ICGC-ARGO Membership Application Form.

The proposal will be reviewed by the Steering Committee after which final approval will be decided by the ICGC Executive.

Please refer to the ICGC Member Guidelines before completing this form (Appendix I).

GENERAL INFORMATION
Name of Proposer:
Email Address:
Name of Organization:

Please select the membership status you are applying for:

Full Member: ☐

Associate Member: ☐

Provisional Member: ☐

1. Overview of Project

Please provide an outline of the project proposed and the scientific rationale. Provide specific details of the clinical or biological questions to be addressed. For groups applying for membership using in-kind service contributions, please describe what services you propose to provide.

2. Clinical Annotation

Please provide details of the clinical data available by appending fields or cross reference with the ICGC mandatory fields outlined in Appendix II.

Not applicable to groups applying for membership using in-kind services.

3. Planned Assays & Samples Numbers

Please provide details of the assays planned (WGS, Exome, Custom Diagnostic and/or whole transcriptome, epigenetic or additional analyses). Note: ICGC-ARGO attribute assay (or equivalent) and transcriptomics on each patient is expected as a minimum.

Not applicable to groups applying for membership using in-kind services

Organ System:
Histopathological subtype:
Molecular subtype information:
Etiological subtype information:
Geographic origin of Donor (if appropriate for cohort):
Ethnic Origin of Donor (if appropriate for cohort):
Loco-regional or Metastatic Disease (if relevant):
Number of Prospective Samples:
Number of Retrospective Samples:

Is the tumour tissue fresh frozen?	YES ☐	NO☐
Is the tumour tissue FFPE derived?	YES ☐	NO☐
What is the source of normal?	Blood ☐	Other☐

Comments and additional information:

Any additional information (free text field)

4. Membership & Financial Commitment

Full Membership ☐
[2000 donor minimum + $10 million commitment]

or

Associate Membership ☐
[500-2000 donors + $5 million, commitment]

Is the requisite funding already in place: ☐Yes ☐No
[If no, please note that your membership will be classified as provisional]

Please provide further details:

NB: Associate and Full Membership will also be considered, on a case by case basis, for groups willing to contribute $5 or $10 million respectively in in-kind services, including genome sequencing, clinical data harmonisation, or data analysis compute capacity.

5. Commitment To ICGC-ARGO
Please tick the following boxes if you agree to the corresponding statement:

The proposed Policies and Guidelines of ICGC-ARGO are acceptable. ☐

We agree to submit clinical and molecular data and metadata to ICGC-ARGO Data Processing Centres upon completion of routine

quality control. ☐

We agree that the participant (donor) consent meets the requirements of inclusion in ICGC-ARGO as outlined in the ICGC-ARGO Participant Assessment Tool in Appendix III. ☐

6. Scientific Leader

Name of Organisation:
Scientific Leader:
Email Address:

Name of Organisation:
Scientific Co-Leader:
Email Address:

Name of Organisation:
Scientific Co-Leader:
Email Address:

Please add any additional information as required.

Any additional information (free text field)

Appendix I - ICGC-ARGO Goals

ICGC-*ARGO* Specific Aims

The central goal of ICGC-*ARGO* is to analyze biospecimens from at least 100,000 cancer patients with high quality clinical data to address current key outstanding questions that are vital to our quest to defeat cancer. To achieve this goal, the acquisition of accompanying high quality clinical information is of utmost importance.

The sources of cohorts of patients that would constitute ICGC-ARGO projects may include:

- Biospecimens from participants enrolled in active clinical trials;
- Analyses of banked samples from past clinical trials;
- Analyses of samples from clinically well-annotated cohorts that satisfy ICGC-ARGO clinical data requirements.
- Longitudinal cohort studies.
- Autopsy studies with detailed clinical data

Membership Guidelines

1. ICGC-*ARGO* Membership is based on a Programme of work, and may contain any number of specific "cohorts" within that umbrella. It is encouraged, that when developing these programmes that the ICGC-*ARGO* Steering Committee is consulted for more detailed guidance. Each programme will be reviewed by the ICGC-*ARGO* Steering Committee to facilitate an interactive process.
2. An ICGC-*ARGO* Programme would generally address a specific cancer type, or a clinically relevant grouping of cancer. Examples include cancers of the Head and Neck, which includes many cancer types and is a reflection of the clinical care pathways that are in place to manage patients. This may include specific clinical trial indications. Cohorts may be a reflection of centralised healthcare facilities such as for paediatric cancer. Broad-based general cancer molecular profiling platforms may also be members, with provision of a proportionate breakdown of cancer types expected.
3. An ICGC-*ARGO* Programme must address a key clinical and/or biological question of relevance to the specific cancer type on which the programme is focused. This will be different for different cancer types and will impact on sample sizes and analyses performed for individual projects within a programme.
4. Clinical annotation is of utmost importance. Whilst clinical trial data is the Gold Standard, clinically well-annotated cohorts of patients that include the mandatory ICGC-*ARGO* clinical dataset are eligible.
5. The goal of ICGC-*ARGO* is to advance discovery, as a consequence, nucleic acid analysis must go significantly beyond the assessment of selected gene sets using panels such as those currently performed in most clinical diagnostic laboratories. Cognizant of the tractability of biospecimen quantity, quality and fixation methods, minimum requirements are either one of the approaches detailed in (a) below; complemented with methodologies listed in (b). The exact composition per project will be defined through discussion with the ICGC-ARGO steering Committee, however, each case **should have a transcriptome** to allow broad pooled data analyses, and a discovery genome sequencing approach. WGS is ideal, however is not often tractable in clinical trials, and whole exome or a "Clinical Genome" that captures attributes beyond point mutations in genes that are clinically relevant may be used.

a) Expected

- **Whole Genome Sequencing** ***OR***
- **Whole Exome Sequencing** ***OR***
- **Clinical Genome** - an assay that captures equivalent data readouts to a WGS. This approach is included as for solid tumours, the above may be intractable for WGS, or less informative (WES). Most clinical trial biospecimens are fixed in formalin or similar fixatives in uncontrolled environments, and up to 50% have low epithelial cellularity which impacts on WGS in particular. This would make over 95% of clinical trials and eligible population based cohorts unable to be used. These composite diagnostics must go well-beyond current diagnostic "panels" and interrogate novel features of clinical and biological relevance in a specific cancer type.

- **ICGC-ARGO Clinical Genome** – ICGC-ARGO is developing a clinical genome diagnostic that may be used. This will become available in 2019.

b) Expected

- **Whole Transcriptome Sequencing**

c) Encouraged

- **Epigenetic Analyses**
- **Additional analyses** eg: proteomic, metabolomic … are encouraged.

6. Financial commitment of $10 million US equivalent per programme. There are no restrictions as to how a programme comes together, or the timing of the investment; however, the investment must be current and active for a minimum of 3 years from the time of membership. Essential to membership is a commitment and a plan for delivery or access of format and content compliant data to the ICGC-*ARGO* DCC and/or tangible mechanism for data sharing as per ICGC procedures and policies. A clear formal structure and governance mechanism for consortia that come together to join ICGC-*ARGO* needs to be articulated and responsible leads identified. Established consortia, networks and co-operative groups are ideally positioned to become ICGC-*ARGO* Members.
7. It is anticipated that the number of donors committed by a programme will be a minimum or 2000 depending on the proposed assays and analyses, and will be arrived at in discussion with the ICGC-*ARGO* Steering Committee on a project-by-project basis if required.
8. Emerging and smaller scale programmes may become Associate Members. Associate members are defined as those that have a commitment equivalent to members but aim to contribute between 500 and 2000 donors with the same commitment as members with regard to data sharing and an investment of $5 million with the same conditions as for full members. Again, specific project related parameters can be defined in discussion with the ICGC-ARGO Steering Committee.
9. Associate and Full Membership will also be considered, on a case by case basis, for groups willing to contribute $5 or $10 million respectively in in-kind services, including genome sequencing, clinical data harmonisation, or data analysis compute capacity.
10. There are no restrictions with regard to Members as to their institution, jurisdiction, or corporate status.
11. Data access is tiered, and aimed not to disadvantage Members or Associate Member Data producers, with a framework that encourages data sharing, yet provides data generators with sufficient time to perform analyses:
    - Up to 12 months from completion of standardised analyses: Access to Programme submitting data only.
    - 12 months: Access to Members.
    - 18 months: Access to Associate Members.
    - 24 months: Accessible by external parties.

Appendix II, November 2017 - Mandatory Clinical Information

Patient (Donor) *(15 features)*	**Sample** *(13 features)*
• Patient identifier	• Specimen ID
• Patient sex	• Specimen type
• Age at diagnosis (in years)	o Primary tumor
• Date of diagnosis (if IRB approved)	o Relapsed tumor
• Cancer type (WHO ICD-10)	o Metastatic tumor
• Patient vital status	o Tumor xenograft
o Alive	o Adjacent normal tissue
o Died of cancer	o Lymph node
o Died of other reasons	o Buffy coat
o Unknown	o Whole blood
• Disease status	o Plasma
o progression yes	o Serum
- loco-regional	o Urine
- distant	o Other (please specify)
o progression no	• Tumor histological type (http://codes.iarc.fr/codegroup/2)
o no disease	• Anatomic location
• Progression status determined by (imaging, etc.)	• Number of regional lymph nodes positive (x from n examined notes)
• Therapy type	• Central pathology confirmed, yes/no Tumor grade (all tumors) at time of sample acquisition (surgery, biopsy)
o Chemotherapy – single agent	
o Chemotherapy – multi agent	• TNM stage (carcinomas) at time of sample acquisition
o Cryotherapy	o Stage (other than carcinomas) at time of sample acquisition
o Hormonal therapy	• TNM stage (carcinomas) at time of recurrence
o Other targeting molecular therapy	o Stage (other than carcinomas) at time of recurrence
o Immunotherapy	• Tissue analysis, percentage of tumor cells
o Radiation – external	• Tissue analysis, percentage of proliferating cells (Ki67)
o Radiation – internal	• Tissue analysis, percentage of inflammatory tissue
o Surgical resection	• Tissue analysis, percentage of stromal cells
o Bone marrow transplant	• Tissue analysis, percentage of necrosis
o No treatment	
o Other	
• Therapy response	
o Complete remission	
o Partial remission	
o Disease progression	
o Relapse	
o Stable disease	
o Unknown	
• Chemotherapy protocol, drug name(s)	
• Chemotherapy protocol, cumulative drug dose	
• Radiation therapy protocol, dosage	
• Radiation therapy protocol, fractions	

Appendix III: ICGC-*ARGO* Assessment Tool for Participation

This document aims to provide guidance on determining whether datasets which include genomic data, are suitable for inclusion in *ICGC-ARGO*. It does not apply to samples and data that have not been consented for genomic research.

Data submitted to the International Cancer Genome Consortium Accelerating Research in Genomic Oncology project (*ICGC-ARGO*) will be maintained in both open and controlled access databases. The *ICGC-ARGO* Core Bioethics Elements present the principles that should have been communicated to potential participants for research studies. We recognise that consent materials may have used different language reflecting requirements from another time and may be ambiguous, or be silent, as to data sharing and potential uses of the data. To help you determine whether your data can be used for *ICGC-ARGO*, the ICGC Ethics and Governance Committee has drawn up the following tool based on the principles found in the Global Alliance for Genomics and Health's Consent Policy[1] and other best practice documents[2].

Step 1: Please answer the following questions[3]:

Is your data consented for:	**Yes**	**No**
1. Any approved future biomedical research?		
2. Deposit of open access fields datasets in open access databases?		
3. Deposit of controlled fields in controlled access databases?		
4. Linkage with other research datasets?		
5. International data sharing?		
6. Are there any restrictions to access by industry partners?		

Step 2: If the answers to all the above are **Yes**, your data can be used for ICGC-ARGO.
If any were **No**, please answer the following questions:

	Yes	**No**
1. Does your consent allow for re-contact of participants?		
2. Is it feasible for you to re-contact and re-consent your participants for inclusion in *ICGC-ARGO*?		

Step 3: If both answers to the above are **Yes**, please re-contact and re-consent.
If either or both are **No**, please answer the following:

	Yes	**No**
1. Is it possible for you to apply to an authorized local committee to obtain an ethics waiver of the re-consent requirement for participation in *ICGC-ARGO*?		

Step 4: If the answer to the above is **Yes**, please request a waiver per your local procedures.
If the answer is **No**, your data cannot be used for ICGC-ARGO.

[1] www.genomicsandhealth.org
[2] In the case of uncertainty regarding the interpretation of steps or questions listed, please contact: Susan Wallace at sew40@leicester.ac.uk
[3] For an explanation of terms, please refer to the Global Alliance for Genomics and Health's Data Sharing Lexicon, available online at: https://www.ga4gh.org/ga4ghtoolkit/regulatoryandethics/