How to apply for endorsement of a research project by ELITA

1. A request should be addressed to the Secretary of ELITA, together with the study protocol.
2. The study should have a multinational and multicenter character.
3. The study should focus on the patients undergoing liver or intestine transplantation.
4. The principal investigator must be member of ELITA.
5. The study protocol should be approved by all ELITA Board members.

1. Once the request has been approved by the ELITA Board, the project will be endorsed under the following conditions:
2. In the official correspondence it is stated that “This study is endorsed by the European Liver and Intestine Transplant Association (ELITA)”. This should be accompanied by the official logo of ELITA.
3. The ELITA Board is regularly updated about the results of the study (see below). In scientific publications arising from the study, it will be acknowledged that the study was endorsed by the European Liver and Intestine Transplant Association (ELITA).
4. The initiator (the principal investigator) of the study remains fully responsible and accountable for the study. ELITA bears no direct or indirect responsibility for the study.

Regulations for ELTR-based Studies and Publications:

1. ELTR data are available to ELITA members whose centres are regularly contributing data to the ELTR. Data can be used to perform scientific studies, which should preferably lead to a publication in a peer-reviewed journal.
2. Requests from third parties: Third parties will be asked to pay a fee for the collection of requested data depending on the extent of dataset and/or for statistical evaluation of the work. An ELITA Board member should be involved in a study concerning clinical issues.
3. To obtain data, a written request should be addressed to the ELITA Secretary with copy to the ELTR General Manager.
   The request should contain:
   - Title and description of the study;
   - Supporting letter by the program director;
   - Names and affiliations of the investigators (depending on the type of the study, max. 2 or 3);
   - A disclosure statement regarding potential conflicts of interest (such as financial affiliations with pharmaceutical companies);
4. At least one of the authors should be a recognized specialist in the subject.
5. The ELITA Secretary sends the request to the ELTR Scientific Committee, who reviews the request and gives its recommendation to the ELITA Board.
6. The ELITA Board decides upon acceptance of the study and assigns one Board member who is the liaison person for the conductance of the study and represents ELITA as a co-author of the study.
7. A fee of € 1000 per dataset for ELITA members from the centers contributing to the ELTR and € 2,000 for members from the centers not contributing to the ELTR will be transferred to ELITA account. If the statistic is requested from ELTR, additional statistical handling will be charged at an hourly rate. For the request from third parties (i.e. industry) a different fee applies.
8. An official notification of the decision of the ELITA Board is sent to the investigator from ELITA Secretary. If the study has been accepted the investigators are requested to sign an agreement with the ELITA regarding the study conduction and publication policy.
9. Authorship of any publication based on ELTR data (abstracts or full papers) is regulated as follows:
   - First, second and last authorship for researchers performing the study;
   - the third and the fourth position will be reserved for ELTR member and ELITA liaison person (persons who proofreads the paper, controls adequate conductance, takes care of communication) and it will be defined by the ELITA Board according to the extent of involvement by the ELTR;
   - As many authors as possible (as allowed by the journal), one per centre, according to the number of patients included in the study
   - After the last author, the statement “for the European Liver and Intestine Transplant Association (ELITA)”;
   - All centres that have participated in the study with patients should be listed in a footnote or appendix, mentioning the program director and one of the collaborators;
   - A paragraph entitled “Acknowledgments” containing the text below should be added at the end of each ELTR manuscript: The ELTR is supported by a grant from Astellas, Novartis, Institut Georges Lopez, Bridge to Life and logistic support from the Paul Brousse Hospital (Assistance Publique – Hôpitaux de Paris). The Organ Sharing Organizations: the French ABM (Sami Djabbour and Alain Jolly), the Dutch NTS (Cynthia Konijn), the Eurotransplant Foundation (Marieke Van Meel and Erwin de Vries), the Spanish ONT (Gloria de la Rosa), the UK-Ireland NHSBT (Mike Chilton and Julia Micciche) are acknowledged for the data cross-check and sharing with the ELTR.

These rules also apply when only a part of the published data is available in the ELTR database.

10. ELITA requires an update on study activities every 6 months beginning from the date of approval of the study, which has to be sent to the Secretary, to the assigned Board member and to the ELTR.

11. ELITA suggests the following timeline for conducting a ELTR-based study:

   o Data collection from ELTR: 3 months from the date of study acceptance by ELITA
   o Additional data collection from the centers (if necessary): 6 months
   o Data evaluation and analysis: 6 months
   o Preparation of the manuscript: 5 months

12. If no progress has been made with the study for 2 years, the ELITA Board has the right to cancel the study.

13. Manuscripts should always be presented to the ELITA Board for approval prior to submission.

14. The choice for a journal is made in agreement with the ELITA Board.

15. In case the requested data is not (completely) available in the ELTR database, it is allowed to approach ELTR centres for additional data. A request to the centres should be presented on ELITA/ELTR letterhead and should be co-signed by one of the ELITA Board members and by the ELTR General Manager.

16. Similar rules apply when abstracts are presented to congresses.
APPENDIX

ELTR/ELITA study agreement

After receiving the dataset from ELTR I agree as follow:

1. The dataset is confidential and it might be only used for the purpose of approved study by the ELITA Board.
2. No additional studies are allowed to be performed with the dataset.
3. The progress of the study has to be reported every six months to the ELITA liaison person, ELITA secretary and ELTR.
4. If no progress has been made with the study for 2 years, the ELITA Board has the right to cancel the study.
5. The manuscript has to be sent to ELITA liaison person before submission for publication.
6. The choice for a journal is made in agreement with the ELITA Board.
7. First, second and last authorship is for researchers performing the study; the third and the fourth position will be reserved for ELTR member and ELITA liaison person.
8. The researchers are encouraged to include as many authors as possible (as allowed by the journal), one per centre, according to the number of patients included in the study.
9. After the last author, the statement “for the European Liver and Intestine Transplant Association (ELITA)” has to be added.
10. All centers that have participated in the study with patients should be listed in a footnote or appendix, mentioning the program director and one of the collaborators.

If the manuscript has been sent for publication or published without the acceptance of ELITA/ELTR, ELITA has a right to contact a journal where the manuscript has been sent and to remove this publication.

Date and signature of Principal Investigator