AUSTRALIAN SCLERODERMA INTEREST GROUP

TERMS OF REFERENCE

September 2017

The Steering Committee of the Australian Scleroderma Interest Group (ASIG) first met in November 2005, and in 2007 it became a special interest group under the auspices of the Australian Rheumatology Association (ARA), a not-for-profit organisation incorporated as a company limited by guarantee in Australia. In January 2012, ARA-ASIG was granted an ABN and registered with the Australian Business Register as an Other Incorporated Entity (ABN: 54 709 736 928). ARA-ASIG is governed by an Executive Committee that operates according to the Constitution of the ARA.

1.0 MISSION STATEMENT

To improve the care of patients with systemic sclerosis (SSc), a.k.a scleroderma through clinical research and the development of guidelines for the investigation, monitoring and management of patients with SSc in accordance with current best practice.

2.0 BACKGROUND

SSc and mixed connective tissue disease (MCTD) are rare, chronic diseases characterised by autoimmunity, vasculopathy and fibrosis. Approximately one quarter of SSc/MCTD patients develop serious complications including pulmonary arterial hypertension (PAH) and/or interstitial lung disease (ILD) as well as other organ systems including the gastrointestinal and renal tracts.

PAH and ILD are recognised as the number one cause of death in patients with SSc. The disease process in the pulmonary arteries which leads to PAH can occur over several years. The signs and symptoms of this disease are often hard to distinguish from other conditions, particularly in the early stages. This frequently delays the formal diagnosis of PAH which is made by right heart catheterisation. As well as the condition often being silent until late in the disease, it may not be detected by less-invasive investigations such as echocardiogram (ECHO) if there is no minor leakiness of the tricuspid valve on the right side of the heart (up
to 39% of people) or if the technician performing the investigations do not have the specific skills required for detecting PAH.

Therapies\textsuperscript{5-8} which reduce the severity of PAH and ILD are now available so regular screening of SSc patients for these complications is recommended by the British Thoracic Society\textsuperscript{9} and the American College of Chest Physicians\textsuperscript{10}.

Prior to the commencement of the ASIG screening programs in 2007, screening was not consistently offered in Australia.

### 3.0 SCOPE

The ASIG will, as appropriate, undertake projects that assist in meeting the mission of the group. The findings of the projects will be:

- reported to the ARA
- distributed to patient groups through The “Scleroderma Connections” newsletter and patient groups
- published in relevant peer-reviewed journals

### 4.0 SPECIFIC ACTIVITIES

1. **The Australian Scleroderma Screening Program (ASSP).**

   The ASSP utilises a screening protocol developed by the group, based on international best practice. Screening occurs at designated centres around Australia that were established according to the standards of the protocol and overseen by a member of ASIG. Australian physicians treating patients with SSc/MCTD have been invited to refer their patients for routine annual screening, with the referring physician retaining responsibility for the ongoing management of their own patients. New centres are welcome to join at any time as listed in Section 5.0. Ensuring a large proportion of Australian SSc patients participate in screening is a priority. Efforts to support the sustainable expansion of existing centres and/or develop new centres are ongoing.

2. **The Australian Scleroderma Cohort Study (ASCs)**

   The aim of this research project is to collate de-identified data collected from consecutive patients attending the screening centres for various research projects with the approval of the ethics committee at each participating centre and with signed informed consent. The research outcomes are used to develop and revise guidelines for providing best care for patients.

   While further recruitment into the research project is important, the collaboration has identified the value of collecting detailed longitudinal data on existing research participants. Ongoing priorities include:

   1. The development of collaborations with international groups.
2. Data analysis and publication.

3. Supervision of students including advanced trainees and higher degree students.

4. Financial sustainability: To minimise the reliance on funds from industry and ensure financial sustainability, applications for sources of competitive funding such as NHMRC and Arthritis Australia are to be made. A mechanism for receipt of donations from patients and other interested members of the community is in place.

5. ASIG biobank (Open Specimen)
   Blood sample collection and processing occurs at most centres and transferred to Adelaide for storage in the ASIG blood biobank (Open Specimen).

5.0 PERSONNEL

Physicians interested in quality improvement and/or research in SSc are encouraged to nominate for membership of ASIG. Full membership will be restricted to rheumatologists. To be eligible for full membership, individuals must have their FRACP, come from a participating ASIG centre and demonstrate a considerable degree of investment in SSc.

Appointment to ASIG membership requires application in writing, nomination by two ASIG members and ratification at the next executive meeting.

A full member is entitled to attend the AGM, be on a committee, vote and be nominated for leadership roles (e.g. chair of a committee).

The responsibilities of a full member are to make a commitment to ASIG every year by completing a membership form, demonstrate investment in ASIG/SSc, which can be purely intellectual and/or contribution of data and demonstrate engagement with ASIG e.g. respond to requests for data cleaning.

Clinicians from other specialities (cardiology and respiratory) and scientists may be eligible for associate membership. Associate members will have no voting rights but can attend relevant teleconferences and meetings, on invitation, including the annual general meeting.

Research Higher Degree students will be invited to join ASIG when they have finished their degree and demonstrated continuing interest.

5.1 ASIG centres:

Physicians with an interest in SSc/MCTD will be eligible to set up ASSP screening centres, providing they agree to the Terms of Reference, and to apply the ASSP Protocol, and Research Protocol, become members of ASIG and have the collaboration of a cardiologist and respiratory physician.
Once membership has been approved and the centre has been established, the centre is considered active if the principal investigator or delegate continues to enter complete patient data for at least one patient within the calendar year.

Members of ASIG provide their time voluntarily to the group.

The Project Officer will provide support for application to the relevant ethics committee, submission of annual reports, and establishment of research processes including collection and transfer of blood samples for the biobank and access to the online database.

**Disengaging inactive centres**

A process for loss of membership will be initiated if, over the course of a calendar year, a centre does not:

- make a commitment to ASIG membership by completing the membership form annually,
- demonstrate a level of investment in ASIG/SSc (can be purely intellectual and/or contribution of data),
- demonstrate engagement with ASIG e.g. respond to requests for data cleaning etc.,
- enter data for a patient.

Process of loss of membership will entail a formal notification of disengagement with an opportunity to re-engage. A letter will be sent thanking the centre for their involvement and advising them of the continued use of their data by ASIG and notification of their ethics committee. The member is expected to notify their patients regarding the withdrawal of their centre.

Disengagement commences 12 months after the last patient data was entered.

Disengaged sites are not automatically entitled to authorship subsequently.

### 6.0 PROJECT ADMINISTRATION

#### 6.1 ASIG EXECUTIVE COMMITTEE

The ASIG is managed by an Executive Committee (EC) comprising the Chair, Treasurer, Secretary, Chair of the Scientific Committee (mini-executive) and one member from each participating centre. Membership of the ASIG Executive Committee is open to physicians who set up a screening centre. Each centre will be asked to nominate a representative for the Executive committee annually.

Decisions of the EC will be made according to a vote at scheduled meetings or by email between meetings. A quorum is defined as a total of 4 individuals with at least two office bearers and at least two members (total of four). In the case of an issue going to vote, each centre will have one voting right.

The roles of the EC with the operational and administrative support of the Project Officer, are to
• Set the strategic direction of ASIG and to provide governance by developing and monitoring priority areas.
• Identify strategies for achieving priority areas.
• Administer the group’s finances, ensuring a quarterly report is submitted to the ARA.
• Identify funding opportunities.
• Ensure that ASIG operates within the constitution of the ARA.
• Oversee and support the Project Officer.

The ASIG EC meets by teleconference at least twice a year as required. Teleconferences are generally held in the evening, with members using a dial-in facility charged to the group. Some decisions can be made via email between meetings providing a consensus is reached.

An additional face to face Annual General Meeting occurs once a year in conjunction with the ARA Annual Scientific Meeting.

The mini-executive is a small working group comprising the office-bearers that meets at least four times a year with the Project Officer to provide guidance on operational matters. Any larger decisions (e.g. expenses greater than $5,000) will be taken to the Executive committee for approval.

7.0 ASIG COMMITTEES

7.1 SCIENTIFIC COMMITTEE

Membership of the Scientific Committee is by expressions of interest in scleroderma research. Members need to confirm continued involvement every year but there is no limit to the size or duration of membership.

The aims of the Scientific Committee are to:

• Devise research strategies for ASIG using ASCS data and patient samples
• Review proposals from other members of ASIG, and provide approval before the projects can commence. Note, members can make an offer to participate to the senior researcher if they believe they can make a contribution.
• Assist with applications for funding to continue the research activities long term
• To publish research findings related to scleroderma and mixed connective tissue disease
• To mentor other early researchers in this field
• To engage and supervise PhD students or Fellows in the Scleroderma field.

This committee meets four times a year. A quorum is defined as at least four members.

7.2 DATABASE COMMITTEE

The Database Committee was established to:

• Oversee the maintenance of the existing ASIG clinical database
• To consider improvements to the clinical database

This committee meets on an ad hoc basis. A quorum is defined as at least three members.

7.3 FINANCE TEAM

In 2012 a Finance Team was established to:

• Approve payments within the ASIG budget

The members of the Finance team are the Chair, Treasurer, Secretary and they have access to on-line banking through CommBiz.

An annual budget is prepared by the PO and approved by the EC at the face to face meeting at the ARA Annual Scientific Meeting in May. Approved budget items will be processed through on-line payment or by credit card with approval from two members of the Finance team. Unbudgeted items of more than $5 000 will need to be approved by the Executive before arrangements are made for them to go ahead.

7.4 APPOINTMENT TO LEADERSHIP ROLES

Nominations for two of the four leadership positions (eg Executive and Scientific Committee Chairs) will be called every two years and for the other two (Treasurer and Secretary) every other alternate year. This model supports the possibility of succession through the roles. Members standing down from these roles will be eligible for nomination for these or other leadership roles.

Nominations will be called two months before the AGM every two years and the voting will occur at the AGM.

8.0 INTELLECTUAL PROPERTY AND OWNERSHIP OF DATA

ASIG requests that publications arising from the ASIG database reflect the aims of the group and therefore:
• Acknowledge the ASIG collaboration – the group and/or individuals who have contributed to the establishment and ongoing maintenance of the research project, including where relevant, the Biobank.

• Be of a standard that contributes to the successful outcomes of the group to ensure future funding of ASIG for the ongoing maintenance of the database.

In addition, ASIG has developed authorship guidelines (see separate document).

8.1 DATA FROM INDIVIDUAL CENTRES

Centres are encouraged to analyse data from their own patients obtained from the ASIG database for publication purposes. The ASIG request that in such publications, references to ASIG follow these guidelines.

POSTERS AND ORAL PRESENTATIONS

There is no need to seek permission for data used in posters and oral presentations however it is expected that acknowledgement be made that the data were collected from the ASIG database as well as a copy of the abstract sent to the project officer on submission and acceptance.

MANUSCRIPTS

With the intention of submission for publication, the ASIG scientific committee would like to be given the opportunity to see the manuscript before submission as any work arising from the ASCS (or a component of it) directly or indirectly represents ASIG on an international level. In reviewing the manuscript, ASIG would like the opportunity to provide constructive comment to the authors for their consideration. The final version should be sent to the committee prior to submission. ASIG would expect to be acknowledged but has the option to request no acknowledgement if the manuscript is deemed to not meet the standards set by the scientific committee.

In all instances the ASIG committee encourage authors to contact the committee regarding their publication if they would like input or comment from the multidisciplinary experts available. Authorship, including the inclusion of members of ASIG, should comply with current guidelines.

8.2 AGGREGATED DATA FROM ALL CENTRES

Projects requiring analysis of patient data from other centres obtained from the database require permission from the ASIG scientific committee following a submission of a written research proposal on the relevant ASIG form.

POSTERS AND ORAL PRESENTATIONS

All posters and oral presentations should acknowledge “Australian Scleroderma Interest Group (ASIG), St Vincent’s Hospital IT Dept and unrestricted educational grants from (relevant pharmaceutical companies).” (to be modified to include any donors of funds used for the study
in question). A copy of the abstract should be sent to the project officer on submission who should then be informed regarding its acceptance or not.
MANUSCRIPTS

With the intention of submission for publication, ASIG requests that manuscripts be sent to the project officer for perusal by the scientific committee prior to submission as any work arising from the ASCS (or a component of it) directly or indirectly represents ASIG on an international level. In reviewing manuscripts with aggregated data, the scientific committee would like the opportunity to contribute constructively and expects to advise regarding appropriate selection of ASIG executive members for authorship, based on a significant contribution to the development phase of ASSP or direct involvement in the study being submitted for publication. Should the manuscript be deemed to not meet the standards set by the scientific committee it will be recommended that it not be submitted for publication.

8.3 SIGNATORIES

A data transfer agreement is required when multi-site raw data is requested by an external organisation or individuals other than the ASIG site principal investigator. The ASIG Executive Chair and/or the Scientific Committee Chair are responsible for authorising the data transfer agreement or any form of release of ASIG data. A delegate can be appointed by the Executive Chair or the Scientific Chair as a signatory to the data transfer when needed.

REFERENCES

RULES FOR AUTHORSHIP OF THE AUSTRALIAN SCLERODERMA INTEREST GROUP

This authorship policy pertains to all publications or abstracts produced using data from one or more ASIG sites obtained from the ASIG central database or using sera or biologic specimens from either the central ASIG bio-bank or from more than one ASIG site. This is an official document of the ASIG and was approved/amended on the date in the footer.

These guidelines do not replace the usual processes for determining authorship based on a substantial contribution to a publication. According to contemporary journal guidelines, an individual listed as an author needs to have made a substantial contribution to two or more of the following: design and inception of the study, collection of data, data analysis, interpretation of results, or preparation of manuscript, and all authors must have read and approved the final manuscript. Such a contribution includes processing and handling of patient samples for analysis.

It is the responsibility of the lead author to ensure all individuals making such a substantial contribution are included as authors. The choice of authors should be determined early in the planning of the project, or at least early in the preparation of the manuscript.

ASIG requests that publications arising from the ASIG database reflect the aims of the group and therefore:

• Acknowledge the ASIG collaboration – the group and/or individuals who have contributed to the establishment and ongoing maintenance of the research project.

• Be of a standard that contributes to the successful outcomes of the group to ensure future funding of ASIG for the ongoing maintenance of the database.

• Wherever possible, acknowledge the contribution of members of ASIG who have contributed patients to the publication by listing them as authors whenever possible within the guidelines of the journal.

A. Publications or abstracts written by a recruiting rheumatologist using only his/her own data.

For publications or abstracts written by a recruiting rheumatologist using only his/her own data extracted from the central database, the primary (the “lead”) investigator will determine authorship policy in discussion with the Chairs of both the Executive and Scientific committees. It is recommended that the investigator, usually the senior author, gives consideration to including among the authors, one or more ASIG member(s) who were instrumental in the establishment, maintenance and ongoing success of ASIG. This should be based on the level of contribution to the paper and might include the chair's activities, data cleaning, scientific/intellectual input, or input of data from a large number of patients. The position of the ASIG member(s) in the authorship list will be at the discretion of the principal author. If not included in the authorship, it is expected that acknowledgement be made that the data were collected from the ASIG database.

B. General authorship policy for publications using multi-site data within the ASIG.

A written research proposal for projects using patient data from multiple ASIG sites must be submitted to the Scientific Committee for approval before they can proceed with obtaining and analysing data (see request for data and data transfer agreement forms). This applies to research students including the ASIG Fellow if they embark on an area of research outside the scope of their fellowship project approved previously by the Scientific Committee.
Where possible, the main principle governing authorship is to be as inclusive as possible to keep members intellectually engaged and to encourage data entry. However, the list of authors can be long and this can be problematic for theses completed by publication as many universities require that the student complete more than 50% of the work and it can be difficult to justify authorship to journals, if individuals only contribute a small amount to the publication. The issue also applies to publications in collaboration with other research groups.

1. The primary investigator for the study shall be considered to be the lead author and will be responsible for determining which authors are to be listed and the order of all other named authors except for those mentioned below.

2. The first and second (or more) author(s) shall be the investigator(s) who have performed most of the work on the particular publication. These names will be determined by the lead author.

3. The Chair of ASIG or nominated senior(s) member of ASIG is a co-author on all manuscripts with his/her name placement a matter of discussion and negotiation with the lead author PRIOR TO submission of the manuscript for publication, unless the Chair of ASIG is the senior or first author.

4. Other named authors will include any person(s) who has contributed substantially to the publication and these names will be determined by the lead author of the study.

5. If the journal permits, all members of ASIG who have contributed patients to the publication should be listed individually as authors in the same order as described in section C.4. If the journal does not permit every contributing member to be listed as an author, those members who have contributed patients as described in C.1-3. will be listed as authors in the same order as described in section C.4. If the journal does not permit all these authors to be listed, the name “Australian Scleroderma Interest Group” will be included on the authorship line, just preceding the senior author. An indicator such as an * will be placed next to the group name and, if the journal permits, the names of the members of the group will be listed on the front page of the publication. If the journal does not permit, they will be listed at the end of the publication. If the group name is listed, the corresponding author will make every effort, the publication so permitting, to ensure that all group members will be listed on the NLM Pubmed database permitting that name to be searched and associated with this publication on Pubmed.

6. For posters and oral presentations, all members of ASIG who have contributed patients to the publication should be listed individually as authors in the same order as described in section C.4. If there is a limit on the number of authors, the centres should be rotated. A copy of the abstract should be sent to the project officer on submission and when known, advice be forwarded concerning acceptance or not.

7. Manuscript should be sent to the ASIG Scientific Committee and to all the listed authors for constructive comment for the authors’ consideration. The final version should be sent to the committee prior to submission and when known, advice be forwarded concerning acceptance or not.

8. Advice concerning acknowledgement of financial support (both industry and competitive grant funding) should be sought from the Scientific Committee.
9. These guidelines will be reviewed following completion of the first ASIG Fellow’s PhD to ensure they do not negatively impact on the success of the thesis.

C. Names to be included under the rubric of the ASIG

The specific names to be included under the rubric of the “Australian Scleroderma Interest Group” will be according to the following rules:

1. The author must be a recruiting rheumatologist according to the by-laws of ASIG. Inactive members can be permitted if there are no limits imposed on the number of authors.

2. The author must have contributed complete patient data for a minimum of 5 patients whose data are used in the study. This means that more than one author can be included from one site if sufficient patients have been included in the study. This will be limited to clinicians who have finished their fellowship and are contributing to publications at a more senior level. To assist in identifying members eligible for authorship, a register of ASIG members who fulfil the criteria can be generated using data from the ASIG database, at short notice.

3. The date of visit of the last patient for whom there is complete data in the database entered by an author must be within one (1) year of first submission of the article for consideration for publication. If a recruiting rheumatologist has stopped submitting data, then one year after the last data entered he/she will no longer be listed as an author, however, his/her patient information in the database will continue to be used for studies.

4. The order of the author list of recruiting ASIG rheumatologists shall be according to the total number of patients recruited with the highest recruiter being named first and the lowest named last. The list will be revised no less frequently than once every 6 months.

D. Authorship policy for publications for which data has been obtained from other databases as well.

These rules apply to situations in which ASIG has collaborated with one or more other research groups and the study involves merging data from more than one source, one of which is ASIG data.

1. The principal investigator(s) of the project and the Directors of each group that contributed data, including the ASIG, must agree on the order of authorship before the ASIG will agree to provide data for the project.

2. The first and second (or more) authors shall be the investigators who have performed most of the work on the particular publication.

3. The primary investigator for the study shall be considered to be the lead author for the study and will be responsible for signing an agreement with the ASIG director determining which other authors are to be listed, and the order of all other named authors.

4. The senior author, who will be listed as the last author, will be at the discretion of the principal investigator.

5. The Chair of ASIG or nominated senior member(s) of ASIG, unless he/she has been listed as first or second author in the list of authors, or he/she has made other specific arrangements with the principal investigator for the study, shall be listed as an author. If other group directors are to be similarly listed, then the order of group directors shall be
such that the group that contributed the data from the largest number of subjects will be listed first, the next most data second etc.

6. Other named authors will include any person(s) who has contributed substantially to the publication. These names will be determined by the principal investigator of the study.

7. In addition, the name “Australian Scleroderma Interest Group” will be included on the authorship line. If other group names are also to be included, then the order of group names shall be such that the group that contributed the data from the largest numbers of patients will be listed first, the next most data second etc…

8. An indicator such as an * will be placed next to the group name and, if the journal permits, the names of the members of the group who fulfil criteria C1-3 will be listed on the front page of the publication. If the journal does not permit they will be listed at the end of the publication. If the journal permits, instead of listing “Australian Scleroderma Interest Group” as an author, all names to be included under the rubric of the “Australian Scleroderma Interest Group” may be listed individually as authors in the same order as described in section C.

9. If the group name is listed, the submitter of the publication will make every effort, the publication so permitting, to ensure that all group members will be listed on the NLM Pubmed database permitting that name to be searched and associated with this publication on Pubmed.

10. A copy of the abstract should be sent to the project officer on submission and when known, advice be forwarded concerning acceptance or not.

11. For posters and oral presentations, a copy of the abstract should be sent to the project officer on submission and when known, advice be forwarded concerning acceptance or not.

12. Manuscripts should be sent to the ASIG Scientific Committee for constructive comment for the authors’ consideration. The final version should be sent to the committee prior to submission and when known, advice be forwarded concerning acceptance or not.

13. Advice concerning acknowledgement of financial support (both industry and competitive grant funding) should be sought from the Scientific Committee.