

Global Standards and Appeals Board (GSAB) Terms of Reference and Constitution

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1. OVERVIEW

This document details both the Terms of Reference and Constitution for the Global Standards and Appeals Board (GSAB) in relation to the quality standards developed and governed by Future Shaper Holdings Ltd. and its subsidiaries.

This document details the structure, roles, responsibilities, procedures, principals that govern the GSAB's operation.

2. GUIDING PRINCIPLES

Fairness – Objectivity – Evidence – Integrity

The GSAB is committed to maintaining and enforcing standards that ensure the end-to-end quality and integrity of the Future Shaper Holdings Ltd. certification and accreditation processes.

The GSAB is committed to fairness and objectivity; ensuring that decisions regarding the award of certifications and accreditations are based solely on the evidence provided to the assessing organisation, by each individual and organisation being assessed.

3. PURPOSE AND SCOPE

The GSAB is constituted to provide an impartial and objective body to which parties (individuals and/or organisations) who have contracted to be assessed for any of the certifications or accreditations Governed by Future Shaper Holdings Ltd. can appeal, should they not be satisfied with the decision(s) resulting through the relevant Appeals Against Decisions Policy/ies.

The GSAB is responsible for ensuring that the following policies are fair, reasonable and fit-for-purpose in the context of the accreditation and certifications Governed by Future Shaper Holdings Ltd:

- IAOCR Appeals Against Decisions Policy
- IAOCR Malpractice & Academic Misconduct Policy
- GCSA Appeals Against Decisions Policy
- GCSA Malpractice & Assessment Misconduct Policy

As part of the GSAB's commitment to continuous improvement, all outcomes of appeals processes will be reviewed and discussed and any outcomes for internal process or communication improvement will be reported to the Executive Committee of Future Shaper Holdings Ltd. by the Chair of the GSAB within 5 UK working days.

4. DEFINITIONS

Accreditation: An IAOCR qualification, awarded to individuals that have completed an IAOCR accreditation assessment and provided evidence that they have met the requisite Learning Outcome and Assessment Criteria.

Appellant: A person or organisation that is appealing against an Accreditation or Certification decision.

Assessment Criteria: Descriptors of the evidence that must be provided by individuals or organisations in order to meet the accreditation or certification standards. These should be observable, measurable and indicate the standard expected when the learner is assessed.

Board Meeting: The formal meeting of members of the GSAB either on a routine or ad hoc basis which shall be scheduled by the Chair and for which summary minutes will be taken and circulated by the Chair (or an assistant appointed by the Chair) to all GSAB members.

Board Member: Any current member of the Board including the Chair whether or not they have participated in a GSAB meeting since their appointment to the GSAB.

BPQC: Business Process Quality Certification

Case: Any appeal that has been initiated by an individual or organisation, that has already participated in the Appeals Against Decisions process and then contacted the GSAB because they are not satisfied with the outcome of the Appeals Against Decisions process. A case will remain open until findings and verdict of the GSAB have been reported to the appellant.

Certification: The recognition awarded following the successful outcome of an assessment for the GCSA, WPQC – Bronze, WPQC – Silver, WPQC - Gold, BPQC standard.

Chairperson : Future Shaper Holdings Ltd.'s Chief Operating Officer.

CRO: Contract Research Organisation.

Executive Committee: A body comprising the executive management team of Future Shaper Holdings Ltd. and appropriate members of the Operations management team as required by invitation.

GCP: Good Clinical Practice.

GCSA: Global Clinical Site Assessment.

GDPR: General Data Protection Regulations.

GSAB: Global Standards and Appeals Board.

Hung or Deadlocked result: A result of 1:1, not including the vote of the Chairperson.

IAOCR: International Accrediting Organisation for Clinical Research.

Learning Outcomes : A summary of the competence that the learner is expected to leave with at the end of the learning process, whatever the context in which the learning has taken place.

NHS: National Health Service.

Quorum: The Chairperson and any two of the four standing members in attendance at a Board Meeting.

SMO: Site Management Organisation, a commercial network or collective of clinical research sites.

Standards: The collective term for the certifications and accreditations both individual and institutional.

Supply Chain Organisation : Any organisation involved in delivering services to or within the clinical research industry.

WPQC: The collective terms for the Bronze, Silver and Gold level Workforce Process Quality Certifications.

Verdict: The final judgement of the GSAB as an outcome of an appeals process.

5. BOARD COMPOSITION

Membership: The Board shall consist of five (5) members including the Chairperson. Members shall be appointed by the Executive Committee of the IAOCR for a term of two years, with the possibility of reappointment for one additional term.

- **Appointment**: Board Members are invited to join the Board by the Chairperson for a period of two (2) years with the option of a continuance by mutual consent.
- **Resignation**: Board Members may stand down at any time by giving 30 days' notice in writing to the Chair.
- **Removal from the Board**: Board Members may be asked to stand down by the Chairperson due to any change in circumstance that adversely affects the impartiality, fairness or objectivity or availability of the Board Member as judged by the Chairperson.
- **Recusal**: Board Members may be asked to recuse themselves from certain Board meeting or from certain sections of any Board meeting relating to Cases where a conflict of interest has been identified by the Chairperson or brought to the attention of the Chairperson by the Board Member concerned.

- **Vacancies:** In the case of vacancies arising from resignations, end of term or other reasons the Chairperson will be responsible for approaching new candidates for the GSAB.
- **Composition:** The GSAB will comprise of representatives from the Clinical Research Delivery Environment to include Public Health & NHS, Commercial Research and SMO, CRO and Pharmaceutical Companies. The Chairperson, with the support of the wider Future Shaper Holdings executive team will aim to select GSAB members from a variety of different types of Supply Chain organisations and geographic regions.

6. ROLES AND RESPONSIBILITIES

- **Chairperson:**
 - Convene the GSAB once yearly and as required on an ad hoc basis in response to any appeal made to the GSAB by an appellant that has already undergone the relevant Appeals Against Decisions process.
 - Be the leading representative and spokesman for the GSAB.
 - Coordinate and Chair GSAB meetings and manage the agenda.
 - Ensure that the GSAB receives accurate, timely and clear information.
 - Direct discussions towards a consensus view and summarise outcomes.
 - Ensure that summary minutes are accurate and also circulated to all GSAB members in a timely fashion.
 - Manage the composition and structure of the Board's membership and appoint administrative support if required.
 - Report the activity of the GSAB as required to both the Executive Committee of Future Shaper Holdings Ltd. and appellant(s), as appropriate.
- **Members:**
 - Participate in all pre-scheduled yearly GSAB meetings or to give apologies in advance to the Chairperson if not possible.
 - Declare any conflict of interest relating to:
 - the activities of Future Shaper Holdings Ltd. and/or its subsidiaries
 - any particular appeal application made by an Appellant
 - Those learners who are repeatedly unable to attend GSAB meetings may be asked to stand down at the request of the Chairperson.

7. MEETINGS

- **Frequency:** The board shall meet on a scheduled, yearly basis in addition to any ad-hoc meetings needed to consider appeals.
- **Notice:**
 - Scheduled, annual board meetings will take place on the 1st Wednesday of July each year.
 - For ad hoc meetings required to review appeals, a minimum of 2 weeks' notice will be provided.
- **Format:** Meetings will be conducted virtually via video / telephone conferencing; unless it is sensible for the GSAB to meet in person due to logistical circumstances.
- **Agenda:** The agenda will be prepared Chairperson and circulated to the GSAB at least forty-eight (48) hours in advance of the meeting.

- **Summary Minutes:** Meetings will be recorded and/or written and circulated to the GSAB as a redacted transcript. The minutes will be circulated by the Chairperson or a administrator responsible to the Chairperson.

8. DECISION-MAKING PROCESS FOR APPEALS

- **Appellant process:** any individual making an appeal for themselves or on behalf of their organisation will need to do so in writing to the Chairperson of the GSAB who will confirm receipt of the appeal within one week.
- **Appeals outcome:** The decision of the GSAB is final and no subsequent appeal is permitted.
- **Details of appeal:** The information provided by the Appellant, as per the Details of Appeal required in Schedule 2 of this document.
- **Meeting timing:** The GSAB will meet within one month of the Appellant lodging the appeal.
- **Meeting Preparation:**
 - The Chairperson will have overall responsibility for collecting all information pertinent to the assessment and appeal and providing it to the GSAB Quorum at least 3 full UK working days before the appeal hearing.
 - The information must be complete and transparent and will include, but not be limited to the following:
 - Details of appeal
 - Full details pertaining to the completed IAOCR and/or GCSA Appeals Against Decisions process
 - Each member must familiarise themselves with the information provided prior to the GSAB meeting.
- **Voting:** Each of the 3 GSAB members present (which includes the Chairperson) will have one vote. The majority vote will provide the final decision.
- **Decision timeline:** Where possible, the GSAB should make an appeal decision within the first meeting. In circumstances where this is not possible e.g. where further information is required in order to inform decision making or a Quorum cannot be formed, the ruling may be carried forward to a further meeting. In this instance the Chairperson will ensure that the appellant is informed by email of the reason for the delay and when the next meeting will take place.
- **Board Members not in attendance:** Will be notified of the outcome of any appeal decision taken in the absence.
- **Verdict.** The outcome of the appeals process is final and is not a subject for further appeal.

9. CONFLICT OF INTEREST

Should any possible conflict of interest arise then the Board Member should recuse themselves from the appeals process / the GSAB. If the Board Member does not recuse themselves and the Chairperson becomes aware of a potential conflict of interest, the Chairperson will instruct the Board Member to exclude themselves from the appeals process / the GSAB. The Chairperson will be responsible for finding a replacement Board Member.

Examples of Possible Conflicts of Interest (please note this is not an exhaustive list):

- Appellant from the same Company or organisation as the concerned Board Member.
- Appellant is known to the Board Member personally or through an existing or previous working relationship.
- Appellant is an organisation that is a direct competitor of the Board Member.

10. ETHICS AND CONFIDENTIALITY

The Eight Principles of the Code of Conduct:

1. **Selflessness:** Board Members must act solely in terms of the interest of the GSAB when engaged in GSAB business.
2. **Integrity:** Board Members must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them. Not act or take decisions in order to gain financial or other material benefit.
3. **Objectivity:** Board Members must act and take decisions impartially, fairly and on merit, considering all evidence and without discrimination or bias.
4. **Accountability:** Board Members must be accountable for their decisions and actions and must be open to scrutiny.
5. **Openness:** Board Members must act and take decisions in an open and transparent manner.
6. **Honesty:** Board Members must be truthful, ethical and principled.
7. **Leadership:** Board Members must actively promote and support the guiding principles of the GSAB.
8. **GDPR compliance:** Board Members must keep and conduct all communications, actions, decisions and material information both tangible and digital in accordance with the European Union General Data Protection Regulations (which is also retained in UK GDPR law).

11. REVIEW AND AMENDMENTS TO THIS DOCUMENT

- **Annual Review:** This document will be reviewed at each scheduled annual GSAB meeting.
- **Change & Review Sign-Off:**
The Chairperson is responsible for ensuring annual review, authorised updates (when appropriate) and annual document sign-off.
- **Procedures:**
 - Changes to this document may be proposed by:
 - The Executive Committee of Future Shaper Holdings Ltd. to the Chairperson
 - The GSAB to the Chairperson
 - Once agreed by both the Board Members and the Executive Committee, the Chairperson will be responsible for updating the Terms of Reference and Constitution, and then:
 - Saving the document in the relevant policies and procedures folder on the FSH shared documents system
 - Distributing the updated document to all Board Members
 - Distributing the updated document to the Chief Quality and Client Officer
 - Distributing the updated document to FSH team member responsible for updating the policies provided on the IAOCR website.

- If it is deemed necessary to propose changes to this document at any time other than during the annual GSAB meeting, the Chairperson will act as a conduit for communication between the Executive Committee and the GSAB.
 - Consensus will be sought for any amendment; however consensus is not a requirement for change.
 - Communication with the GSAB regarding changes to the Terms of Reference and Constitution can take place via a meeting, for which minutes must be recorded OR via email communication.
 - As far as possible changes should not be made unless the majority of Board Members are in agreement to the change. If there is an equal split of Board Members supporting and not supporting the change(s), the Chairperson will make the final decision.

12. DISSOLUTION – REASONS AND PROCESS

Future Shaper Holdings Ltd. may dissolve the GSAB (a) if the GSAB is deemed to no longer be effective or necessary and/or (b) if, as part of the business's continuous improvement process and/or evolutions of standards and/or industry needs and requirements a more effective/appropriate oversight process is

Process: If dissolution of the GSAB is required, the following process will be followed:

1. The Executive Committee will inform the Chairperson of the need to dissolve the GSAB and the reasons for dissolution.
2. Within 2 working days of receiving the instruction, the Chairperson will call a Board Meeting; providing no less than 5 working days' notice to the Members. At the time of calling the Board Meeting, the Chairperson will communicate the reason(s) why the Executive Committee wish to dissolve the GSAB.
3. At the Board Meeting, the Board Members will review any outstanding matters; ensure the Chairperson is appropriately briefed on any handover matters and ensure that any documentation, evidence regarding appeals, etc. is in good order.
The Chairperson will ensure that they have all information that is needed and seek to gain agreement from the Board Members that s/he may follow-up with them to gain further information if anything else is needed.
4. Following dissolution of the GSAB, the Chairperson will be responsible for handing over any and all matters to another body; should another body be appointed to take over the responsibilities of the GSAB.

13. MISCELLANEOUS PROVISIONS

- **Legal Compliance:** This Board will comply with all relevant laws and regulations pertaining to its function.
- **Records:** All records, minutes, outcomes, judgments, verdicts, opinions data relating to the operation of this board will be managed in accordance with GDPR and filed in the Future Shaper Holdings Ltd. electronic records filing system.

Schedule 1 – Visual Marks of Accreditations and Certification

Upon awarding each of the marks below a unique identifier code is provided in order that accreditations and certifications can be verified with the awarding organisation.

Organisational Certification Awards					
	Awarded to GCSA Certified Clinical Research Sites (Site Business Processes)	Awarded to Gold Level Certified Clinical Research Organisations (Workforce Processes)	Awarded to Silver Level Certified Clinical Research Organisations (Workforce Processes)	Awarded to Bronze Level Certified Clinical Research Organisations (Workforce Processes)	Awarded to Clinical Research Supply Chain Organisations (Business Processes)
Individual Accreditation Awards					
	Awarded for L.2 MCQ Accreditations	Awarded to Foundational Level Accredited Clinical Research Professionals	Awarded to IAOCR Accredited Clinical Research Professionals	Awarded to IAOCR Qualified Clinical Research Managers/Leaders	

Detail of the specific award is added to the above marks before they are awarded to individuals achieving accreditation.



Schedule 2 – Details of Appeal

If the Appellant has fully participated in the Appeals Against Decisions process and is dissatisfied with the outcome of the decision*, the Appellant may appeal to the Global Standards and Appeals Board within 7 days of receiving the outcome of from the Appeals Against Decisions process.

*Please note that Appellants are not eligible to appeal to the Global Standards and Appeals Board if they have admitted to cheating, plagiarism, or any other unethical or dishonest behaviour that may have impacted on the integrity of a certification or accreditation process that is governed by Future Shaper Holdings Ltd.

Disqualification Period

Any person or organisation that has admitted to cheating, plagiarism, or any other unethical or any type of dishonest behaviour that may impact on the integrity of a certification or accreditation is automatically disqualified from all Certification and Accreditation processes governed by Future Shaper Holdings Ltd. for one calendar year. Following one calendar year the individual or organisation may re-enter the certification and/or accreditation process from the beginning and upon payment of the full fee as relevant to the full assessment fee at the time of reapplying.

Instructions for Appealing Against a Decision

Appellants wishing to appeal against the conclusion made through the Appeals Against Decisions process must email full details of their complaint to appeals@iaocr.com using FAO Global Standards and Appeals Board in the email subject line.

Complaint details must include (but are not limited to) the following:

- Details of the complaint.
- Reason(s) why the Appellant believes the conclusion of the Appeals Against Decisions process is unjust / incorrect.
- What the Appellant is requesting in order to rectify the situation.
- Electronic copies of all paperwork, evidence, and communication relevant to the complaint.
- Any other information that the Appellant believes is appropriate and relevant provide.
- Full contact details of the Appellant.

Schedule 3 – Related Documents

- IAOCR Appeals Against Decisions Policy
- IAOCR Malpractice and Academic Misconduct Policy
- GCSA Appeals Against Decisions Policy
- GCSA Malpractice and Assessment Misconduct Policy
- Future Shaper Holdings Ltd. GDPR Policy
- Future Shaper Holdings Ltd. Assessment Anti-Discrimination Policy

Tracking Record

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