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 multicentre 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 Scientific Committee. Once the request has been approved by the ELITA Scientific Committee, the project will be endorsed under the following conditions:
   A. 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.
   B. 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).
   C. 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:

Who can access to the data:

1. ELTR data are available to ELITA members to perform scientific studies, which should preferably lead to a publication in a peer-reviewed journal.
2. Third parties (not ELITA members) 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.

Dataset rules:

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. 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.

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How to obtain the data:

To obtain data, a written request should be addressed to the ELITA Secretary with copy to the ELTR General Manager.

The request should contain:

1) Title and full description of the study.
2) Supporting letter by the program director.
3) Names and affiliations of the investigators (depending on the type of the study, max. 2- 3). At least one of the authors should be a recognized specialist in the subject.
4) A disclosure statement regarding potential conflicts of interest (such as financial affiliations with pharmaceutical companies)

Once the request is submitted:

1. The ELITA Secretary sends the request to the ELITA Scientific Committee who reviews the request and give its feedback.
2. Once the scientific evaluation is achieved, the ELITA Scientific Committee 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.
3. 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.

Data Fees:

1. A fee of 500 or 1000 € per dataset for paying and non-paying ELTR members/centres, respectively, or 2000 € for centres not contributing to the ELTR database will be transferred to the ELITA account. If additional statistical analysis is requested from ELTR, this will be charged at an hourly rate.
2. For the request from third parties (i.e. industry) a different fee applies to be determined according to the type of applicant (ELTR sponsor or not) and the size of the project.
3. No data fees will be charged for study requests from ESPAGHAN members.

Authorship guidelines of any publication based on ELTR data (abstracts of full papers):

Authorship guidelines of any publication based on ELTR data is regulated as follows:

1. First, second and last authorship for researchers performing the study. Those ones are who design the study, collect and analyse data and write the paper.

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 and their expertise in the field of the request.

2. As many authors as possible included as allowed by the journal. In the case that the journal has a limitation with the number of authors, the authorship will be stablished according to the number of patients included in the study and only one author per centre. After the last author, the statement "for the European Liver and Intestine Transplant Association (ELITA)" should be added.

   Nevertheless, all centres and authors that have participated in the study should be listed in a paragraph after discussion/conclusion and before references mentioning at first the program director and one or two of the collaborators.

3. The title of the paper should mention the topic of the study with the mention: "*an ELTR study*"

4. The text below should be added in the manuscript: "This study is endorsed by the European Liver and Intestine Transplant Association (ELITA). We thank all investigators and their participating center. The European Multicenter Study Group consisted of the following centers and committees: [The structure of the citation will be referred as follow: country, institutions per country and authors per institution]. All collaborators should be mentioned in major research websites (i.e. PUBMED, Scopus), if its editorial policy accept".

5. The paragraph entitled "Aknowledgments" containing the text below must be added at the end of each ELTR based on manuscript: "The ELTR is supported by a grant from…: (partners to be reviewed by ELITA Governing Board every year). 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."

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

Study performance:

1. ELITA suggests the following timeline for conducting an ELTR-based study:
   - After the payment of the fee the request dataset will be sent to the investigator.
   - Data collection from ELTR: 3 months since the dataset has been sent to the participants.
   - Additional data collection from the centres (if necessary): 6 months
   - Data evaluation and analysis: 6 months
   - Preparation of the manuscript: 5 months
2. 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 ELITA Secretary, to the assigned Board member and to the ELTR Data Manager.
3. If no progress has been made with the study for 2 years, the ELITA Board has the right to cancel the study.

Publication methodology:

1. Manuscripts should always be presented to the ELITA Board for approval prior to submission.
2. The choice for a journal is made in agreement with the ELITA Board
3. If the manuscript has been sent out 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.
4. 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 Scientific Committee.
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 Data Manager.
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). In case that the journal has a limitation with the number of authors, the authorship will be according to the number of patients included in the study and only one per centre.
9. After the last author, the statement "*for the European Liver and Intestine Transplant Association (ELITA)*" hast to be added.
10. All centres and authors that have participated in the study with patients should be listed in a paragraph after discussion/conclusion and before references mentioning at first the program director and one or two of the collaborators.
11. 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