GeCIP Rules

Rules of the Genomics England Clinical Interpretation Partnership (GeCIP)

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1 Introduction

1.1 The Genomics England Clinical Interpretation Partnership (GeCIP) is the collective term for the community of individual medical researchers, NHS clinical disease experts, NHS healthcare professionals and trainees who are given free access to the dataset of whole genome sequences and associated phenotype and clinical data arising out of the 100,000 Genomes Project for the purposes of carrying out research and improving the understanding and practice of clinical genomics.

1.2 The GeCIP is administered in accordance with these Rules.

1.3 These Rules are issued by the GeCIP Board, a committee appointed by Genomics England Limited.

1.4 The GeCIP Steering Committee is given responsibility for the operation of the GeCIP as specified in these Rules. The GeCIP Steering Committee reports directly to the GeCIP Board.

1.5 The GeCIP is managed and administered on a day-to-day basis by the Office of the Chief Scientist.

1.6 These Rules apply to all individual GeCIP Members. These Rules set up the position as between Genomics England and individual GeCIP Members including with regard to rights over GeCIP intellectual property rights (IPRs). Rights of GeCIP Institutions are as set out in the GeCIP Participation Agreement.

1.7 The GeCIP and the GeCIP Domains are not legal entities and are not partnerships in the legal sense.

1.8 The GeCIP Rules and the IP Policy are living documents, which the GeCIP Board and the Genomics England Board will update from time to time. Genomics England commits to a review of these Rules in the light of experience at least on annual basis following their adoption.

1.9 Terms used in these Rules are defined in the Definitions section at the end.

2 Aims of the GeCIP

2.1 The overall aim of the GeCIP is to create a thriving, sustainable environment for individual medical researchers, NHS clinical disease experts, NHS healthcare professionals and trainees that function as a multi-disciplinary team offering a variety of key skills to improve clinical interpretation. The GeCIP will analyse and regularly refine the clinical interpretation of the 100,000 Genomes Dataset.

2.2 There are three overarching aims of the GeCIP:

2.2.1 to optimise clinical data and sample collection, clinical reporting and data interpretation for return to clinicians and patients;

2.2.2 to perform research to further improve understanding of the implications of the findings for genomic medicine in the clinical setting; and

2.2.3 to provide a rich training environment for trainees.

3 GeCIP membership

3.1 Any Eligible Person may apply to become a member of GeCIP by making an application for membership in the manner prescribed by the Office of the Chief Scientist as made available on the GeCIP section of the Genomics England website.

3.2 An Eligible Person who applies to become a member of GeCIP shall provide all of the information requested in the application form, including (if requested) details of all:-

3.2.1 contracts of employment;

3.2.2 educational institutions at which he or she is a student; and

3.2.3 other terms of engagement to which he/she is party and/or offices or positions that he/she holds, whether honorary, paid or unpaid, with any organisation.

3.3 Once admitted to membership, a GeCIP Member shall promptly notify the Office of the Chief Scientist of any changes to such details as are provided in accordance with Rule 3.2 and promptly provide details of any new contracts of employment, involvement as a student, or terms of engagement into which he/she enters, or new offices or positions that she assumes, with any organisation.

3.4 An individual's GeCIP membership shall be renewed automatically on 31 January in each year unless the Office of the Chief Scientist notifies the individual that his or her GeCIP membership has not been renewed.

3.5 An individual may terminate his or her GeCIP membership by giving written notice of resignation to the Office of the Chief Scientist.

3.6 Each GeCIP Member shall:

3.6.1 be responsible for informing the GeCIP Domain Leader and the Office of the Chief Scientist about his/her group's experimental plans;

3.6.2 be expected to contribute significantly to GeCIP, bringing his/her particular expertise to bear on accomplishing the goals of the Domain he/she is a member of in a timely manner. Participation in a Domain should consist of more than deposition of data into the shared database and should include substantial intellectual contributions to the Project;

3.6.3 share results within GeCIP in accordance with any applicable policy;

3.6.4 take part in group activities, including attending periodic workshops to discuss the project's progress and coordinating the publication of research results; and

3.6.5 fully disclose all publicly funded algorithms, software source code and experimental methods to the other GeCIP Members and the Office of the Chief Scientist for purposes of scientific evaluation and is strongly encouraged to disseminate this information to the broad scientific community.

3.7 If a GeCIP Member breaches any of these Rules, the GeCIP Steering Committee or Office of the Chief Scientist may terminate that individual's GeCIP membership with immediate effect by giving such individual written notice of termination.

4 GeCIP Domains

GeCIP Domains

4.1 The activities undertaken within GeCIP are organised within such disease-facing, cross-cutting and/or other domains as the GeCIP Board shall at its absolute discretion from time to time determine. GeCIP domains comprise:

4.1.1 Disease-facing GeCIP domains within either cancer or rare diseases.

4.1.2 Cross-cutting GeCIP domains.

An up-to-date domain list is available on the Genomics England website.

4.2 A cross-cutting GeCIP Domain should not undertake work that significantly overlaps with work undertaken by another GeCIP Domain. By way of example: a cross-cutting GeCIP Domain should not undertake analyses that duplicate those undertaken by any of the disease-facing GeCIP Domains. The Domain Leader of any cross-cutting GeCIP Domain shall consult with the Domain Leader of any disease-facing GeCIP Domain prior to approving work that might fall within this Rule.

GeCIP Activities

4.3 The GeCIP's activities shall be undertaken by GeCIP Domains.

4.4 The GeCIP Domains shall aim to achieve the expectations set out in the Guidance for expressions of interest to form domains within GeCIP made available on the GeCIP section of the Genomics England website.

Participation in the GeCIP Domains

4.5 All GeCIP Members must participate in at least one GeCIP Domain.

4.6 A GeCIP Member may participate in more than one GeCIP Domain.

4.7 Membership of a GeCIP Domain is subject to the approval of the GeCIP Domain Leader and the Office of the Chief Scientist.

4.8 Notwithstanding Rule 4.7, the Office of the Chief Scientist may allocate a GeCIP Member to any appropriate GeCIP Domain if he/she would otherwise not be in a GeCIP Domain.

Application for Approval as a GeCIP Domain

4.9 A group of Eligible Persons may self-organise as a proposed GeCIP Domain and shall follow the application procedure prescribed by the GeCIP Steering Committee as made available on the GeCIP section of the Genomics England website.

4.10 Each individual to be included in a proposed GeCIP Domain who is not already a GeCIP Member must make an application to become a GeCIP Member in the manner prescribed by the GeCIP Steering Committee.

Submission of Detailed Research Plan

4.11 A GeCIP Domain must, prior to accessing any data, submit to the GeCIP Steering Committee a structured and detailed document detailing allocations of activities, plans for research, plans for collaborations, timelines for delivery, and timelines for acquisition of funding (Detailed Research Plan). The Detailed Research Plan to be submitted by the Education and Training Domain should be adapted accordingly to reflect the objectives of that Domain. The GeCIP Domain Leader shall be responsible for updating the Detailed Research Plan if additional research areas are planned.

Applications for Data Access

4.12 A GeCIP Domain shall submit its Detailed Research Plan and proposed members before being granted access to any data or samples. Detailed Research Plans will require the approval of the Access Review Committee. Applications will be administered by the Office of the Chief Scientist. Where the Access Review Committee approves access to data or samples, the Office of the Chief Scientist will require all GeCIP Members who require data access and their affiliated institutions to sign such documentation as relates to access as it may reasonably require including material transfer and data access agreements.

GeCIP Domain Monitoring

4.13 The activities and progress of each GeCIP Domain will be reviewed to ensure that it is delivering and progressing its programme of research and training. If it is seen to be failing to do so, the GeCIP Domain may be required to restructure or terminate. The reviews will be carried out by:

4.13.1 The GeCIP Steering Committee, annually.

4.13.2 The Access Review Committee, every six months.

Renewal of term of a GeCIP Domain

4.14 Each GeCIP Domain shall be renewed on 31 January in each year unless the GeCIP Steering Committee notifies the GeCIP Members that participate in the GeCIP Domain that the term of that GeCIP Domain has not been renewed.

GeCIP Domain Leader

4.15 Each GeCIP Domain shall nominate one of its number to be its leader who may be clinical or non-clinical. A GeCIP Domain Leader must be engaged under a contract of employment or other terms (which may include honorary terms) of engagement with an NHS body, Public Health England, or a UK academic institution. The GeCIP Steering Committee shall approve such nominee or such other GeCIP Member as it determines to be suitable to be that group's GeCIP Domain Leader.

4.16 The GeCIP Domain leader:

4.16.1 may be invited to sit on the GeCIP Steering Committee;

4.16.2 may be invited to sit on the GeCIP Board;

4.16.3 shall be responsible for submitting and updating the Detailed Research Plan for his or her GeCIP Domain from time to time as required by the GeCIP board or GeCIP Steering Committee;

4.16.4 shall co-operate with the Access Review Committee in relation to its six monthly review of the activities and progress of his or her Domain;

4.16.5 shall promote patient involvement in the GeCIP Domain;

4.16.6 shall give effect to guidance/recommendations issued by the GeCIP Steering Group; and

4.16.7 shall coordinate activities within his or her GeCIP Domain and, subject to Rule 4.16.6, be responsible for decisions relating to his or her Domain.

4.17 A GeCIP Member's appointment as a GeCIP Domain Leader shall be automatically renewed on 31 January each year unless the GeCIP Steering Committee notifies the GeCIP Member that his or her appointment as a GeCIP Domain Leader has not been renewed.

4.18 The GeCIP Steering Committee may at any time terminate an individual's role as a GeCIP Domain Leader and replace him or her with another GeCIP Member.

4.19 A GeCIP Domain Leader shall cease to be a GeCIP Domain Leader if he or she no longer holds a substantive or honorary contract with an NHS body, Public Health England, or a UK academic institution.

GeCIP Domain Education and Training Representative

4.20 The GeCIP Steering Committee shall approve such nominee or such other person as it determines to be suitable from among the GeCIP Domain to be that group's GeCIP Domain Education and Training Representative.

4.21 The GeCIP Domain Education and Training Representative shall:

4.21.1 be responsible for preparing and updating a training plan for the Domain;

4.21.2 have regard to any recommendations or guidance issued by the GeCIP Steering Group; and

4.21.3 co-operate with the Domain Leader.

4.22 A GeCIP Member's appointment as a GeCIP Domain Training Director shall be renewed on 31 January in each year unless the GeCIP Steering Committee notifies the GeCIP Member that his or her appointment as a GeCIP Domain Education and Training Representative has not been renewed.

4.23 The GeCIP Steering Committee may at any time terminate an individual's role as a GeCIP Domain Education and Training Representative and replace him or her with another GeCIP Member.

Restructuring or Termination of a GeCIP Domain

4.24 If, in the opinion of the GeCIP Steering Committee, a GeCIP Domain is ineffective or dysfunctional, the GeCIP Steering Committee may at any time serve written notice on the GeCIP Members that participate in that GeCIP Domain:

4.24.1 requiring that GeCIP Domain to change the way it operates; or

4.24.2 if requiring the GeCIP Domain to change the way it operates does not resolve the issue, dissolving that GeCIP Domain with immediate effect.

Termination of participation in a GeCIP Domain

4.25 A GeCIP Member may at any time end his or her participation in any GeCIP Domain by giving written notice of resignation to the Office of the Chief Scientist.

4.26 If a GeCIP Member breaches any of these Rules, the GeCIP Steering Committee or the Office of the Chief Scientist may end that GeCIP Member's participation in any GeCIP Domain with immediate effect by giving such individual written notice of removal.

5 GeCIP Board

5.1 The GeCIP Board is a committee appointed by the Board of Genomics England Limited to:

5.1.1 oversee the GeCIP and act as a focus for coordination;

5.1.2 receive advice and recommendations from Genomics England's Advisory Committees; and

5.1.3 provide advice to, and comply with, any directions of the Genomics England Board.

5.2 The terms of reference and composition of the GeCIP Board are determined by the Board of Directors of Genomics England and are available on the GeCIP section of the Genomics England website.

6 GeCIP Steering Committee

6.1 The GeCIP Steering Committee is a committee of the GeCIP Board and administered by the Office of the Chief Scientist to oversee and ensure the smooth running of, and transfer of knowledge across, the GeCIP Domains.

6.2 The terms of reference and composition of the GeCIP Steering Committee are determined by the GeCIP Board and are available within the GeCIP Board terms of reference on the GeCIP public documentation pages.

7 Office of the Chief Scientist

7.1 The Office of the Chief Scientist will provide oversight of the GeCIP on a day-to-day basis. It will oversee the following matters in relation to the GeCIP:-

7.1.1 management and coordination of the GeCIP;

7.1.2 the appointment process for GeCIP Domains;

7.1.3 the work of the GeCIP Domains, meetings and knowledge sharing and administrative support;

7.1.4 the relationship with GeCIP funders;

7.1.5 the relationship with NHS England, clinical regulatory bodies, NICE and MHRA;

7.1.6 the relationship with the royal colleges;

7.1.7 Health Education England's and other funders' training programmes;

7.1.8 informatics training and support;

7.1.9 input to Genomics England data sharing agreements and contracts with users;

7.1.10 the Genomics England Research Environment (access to anonymised data and Genomics England Knowledge Base for the disease area in question);

7.1.11 assurance to the Genomics England Board on contractual obligations and data security and ethical governance compliance within the GeCIP environment and user community; and

7.1.12 maintenance of the list of pathogenic variants that may be fed back to clinicians treating patients (incidental findings).

7.2 The Office of the Chief Scientist shall be a member of each Domain and shall be entitled to invite such persons as it deems appropriate to attend any meeting of a Domain.

8 Preferential analysis rights to the 100,000 Genomes Project dataset

8.1 A GeCIP Member will be given access to all main programme data that are available in the GeCIP Research Environment.

8.2 Each Disease-facing Domain shall be entitled to an exclusive moratorium period of nine months ("Moratorium Period") to analyse and export results for publication from the Research Environment.

8.3 The Moratorium Periodshall begin for the data currently available in the research environment three months after a domain is granted access to the environment, allowing for a one-off 3-month familiarisation period. Subsequent data releases entering the Research Environment begin a new Moratorium Period for that data only, so that all data have the same protection.

8.4 The Moratorium Period can be waived on a case-by-case basis by the GeCIP Domain Leader, or where a collaborative project is being carried out between Domains. Further information is detailed on the GeCIP Publication Moratorium page.

8.5 All research to be carried out within the GeCIP Research Environment shall be registered in the Research Registry to prevent research duplication, promote collaboration and ensure that the use of data is in accordance with the 'acceptable uses of data' for which Access Review Committee approval was granted. The project must be registered in the Research Registry at least three months before data is exported for publication. The Office of the Chief Scientist can waive this three-month requirement in exceptional circumstances, such as for rapid turnaround publications.

8.6 Where research plans are registered with intention to analyse data under another Domain's Moratorium Period, authors will be alerted that to export their results they will need to obtain permission from the relevant GeCIP Domain Leader, or wait until the Moratorium Period has passed.

8.7 Where multiple research projects are registered with overlap in scope, but both have permission to publish on the data under the moratorium, no restrictions will be applied. However, authors will be encouraged to collaborate where appropriate.

8.8 Genomics England shall enforce a Moratorium Period by reviewing the Research Registry entries to assess that the moratorium criteria outlined in paragraphs 8.2 and 8.5 are met. Genomics England can halt the summary data export process via Airlock should one or more criteria be unfulfilled.

9 Access to the GeCIP Research Environment

Access

9.1 Whilst they remain GeCIP Members, GeCIP Members will, subject to Rule 4.12, be given access to the information and data held in the GeCIP Research Environment and be able to use the GeCIP Research Environment to analyse such information and data, including using certain tools and functions held on the GeCIP Research Environment.

9.2 GeCIP Members shall use such access solely for the purpose of carrying out the research and/or training plans for the GeCIP Domains in which they participate and which have been approved by the Access Review Committee.

9.3 MRC and Genomics England have provided a Research Environment with a specific capacity for storage and processing. GeCIP Domains should describe in their Detailed Research Plans their requirements for storage and processing so that Genomics England can maximise the value of the investment. Detailed Research Plans that involve particularly computationally intensive uses may exceed the purchased capacity of the Research Environment and require either a rescheduling of use or lead to Genomics England charging for such intensive use.

Patient Personal Data

9.4 GeCIP Members acknowledge the paramount importance of protecting the privacy rights of the patients and relations who have contributed DNA samples to the 100,000 Genomes Project and that any unauthorised disclosure, use or other processing of personal data may cause distress and damage to the contributors and the 100,000 Genomes Project.

9.5 GeCIP Members must not re-identify data within the GeCIP Research Environment (e.g. from their knowledge of particular patients) or attempt to do so or assist any third party to do so.

Data Security

9.6 GeCIP Members shall comply with the Protocol and relevant Genomics England/GeCIP policies and procedures published on the GeCIP section of the Genomics England website (as updated and re-issued from time to time).

9.7 GeCIP Members shall not access or attempt to access the GeCIP Research Environment beyond their authorisation and shall not assist anyone else to gain unauthorised access to GeCIP Research Environment.

9.8 GeCIP Members shall not disclose access codes to any third party and shall keep the access codes secure.

9.9 The GeCIP Research Environment is a reading library and not a lending library and no GeCIP Member shall copy primary data out of the GeCIP Research Environment. Any

GeCIP Member wishing to export data must submit a formal Airlock request under the Airlock Policy.

9.10 GeCIP Members shall take reasonable care to ensure that they do not introduce malicious or harmful software into the GeCIP Research Environment.

9.11 Access to the GeCIP Research Environment may be monitored and recorded. Access to all or part of the GeCIP Research Environment may be withdrawn or suspended without notice at any time and for any reason.

10 Intellectual property

10.1 Section 10 of these Rules is subject to the terms of any separate written agreements under which Genomics England has agreed alternative terms governing the ownership and use of specific GeCIP Outputs and GeCIP IPRs and to any determination by Genomics England under section 6 of the Genomics England IP Policy.

10.2 Nothing in these Rules shall assign or purport to assign any IPR that is (i) owned by a GeCIP Member prior to the date on which such individual is admitted to membership of the GeCIP; and/or (ii) developed outside the GeCIP and not in the GeCIP Research Environment.

10.3 All GeCIP Outputs and GeCIP IPRs shall be solely owned by Genomics England.

10.4 Each GeCIP Member hereby assigns to Genomics England all right, title and interest the GeCIP Member may have in the GeCIP Outputs and the GeCIP IPRs. To the extent the foregoing is not effective to assign to Genomics England, all right, title and interest, the GeCIP Member may have in the GeCIP Outputs and GeCIP IPRs, the GeCIP Member shall hold such right, title and interest in the GeCIP Outputs and GeCIP IPRs on trust for the sole benefit of Genomics England. As and when requested, by Genomics England, the GeCIP Member shall, free of charge, assign all such right, title, and interest to Genomics England by executing an assignment in a form reasonably specified by Genomics England.

10.5 Each GeCIP Member shall ensure that any GeCIP Outputs that the GeCIP Member creates or develops in whole or in part are fully disclosed to the Office of the Chief Scientist prior to publication or disclosure.

10.6 As and when requested by the Office of the Chief Scientist, a GeCIP Member shall provide promptly to Genomics England (and/or Genomics England's advisers) reasonable assistance to register IPRs in respect of any GeCIP Outputs created or developed in whole or in part by that GeCIP Member. Genomics England shall reimburse the GeCIP Member for any reasonable out-of-pocket expenses incurred by the GeCIP Member providing such assistance.

10.7 No GeCIP Member shall incorporate into any GeCIP Output any Third Party Works without the prior written consent of the Office of the Chief Scientist.

10.8 If a GeCIP Member wishes to incorporate any Third Party Works into GeCIP Output, the GeCIP Member shall inform the Office of the Chief Scientist of the Third Party Works concerned, the reason for using such Third Party Works and, if known, the holder or holders of the rights of such Third Party Works.

10.9 If a GeCIP Member becomes aware that any GeCIP Output or any activities carried out by the GeCIP is likely to infringe or is alleged to infringe any third party rights (including, without limitation, intellectual property rights), that GeCIP Member shall inform the Office of the Chief Scientist promptly.

10.10 GeCIP Members shall not sell, licence, assign, commercialise or otherwise deal with any GeCIP Outputs or GeCIP IPRs without the prior written consent of Genomics England. Institutions will be granted a non-exclusive licence to use GeCIP Outputs created or developed by the GeCIP Members for the sole purpose of undertaking non-commercial, academic research. Institutions will also have a right to negotiate a fair and reasonable licence for the commercialisation of GeCIP Outputs created or developed by GeCIP Members.

10.11 Genomics England grants to each GeCIP Member a limited, non-sublicensable, non-transferable, non-exclusive licence to use the parts of the GeCIP Research Environment that the GeCIP Member is authorised to access, for the sole purpose of carrying out the research and/or training plans of the GeCIP Domains in which the GeCIP Member participates. This licence terminates automatically if, for any reason, the GeCIP Member ceases to be a GeCIP Member.

11 Confidentiality

11.1 The GeCIP Member shall treat all Confidential Information as secret and confidential and shall not use, copy or disclose to any third party any Confidential Information except that the GeCIP Member may:-

11.1.1 use or copy the Confidential Information solely for the purposes of carrying out the research and/or training plans for the GeCIP Domains in which the GeCIP Member participates;

11.1.2 publish the Confidential Information in accordance with the provisions of the GeCIP Publication Policy;

11.1.3 disclose Confidential Information to other GeCIP Members who participate in the same GeCIP Domains as the GeCIP Member;

11.1.4 disclose the Confidential Information to the Office of the Chief Scientist, GeCIP Steering Committee and members of the GeCIP Board; and/or

11.1.5 after giving written notice to the Office of the Chief Scientist, disclose any part of the Confidential Information solely to the extent that it is legally required to do so pursuant to an order of a court of competent jurisdiction or

governmental authority provided that the GeCIP Member shall use its best endeavours to limit such disclosure and to provide the Office of the Chief Scientist with an opportunity to make representations to the relevant court or governmental authority.

11.2 All documents and other items (including items in electronic form), and any copyright therein, containing Confidential Information shall remain the absolute property of Genomics England.

11.3 Each GeCIP Member shall at all times maintain documents and other items (including items in electronic form) containing Confidential Information and any copies thereof, in a secure fashion by taking reasonable measures to protect them from theft and unauthorised copying, disclosure and without prejudice to the foregoing shall exercise at least the same degree of care to prevent unauthorised disclosure and/or use of the Confidential Information as the GeCIP Member exercises in respect of his/her own confidential information of like importance.

11.4 The GeCIP Member shall notify Genomics England immediately if the GeCIP Member becomes aware of any unauthorised use or disclosure of, or any unauthorised access to or of any theft or loss of any copies of any Confidential Information.

11.5 Each GeCIP Member shall be required to comply with the confidentiality provisions set out in these Rules so long as the GeCIP Member has knowledge of any Confidential Information. The confidentiality provisions of the Rules shall, for the avoidance of doubt, survive termination or expiry of the GeCIP membership of the GeCIP Member.

12 Publication

12.1 GeCIP Members must comply with the Genomics England Publication Policy.

12.2 Authorship and co-authorship of any publication or output should be defined in accordance with the guidelines issued by the International Committee of Medical Journal Editors (ICMJE) and outlined in the Genomics England Publication Policy.

13 Declaration of interests and conduct

13.1 GeCIP Members are required to disclose to Genomics England any potential or actual conflict of interest or competing interests (financial or otherwise). These shall be required to be disclosed by potential members as part of the application process and, where an application has been successful, at any time as they may arise during the GeCIP Member's work as part of the GeCIP.

13.2 Disclosure to chiefscientist@genomicsengland.co.uk will allow for the conflict of interest or competing interest to be appropriately managed by the appropriate staff at Genomics England in conjunction with the (potential) GeCIP Member, in order to mitigate any potential for harm.

13.3 Where a potential or actual conflicted or competing interest is identified, these interests will be discussed with the (potential) GeCIP Member and others as required in order to develop together with Genomics England an appropriate plan to manage the actual or potential conflict. Where appropriate, the (potential) GeCIP Member will be requested to set out how the competing interest would be managed, for the consideration of Genomics England.

13.4 GeCIP Members must not bring GeCIP, Genomics England or the 100,000 Genomes Project into disrepute.

13.5 If any GeCIP Member makes any use of any results, analysis or information arising out of access to the GeCIP Research Environment in relation to the healthcare of any person, he/she shall do so at his or her own risk.

Guidance Note

- A conflict of interests has been described as: *'…a set of conditions in which professional judgment concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).'*[1]
- Competing interests are currently defined by the Journal Nature as: *'…those of a financial nature that, through their potential influence on behaviour or content or from perception of such potential influences, could undermine the objectivity, integrity or perceived value of a publication.'*[2]
- The NHS/Health Research Authority's National Research Ethics Advisers' Panel Guidelines to NRES REC Chairs/RECS on Conflicts of Interest/ Competing Conflicts, Health Research Authority, 2012[3] notes that:

'Society has a vested interest in the integrity of research and researchers. Unfettered and unmanaged conflicts of interests may threaten the integrity of the research enterprise through interference with the principle of objectivity essential for the advancement of knowledge and may lead to a reduction in public support for, and inclination to take part in, research'.

14 Research integrity

14.1 GeCIP Members must comply with the standards outlined in the 2012 Concordat[4] to support Research Integrity, as well as all other applicable legal and regulatory standards for the acceptable conduct of research. Genomics England may introduce any other standards as a requirement for GeCIP Members to adhere to in recognition of the rapidly-developing nature of genomics and related fields.

Explanatory Note

The Concordat to support Research Integrity seeks to provide a comprehensive national framework for good research governance, by:

- maintaining the highest standards of rigour and integrity in all aspects of research
- ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards
- supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers
- using transparent, robust and fair processes to deal with allegations of research misconduct should they arise
- working together to strengthen the integrity of research and to reviewing progress regularly and openly

15 Amendment of the rules and the GeCIP IP Policy

15.1 The Rules and the GeCIP IP Policy may be amended by the GeCIP Board from time to time.

15.2 Any revised Rules or GeCIP IP Policy must be issued to GeCIP Members. Revised Rules will be binding 30 days after they are issued. A GeCIP Member will be deemed to have accepted the revised Rules unless he/she has resigned within the 30 day period.

16 Contractual effect of rules

16.1 It shall be a condition of an Eligible Person becoming a GeCIP Member that:

16.1.1 he or she enters into a GeCIP membership agreement with Genomics England under which he or she agrees to be bound by these Rules; and

16.1.2 the individual's relevant employer or education provider indicates its consent to the individual's participation in GeCIP under the arrangements set out in these Rules by including the individual on a list of approved persons signed by the employer or education provider and submitted to Genomics England.

17 General

17.1 No GeCIP Member may assign or deal in any other manner with any or all of its rights as a GeCIP Member.

17.2 No GeCIP Member may make or authorise any person to make any public announcement or communication to the press or media regarding the GeCIP and its operation and work without the prior written consent of the Office of the Chief Scientist.

17.3 Genomics England shall be entitled at any time on reasonable notice to audit a GeCIP Member's compliance with the provisions of these Rules and may:

17.3.1 where materials have been provided to a GeCIP Member choose to inspect the premises and other facilities of the GeCIP Member in order to review the security, storage and other arrangements for the materials;

17.3.2 where a research project has been approved, request such additional information about the research project and/or its progress as it may from time to time reasonably require.

17.3.3 Genomics England shall bear the costs of such audits in all cases.

17.4 Notices given under these Rules by the GeCIP Board or the GeCIP Steering Committee or the Office of the Chief Scientist to a GeCIP Member shall be given in writing to the address or email address given in the GeCIP Member's application for membership (or to such other address or email address as the GeCIP Member may notify to the Office of the Chief Scientist from time to time).

17.5 Notices given under these Rules by a GeCIP Member to the GeCIP Board/the Office of the Chief Scientist shall be given in writing to the following address or email address chiefscientist@genomicsengland.co.uk (or to such other address or email address as the Office of the Chief Scientist may notify to GeCIP Members from time to time).

17.6 Notices given under these Rules shall be:

17.6.1 delivered personally; or

17.6.2 delivered by commercial courier; or

17.6.3 sent by email; or

17.6.4 sent by pre-paid first class post; or

17.6.5 (if a hard copy notice is to be served outside the country from which it is sent) sent by reputable international overnight courier.

17.7 If a notice has been properly sent or delivered in accordance with Rule 17.6, it will be deemed to have been received as follows:

17.7.1 if delivered personally, at the time of delivery; or

17.7.2 if delivered by commercial courier, at the time of signature of the courier's delivery receipt; or

17.7.3 in the case of email, at the time of transmission; or

17.7.4 in the case of pre-paid first class post, two Business Days from the date of posting; or

17.7.5 in the case of reputable international overnight courier, 2 Business days from the date of posting.

17.8 The provisions of Rules 17.4 to 17.7 (inclusive) of these Rules do not apply to the service of any proceedings or other documents in any legal action or proceedings.

18 Disputes

18.1 These Rules and any disputes or claims arising out of or in connection with them shall be governed by and construed in accordance with the law of England and Wales, and, subject to Rules 18.2 – 18.3, the courts of England and Wales shall have exclusive jurisdiction to settle any such dispute or claim.

18.2 Any party to these Rules may by written notice refer the dispute to the Office of the Chief Scientist for a determination.

18.3 If the dispute is not resolved by the Office of the Chief Scientist within ten (10) business days of the written notice served under Rule 18.2, any party involved in the dispute may refer the dispute to mediation in accordance with the CEDR Model Mediation Procedure. If the matter is not referred to mediation or if the relevant parties fail to resolve the dispute in this way, the relevant parties shall be entitled to pursue the dispute through the courts in accordance with Rule 18.1.

19 Definitions

In these Rules, the following definitions shall have the meanings set out opposite them respectively:

100,000 Genomes Dataset: the genomic data derived from the 100,000 Genomes Project andmade available in the GeCIP Research Environment.

100,000 Genomes Project: a programme of whole genome sequencing announced by the Prime Minister in December 2012, the principal objective of which is to sequence 100,000 genomes from patients with cancer, rare inherited disorders and infectious diseases drawn from the NHS in England, and to link the sequence data to a standardised, extensible account of diagnosis, treatment and outcomes.

Access Review Committee: the independent committee established by Genomics England to review applications for access to data and samples.

Business Day: a day (other than a Saturday or Sunday or public holiday in the United Kingdom) on which clearing banks in the City of London are generally open for business.

Confidential Information: any and all data, results, know-how, interpretation, images, databases, software, algorithms, inventions, designs, trade secrets, analyses, valuations, processes, protocols, research, technical information, or other information whether oral, in writing, in electronic form, or in any other form, that is created, developed or received by each GeCIP Member in the course of such GeCIP Member's involvement and/or activity under the GeCIP, provided that Confidential Information shall not include any information which the GeCIP Member can prove:-

(a) is or becomes public knowledge through no improper conduct on the part of the GeCIP Member;

(b) is already lawfully possessed by the GeCIP Member without any obligations of confidentiality or restrictions on use prior to first receiving it, save that this provision shall not apply to any Confidential Information that is created by the GeCIP Member in the course of the GeCIP Member carrying out his/her activities under the GeCIP; and/or

(c) is obtained subsequently by the GeCIP Member from an individual that is not a GeCIP Member, without any obligations of confidentiality and such individual is in lawful possession of such Confidential Information and not in violation of any contractual or legal obligation to maintain the confidentiality of such Confidential Information.

Eligible Person: a person whether or not resident in England who is:-

(a) a researcher employed or engaged by a bona fide higher education institution; or

(b) a clinician employed or engaged by the NHS or Public Health England; or

(c) a healthcare professional employed or engaged by the NHS or Public Health England; or

(d) a clinician or healthcare professional employed or engaged by an organisation other than the NHS or Public Health England provided that it is not a 'for-profit' commercial enterprise; or

(e) a person who is training at a bona fide higher education institution to be one of the above, and

(f) a person who contributes samples and/or data or can otherwise demonstrate that he or she can add value to the 100,000 Genomes Project and provided that he/she is not employed by a 'for-profit' commercial enterprise.

Detailed Research Plan: the document required to be provided by a GeCIP Domain in accordance with Rule 4.11 of these Rules.

GeCIP Domain/Domain: as the context requires, a disease-facing, cross-cutting or other domain identified by the GeCIP Board as a domain for work within the GeCIP or a group of GeCIP Members approved in accordance with these Rules as a group undertaking work in a particular area.

GeCIP Domain Leader: a leader of a Domain appointed in accordance with Rule 4.15 of these Rules.

GeCIP IP Policy: the policy named as such and published on the Genomics England website, as updated from time to time.

GeCIP Knowledge Base: the clinical, genomic and phenotypic data derived from the 100,000 Genomes Project made available in the GeCIP Research Environment and to which GeCIP Members will have access in accordance with these Rules and such policies and procedures as Genomics England shall publish from time with regard to the operation and use of theGeCIP Research Environment.

GeCIP IPRs: all Intellectual Property Rights arising out of activities carried out by the GeCIP including, but not limited to, all Intellectual Property Rights in the GeCIP Outputs other than the Intellectual Property Rights in any Third Party Works incorporated into the GeCIP Outputs.

GeCIP Member: an individual admitted to membership of GeCIP in accordance with these Rules.

GeCIP Outputs: all discoveries, inventions, results, data, analysis, interpretation, algorithms, papers, publications, documents, diagrams, images, files, databases, software and other items created or developed in the course of activities carried out by the GeCIP.

GeCIP Training Director: an individual appointed in accordance with Rule 4.20 of these Rules to be responsible for training trainers in a Domain.

Genomics England: Genomics England Limited, a company incorporated in England under company registration number 08493132 whose principal offices are at Dawson Hall, Queen Mary University of London, Charterhouse Square, London, EC1M 6BQ.

Institution: the employer or education provider of the GeCIP Member who consents to the person's participation in the GeCIP in accordance withthe Participation Agreement.

IPR: patents, any extensions of the exclusivity granted in connection with patents, petty patents, utility models, registered designs, applications for any of the foregoing (including, but not limited to, continuations, continuations-in-part and divisional applications), the right to apply for and be granted any of the foregoing, rights in inventions, copyrights, design rights, database rights, publication rights, rights in know-how, trade secrets and confidential information and all other forms of intellectual property right having equivalent or similar effect to any of the foregoing which may exist anywhere in the world.

Main Programme: the activities under the 100,000 Genomes Project co-ordinated by NHS England under the GMC Contracts.

Participation Agreement: the agreement to be entered into between Genomics England and an Institution under which the Institution consents to a GeCIP Member participating in the GeCIP.

Protocol: the document entitled "100,000 Genomes Project Protocol Version 4" as amended and REC approved from time to time.

Publication Policy: the policy named as such and published on the Genomics England website as updated from time to time.

Research Environment: Genomic England's IT systems used to store, provide access to and facilitate analysis of the dataset of whole genome sequences arising out of the 100,000 Genomes Project, additional data and annotations, including the analytical tools and GeCIP Knowledge Base made available through Genomic England's IT systems.

Research Registry: the register within the GeCIP collaboration portal.

Third Party Works: all documents, diagrams, images, files, databases, software and other works: (i) the copyright and/or database rights which are not owned by Genomics England and/or (ii) are subject to confidential rights held by a third party.