



CELLULAR THERAPY CODING AND LABELING ADVISORY GROUP (CTCLAG) Terms of Reference

Introduction

These Terms of Reference describes the responsibilities and membership of the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). It is intended for use by the CTCLAG Chair and members, Boards of Directors of member organizations and staff of member organizations.

Mandate

The CTCLAG is established by and responsible to the Board of Directors of ICCBBA and is currently co-sponsored by: AABB, American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), ISCT Europe, Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). Cellular Therapy standards setting bodies in other areas of the world will be encouraged to participate in sponsoring the CTCLAG as appropriate.

The CTCLAG is required to operate in accordance with these terms of reference and with the relevant policies of the ICCBBA Board of Directors.

Membership

Sponsoring bodies of CTCLAG may each nominate a member to the advisory group. The CTCLAG must approve nominations. Additional technical experts may be appointed by ICCBBA at the request of the members.

Technical experts are appointed for a three year term and may be re-appointed for consecutive terms.

Liaisons

ICCBBA invites liaison representatives from appropriate organizations. Liaisons are non-voting attendees. The current liaison is US FDA.

Observers

ICCBBA invites observers from licensed vendors, and facilities and/or countries that are interested in introducing *ISBT 128*. Observers are non-voting attendees.

Attendance at individual meetings is at the discretion of the meeting Chair.

ICCBBA Staff

ICCBBA staff members attend meetings as necessary. At least one ICCBBA staff member must be present at each CTCLAG meeting.

Quorum

Meetings require a minimum of four voting members and an ICCBBA staff member.

Binding decisions require the presence of at least 60% of the voting membership and must include those organizations whose standards mandate the use of *ISBT 128*.

Elected chair/secretary

Voting members of the CTCLAG shall elect a Chair and Secretary from among their numbers. Appointment is for two years with the possibility of re-nomination.

The Chair, in liaison with ICCBBA staff, will be responsible for scheduling meetings, preparing the agenda, and for ensuring the meeting functions in accordance with this charter and standard meeting protocol.

The Secretary will be responsible for taking the minutes of the meeting and providing these to the ICCBBA office within 3 weeks of the meeting for distribution and posting.

Responsibilities of participants

The responsibilities of participants are:

- To be prepared for each meeting by reading all meeting materials posted on the ICCBBA website in advance of the meeting.

- To participate in the debate to ensure that full consideration is given to relevant issues.

- To communicate information about the needs of the user community

- To submit proposals based on the needs of the user community

- To communicate successes and obstacles encountered by the user community

- To actively participate in workgroups appointed to address user problems,

promote standardization in implementation or create educational materials and tools to aid in the implementation/use of *ISBT 128*.

To support the decisions of the advisory group outside of meetings.

Purpose

Advise on the ongoing development of the *ISBT 128* standard to support new developments in cellular therapy.

To generate, review and comment upon proposed changes to the *ISBT 128* Information Standard and supporting documents.

Provide a focus for the standardization of terminology and product naming;

Promote the adoption of the *ISBT 128* standard in facilities around the world;

Provide advice and support to facilities introducing the standard;

Meetings

CTCLAG shall meet at least once a year in person. Conference calls will be held as required.

Minimum notice of face-to-face meetings

Members, liaisons and observers from recent meetings will be notified of the date and city of face-to-face meetings at least four months in advance. They will be required to return a registration form by a specified date in order to attend the meeting.

Participants should submit requests for business items and/or presentations to be put on the agenda to the Chair at least four weeks in advance of the meeting date. Last minute additions to the agenda will be at the discretion of the Chair.

A meeting agenda will be provided at least one week in advance of the meeting.

Minimum notice for conference calls

Members, liaisons and observers from recent meetings will be notified of the date and time of a conference call at least two weeks in advance.

Participants should submit requests for business items and/or presentations to be put on the agenda to the Chair at least one week in advance of the meeting date. Last minute additions to the agenda will be at the discretion of the Chair.

A meeting agenda will be provided at least three days in advance of the call.

Administration

Minutes shall be taken at all meetings and conference calls.

ICCBBA will provide a web presence for the Advisory Group and publish notices of meetings and minutes.

A meeting summary shall be posted in the public area of the ICCBBA website.