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## CELLULAR THERAPY CODING AND LABELING ADVISORY GROUP (CTCLAG)

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### INTRODUCTION

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These Terms of Reference describe the responsibilities and membership of the ICCBBA 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, staff of member organizations, and ICCBBA Standards Committee.

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### MANDATE

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The CTCLAG is established by and responsible to the ICCBBA Board of Directors and is currently co-sponsored by:

- AABB
- APBMT (Asia Pacific Blood and Marrow Transplantation Group)
- ASBMT (American Society for Blood and Marrow Transplantation)
- ISCT (International Society for Cell and Gene Therapy)
- ASFA (American Society for Apheresis)
- EBMT (European Society for Blood and Marrow Transplantation)
- FACT (Foundation for the Accreditation of Cellular Therapy)
- ISBT (International Society of Blood Transfusion)
- JACIE (Joint Accreditation Committee ISCT-Europe and EBMT)
- NMDP (National Marrow Donor Program)
- WMDA (World Marrow Donor Association)

Cellular Therapy standards setting bodies in other areas of the world are 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.

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### PURPOSE

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- Advise on the ongoing development of the ISBT 128 Information Standard to support new developments in cellular therapy.
- 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.
- Receive reports on the progress of ISBT 128 implementation and consider any issues raised by these reports.
- Provide advice and support to facilities introducing the ISBT 128 Information Standard.
- Prepare educational materials and tools to support the implementation of ISBT 128.
- Promote the adoption of the ISBT 128 Information Standard in facilities around the world.

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### REPRESENTATIVES

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Organizational Representatives of the CTCLAG are appointed by co-sponsoring organizations. ICCBBA may invite at their discretion representatives from organizations that support the purpose of the TAG. Representatives have voting rights. Where an organization has more than one Representative, only one vote may be cast.



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## **TECHNICAL EXPERTS**

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Technical Experts of the CTCLAG are appointed for a two-year term by ICCBBA and have voting rights.

Technical experts may be re-appointed.

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## **LIAISONS**

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ICCBBA invites liaisons from related organizations, regulatory authorities, government departments, and supra-governmental organizations. Additionally, liaisons from other TAGs may participate. Liaisons are non-voting attendees.

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## **OBSERVERS**

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

Attendance at individual meetings may be limited by meeting room size.

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## **STAFF**

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

ICCBBA staff are non-voting attendees.

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## **QUORUM**

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Meetings require a minimum of: Chair or appointed Chair Representative; one ICCBBA staff member; and three voting members.

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

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## **ELECTED CHAIR**

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Voting members shall elect a Chair from among their numbers. The appointment will require the approval of the Board of Directors. Appointment is for three years with the possibility of re-nomination.

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

ICCBBA in conjunction with the Chair may appoint a Chair Representative to conduct meetings in the absence of the Chair. This would be on a per-meeting basis in case the elected Chair is unable to attend.

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## **RESPONSIBILITIES OF PARTICIPANTS**

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- To be prepared for each meeting by reading all meeting materials provided or 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, and 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.
- Representatives and Liaisons: To communicate between their organizations and the TAG.

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## **MEETINGS**

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The CTCLAG shall have face-to-face meetings and conference calls as required.

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## **CONFLICT OF INTEREST**

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The CTCLAG members are required to bring to the attention of the Chair any conflict of interest or potential conflict they may have with any item on the CTCLAG agenda.

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## **MINIMUM NOTICE FOR FACE-TO-FACE MEETINGS**

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Voting members, liaisons, and observers will be notified of the date and city of face-to-face meetings at least four months in advance.

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 two weeks in advance of the meeting.

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## **MINIMUM NOTICE FOR CONFERENCE CALLS**

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Voting members, liaisons, and observers 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.

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## **ADMINISTRATION**

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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.



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## **EVALUATION AND REVIEW**

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The CTCLAG shall review its Terms of Reference every three years and provide a report, including any recommendations, to the ICCBBA Standards Committee.