MAGIC

Malignant Germ Cell
International Consortium

Governance Policy Manual

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Glossary of Terms

Ad-Hoc Committee	A temporary working group formed for a specific task or objective, with the intent to dissolve after the completion of the task or achievement of the objective.
Biologic Specimen	Any blood, tissue, saliva, urine or other biologic material that may be used towards achieving the biologic aims of MaGIC.
Clinical & Genomic Data	Any data resulting from analysis of amalgamated clinical trials data and/or genomic analysis. This data will be housed in the Data Commons.
Committees	Working groups within MaGIC, established to focus on specific areas of development and/or maintenance. Committees are defined as either “ad hoc” or “standing” committees.
Committee Chair	A member selected by the Executive Committee to govern a specific committee. Tasks include: development of committee’s goals and aims, monitoring participation of committee members, establishing agendas, convening and conducting meetings and representing the committee with a seat on the Executive Committee.
Committee Vice-Chair	A member elected to serve in place of the Committee Chair should he or she is unable or unavailable to perform his or her duties.
Consortium Headquarters	The headquarters is responsible for the day-to-day management and oversight of all administrative and regulatory tasks, and responsibilities of the Consortium. The Consortium Headquarters is currently located at Dana-Farber Cancer Institute, 450 Brookline Avenue, Boston, MA 02115.

Consortium Chair	The presiding officer of MaGIC and the Executive Committee.
Consortium Vice-Chair	The second presiding officer of MaGIC and the Executive Committee. The Consortium Vice-Chair will serve as the Chair, should the Chair be unable to perform his or her duties.
Data Analysis Proposal	A formal request to use data stored in the MaGIC Data Commons. The Data Analysis Proposal form describes the objectives of the study, inclusion and exclusion criteria, the required data elements, a detailed analysis plan, the identification of the statistician who will be working with the data and the anticipated list of authors, including first and last. The form must be submitted to the Clinical Research and Publications Committee for review and approval prior to the release of data.
Data Commons	A pooled database of all MaGIC data, including clinical, genomic and biologic data of GCT patients provided by MaGIC Affiliate Institutions or Organizations. All data within the data commons is anonymized.
Data Contributor	An organization or institution that is actively involved in the research aims of MaGIC, and has contributed data or access to biospecimens to MaGIC.
Data Contributor Alternate Principal Investigator (Alternate PI)	An individual belonging to an Affiliate organization or institution who has been selected by the Affiliate members to take the place of the Affiliate PI, should he or she for any reason be unable to perform the required duties.
Data Contributor Principal Investigator (PI)	An individual belonging to an Affiliate organization or institution who has been selected by the Affiliate members to hold a seat on the MaGIC Executive Committee, and act as the representative for the organization or institution.

Data Commons Service Provider	The party responsible for the safe custody and storage of data housed in the MaGIC Data Commons
Executive Committee (EC)	The governing body of MaGIC established to provide structure, oversight and guidance in line with the Consortium's mission and goals.
MaGIC Analyses	The analyses of any reports, including statistical codes and "frozen" datasets, resulting from any data from the Data Commons.
MaGIC-endorsed Protocols	Any clinical trial that has been initiated by members of MaGIC and/or any trial that is in line with the Consortium's mission, and which the MaGIC EC actively promotes members to participate in.
Standing Committee	A permanent working group that focuses on a particular area of the consortium, which requires ongoing consideration and development.

Charter of MaGIC

Who we are

MaGIC is comprised of an international group of pediatric and adult oncologists, surgeons, pathologists, epidemiologists, statisticians, bioinformaticists and basic scientists dedicated to the common goal of advancing the field of germ cell tumor research.

Our Mission

The mission of MaGIC is to improve outcomes and reduce long-term toxicities for patients with malignant germ cell tumors (GCTs) through clinical and scientific collaboration.

Our Vision

MaGIC exists to support the inter-disciplinary collaboration of the world's leading clinical and basic scientists in the field of germ cell tumors. We believe that collaboration is the key to accelerating break-through scientific discoveries and advances in treatment

Our Goals & Aims

MaGIC has developed a number of overarching goals, coinciding with its mission and vision. These goals are defined as the following:

- Generate new insights into GCT etiology, prognosis, toxicity reduction and optimal treatment
- Foster a more conducive international environment for GCT research across gender and age groups
- Enhance research impact through common strategic objectives, programmatic convergence, concerted action, and fostering of innovation
- Provide an overarching data sharing structure, the MaGIC Data Commons, to facilitate evidence-based design and implementation of clinical trials, the collection of annotated biologic specimens and overall scientific collaboration

Our Strategy

In order to effectively and efficiently achieve our goals, MaGIC has prioritized three main areas of research brought together by the MaGIC Data Commons:

- *Clinical Trial Design & Development* focuses on the development of international clinical trials that incorporate pediatric, adolescent, and adult male and female GCT patients.
- *Biologic Research* promotes the basic scientific understanding of the etiology of germ cell tumors and the molecular markers of prognosis.
- *Clinical Research* utilizes the amalgamated clinical trials data from our Affiliate institutions and organizations to inform clinical research questions and trial design.

Section 1

Membership, Categories, Criteria & Standards SOP

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to identify the categories, criteria, and performance standards for membership in the MaGIC.

PROCEDURES

1.1. Membership Categories

i) *MaGIC Data Contributors*

(1) *MaGIC Data Contributors* are organizations, cooperative groups or institutions that contribute clinical or biologic data to the MaGIC Data Commons.

ii) *MaGIC Members*

(1) *MaGIC Members* are individuals who demonstrate an active role in one or more of the key activities of MaGIC including clinical trial design, clinical data analysis or biologic inquiry and/or serve as a Chair or Co-Chair of a *MaGIC-endorsed clinical trial.

iii) MaGIC Young Investigators

(1) *MaGIC Young Investigators* are early-career faculty, post-docs or fellows within the first 10 years of completion of their training who have a predominant interest in clinical, epidemiologic or biologic research in the field of germ cell tumors.

iv) MaGIC Patient Advocates

(1) *MaGIC Patient Advocates* are individuals who have a personal experience with germ cell tumor, either as a patient or family member of patient who has been treated, who are passionate about the study of germ cell tumors.

**A MaGIC-endorsed trial refers to any clinical trial that has been initiated by members of MaGIC and/or any trial that is in line with MaGIC's mission and which the MaGIC EC actively promotes members to participate in.*

1.2. Benefits of Membership

i) All members of MaGIC will have the following opportunities:
   (1) Access to the MaGIC website and Data Commons (pending submission and approval of Data Analysis Proposal).
   (2) Authorship, if journal and consortium requirements are met, on MaGIC manuscripts.
   (3) Participation in the development of future MaGIC objectives.
   (4) Invitation, participation and representation in membership meetings, which are defined as:
      (a) Quarterly teleconferences
      (b) In-person Annual Meeting

1.3. Performance Standards

i) Members of all MaGIC Membership Categories are required to meet the following performance standards:
   (1) Make a substantial, direct, and intellectual contribution (as defined by the EC) to MaGIC work and research activities.
   (2) Agree to adhere to MaGIC's Standard Operating Procedures (SOPs)
   (3) Attend the Annual Meeting, if applicable (members must not miss 2 consecutive Annual Meetings).
   (4) Actively serve on at least one standing committee (see *MaGIC Committees SOP*).
   (5) All members of the EC must participate in *50% of the quarterly teleconferences (annually).
   **Exceptions may be made on a case-by-case basis, after review by the Steering Committee.*

ii) *MaGIC Data Contributors* are additionally required to:
   (1) Elect a Principal Investigator (PI) from the organization or institution who will serve on MaGIC's Executive Committee (EC).
   (2) Elect an Alternate PI to serve in the PI's place, should he or she be unavailable or unable to perform his or her duties.
   (3) Sign a Memorandum of Understanding (MoU) between the organization or institution and other constituents that form MaGIC.

iii) *MaGIC Young Investigators* are additionally encouraged to:
   (1) Participate in at least one MaGIC project
   (2) Pair with a mentor, a current active member of MaGIC, based on their research interests. The Membership and Nominating Committee will help to facilitate and monitor mentorship parings.

iv) MaGIC Patient Advocates are additionally encouraged to:
   (1) Pair with a mentor, a current active member of MaGIC, based on their interests and which committee they are assigned to. The Membership and Nominating Committee will help to facilitate and monitor mentorship parings.

1.4 Membership Application Process

i) Interested organizations, institutions and individuals meeting the requirements of membership outlined in this SOP may apply for membership by filling out the appropriate application which can be found in the Appendices of this document or on the MaGIC website.

ii) All Data Contributors are required to submit one application for their organization or institution. This is the responsibility of the Data Contributor PI.
iii) Applicants will be sent notification that an application has been successfully received.
iv) Complete applications will be reviewed by the Nominating and Membership Committee. A 2/3 majority vote is required to approve applicant membership.
v) Once approved by the Nominating and Membership Committee, the committee chair will present the applicant to the Executive Committee. A 2/3 majority vote will also be required by the EC.
vi) Applicants will be notified via email of their acceptance status.
vii) Applications will be accepted on an ongoing basis, but final review and approval by the EC will occur on a quarterly basis.

1.5 Membership Renewal, Probation and Termination

i) MaGIC Members will serve three-year terms with no limit to the number of terms that can be served.
ii) At the end of a member's term, membership will be reviewed by the Nominating & Membership Committee to assess member performance standards and review membership extensions, or, in the case of MaGIC Young Investigators, the opportunity to change membership categories.
iii) If Members are in compliance with the performance standards, membership will be extended. (Members will not receive notice of an extended membership)
iv) If Members are deemed to be in violation of the established performance standards, the procedures listed below will be followed:
    (1) A notice will be sent per email to the member.
    (2) An initial probation period of one year will be applied. During this time, members should make every effort to meet the member performance standards outlined in section 1.3
    (3) At the end of the probation period, the EC, in conjunction with the Nominating & Membership Committee, will review performance and grant removal of probation, extension of probation for one more year or termination of membership. The appropriate notice will be sent by the EC.
    (4) Membership may also be terminated for any of the following reasons:
        (a) Failure to disclose conflicts of interest that affect MaGIC's research and goals
        (b) At the discretion of the MaGIC EC

MAINTENANCE RESPONSIBILITY

The MaGIC Governance Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the MaGIC EC.

AUTHORIZATION

This SOP was developed by the Governance Committee and reviewed and approved by the MaGIC EC.

VERSION / REVISION HISTORY

V2.0 / last modified July 2020

Section 2

Executive Committee SOP

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the structure, members and responsibilities of the Malignant Germ Cell Tumor International Consortium (MaGIC) Executive Committee (EC).

PROCEDURES

2.1. Structure

The EC will be made up of the following roles and individuals:

i) Consortium Chair
   (1) The Consortium Chair will serve as the presiding officer of the EC.
   (2) The Chair will be appointed by the Nominating & Membership Committee and must be confirmed by a 2/3 majority votes.
   (3) Any change to the Chair will be proposed by the Nominating & Membership Committee to the EC and must be confirmed by a 2/3 majority vote of the EC. Changes in Chair must be reported to the appropriate granting organizations.
   (4) Chair responsibilities include the following:
      (a) Act as Consortium spokesperson both internally and externally.
      (b) Oversee adherence of all MaGIC members, research, projects and protocols to the consortium standards and guidelines as outlined in the MaGIC Governance Policy Manual.
      (c) Serve as PI or Co-PI of Consortium-related funding proposals.
      (d) Serve as an ex officio member (with a vote) on all standing and ad hoc committees.
      (e) Ensure that reports and updates from standing and ad hoc committees are submitted to the EC as appropriate.

ii) Consortium Vice Chair
   (1) The Consortium Vice Chair will serve as the second presiding officer of the EC.
   (2) The Vice Chair will temporarily act in the Chair's place should the Chair be unavailable or unable to fulfill his or her responsibilities.
   (3) The Vice Chair will be appointed by the Nominating & Membership Committee and must be confirmed by a 2/3 majority votes.
   (4) Any change to the Vice Chair will be proposed by the Nominating & Membership Committee to the EC and must be confirmed by a 2/3 majority vote of the EC.
   (5) Vice Chair responsibilities include the following:
      (a) Assist and support the EC chair in the activities detailed above.
      (b) Serve in the position of the Chair, should the Chair be unavailable.

iii) Data Contributor Principal Investigators (PIs)
   (1) PIs from each Data Contributor organization or institution will serve on the EC.
   (2) Any change to the Affiliate PI will be proposed by the Full Members of the Affiliate, and must be confirmed by a 2/3 majority vote of the EC.

iv) Committee Chairs
   (1) The Chair of each established standing and any ad hoc committees will serve on the EC.
   (2) Any change to Committee Chairs will be proposed by the EC and confirmed by a 2/3 majority vote.

v) Statistician
   (1) At least one Statistician will be appointed to the Executive Committee by mutual agreement of the Data Contributors
   (2) Any change to Statistician(s) will be proposed by the EC and confirmed by a 2/3 majority vote.

vi) Ex Officio Members
   (1) MaGIC Consortium Headquarters personnel will serve as non-voting members of the EC and may include but are not limited to those listed below.
      (a) Program and/or resource managers
      (b) Clinical research coordinators
      (c) Grant management officers

vii) Other non-voting members may be appointed at the discretion of the EC Chair.

2.2. EC Function & Responsibilities

i) The EC will be considered the key body within the governance structure, responsible for the sustained growth and development of the Consortium.

ii) EC responsibilities & duties include the following:
   (1) Consortium Governance - the EC will provide oversight and deliberation for matters pertaining to MaGIC as listed below:
      (a) Provide scientific direction for the Consortium.
      (b) Resolve disputes that arise within MaGIC committees.
      (c) Evaluate potential and reported conflicts of interest.

(d) Develop strategic and long-term plans to ensure the Consortium's future success.
(e) Liaise with and promote productive interaction with groups of similar aims and interests.
(f) Oversee Standing and Ad Hoc Committee functioning and development.

(2) Reviews and Approvals - the EC will be responsible for final review and approval of the following proposals and processes:
(a) Standard Operating Procedures and other Consortium governance documents
(b) New applications for membership (as per the process defined in Section 1)
(c) Pending membership terminations
(d) Committee membership
(e) Nominations proposed by the Nominating & Membership including Committee Chairs, Data Contributor PIs, Consortium Chair, and Vice Chair.

2.3. Meetings

i) Meetings of the EC will occur quarterly in the form of teleconferences. There will be one additional in-person meeting in the event that an Annual Meeting is held.
ii) Participation is required for all members of the EC. Other participants may be invited at the discretion of the Executive Committee.
iii) Meeting dates, times, and location, if applicable, will be communicated at least 30 days in advance of the event.
iv) Special meetings of the EC may be called by the Consortium Chair or at the request of a majority of EC members.
v) MaGIC Consortium Headquarters personnel are responsible for organizing meetings that support the business of the Consortium.

2.4. Voting

i) EC members eligible to vote on Consortium matters, as defined in Section I, include the Chair, Vice Chair, Data Contributor PIs (or Alternate PIs, if applicable), and Committee Chairs.
ii) Votes may take place during teleconferences, at in-person meetings, and/or electronically.
2. Members will be notified of an in-person or telephone vote at least 3 weeks prior to the vote.
3. Voting deadlines will be strictly adhered to, and any votes falling outside of deadlines will not be counted.
iii) Voting may only take place when there is a quorum present (a quorum consists of at least 2/3 of the Executive Committee).
iv) A 2/3 majority affirmative vote is required to pass a measure unless otherwise noted or announced.
v) Individuals eligible to serve on the EC due to multiple roles within the Consortium may only cast one vote.

2.5. Executive Committee Elections & Terms

i) Members of the EC will serve three-year terms with no limit on the number of terms that can be served.
ii) Staggered Elections

(1) At the end of the defined term*, an official election will be held. Re-election of current members is permitted, pending performance review by the Nominating & Membership Committee.
**terms will be staggered by positions in an effort to avoid overburdening the Nominating & Membership Committee.*

(2) Staggered elections for the following positions (which comprise the Executive Committee) will occur at the end of each term:
   (a) Consortium Chair and Vice-Chair
   (b) Data Contributor PIs and Alternate PIs
   (c) Committee Chairs and Vice-Chairs

(3) In the event that a seat becomes vacant prior to an official election, the Nominating & Membership Committee will present a replacement candidate to the EC which will be affirmed by a 2/3 majority vote. The elected member will hold the seat until the official election period.

iii) Resignations from the EC should be made in writing to the Chair.

MAINTENANCE RESPONSIBILITY

The Governance Committee is responsible for the annual review of this SOP. Any amendments or changes must be approved by the EC.

AUTHORIZATION

This SOP was developed by the Governance Committee and reviewed and approved by the EC.

VERSION / REVISION HISTORY

V2.0 / last modified July 2020

Section 3

Committees SOP

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to ensure the effective and efficient functioning and operation of MaGIC Committees.

PROCEDURES

3.1. Committee Design

i) All MaGIC Committees will be categorized as either a "Standing" or an "Ad Hoc" Committee.
   (1) A "Standing Committee" is a permanent working group that addresses a specified area of ongoing development.
   (2) An "Ad hoc Committee" is a temporary working group formed for a specific task or objective, and with the intent to dissolve after the completion of the task or achievement of the objective.

3.2. Committee Structure

i) Committee Chair
   (1) A Committee Chair will be elected by the Executive Committee for each committee.
   (2) Roles & Responsibilities of the Chair include:
      (a) Serving on MaGIC's Executive Committee.
      (b) Ensuring committee efforts align with the established directives for the group.
      (c) Monitoring participation of committee members.
      (d) Establishing the agenda, convening and conducting meetings.
      (e) Submission of quarterly updates to the EC.

ii) Committee Vice-Chair
   (1) A Vice-Chair will also be elected by the Executive Committee.

(2) Roles & Responsibilities of the Vice-Chair include:
   (a) Serving on MaGIC's EC in the absence of the Committee Chair.
   (b) Assisting the Committee Chair in his or her responsibilities.
   (c) Filling the role of Committee Chair in the event that the Chair is absent or unable to perform his or her duties.

iii) Committee Members
   (1) When a committee is created, the Executive Committee will propose a slate of Committee Members for the committee.
   (2) Any individual proposed to a committee may request reassignment if he or she does not wish to serve on the selected committee.
   (3) As new members join the Consortium, they must choose at least one standing committee to serve on.
   (4) Roles & responsibilities of committee members include:
      (a) Attendance and adequate participation in committee meetings and activities (requirements may vary per committee).
      (b) Familiarity with and understanding of the purpose and objectives of the committee.

3.3. Committee Purpose, Goals and Objectives

i) Each Committee is required to establish the Committee purpose, goals and objectives. This will be developed in collaboration with the EC.
ii) Committee activities, goals & objectives should be clearly outlined.

3.4. Committee Expectations

i) Committees should convene regularly following a schedule defined by the Committee Chair and Executive Committee.
ii) Committee Chairs must present quarterly updates to the EC.
iii) The Committee Chair will work with the EC to establish realistic timelines, that the Committee is expected to adhere to.

MAINTENANCE RESPONSIBILITY

The MaGIC Governance Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the EC.

AUTHORIZATION

This SOP was developed by the Governance Committee and reviewed and approved by the MaGIC EC.

VERSION / REVISION HISTORY

V2.0 / last modified July 2020

Section 4

Data Collection and Management SOP

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define procedures in place for the safeguarding and storage of data within the MaGIC Data Commons.

PROCEDURES

4.1 Types of Data

i) The following types of data will be stored in the MaGIC Data Commons:
   (1) Retrospective clinical trials data
   (2) Retrospective clinical registries and datasets
   (3) Genomic analysis

4.2 Data Collection

i) All potential data contributors will be asked to complete a Data Submission Intake Form (see appendix), in which contributors will be asked to provide a brief overview of the data characteristics and elements.
ii) The Clinical Research and Publications Committee will review all Data Submission Intake Forms prior to submission to the Data Commons Committee and Executive Committee for final approval.
iii) Data collection will be managed directly by the Data Commons Service Provider.
iv) Data contributors must follow the policies, procedures and guidelines required by the Data Commons Service Provider.

4.3 Data Storage

i) The Data Commons Service Provider will be responsible for the storage, protection and management of all data in the MaGIC Data Commons.

ii) The Data Commons Service Provider must adhere to the laws and regulations to which organizations are subject, including the GDPR as required in the DCA.

iii) In order to protect patient information and identity, the following procedures will be followed:

(4) Appropriate documentation and consent must be traceable for all data & specimens that are stored under the auspices of MaGIC.

(5) All specimens must be de-identified to remove protected health information.

(6) Access to the data in the data commons will be restricted to the Data Commons Committee, and parties who have been granted access after submission of a Data Analysis Proposal.

(7) Under the leadership of the Data Commons Committee Chair, the Committee will review submitted data for quality assurance, as well as to ensure the data is appropriately de-identified. The data will then be transferred into the database.

(1) For data already included in the database, any clinical updates will be processed by the Data Commons Committee under the supervision of the Committee Chair.

MAINTENANCE RESPONSIBILITY

The MaGIC Governance Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the MaGIC EC.

AUTHORIZATIONa

This SOP was developed by the Governance Committee and reviewed and approved by the MaGIC EC.

VERSION / REVISION HISTORY

V2.0 / last modified July 2020

Section 5

Data Use and Publications SOP

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the process for requesting and utilizing MaGIC data in clinical research. The SOP also aims to assure equitable authorship assignment, in addition to timely manuscript development.

PROCEDURES

5.1 Data Use

i) All investigators who wish to utilize the data in the data commons must submit a Data Analysis Proposal Form (see Appendix). The Data Analysis Proposal Form should describe the objectives of the study, inclusion and exclusion criteria, the required data elements, a detailed analysis plan, and the anticipated list of authors, specifying the proposed first and last authors.

ii) The MaGIC Clinical Research & Publications Committee will review each request, taking the following considerations into account:
   (1) whether the proposed analysis is feasible given the data available in the database.
   (2) whether the proposed analysis overlaps with past or present investigations.
   (3) whether the proposed analysis has scientific merit and interest.

iii) If deemed appropriate, the Clinical Research & Publications Committee will vote on approval (2/3 majority vote in favor required for approval).

iv) After approval by the Clinical Research & Publications Committee, the proposal will be sent to the Executive Committee for final review and approval (2/3 majority vote in favor is required for approval)

v) Data Analysis Proposals should be sent per email or submitted via the MaGIC website to the Clinical Research & Publications Committee Chair for review.

5.2 Data Release Conditions

i) For the release of data, investigators must follow the processes and procedures required by the Data Commons Service Provider. This includes entering into a Data Use Agreement with the Data Commons Service Provider directly.

ii) Investigators must agree to use the data exclusively for the approved research project. If the Investigator later wishes to use the data for another project, a new proposal must be submitted.

iii) The data may only be shared with the team conducting the analysis. Electronic data must be secured within two layers of password protection.

5.3 Data Analysis and Statistical Support

i) Investigators may conduct their own statistical analysis or, if they are a member of MaGIC, they may utilize MaGIC's statistician. This will be jointly decided by the Clinical Research & Publications Committee, MaGIC investigator and statistician.

ii) Investigators who will be conducting their own analysis must name the statistician who will be assigned to the project prior to obtaining data from MaGIC.

5.4 Authorship

i) Investigators will be asked to define anticipated authorship, specifying first and last author, prior to the release of MaGIC data.

ii) All authors listed on the manuscript are expected to make a significant scientific input and/or substantial intellectual contribution to the design, conduct and/or data analysis of the project.

iii) At least one MaGIC member from each Data Contributor whose data is being used in the analysis should be invited as an author on the manuscript. The member may decline authorship. If invitation of authorship is accepted, author contributions should be consistent with the International Committee of Medical Journal Editors' (ICMJE) guidelines.

iv) If questions or issues arise in authorship, the ICMJE's authorship guidelines and recommendations will be referred to and followed accordingly.

5.5 Manuscript Timelines

i) All investigators requesting data should ensure that the project is completed within a reasonable timeframe. Every effort should be made to meet the timepoints outlined below:

(1) Within 6 months of obtaining the data, investigators should present the tables and figures of the manuscript to the Clinical Research & Publications Committee.

(2) Within 12 months, investigators should submit the final draft of the manuscript to the Clinical Research & Publications Committee.

(3) Within 1 month of submission of the final draft, the Clinical Research & Publications Committee will provide comments and feedback to the investigator.

(4) The final manuscript must be submitted within 1 month of receiving feedback from the Clinical Research & Publications Committee.

ii) If an investigator fails to meet these timepoints, the Clinical Research & Publications Committee reserves the right to inquire on progress, set new deadlines and, if necessary, reassign authorship.

5.6 Publication Policy

i) Copies of all manuscripts associated with the data and project must be sent to the Clinical Research & Publications Committee for review prior to submission.

ii) All abstracts and publications that incorporate data from MaGIC Data Commons must include a statement of acknowledgement: "In Collaboration with the Malignant Germ Cell International Consortium supported by the St. Baldrick's Foundation Consortium Research Grant Award 358099."

iii) Additionally, each Data Contributor may specify a line of attribution that will be applied to any publication that utilizes the group's contributed data.

MAINTENANCE RESPONSIBILITY

The MaGIC Governance Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the MaGIC EC.

AUTHORIZATION

This SOP was developed by the Governance Committee and reviewed and approved by the MaGIC EC.

VERSION / REVISION HISTORY

V2.0 / last modified July 2020

Appendices

MaGIC Commitees

There are currently eight standing committees of MaGIC. The committees serve to perform a specific needed service or function within the Consortium.

Executive Committee *Chair: Lindsay Frazier* *Vice-chair: James Nicholson*	Oversees Consortium governance and provides oversight and deliberation for all matters relating to the scope, mission, and functionality of the Consortium.
Annual Meeting Planning Committee *Chair: Tom Olson* *Vice-chair: James Nicholson*	Coordinates and plans MaGIC's annual meetings and other in-person, consortium-related events.
Biology Committee *Co-chairs: Jim Amatruda* *Matt Murray*	Convenes on a regular basis to share knowledge among its members, who are actively involved in biological and genomic research.
Clinical Research & Publications Committee *Chair: Furqan Shaikh* *Vice-chair: Aditya Bagrodia*	Oversees the development, scope, and utilization of MaGIC's shared Data Commons, pre-reviews MaGIC data analysis proposals before they are sent to the Executive Committee, and oversees manuscript development and timelines.
Clinical Trials Design & Development Committee *Chair: Sara Stoneham* *Vice-chair: Robert Huddart*	Oversees the design and development of new trials that will be led by members of the Consortium. MaGIC is not a clinical trial organization, rather, this committee works to identify opportunities for novel and collaborative clinical trial development.
Communications Committee *Chair: Lindsay Frazier* *Vice-chair: James Nicholson*	Responsible for developing, updating and monitoring MaGIC's communications policies, visual and social media presence, and public relations.

Data Commons Committee *Chair: Sam Volchenboum* *Vice-chair: Yang Xie*	Oversees the development and maintenance of the MaGIC Data Commons, including input and output of data, and ensuring information privacy and data protection.
Governance Committee *Chair: Farzana Pashankar* *Vice-chair: Girish Chinnaswamy*	Responsible for the creation, approval, and maintenance of the governing documents for MaGIC, including the Consortium Memorandum of Understanding, the Data Contributor Agreements, and the other Standard Operating Procedures.
Nominating & Membership Committee *Chair: Girish Chinnaswamy* *Vice-chair: Rod Rassekh*	Maintains and reviews MaGIC memberships, oversees new member applications, and is responsible for presenting a slate of qualified candidates to the Executive Committee for review and approval.

MaGIC Data Contributor Application Form

Organization or Institution Click or tap here to enter text.

Data Contribution *(please specify what type of data the Institution or Organization has shared with MaGIC – i.e. biologic specimens or clinical data)* Click or tap here to enter text.

Principle Investigator (PI) Information
(This section refers to the Principle Investigator who has been nominated by the Full Members belonging to the Data Contributor organization or institution to act as the representative for the group and serve as a member on the Executive Committee)

PI Name *(first & last)* Click or tap here to enter text.

Degrees Click or tap here to enter text.

Department Click or tap here to enter text.

Institution Click or tap here to enter text.

Institution Address Click or tap here to enter text.

Email Address Click or tap here to enter text.

Office Phone Number Click or tap here to enter text.

Cell Phone Number Click or tap here to enter text.

****Please attach CV to this application****

Alternate Principle Investigator (Alternate PI) Information
(This section refers to the Alternate Principle Investigator who has been nominated by the Full Members belonging to the Data Contributor organization or institution to act as the representative for the group and serve as a member on the Executive Committee)

Alternate PI Name *(first & last)* Click or tap here to enter text.

Degrees Click or tap here to enter text.

Department	Click or tap here to enter text.
Institution	Click or tap here to enter text.
Institution Address	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Office Phone Number	Click or tap here to enter text.
Cell Phone Number	Click or tap here to enter text.

****Please attached CV to this application****

V2.0 / last modified July 2020

MaGIC Member Application Form

Name *(first & last)*	Click or tap here to enter text.
Degree *(please list all)*	Click or tap here to enter text.
Title *(official academic title)*	Click or tap here to enter text.
Department	Click or tap here to enter text.
Institution *(with whom you are employed)*	Click or tap here to enter text.
Institution Address	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Office Phone Number	Click or tap here to enter text.
Cell Phone Number	Click or tap here to enter text.

1. If applicable, please list any GCT-related *clinical trials* that you have been or are currently involved in:

Click or tap here to enter text.

2. If applicable, please list any GCT-related *research projects* that you have or are currently involved in:

Click or tap here to enter text.

3. We ask that all MaGIC membership applicants list two references who are current members of MaGIC. Please list references below

Click or tap here to enter text.

4. **As a Member of MaGIC, you will be asked to participate in a minimum of one Committee. Please indicate which of the following Committee you would be most interested in participating in** *(you may indicate more than one Committee)*

☐ Governance Committee

☐ Annual Meeting Planning Committee

☐ Clinical Research & Publications Committee

☐ Biology Committee

☐ Clinical Trials Design & Development Committee

☐ Nominating & Membership Committee

****Please attached CV to this application****

V2.0 / last modified July 2020

MaGIC Young Investigator Membership Application Form

Name *(first & last)*	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Degree *(please list all)*	Click or tap here to enter text.
Department	Click or tap here to enter text.
Institution *(with whom you are employed)*	Click or tap here to enter text.
Institution Address	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Office Phone Number	Click or tap here to enter text.
Cell Phone Number	Click or tap here to enter text.

1. **If applicable, please list any GCT-related *clinical trials* that you have been or are currently involved in:**

   Click or tap here to enter text.

2. **If applicable, please list any GCT-related *research projects* that you have been or are currently involved in:**

   Click or tap here to enter text.

3. **If are currently not involved in any GCT clinical or biologic research, please explain your interest in MaGIC and how you feel you can contribute to the group.**

   Click or tap here to enter text.

4. **We ask that all MaGIC membership applicants list one references who are current members o MaGIC. Please list references below:**

   Click or tap here to enter text.

5. **Please indicate which of the following areas of germ cell tumor research you are most interested in participating in.**
   (you may indicate more than one area)

   ☐ Basic Science / Biology
   ☐ Clinical Research
   ☐ Clinical Trial Development
   ☐ Epidemiology
   ☐ Pathology
   ☐ Translational Research

****Please submit CV with this application****

V1.0 / last modified July 2020

MaGIC Patient Advocate Membership Application Form

Name *(first & last)*	Click or tap here to enter text.
Email Address	Click or tap here to enter text.
Office Phone Number	Click or tap here to enter text.
Cell Phone Number	Click or tap here to enter text.

1. **Please explain your interest in germ cell tumors and your reasons for wanting to work with MaGIC:**

   Click or tap here to enter text.

2. **How did you hear about MaGIC?**

   Click or tap here to enter text.

3. **How do you feel your skills and experiences would enable you to fulfil the requirements of this role?**

   Click or tap here to enter text.

4. **What is your experience with research – have you participated in a clinical trial or other research? Were you ever asked to take part in research of any sort?**

   Click or tap here to enter text.

5. **What would you hope to achieve as a MaGIC patient advocate member, both in fulfilling the role itself and also in your own development?**

   Click or tap here to enter text.

6. **What are your interests when serving as a patient research advocate?**
   Note: This information does not commit you to any research project particular role. It simply gives us a better idea of which opportunities may be of interest to you. You may select more than one:
   - ☐ Attending regular committee meetings to provide the patient's perspective
   - ☐ Helping review research grant applications
   - ☐ Advocating for germ cell tumors and raising awareness of important issues with community organizaitons, government or funding agencies, either through direct contact or through media/social media
   - ☐ Fundraising activities to help support MaGIC
   - ☐ Being involved in the creation of support networks for germ cell tumor patients and families

7. **Given that we are an international consortium, it is always useful to know what languages our members are knowledgeable in. Please list the languages you speak below.**

   Click or tap here to enter text.

8. **Having read the role and description, please describe any specific training that you would find of value to support you in this role. We will provide mentorship for the successful applicant in the scientific elements of what we do and in effective advocacy.**

   Click or tap here to enter text.

MaGIC Data Intake Form

Clinical Trial Datasets

Part I – Study Characteristics

1. Submitting PI(s):

2. Contact for Questions on Database and Data Dictionary:
   Email
   Phone

3. Participating Centre(s):

4. Study Name / Protocol Number:

5. Site of IRB/REB:

6. Date of Initial IRB Approval of the Protocol:

7. Grant Numbers *(to be reported in any publication utilizing this data source):*

Part II – Outcomes and Definitions

Please answer the following questions in relation to criteria as defined in the clinical trial.

8. Was elevation of tumor markers alone, without pathologic verification of germ cell tumor sufficient for enrollment on the trial?

9. What is the definition of disease progression or relapse?
   Mass: What percent increase in the size of the mass is used to define disease progression?
   Tumor Markers: How is a rise in tumor markers defined? Must tumor markers exceed a threshold level to be considered a relapse? If yes, what level?

10. Was a new site of disease that contained only teratoma coded as a progressive disease?

11. Does the protocol define and capture growing teratoma syndrome as an outcome?

12. Was immature teratoma considered a benign or malignant histology on this trial?

13. If included as a category of histology in the protocol, please define “mixed GCT”.

14. If included as a category of histology in the protocol, please define “malignant teratoma”.

15. Key variables
Please indicate which key variables are available in the clinical trial dataset, and, if variable is available, please specify the variable name, as defined in the dataset

Variables	Available (Y/N)	If yes, variable name in Data Dictionary	Comments
Date of diagnosis			
Date of birth			
Date of enrollment on trial			
Dates of Surgeries: biopsy, initial resection and second look surgery			
Date of Start of Chemotherapy			
Date of Start of Radiation Therapy			
Data of Disease Progression or Relapse			
Date of Secondary Malignant Neoplasm			
Date of Last Follow-up			
Date of Death			

Part III – Patient Characteristics

16. Please complete the following Table of Patient Characteristics
Please distinguish between none, not collected, or unknown/missing

	N (#)	%
Age		
Mean		n/a
Range		n/a
Unknown/missing		
Sex		
Male		
Female		
Unknown/missing		
Primary Site		
Testicular		
Ovarian		

Mediastinal		
Sacrococcygeal		
Other		

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MaGIC Data Intake Form

Registry Datasets

Part I – Study Characteristics

1. Submitting PI(s):

2. Contact for Questions on Database and Data Dictionary:
   Email
   Phone

3. Participating Centre(s):

4. Registry or Dataset Title:

5. Site of IRB/REB, if applicable:

6. Date of Initial IRB Approval of the Registry, if applicable:

7. Grant Numbers *(to be reported in any publication utilizing this data source):*

8. Specify if data was collected as part of a:
   ☐ Prospective Registry
   ☐ Retrospective Chart Review
   ☐ Both
   ☐ Other:

Part II – Outcomes and Definitions

Please answer the following questions in relation to criteria as defined in the registry or dataset protocol.

9. How did you identify the patients included in this registry? What were the exclusion criteria for the registry/dataset? (i.e. patients seen for consult only, age, gender, diagnosis, stage, specific histology, primary site, risk-group, etc)

10. Please provide the following information:
    Staging system
    Risk classification system
    Chemotherapy regimen(s) used:
    ☐ BEP
    ☐ EP
    ☐ VIP
    ☐ Other:

11. How were events defined in this study? *(Please specify how progressive disease, growing teratoma syndrome, benign/teratoma recurrence, or second malignant neoplasms were handled in the analysis of events)*

12. Was immature teratoma considered a benign or malignant histology in this registry/dateset? How were patients with immature teratoma treated?

13. If included as a category of histology in the protocol, please define "mixed GCT".

14. If included as a category of histology in the protocol, please define "malignant teratoma".

15. Key variables

    Please indicate which key variables are available in the clinical trial dataset, and, if variable is available, please specify the variable name, as defined in the dataset

Variables	Available (Y/N)	If yes, variable name in Data Dictionary	Comments
Date of diagnosis			
Date of birth			
Date of enrollment on trial			
Dates of Surgeries: biopsy, initial resection and second look surgery			
Date of Start of Chemotherapy			
Date of Start of Radiation Therapy			
Data of Disease Progression or Relapse			
Date of Secondary Malignant Neoplasm			
Date of Last Follow-up			
Date of Death			

Part III – Patient Characteristics

16. Please complete the following Table of Patient Characteristics

    Please distinguish between none, not collected, or unknown/missing

	N (#)	%
Age		
Mean		n/a
Range		n/a
Unknown/missing		

Sex		
Male		
Female		
Unknown/missing		
Primary Site		
Testicular		
Ovarian		
Mediastinal		
Sacrococcygeal		
Other		

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Data Analysis Proposal Form

If you are interested in utilizing data from the MaGIC Data Commons for a research project or analysis, please complete the following form and submit to magic@dfci.harvard.edu and furqan.shaikh@sickkids.ca, Chair of the Clinical Research & Publications Committee.

Date

Click or tap here to enter text.

Project Investigator

Click or tap here to enter text.

Institute Affiliation

Click or tap here to enter text.

Email Address

Click or tap here to enter text.

First & Last Authors

Please specify first and last author

Click or tap here to enter text.

Co-Authors

Please specify anticipated co-authors
(Please note at least one MaGIC member from each data contributing site should be invited as an author on the manuscript. All authors listed on the manuscript are expected to make a significant scientific and/or intellectual contribution to the design, conduct and/or data analysis of the project.)

Click or tap here to enter text.

Title of Research Proposal

Click or tap here to enter text.

Background and Significance

Please provide a brief summary of the research project's background, including a clear description of the project's significance

Click or tap here to enter text.

Specific Aims

Please provide in list form a description of the specific aims of the project, including the study objective and hypothesis to be evaluated

Click or tap here to enter text.

Methods

Please provide in list form a clear description of the research methods to be used to address each of the specific aims. Please include inclusion and exclusion criteria, main outcome measure and any other variables of interest.

Click or tap here to enter text.

Statistical Analysis Plan

Please describe in list form how you will analyze the requested data, including descriptive, bivariate and multivariable analyses and any other planned advanced analyses.

Click or tap here to enter text.

Statistician

Please specify the statistician (and their affiliated institution/organization) who will be assigned to the project.

Click or tap here to enter text.

Project Timeline

All investigators requesting data should ensure that the project is completed within a reasonable timeframe. Every effort should be made to meet the timepoints outlined below:

Within 6 and 12 months of receipt of the data, the investigator is asked to provide the tables & figures and final draft of the manuscript, respectively. Within 1 months of the submission of the final draft, the Clinical Research & Communications committee will provide feedback. Investigators will be asked to submit the final manuscript within 1 months of receiving feedback.

If you foresee challenges in adhering to this timeline, please describe below:

Click or tap here to enter text.

Funding, if applicable

Please explain how the project will be supported.

Click or tap here to enter text.

Please note all abstracts and publications that incorporate data from MaGIC Data Commons must include a statement of acknowledgement: "In Collaboration with the Malignant Germ Cell International Consortium supported by the St. Baldrick's Foundation Consortium Research Grant Award 358099." Additionally, each Data Contributor may specify a line of attribution that will be applied to any publication that utilizes the group's contributed data.

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