Fit for Health 2.0

Support to SMEs & Researchers in FP7 and Horizon 2020 health-oriented projects

Grant Agreement Preparation in EDCTP2 projects

EDCTP

European & Developing Countries Clinical Trials Partnership

www.fitforhealth.eu

This project has received funding from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement N° 602428.

05.08.2016 | WEBINAR

Dr Claudia Schacht & Julia Büch | Eurice GmbH

Main action points during the Grant Preparation Phase

- Preparation of the **Grant Agreement**
- Negotiation & conclusion of **Consortium Agreement**
- Submission of institutional **forms** & **supporting documents**
- Implementation of **Ethics Review** and/or **Security Scruitiny**
- **Grant Signature**

The Grant Agreement (GA)

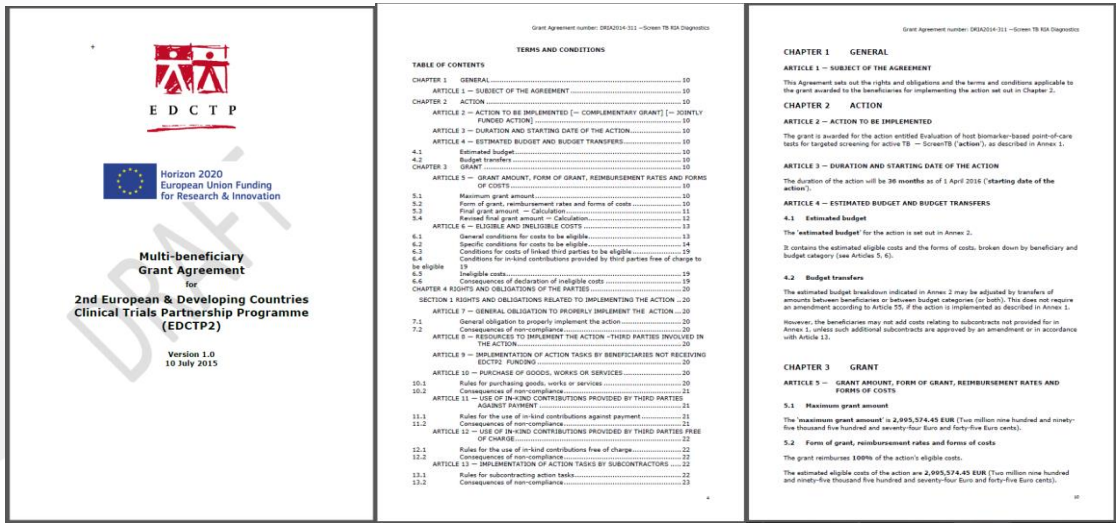
defines the relation between the EDCTP and the Coordinator / the Consortium

EDCTP Grant Agreement

- Grant Agreement is concluded between EDCTP and institutions (not individuals)
- Grant Agreement is signed by the authorized legal representatives
- All partners in the consortium must accede to/sign the Grant Agreement
- Grant ”belongs” to the institution with rights and obligations

Core Grant Agreement

- The **Core Grant Agreement** contains all essential project details (title, consortium members, amount of pre-financing, maximum funding, etc.) as well as all rights and obligations of the EDCTP and the beneficiaries (including all financial rules and regulations)



E D C T P

Horizon 2020
European Union Funding
for Research & Innovation

DRAFT

Multi-beneficiary
Grant Agreement
for
2nd European & Developing Countries
Clinical Trials Partnership Programme
(EDCTP2)

Version 1.0
10 July 2015

Grant Agreement number: DRIA2014-311 –Screen TB RIA Diagnostics

TERMS AND CONDITIONS

TABLE OF CONTENTS

Grant Agreement number: DRIA2014-311 –Screen TB RIA Diagnostics

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB — ScreenTB ('**action**'), as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be **36 months** as of 1 April 2016 ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

However, the beneficiaries may not add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved by an amendment or in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **2,995,574.45 EUR** (Two million nine hundred and ninety-five thousand five hundred and seventy-four Euro and forty-five Euro cents).

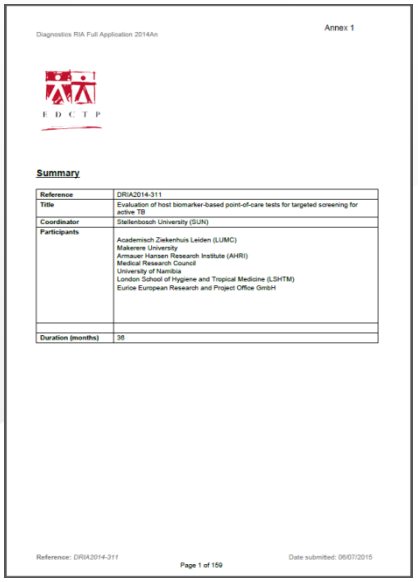
5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses **100%** of the action's eligible costs.

The estimated eligible costs of the action are **2,995,574.45 EUR** (Two million nine hundred and ninety-five thousand five hundred and seventy-four Euro and forty-five Euro cents).

Description of the Action and Budget

- The Description of the Action (DoA) is **Annex I** to the Grant Agreement. It contains the implementation details: work packages, deliverables, milestones – and a detailed narrative description of the work.


Annex 1

Summary

Reference	DRIA2014-311
Title	Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB
Coordinator	Stellenbosch University (SUN)
Participants	Academisch Ziekenhuis Leiden (LUMC) Makerere University Armauer Hansen Research Institute (AHRI) Medical Research Council University of Namibia London School of Hygiene and Tropical Medicine (LSHTM) Eurice European Research and Project Office GmbH
Duration (months)	36

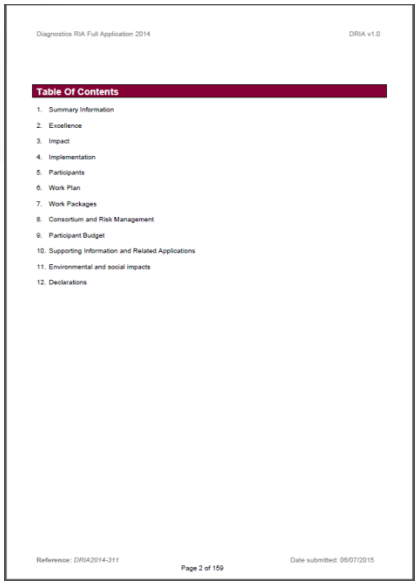


Table Of Contents

1. Summary Information
2. Excellence
3. Impact
4. Implementation
5. Participants
6. Work Plan
7. Work Packages
8. Consortium and Risk Management
9. Participant Budget
10. Supporting Information and Related Applications
11. Environmental and social impacts
12. Declarations

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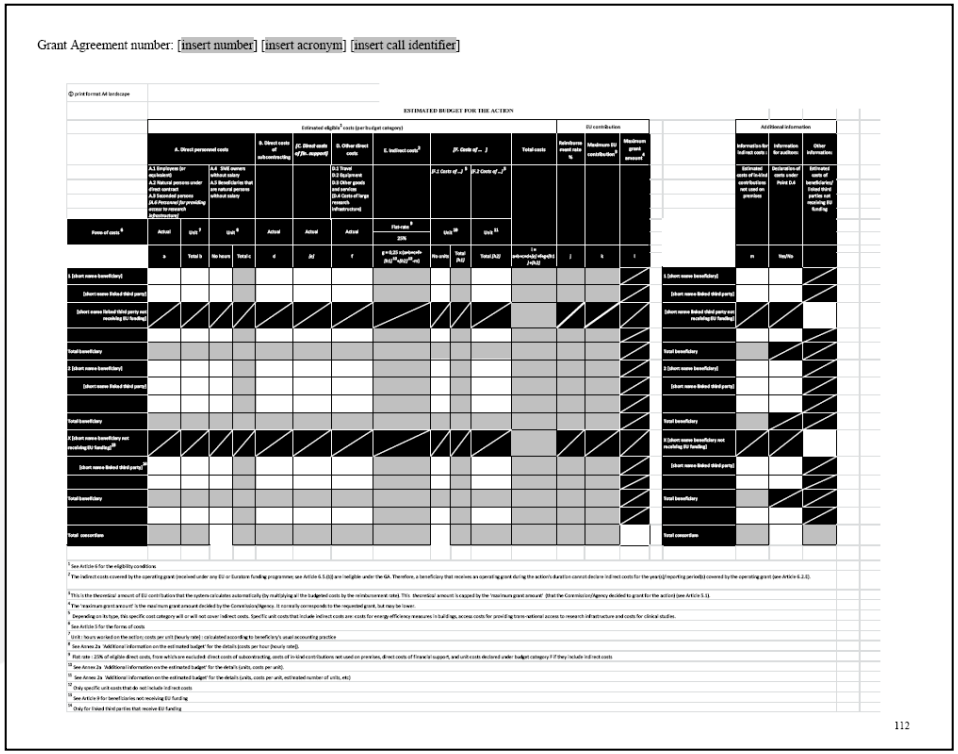
Description of the Action and Budget

- The budget Table is **Annex II** to the Grant Agreement



Grant Agreement number: [insert number] [insert acronym] [insert call identifier]

ESTIMATED BUDGET FOR THE ACTION

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The Consortium Agreement (CA)

regulates the relation between consortium partners (= beneficiaries)

istockphoto.com/Frank Ramspott

Consortium Agreement

- **Consortium Agreement** is **mandatory** in EDCTP projects for multi-beneficiary actions!
- Consortium Agreement is building on GA as a legal basis
- Should be negotiated and concluded **before signing the GA**

- Aspects to be addressed:

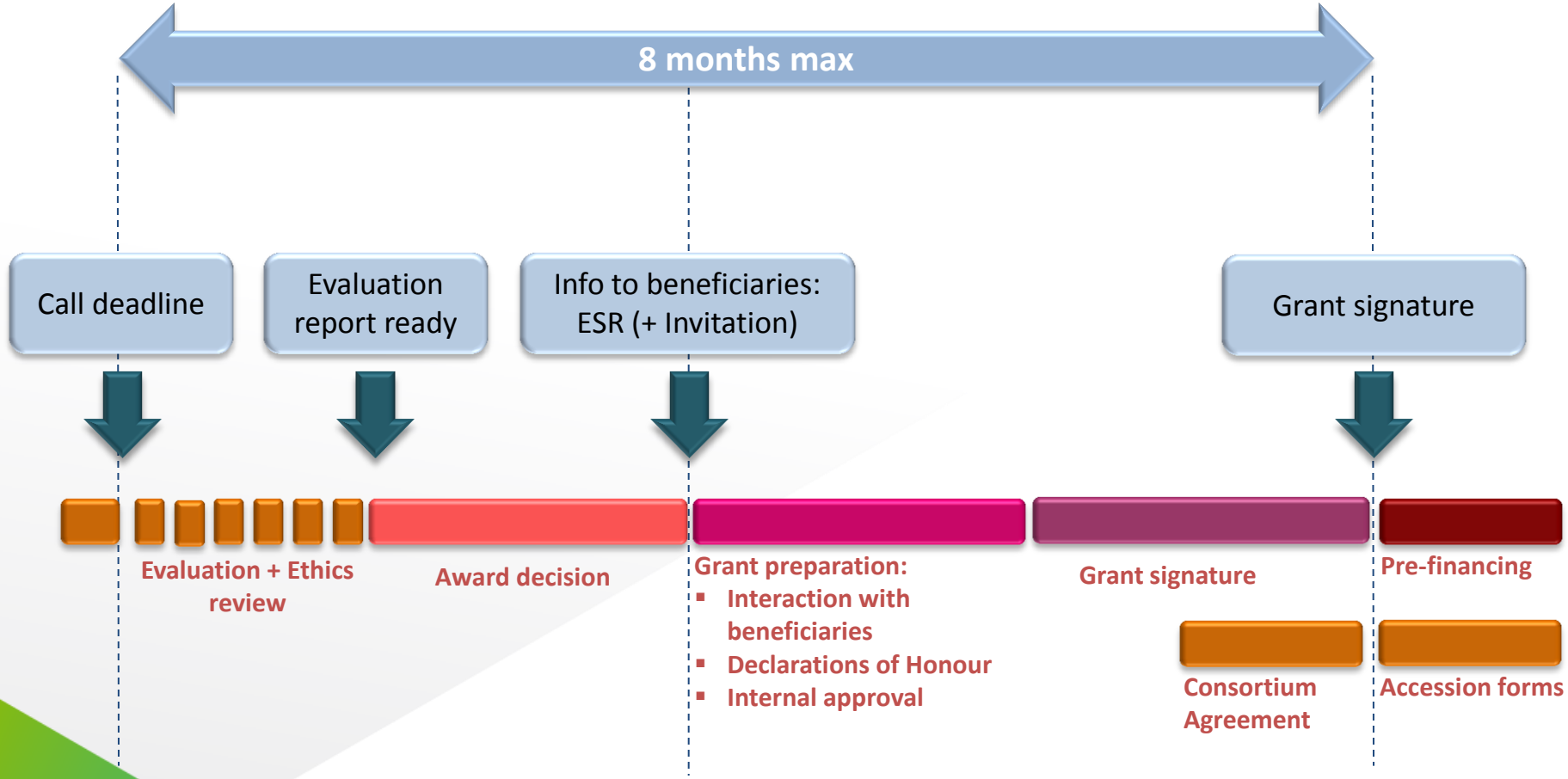
  Management and decision making; Ownership of results; Settlement of disputes; Reporting obligations and timelines; Sharing of costs; Distribution of EDCTP funds between partners, etc.

DESCA – an established CA model

DESCA
Horizon 2020 Model Consortium Agreement
www.DESCA-2020.eu

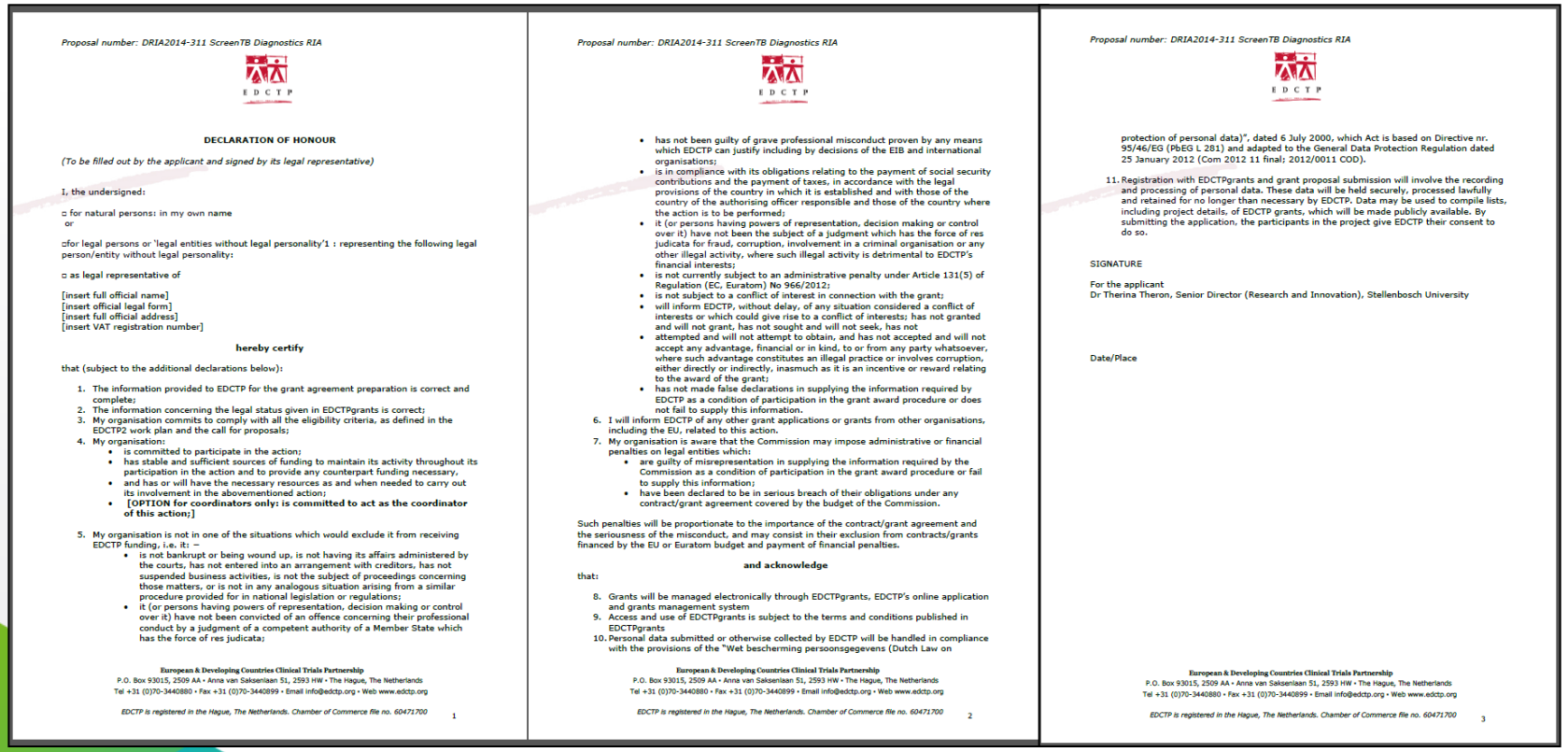
- **De**velopment of a **S**implified **C**onsortium **A**greement
- European Initiative by key FP actors, co-developed by the FP community
- www.desca-2020.eu

Grant Agreement Preparation



First step: Declaration of Honour

- to be signed by <u>all project partners</u>



Proposal number: DRIA2014-311 ScreenTB Diagnostics RIA

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DECLARATION OF HONOUR

(To be filled out by the applicant and signed by its legal representative)

I, the undersigned:

□ for natural persons: in my own name
or

□for legal persons or 'legal entities without legal personality'1 : representing the following legal person/entity without legal personality:

□ as legal representative of

[insert full official name]
[insert official legal form]
[insert full official address]
[insert VAT registration number]

hereby certify

that (subject to the additional declarations below):

1. The information provided to EDCTP for the grant agreement preparation is correct and complete;
2. The information concerning the legal status given in EDCTPgrants is correct;
3. My organisation commits to comply with all the eligibility criteria, as defined in the EDCTP2 work plan and the call for proposals;
4. My organisation:
   - is committed to participate in the action;
   - has stable and sufficient sources of funding to maintain its activity throughout its participation in the action and to provide any counterpart funding necessary,
   - and has or will have the necessary resources as and when needed to carry out its involvement in the abovementioned action;
   - **[OPTION for coordinators only: is committed to act as the coordinator of this action;]**
5. My organisation is not in one of the situations which would exclude it from receiving EDCTP funding, i.e. it: –
   - is not bankrupt or being wound up, is not having its affairs administered by the courts, has not entered into an arrangement with creditors, has not suspended business activities, is not the subject of proceedings concerning those matters, or is not in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
   - it (or persons having powers of representation, decision making or control over it) have not been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;

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EDCTP is registered in the Hague, The Netherlands. Chamber of Commerce file no. 60471700

1

Proposal number: DRIA2014-311 ScreenTB Diagnostics RIA

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- has not been guilty of grave professional misconduct proven by any means which EDCTP can justify including by decisions of the EIB and international organisations;
- is in compliance with its obligations relating to the payment of social security contributions and the payment of taxes, in accordance with the legal provisions of the country in which it is established and with those of the country of the authorising officer responsible and those of the country where the action is to be performed;
- it (or persons having powers of representation, decision making or control over it) have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity, where such illegal activity is detrimental to EDCTP's financial interests;
- is not currently subject to an administrative penalty under Article 131(5) of Regulation (EC, Euratom) No 966/2012;
- is not subject to a conflict of interest in connection with the grant;
- will inform EDCTP, without delay, of any situation considered a conflict of interests or which could give rise to a conflict of interests; has not granted and will not grant, has not sought and will not seek, has not
- attempted and will not attempt to obtain, and has not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to the award of the grant;
- has not made false declarations in supplying the information required by EDCTP as a condition of participation in the grant award procedure or does not fail to supply this information.

6. I will inform EDCTP of any other grant applications or grants from other organisations, including the EU, related to this action;
7. My organisation is aware that the Commission may impose administrative or financial penalties on legal entities which:
   - are guilty of misrepresentation in supplying the information required by the Commission as a condition of participation in the grant award procedure or fail to supply this information;
   - have been declared to be in serious breach of their obligations under any contract/grant agreement covered by the budget of the Commission.

Such penalties will be proportionate to the importance of the contract/grant agreement and the seriousness of the misconduct, and may consist in their exclusion from contracts/grants financed by the EU or Euratom budget and payment of financial penalties.

and acknowledge

that:

8. Grants will be managed electronically through EDCTPgrants, EDCTP's online application and grants management system
9. Access and use of EDCTPgrants is subject to the terms and conditions published in EDCTPgrants
10. Personal data submitted or otherwise collected by EDCTP will be handled in compliance with the provisions of the "Wet bescherming persoonsgegevens (Dutch Law on

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2

Proposal number: DRIA2014-311 ScreenTB Diagnostics RIA

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protection of personal data)", dated 6 July 2000, which Act is based on Directive nr. 95/46/EG (PbEG L 281) and adapted to the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD).

11. Registration with EDCTPgrants and grant proposal submission will involve the recording and processing of personal data. These data will be held securely, processed lawfully and retained for no longer than necessary by EDCTP. Data may be used to compile lists, including project details, of EDCTP grants, which will be made publicly available. By submitting the application, the participants in the project give EDCTP their consent to do so.

SIGNATURE

For the applicant
Dr Therina Theron, Senior Director (Research and Innovation), Stellenbosch University

Date/Place

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P.O. Box 93015, 2509 AA • Anna van Saksenlaan 51, 2593 HW • The Hague, The Netherlands
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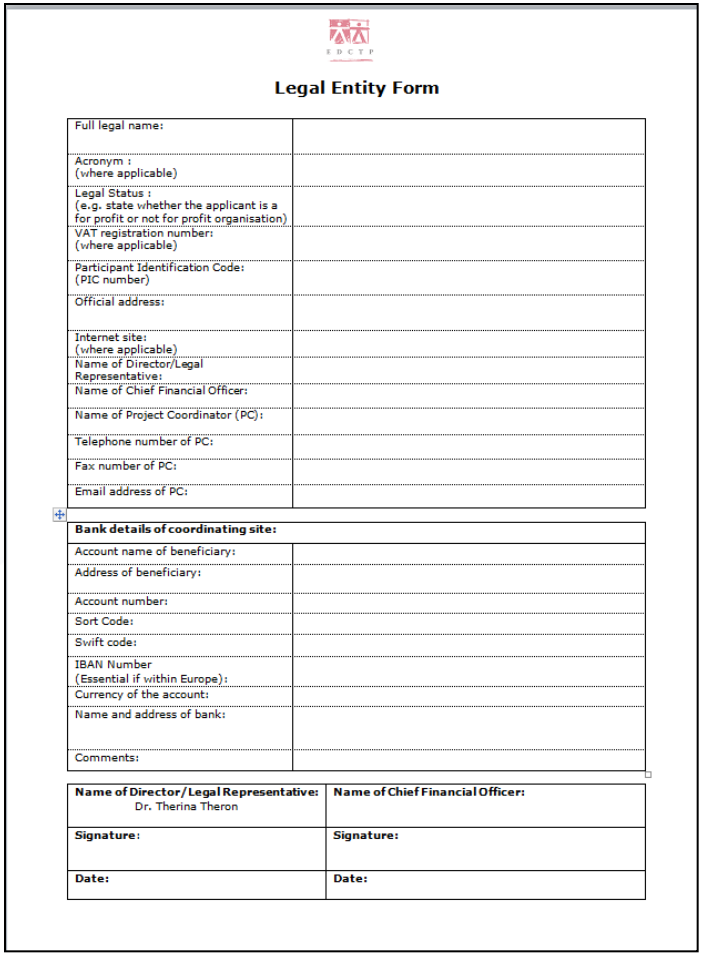
3

Second step: Legal Entity Form

- to be stamped and signed by all partners
- must be submitted to EDCTP



Legal Entity Form

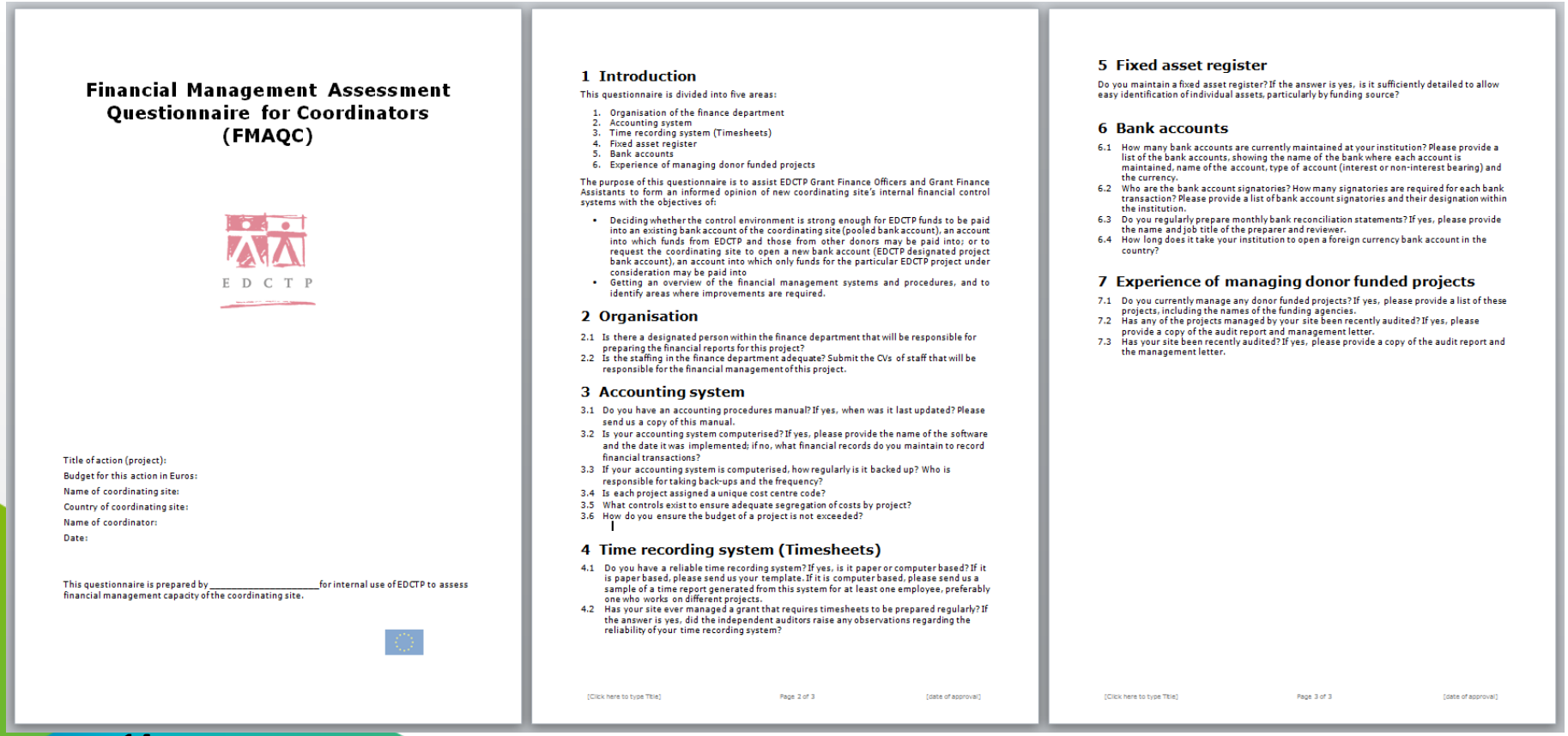
Full legal name:	
Acronym : (where applicable)	
Legal Status : (e.g. state whether the applicant is a for profit or not for profit organisation)	
VAT registration number: (where applicable)	
Participant Identification Code: (PIC number)	
Official address:	
Internet site: (where applicable)	
Name of Director/Legal Representative:	
Name of Chief Financial Officer:	
Name of Project Coordinator (PC):	
Telephone number of PC:	
Fax number of PC:	
Email address of PC:	

Bank details of coordinating site:	
Account name of beneficiary:	
Address of beneficiary:	
Account number:	
Sort Code:	
Swift code:	
IBAN Number (Essential if within Europe):	
Currency of the account:	
Name and address of bank:	
Comments:	

Name of Director/Legal Representative: Dr. Therina Theron	**Name of Chief Financial Officer:**
Signature:	**Signature:**
Date:	**Date:**

Coordinator: Financial Management Assessment Questionnaire

- to be submitted to EDCTP



Financial Management Assessment Questionnaire for Coordinators (FMAQC)

E D C T P

Title of action (project):
Budget for this action in Euros:
Name of coordinating site:
Country of coordinating site:
Name of coordinator:
Date:

This questionnaire is prepared by _____ for internal use of EDCTP to assess financial management capacity of the coordinating site.

1 Introduction

This questionnaire is divided into five areas:

1. Organisation of the finance department
2. Accounting system
3. Time recording system (Timesheets)
4. Fixed asset register
5. Bank accounts
6. Experience of managing donor funded projects

The purpose of this questionnaire is to assist EDCTP Grant Finance Officers and Grant Finance Assistants to form an informed opinion of new coordinating site's internal financial control systems with the objectives of:

- Deciding whether the control environment is strong enough for EDCTP funds to be paid into an existing bank account of the coordinating site (pooled bank account), an account into which funds from EDCTP and those from other donors may be paid into; or to request the coordinating site to open a new bank account (EDCTP designated project bank account), an account into which only funds for the particular EDCTP project under consideration may be paid into
- Getting an overview of the financial management systems and procedures, and to identify areas where improvements are required.

2 Organisation

2.1 Is there a designated person within the finance department that will be responsible for preparing the financial reports for this project?
2.2 Is the staffing in the finance department adequate? Submit the CVs of staff that will be responsible for the financial management of this project.

3 Accounting system

3.1 Do you have an accounting procedures manual? If yes, when was it last updated? Please send us a copy of this manual.
3.2 Is your accounting system computerised? If yes, please provide the name of the software and the date it was implemented; if no, what financial records do you maintain to record financial transactions?
3.3 If your accounting system is computerised, how regularly is it backed up? Who is responsible for taking back-ups and the frequency?
3.4 Is each project assigned a unique cost centre code?
3.5 What controls exist to ensure adequate segregation of costs by project?
3.6 How do you ensure the budget of a project is not exceeded?

4 Time recording system (Timesheets)

4.1 Do you have a reliable time recording system? If yes, is it paper or computer based? If it is paper based, please send us your template. If it is computer based, please send us a sample of a time report generated from this system for at least one employee, preferably one who works on different projects.
4.2 Has your site ever managed a grant that requires timesheets to be prepared regularly? If the answer is yes, did the independent auditors raise any observations regarding the reliability of your time recording system?

[Click here to type Title] Page 2 of 3 [date of approval]

5 Fixed asset register

Do you maintain a fixed asset register? If the answer is yes, is it sufficiently detailed to allow easy identification of individual assets, particularly by funding source?

6 Bank accounts

6.1 How many bank accounts are currently maintained at your institution? Please provide a list of the bank accounts, showing the name of the bank where each account is maintained, name of the account, type of account (interest or non-interest bearing) and the currency.
6.2 Who are the bank account signatories? How many signatories are required for each bank transaction? Please provide a list of bank account signatories and their designation within the institution.
6.3 Do you regularly prepare monthly bank reconciliation statements? If yes, please provide the name and job title of the preparer and reviewer.
6.4 How long does it take your institution to open a foreign currency bank account in the country?

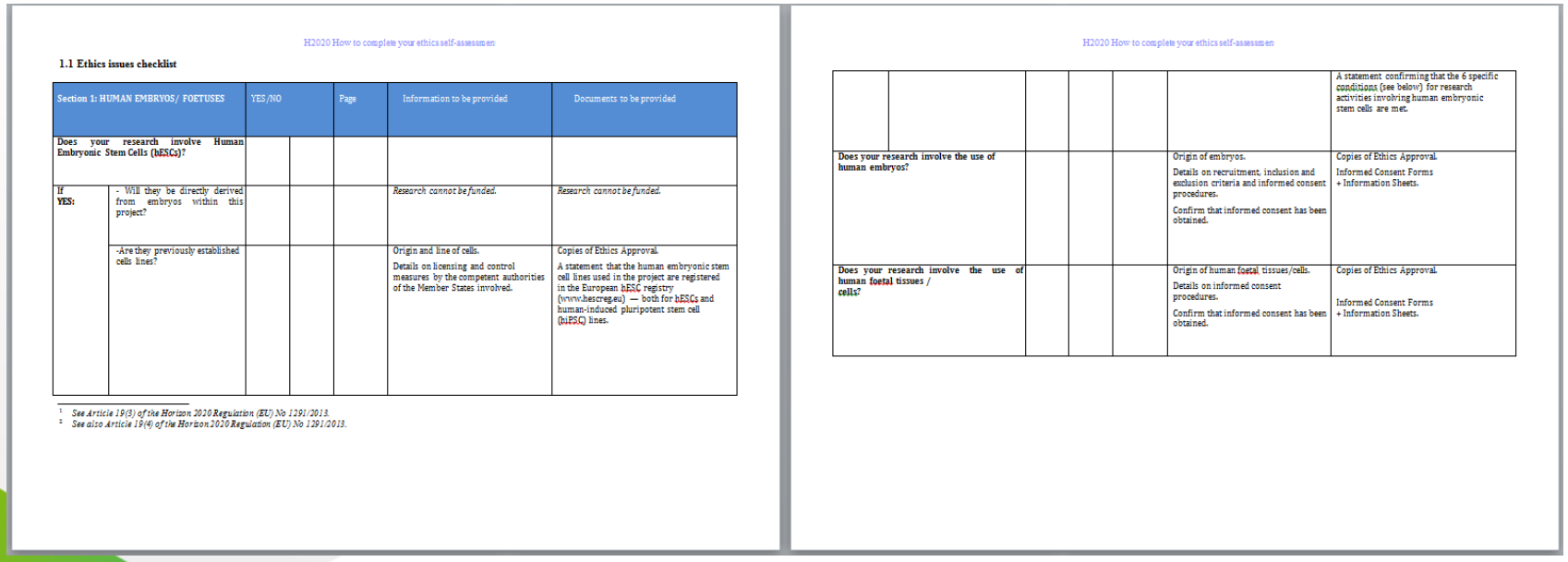
7 Experience of managing donor funded projects

7.1 Do you currently manage any donor funded projects? If yes, please provide a list of these projects, including the names of the funding agencies.
7.2 Has any of the projects managed by your site been recently audited? If yes, please provide a copy of the audit report and management letter.
7.3 Has your site been recently audited? If yes, please provide a copy of the audit report and the management letter.

[Click here to type Title] Page 3 of 3 [date of approval]

Coordinator: Ethics self assessment template

- narrative part + ethics tables
- guidance notes are provided



H2020 How to complete your ethics self-assessmen

1.1 Ethics issues checklist

Section 1: HUMAN EMBRYOS/ FOETUSES		YES/NO		Page	Information to be provided	Documents to be provided
Does your research involve Human Embryonic Stem Cells (hESCs)?						
If YES:	- Will they be directly derived from embryos within this project?				*Research cannot be funded.*	*Research cannot be funded.*
	-Are they previously established cells lines?				Origin and line of cells. Details on licensing and control measures by the competent authorities of the Member States involved.	Copies of Ethics Approval. A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) — both for hESCs and human-induced pluripotent stem cell (hiPSC) lines.

[1] *See Article 19(3) of the Horizon 2020 Regulation (EU) No 1291/2013.*
[2] *See also Article 19(4) of the Horizon 2020 Regulation (EU) No 1291/2013.*

H2020 How to complete your ethics self-assessmen

						A statement confirming that the 6 specific conditions (see below) for research activities involving human embryonic stem cells are met.
Does your research involve the use of human embryos?					Origin of embryos. Details on recruitment, inclusion and exclusion criteria and informed consent procedures. Confirm that informed consent has been obtained.	Copies of Ethics Approval. Informed Consent Forms + Information Sheets.
Does your research involve the use of human foetal tissues / cells?					Origin of human foetal tissues/cells. Details on informed consent procedures. Confirm that informed consent has been obtained.	Copies of Ethics Approval. Informed Consent Forms + Information Sheets.

Changes to be implemented

Successful proposals are expected to be **mature and ready** to be implemented.

No substantial changes are allowed between the proposal and the project. NO NEGO approach!

Optional changes:

Obvious errors or inconsistencies may be removed

Coordinator may correct minor shortcomings identified by the experts during evaluation

Necessary changes:

Ethics review or security scrutiny

Removal or replacement of a participant (if agreed with EDCTP)

Major shortcomings identified by the expert evaluators or the EDCTP secretariat during evaluation or grant preparation

Ethics Review and Security Scrutiny

The **results of the ethics review** and/or a **security scrutiny must be implemented** in the grant agreement

- Coordinator needs to update the ethics section in Anney I(DoA) to ensure that any 'ethics requirements' are met
- There may be 'ethics requirements' that need to be met before the grant can be signed
- The same applies for security scrutiny

Budget Table

- Currently: Excel file with budget summary and individual site budgets
- Individual budget items might need to be adjusted during Grant Preparation (e.g. remove tuition fees, add audit costs, etc.)
- Plan: Budget to be managed electronically in the future via EDCTPgrants system

Formal data and further information

- Authorized legal representative: proof needed
  → at the moment either through
  - screenshot of corresponding role (LSign) in H2020 Research Participant Portal or
  - legal documents (e.g. university constitution)

- Additional information needed:
  Address of legal entity
  Type of organization
  Registration number in country of origin
  VAT number

CV information of scientists involved must be up-to-date and complete (EDCTPgrants system)

Grant Agreement signature process

- The GA is send (by e-mail) to the Coordinator for signature by the legal representative.
- The GA is returned to EDCTP for counter-signing: the GA enters into force. **Project starts on first day of following month**.
- All Partners must sign the Accession Form within 30 days. The Coordinator must collect the Accession Forms and submit them to EDCTP.
- If one (or more) partners do not sign the Accession Form Coordinator must propose an alternative and submit an amendment request within 30 days.

Some helpful advice

- Coordinators: Get in touch with EDCTP Project Officer in charge right away! Frequent and open communication is a benefit.
- Keep deadlines set by EDCTP! If there are delays, **inform your Project Officer**!
- If someting is unclear – ask.

Some helpful advice

- Start early with preparation of Consortium Agreement; use an established Model Agreement
- Coordinators: Collect bank details from project partners as you must forward the EDCTP payment to them
- Coordinators: Prepare a ‚payment table' indicating how much pre-financing each partner will receive
- Payments can only be forwarded to partners once they have signed the Accession Forms

Further information

European IPR helpdesk:
https://www.iprhelpdesk.eu/

Fit for Health 2.0:
http://www.fitforhealth.eu/
(including answers to questions asked today, and future webinar on EDCTP2 project implementation and management)

Proposal submission tool:
https://www.edctpgrants.org/

Current calls:
http://www.edctp.org/funding-opportunities/calls/

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EURICE
EUROPEAN RESEARCH AND PROJECT OFFICE GMBH

Thank you!

Dr Claudia Schacht & Julia Buech | Eurice GmbH

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