to and ownership of all intellectual property rights in the processes used or enhanced by GMG in the provision of the Services vest in GMG.

15. Confidentiality

- 15.1. Subject to clause 15.2, each party must:
 - 15.1.1. keep confidential;
 - 15.1.2. take reasonable steps to ensure that the party's employees do not disclose to a third party;
 - 15.1.3. maintain proper and secure custody of; and
 - 15.1.4. not use or reproduce in any form,

any Confidential Information belonging to the other party without the written consent of the other Party or as required by law.
- 15.2. GMG may disclose Confidential Information to its sub-contractors to the extent necessary for the performance of the Services, provided that the sub-contractors are aware of the confidentiality obligations under this clause 15 and undertake to observe those obligations as though they were GMG.
- 15.3. The obligations of the parties under this clause survive after the Services have been completed and the Fee paid (and otherwise survive the termination of the contract formed by acceptance of a Request under these Terms and Conditions).

16. Liability

- 16.1. This clause 16 applies only where GMG has provided Services in response to a Request for a research test and does not apply where GMG has provided Services in response to a Request for a clinical diagnostic test.
- 16.2. Any representation, warranty, condition or undertaking which (but for this clause) would be implied in these Terms and Conditions by law, is excluded to the fullest extent permitted by law.
- 16.3. The liability of GMG for breach of a guarantee implied by the Australian Consumer Law (other than a guarantee under section 51, 52 or 53) in relation to the supply of goods or services not of a kind ordinarily acquired for personal domestic or household use or consumption, is limited, at GMG's option, to:
 - 16.3.1. in the case of goods – the replacement of the goods, the supply of equivalent goods, the payment of the cost of replacing the goods or the payment of the cost of acquiring equivalent goods; or
 - 16.3.2. in the case of services – the supplying of the services again or the payment of the cost of having the services supplied again.
- 16.4. To the fullest extent permitted by law, GMG will not be liable to the Client for consequential, indirect or special losses or damages of any kind (including loss of profit, loss of or damage to goodwill, loss or corruption of data, or business interruption) suffered by the Client as a result of any act or omission whatsoever of GMG, its employees, agents or sub-contractors.
- 16.5. Nothing in these Terms and Conditions is to be read as excluding, restricting or modifying the application of any legislation which by law cannot be excluded, restricted or modified.

17. Force Majeure

If GMG is delayed or hindered in or prevented from performing any of its obligations under these Terms and Conditions due to any event or circumstance beyond its reasonable control (including action or inaction by a third party supplier or sub-contractor), GMG will have no liability to the Client in respect of such non-performance and the time for performing the same will be extended until the event or circumstance has ceased.

18. General

- 18.1. These Terms and Conditions may only be varied or replaced by a document duly executed by the parties.

- 18.2. These Terms and Conditions contain the entire understanding between the parties as to their subject matter. All previous agreements, representations, warranties, explanations and commitments, expressed or implied, affecting this subject matter are superseded by these Terms and Conditions and have no effect.
- 18.3. The failure of a party at any time to insist on performance of any provision of these Terms and Conditions is not a waiver of the party's right at any later time to insist on performance of that or any other provision of these Terms and Conditions.
- 18.4. GMG may transfer, novate or assign, any right or obligation under these Terms and Conditions to a related body corporate of Garvan.
- 18.5. If a provision in these Terms and Conditions is held to be illegal, invalid, void, voidable or unenforceable, that provision must be read down to the extent necessary to ensure that it is not illegal, invalid, void, voidable or unenforceable. If it is not possible to read down a provision as required in this clause, that provision is severable without affecting the validity or enforceability of the remaining part of that provision or the other provisions in these Terms and Conditions.
- 18.6. Clauses 9, 10, 12, 13, 14 and 15 survive the expiry or termination of the contract formed by acceptance of a Request under these Terms and Conditions.
- 18.7. Each indemnity in these Terms and Conditions is a continuing obligation, separate and independent from the other obligations of the parties and survives the expiry or termination of the contract formed by acceptance of a Request under these Terms and Conditions.
- 18.8. It is not necessary for a party to incur expense or make payment before enforcing a right of indemnity conferred by these Terms and Conditions.

19. Definitions

In these Terms and Conditions unless expressed or implied to the contrary:

Australian Consumer Law has the meaning given in the *Competition and Consumer Act 2010* (Cth).

Australian Privacy Principle has the meaning given in the *Privacy Act 1988* (Cth).

Business Day means Monday to Friday excluding public holidays in New South Wales, Australia.

Claims includes actions, proceedings, suits, causes of action, arbitrations, verdicts and judgments either at law or in equity or arising under a statute, debts, dues, demands, claims of any nature, costs and expenses.

Client means a Specialist or researcher (as applicable) who makes a Request under these Terms and Conditions.

Confidential Information means all information and materials, in any form, which comes into a party's possession about the other party pursuant to, or as a result of or in performance of activities contemplated by, these Terms and Conditions excluding information:

- (a) which at the time of its first disclosure or observation under these Terms and Conditions was in the public domain;
- (b) which, after disclosure or observation under these Terms and Conditions, comes into the public domain otherwise than by disclosure in breach of these Terms and Conditions;
- (c) which is received by either party from a third party who has the right to provide the information;
- (d) which was already in the receiving party's possession or knowledge without restriction prior to its disclosure or observation; or
- (e) which the disclosing party is required by law to disclose.

Fee means the fees and charges payable by the Client for the Services in accordance with the schedule of fees for Services published by GMG from time-to-time (or as otherwise negotiated and agreed between the Client and GMG).

Garvan means the Garvan Institute of Medical Research ABN 62 330 391 937, a statutory corporation established under the *Garvan Institute of Medical Research Act 1984* (NSW).

GMG means Garvan Molecular Genetics, being the business unit of Garvan responsible for providing NATA Accredited clinical genetic testing services.

GMG Privacy Collection Statement means a document prepared by GMG notifying a Patient or Participant (as applicable) or other relevant individual whose Personal Information will be disclosed to the GMG by a Client of the matters required by Australian Privacy Principle 5 (notification of the collection of personal information) and equivalent provisions under Privacy Laws.

GST Law has the meaning given to that term in the *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

HREC means a human research ethics committee:

- (a) constituted in accordance with the National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research*; or
- (b) otherwise approved by GMG (in its absolute discretion).

For a Client based outside of Australia, a HREC includes an institutional review board (or equivalent) approved by GMG (in its absolute discretion).

NATA Accreditation means, as applicable to the Services:

- (a) the accreditation of GMG's laboratory as a medical testing laboratory (in accordance with the requirements of NPAAC); or
- (b) the accreditation of GMG's laboratory as a biological testing laboratory, by the National Association of Testing Authorities, Australia.

NPAAC means the National Pathology Accreditation Advisory Council of Australia.

Online Sample Submission Manifest means a document for making a Request created using GMG's online Sample Submission Portal (substantially in the form specified by GMG from time-to-time). The Sample Submission Portal can be accessed at <https://gmg-submit.gimr.garvan.org.au/#/login>.

Participant means a person who is the subject of research to which a Request relates (and includes any person involved in research from whom a Specimen has been obtained).

Patient means a person who is the subject of a Request for a clinical diagnostic test (and includes any person from whom a Specimen has been obtained).

Personal Information has the meaning given in Privacy Laws.

Privacy Laws means the *Privacy Act 1988* (Cth), the *Health Records and Information Privacy Act 2002* (NSW) and such other legislation or binding schemes relating to the privacy of personal information and health records.

Report means a document providing results and interpretation in relation to the Specimen (and/or the Patient from whom the Specimen has been obtained).

Request means a communication (which may be in the form of an electronic message) from the Client to GMG requesting that GMG perform the Services in relation to a Patient or one or more Participants.

Services means:

- (a) receipt and accessioning of the Specimen and any accompanying documentation and information (electronic or otherwise, including an Online Sample Submission Manifest);
- (b) extraction of the DNA from the Specimen;
- (c) DNA sequencing by the Sanger method;
- (d) delivery of a Report to the Client; and
- (e) such other services specified in the Request and accepted by GMG under clause 4.

Specialist means a medical practitioner who has been recognised for the purposes of the *Health Insurance Act 1973* (Cth) as a Specialist or consultant physician.

Specimen means a biological specimen provided to GMG for the purpose of providing the Services.

Specimen Acceptance Policy means GMG's policies and procedures regarding the receipt and review of Requests and the receipt and inspection of Specimens (as applicable to the specific Service requested).

Terms and Conditions means this document.

20. Interpretation

- 20.1. These Terms and Conditions are governed by and are to be construed in accordance with the laws of New South Wales, Australia. Each Party irrevocably and unconditionally submits to the non-exclusive jurisdiction of the courts of New South Wales and waives any right to object to proceedings being brought in those courts.
- 20.2. In these Terms and Conditions, unless expressed to the contrary:
 - 20.2.1. words denoting the singular include the plural and vice versa;
 - 20.2.2. the word 'includes' in any form is not a word of limitation;
 - 20.2.3. where a word or phrase is defined, another part of speech or grammatical form of that word or phrase has a corresponding meaning;
 - 20.2.4. headings and sub-headings are for ease of reference only and do not affect the interpretation of these Terms and Conditions; and
 - 20.2.5. no rule of construction applies to the disadvantage of the party preparing these Terms and Conditions on the basis that it prepared or put forward these Terms and Conditions or any part of it.
- 20.3. In these Terms and Conditions, unless expressed to the contrary, a reference to:
 - 20.3.1. a gender includes all other genders;
 - 20.3.2. any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced and includes any subordinate legislation issued under it;
 - 20.3.3. any document (such as a deed, agreement or other document) is to that document (or, if required by the context, to a part of it) as amended, novated, substituted or supplemented at any time;
 - 20.3.4. writing includes writing in digital form;

- 20.3.5. 'these Terms and Conditions' is to these Terms and Conditions as amended from time to time;
- 20.3.6. 'A\$', '\$', 'AUD' or 'dollars' is a reference to Australian dollars;
- 20.3.7. a clause, schedule or attachment is a reference to a clause, schedule or attachment in or to these Terms and Conditions;
- 20.3.8. any property or assets of a person includes the legal and beneficial interest of that person of those assets or property, whether as owner, lessee or lessor, licensee or licensor, trustee or beneficiary or otherwise;
- 20.3.9. a person includes a firm, partnership, joint venture, association, corporation or other body corporate;
- 20.3.10. a person includes the legal personal representatives, successors and permitted assigns of that person, and in the case of a trustee, includes any substituted or additional trustee;
- 20.3.11. any body (Original Body) which no longer exists or has been reconstituted, renamed, replaced or whose powers or functions have been removed or transferred to another body or agency, is a reference to the body which most closely serves the purposes or objects of the Original Body; and
- 20.3.12. if a payment or other act is required by these Terms and Conditions to be made or done on a day which is not a Business Day, the payment or act must be made or done on the next following Business Day.