Fit for Health 2.0

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

Clinical Trials in Horizon 2020

www.fitforhealth.eu

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04.04.2017 | WEBINAR

Dr Birte Kretschmer | Eurice GmbH

What is a 'clinical study/trial' in H2020?

Or more specifically: What needs to be described as a ‚clinical study/trial' in a H2020 proposal?

*A '**clinical study**' in the context of **Horizon 2020** means any **clinical research** involving a **substantial amount of work** related to*

- *the observation of,*
- *data collection from,*
- *or diagnostic or therapeutic intervention*

*on **multiple or individual** patients or study subjects.*

*This includes **different types of studies** (such as observational studies, interventional studies, and other) **as well as all phases** (Phase I – IV), and is not limited to clinical studies & trials in the sense of the* EU Clinical Trials Directive (2001/20/EC) and the Regulation (EU 536/2014).

A ‘clinical study/trial’ in H2020 can be…

- …the **core of** a project
- …or **part of** a project
- …included in a project designed **in response to a topic** that specifically asks for a clinical study, **or not**
- …a **highly relevant issue** for many proposals to be submitted **under Societal Challenge 1**

Why clinical studies?

The implementation of clinical studies in a collaborative, transnational approach has a **clear European added value**:

- easier to reach **sufficient patient numbers** (especially in the case of rare diseases and stratified treatment groups)
- **faster recruitment rates**
- **consolidated expertise**

In addition, clinical studies are the **ultimate validation step for any innovation in clinical Health Research**, bringing innovations to markets and patients – one of the main objectives of Horizon 2020.

Overview

1. **Proposal preparation**:
    a) Planning:
        1. Composition of the consortium
        2. Budget issues
        3. Time planning
    b) Writing
        1. Description of the study
        2. Ethics (ethics issues, section 5.1 and annexes)
        3. Changes between stage 1 and stage 2
2. **Implementation**:
    a) Management
    b) Monitoring

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Consortium

Composition of the consortium

- Clinical studies (CS) are always a challenge: **Experienced partners needed**!

- **2 different approaches**:
  - make study visible and living part of the project, full inclusion
  - Study as data source, outsource in (large) parts

- **Recruiting centers:** different options to be involved
- Inclusion of a **Contract Research Organisation** (CRO)

Consortium

How to involve a study site?

Study site included as	Pro's	Con's
Partner (Beneficiary)	Preferred option for the EC Clear rules Overhead Visibility	Large consortium Inflexible (e.g. recruitment, selection of sites)
Subcontractor (Art. 13 GA)	Small consortium High flexibility Simple administration Profit possible	Not applicable for core tasks Task must be identified in DoA -- not the subcontractor Procurement rules to be applied „best value for money" No overhead for beneficiary
In-kind contribution (patient data) provided by third parties against payment; (Art. 11 GA)	Small consortium Overhead can be claimed by 3rd party Unit costs or actual costs	Must be identified in DoA → inflexible No profit High documentation load (cost documentation as for beneficiaries) Requires prior agreement with beneficiary – prior to start of work, not necessarily prior to signature of GA
Affiliated entities and third parties with a legal link to a beneficiary; (Art. 14 GA)	Small consortium Overhead can be claimed by 3rd party	Must prove 'legal link' No profit

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Consortium

Inclusion of Contract Research Organizations (CROs)

- If CS is the **main activity of the project** → core CS expertise (e.g. study design, general regulatory expertise, study management & oversight) needs to be available in consortium

  BUT: subcontracting of specialized services e.g. for professional study monitoring from CROs possible

- If CS is just a **small part of the action**, i.e. if most of the research performed is preclinical activity, the clinical study might be subcontracted in its entirety.

Consortium

Inclusion of Contract Research Organizations (CROs)

- **'Academic CROs' exist** (e.g. ECRIN network):
  might be willing to become a beneficiary; in that case: full partners, i.e. involved from the planning phase on and active partners in study design;
  alternatively: provide guidance/support as part of an advisory board?

- Inclusion of a **commercial CROs:**
  as beneficiaries also possible but commercial CROs usually work 'for profit'
  → might not be willing to become a beneficiary
  → in these cases, subcontracting could be an option

  BUT: In most cases, only limited part of the action can be subcontracted

Budget

CS are even more prone to under-budgeting than ‚regular' H2020 projects

- Include all needs
- EU project budgeting is done by adding up of individual components, not by giving an overall total → profit margins are not allowed

Budget

Unit Costs

- Clinical studies are subject to the same legal provisions and guidance notes as other activities in H2020 projects. No special 'derogations' → with the exception of special **'unit costs'**

- Use of unit costs is **voluntary** (alternative to using actual direct costs)

Budget

Unit Costs

Based on Commission Decision C(2016) 7553[1] Unit costs are:

- a fixed reimbursement amount
- for each study subject enrolled
- in a given centre
- calculated according to a defined methodology[2]
- based on historical costs of the beneficiary/third party in last closed accounts
- for the entire funding period of an action

MUST READ!

[1]http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/unit_costs/unit_costs_clinical_studies.pdf

[2]*Described in detail in Annex 1 of the Clinical Study Template „Method to determine the unit costs" (= the only valid method!)*

Budget - How to calculate Unit Costs?

Per clinical study subject: Estimation of the resources:

- per task on the basis of the protocol,
- the same for all beneficiaries involved (applying unit costs).

Per beneficiary/third party: Calculation of costs based on its historical costs:

- recorded in its certified or auditable profit and loss accounts,
- for last closed financial year at the time of submission of the proposal.
- costs can vary between partners

How to calculate Unit Costs – direct cost categories

Table X.9: Unit cost declaration for (identifier, see 1.1)

Task, Direct cost categories	Resource per patient	Costs in year N-1 Benef.[a] 1 (short name)	Costs in year N-1 Benef.[a] 2 (short name)
Task No. 1 *Blood sample*			
(a) Personnel costs: - Doctors			
- Other Medical Personnel	*Phlebotomy (nurse), 10 minutes*	*8,33 EUR[b]*	*11,59 EUR[b]*
- Technical Personnel	*Sample Processing (lab technician), 15 minutes*	*9,51 EUR[b]*	*15,68 EUR[b]*
(b) Costs of consumables:	*Syringe*	*XX EUR*	*XX EUR*
	Cannula	*XX EUR*	*XX EUR*
	Blood container	*XX EUR*	*XX EUR*
(c) Costs of the medical equipment:	*Use of -80° deep freezer, 60 days*	*XX EUR*	*XX EUR*
....	*Use of centrifuge, 15 minutes*	*XX EUR*	*XX EUR*
(d) Services			
Task No. X ...			
...			
Total amount:		*XX EUR*	*XX EUR*

*The categories covered by the unit costs **exclude the travel and subsistence costs of patients or study participants**.*
*→ will be reimbursed on the basis of eligible costs actually incurred under the cost category **"other direct costs"**.*

Unit Costs - the component ‘personnel costs’

3 unique and <u>exclusive</u> personnel categories:

- Doctors
- Other medical personnel
- Technical personnel

No other personal category / calculation base for personal costs possible

(e.g. separate categories for 'nurses‘, 'study nurses' or 'pharmacists' do not exist)

Budget

- **Unit costs** and/or **actual costs***:* combination within one study is possible
  → to be decided by each partner / clinical site individually

  → **Exception:** for the **costs of personnel directly** assigned to the conduct of CS, each beneficiary or third party may only choose **one** of the forms
  NB: does not apply to personnel costs for horizontal tasks (e.g. study monitoring or coordination).

- Costs that are covered by unit costs **cannot** be declared as actual costs

- Unit costs have to be requested in the proposal → detailed and complete calculation must be provided with the "Template for essential information…"

Budget

Unit Costs

Advantages

- Ex-ante acceptance of unit costs = No need for time sheets and detailed tracking of resources used!

  Items audited: no. of patients enrolled & correctness of historical costs listed

- Consortia more realistic estimate their budget and time management for CSs.

Disadvantage

- NOT a flexible tool, amount of unit costs per patient is fixed in the GA.

  Unit cost modification only if: protocol change & change of estimation of resourced needed; error in cost identification for year N-1

Budget

Unit Costs – practical tips to minimize risks

- **Underestimation of costs involved**

Have an **experienced clinician** together with an experienced project manager set up your unit cost system. Plan **enough time** for several rounds of circulation and of feedback to the elements involved by all sites.

- **Loss of funds due to drop-outs**

Possible to divide into steps (e.g. recruitment + intervention one, intervention two, follow-up) → **establish sequential unit costs**

- **Loss of funds after audit**

Pay utmost attention that beneficiary/third party has used the accounting data of year N-1. **No cost estimates!** Mistakes in this step of the planning process may result in significant loss of funds for the respective site.

Time planning

Don‘t be over ambitious – be realistic!

Experience has shown that even among ‘regular’ FP7 projects ~50% of grants were not completed in time.
Proper time planning is even more of a challenge for clinical studies activities:

- Project start date ≠ start of the study… esp. if ethical approval still needs to be obtained
  (which is usually the case if a new/additional approval is needed for work under the project)
- Time for protocol development (proposal includes draft protocol only.. development of final protocol may take some time, esp. if initiated after start of the project as part of the work plan)
- Slow recruitment

Time planning

Don‘t be over ambitious – be realistic!

- **impossible to adjust** timelines or patient recruitment numbers during GA preparation or through amendments during project run time

- declared goal under Horizon 2020: **timely completion** of projects & **quick translation** of research results into application

→ No flexibility regarding duration – **project extensions can generally <u>not</u> be granted in H2020**
→ Non-compliance with expected timelines and recruitment estimates (significantly delayed key study milestones) might lead to **reduced EU contribution** or the **termination of the grant agreement**.

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Description of the Clinical Study

Where in the full proposal do I describe my study, and what's the appropriate amount of detail?

- **Description of the study:**
  - **Clinical Study Template** → *in standardized format, in great detail, one description per study*
  - proposal sect. 1 "Excellence" & 3 "Implementation" (part B) → *in condensed format, summarizing the essence, with cross references to the study template / Annex*

- **Consortium composition:**
  - proposal submission form (part A)
  - proposal sect. 3.3 "Consortium as a whole" (part B)
  - proposal sect. 4 "Participant description" (part B)

- **Indication of costs:**
  - proposal submission form (part A) AND **Clinical Study Template**

- **Description of ethical and regulatory aspects:**
  - proposal submission form (part A)
  - proposal sect. 5 "Ethics" (part B)

Proposal structure - Description of the CS

1. Excellence
   - 1.1 Objectives
   - 1.2 Relation to the work programme
   - 1.3 Concept and methodology
   - 1.4 Ambition
2. Impact
   - 2.1 Expected impacts
   - 2.2 Measures to maximise impact
     - Dissemination and exploitation of results
     - Communication activities
3. Implementation
   - 3.1 Work plan - Work packages, deliverables
   - 3.2 Management structure, milestones and procedures
   - 3.3 Consortium as a whole
   - 3.4 Resources to be committed
4. Members of the consortium
   - 4.1. Participants (applicants)
   - 4.2. Third parties involved in the project (including use of third party resources)
5. Ethics and Security
   - 5.1 Ethics
   - 5.2 Security

Page limit

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3 mandatory Ds!

Mandatory deliverables for H2020 clinical studies

1. **'First study subject approvals package'**
    a. Final version of the study protocol
    b. Registration number of clinical study
    c. Regulatory and/or ethics approvals

2. **'Midterm recruitment report'**
    to be scheduled for the time point when 50% of the study population is expected to have been recruited

3. **'Report on status of posting results' in the study registry(s)**

Description of the study: Template

Clinical study No.1

- 1.1 Identifier
- 1.2 Study design and endpoints / relevant guidance documents
- 1.3 Scientific advice / protocol assistance / communication with regulatory authorities / ethics committees
- 1.4 Subjects/population(s)
- 1.5 Statistic analysis planning and power calculation
- 1.6 Cumulative safety and efficacy information
- 1.7 Conduct (7 subheaders: *schedule with key study milestones, recruitment strategy, assignment of intervention, study management, monitoring, data and sample management, sponsor, committees, study medication, clinical centres*)
- 1.8 Orphan designation
- 1.9 'Unit costs per patient' for clinical trials / studies / investigations

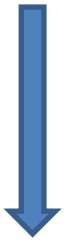
If no beneficiary intends to use unit costs, the unit costs section does not need to be completed!

Clinical study No.2

- 2.1 Identifier
- …

Description of the study: Template

- Each section must be shortly and concisely described.
- In case one or more issues do not apply to a particular study, please briefly explain/justify.
- Available on the Participant Portal - always download the most recent clinical study template (current version from Dec, 15 2016)!



http://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_en.pdf

Clinical Study template: mandatory for…

…2017 SC1 2-stage topics

- PM-02: New concepts in patient stratification
- PM-07: Promoting mental health and well-being in the young
- PM-08: New therapies for rare diseases
- PM-10: Comparing the effectiveness of existing healthcare interventions in the adult population

…2017 SC1 single stage topics

- HCO-07-2017: Global Alliance for Chronic Diseases (GACD) prevention and management of mental disorders
- PM-11-2017: Clinical research on regenerative medicine

For all other topics, if a proposal contains clinical studies:
you are welcome (but not obliged) to use the structure provided in the template (or an adapted version) and integrate this information in respective proposal sections

Ethics

Ethical approval

- Not required for proposal submission, but indispensable for uptake of activities
- H2020: very short time to grant!

If not in place already: Designate one person in charge who will drive protocol development and ethics applications.

Note: costs for related activities can only be reimbursed if they occur during project duration.

Ethics

Where in the proposal do I deal with ethical aspects of my planned work, and what's the appropriate degree of detail?

- Ethics issues table (part of proposal submission form)
- Proposal section 5.1 (Part B)
- "Supporting documents" (as annex)

Ethics

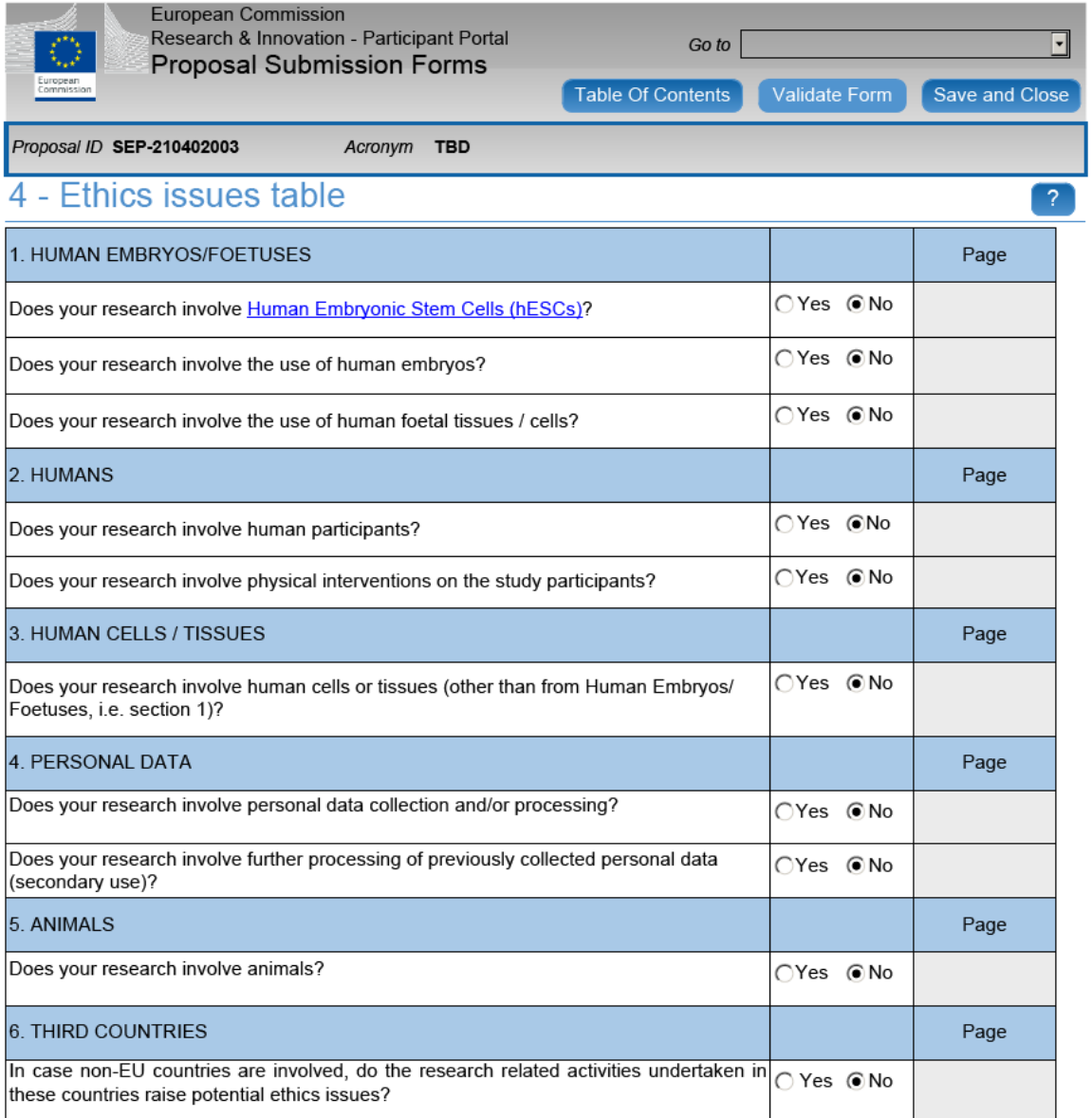
Ethics issues table online:

- collect from all partners

- have coordinator check / complete

THEN

optimally:
have one designated person in charge of all ethics aspects in your proposal
(…and project)



European Commission
Research & Innovation - Participant Portal
Proposal Submission Forms

Go to | Table Of Contents | Validate Form | Save and Close

Proposal ID **SEP-210402003** *Acronym* **TBD**

4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve Human Embryonic Stem Cells (hESCs)?	○ Yes ◉ No	
Does your research involve the use of human embryos?	○ Yes ◉ No	
Does your research involve the use of human foetal tissues / cells?	○ Yes ◉ No	
2. HUMANS		**Page**
Does your research involve human participants?	○ Yes ◉ No	
Does your research involve physical interventions on the study participants?	○ Yes ◉ No	
3. HUMAN CELLS / TISSUES		**Page**
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	○ Yes ◉ No	
4. PERSONAL DATA		**Page**
Does your research involve personal data collection and/or processing?	○ Yes ◉ No	
Does your research involve further processing of previously collected personal data (secondary use)?	○ Yes ◉ No	
5. ANIMALS		**Page**
Does your research involve animals?	○ Yes ◉ No	
6. THIRD COUNTRIES		**Page**
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	○ Yes ◉ No	

Ethics

Proposal section 5.1:

In section 5.1

In sub-sections of section 5.1 (one for each issue ticked… see guide)

In Annex „supporting docs“

5.1 Ethics

⚠ For more guidance, see the document "How to complete your ethics self-assessment"

If you have entered any ethics issues in the ethical issue table in the administrative proposal forms, you must:

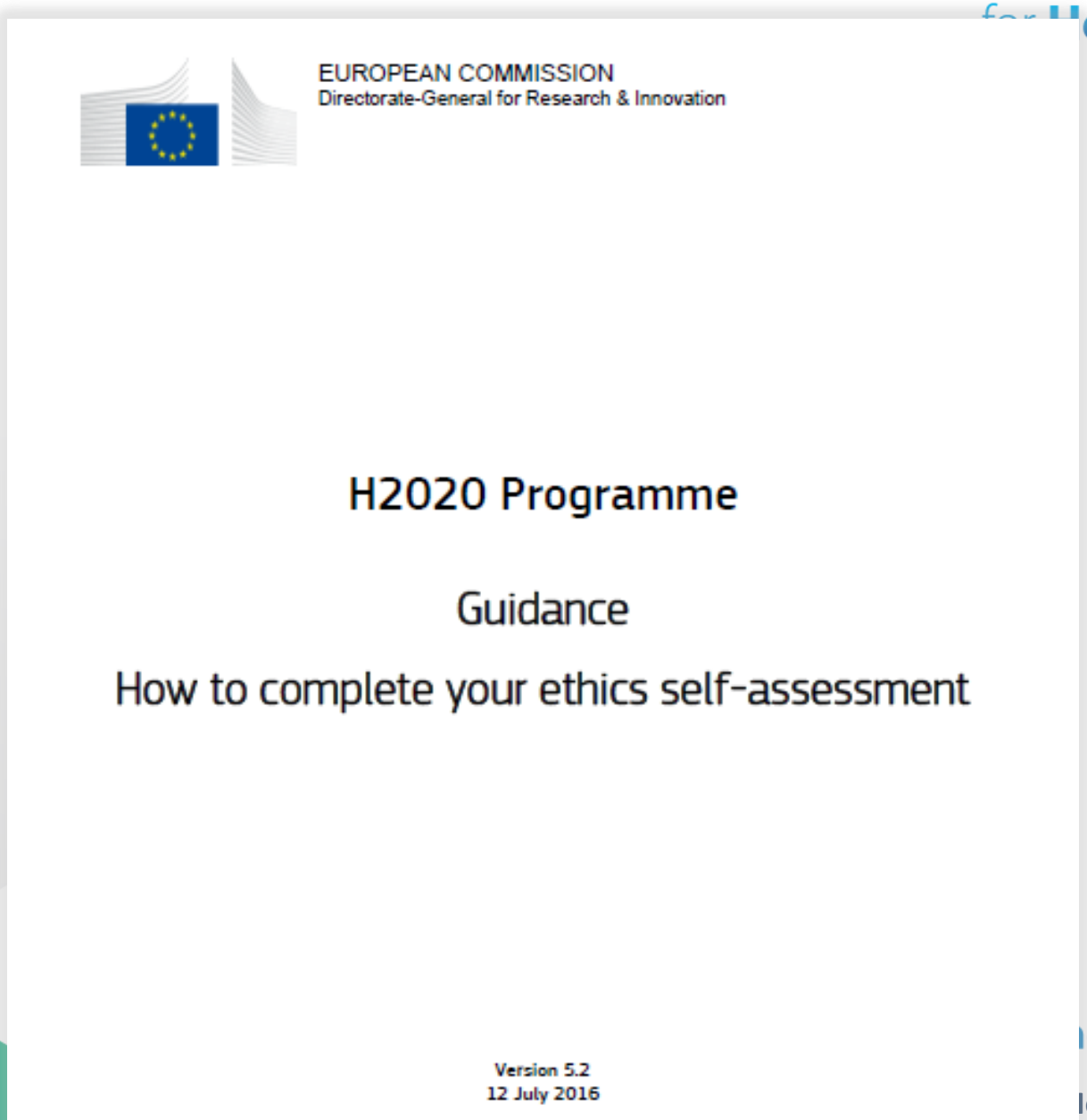
- submit an ethics self-assessment, which:
  - describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out;
  - explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:
    - research objectives (e.g. study of vulnerable populations, dual use, etc.)
    - research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
    - the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, misuse , etc.).
- provide the documents that you need under national law(if you already have them), e.g.:
  - an ethics committee opinion;
  - the document notifying activities raising ethical issues or authorising such activities

⚠ *If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned).*

⚠ *If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.*

Ethics

EC guide:


EUROPEAN COMMISSION
Directorate-General for Research & Innovation

H2020 Programme

Guidance

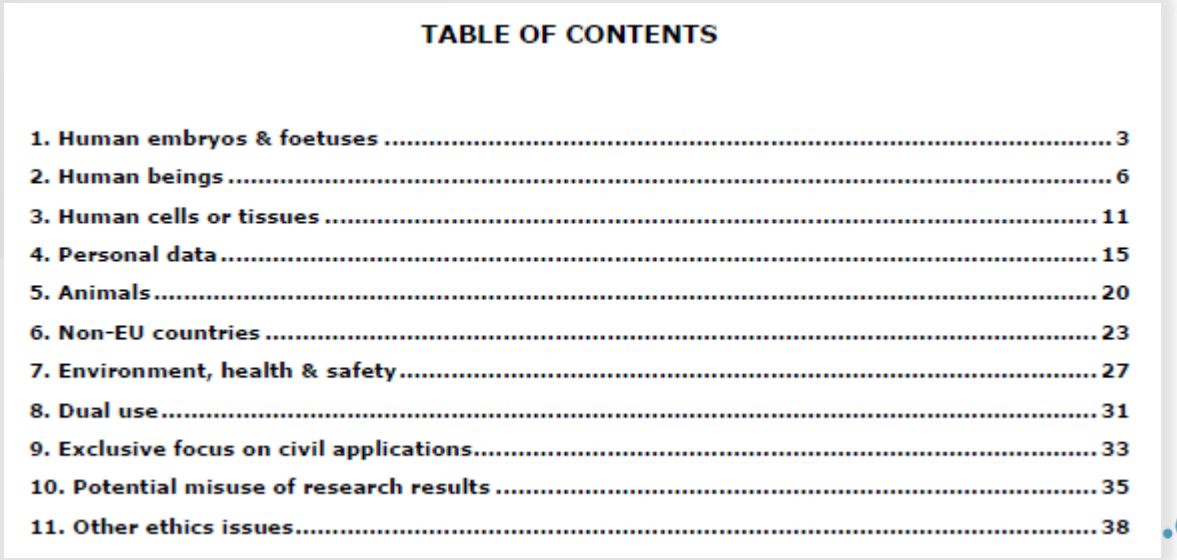
How to complete your ethics self-assessment

Version 5.2
12 July 2016

Ethics

„How to complete your ethics self assessment“

- Very helpful ‘how to’ guide
- Detailed step-by-step advice on how to deal with classic cases (what to describe, how to describe, what documentation to add)
- Ethics issues that are not covered must be dealt with outside the guide!



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Ethics

EC Guide "How to complete your ethics self-assessment"

For each item in checklist:

- **Info** to be provided **in section 5.1**
- **Documentation** to be provided in Annex **"supporting documents"**

Section 2: HUMANS		YES/ NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?		☐	☐		Confirm that informed consent has been obtained. **plus:**	Informed Consent Forms + Information Sheets. **plus:**
If	- Are they social or human sciences research?	☐	☐		Details of recruitment, inclusion and exclusion criteria and informed consent procedures.	Copies of ethics approvals (if required).
	- Are they persons unable to give informed consent children/minors)?	☐	☐		Details of your procedures for obtaining approval from the guardian/ legal agreement of the children o other minors. What steps will you take to ensure that participants are not subjected to any form of coercion?	Copies of ethics approvals.
	- Are they vulnerable individuals or groups?	☐	☐		Details of the type of vulnerability. Details of recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate appropriate efforts to ensur fully informed understanding of the implications of participation	Copies of ethics approvals.
	- Are they	☐	☐		Details of the age range.	Copies of ethics

Changes btw. proposal stage 1 and stage 2

Need to be explicitly addressed:

6. Preparation of a stage 2 proposal

If I am successful at stage 1, can I make changes to my proposal when submitting the full version to stage 2?

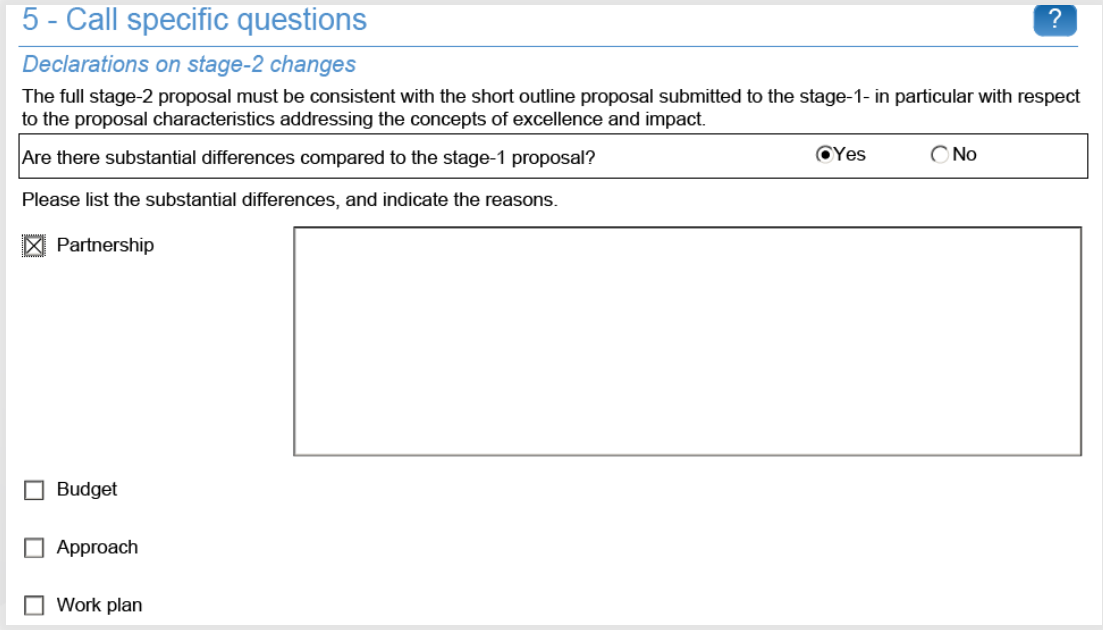
Section III.5.2 of the Horizon 2020 Grants manual: Section on: proposal submission and evaluation states that for two-stage submission schemes, 'the full proposal must be consistent with the short outline proposal and may not differ substantially'.

This means that changes are not recommended, but if absolutely necessary, they should be clearly explained and the evaluators will determine whether or not these changes are legitimate, and whether or not their insertion compromises the evaluator judgement made at stage 1.

Changes btw, proposal stage 1 and stage 2

Need to be explicitly addressed

- SC1 topics: 'Call specific questions' (Declarations on stage-2 changes)


5 - Call specific questions

Declarations on stage-2 changes

The full stage-2 proposal must be consistent with the short outline proposal submitted to the stage-1- in particular with respect to the proposal characteristics addressing the concepts of excellence and impact.

Are there substantial differences compared to the stage-1 proposal? ◉Yes ○No

Please list the substantial differences, and indicate the reasons.

☒ Partnership

☐ Budget

☐ Approach

☐ Work plan

- In addition:
  - highlight **at the very beginning** of your proposal body, or
  - highlight **in the proposal section where it the issue is mentioned** (e.g. consortium: on cover page; duration: where mentioned,...)

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Management

- CS is like a project within your project, with its specific set of actions, large number of individuals involved, need for harmonization, communication, coordination… → to be managed by a **highly experienced (clinical) partner or CRO**

- to be complemented by the **management of (and guidance for) ethical issues** → by an ethics expert (committee), and

- to be integrated into the H2020 project and regulatory framework → management of interfaces and H2020 project itself by a **classical project manager**

Management issues: working with patients

- **Patient availability / recruitment delays**
  - Estimates based on thorough feasibility analyses
  - Common challenges: higher drop-outs than expected, new competing studies, changes in legislation, changes related to personnel conducting the work…
  - Upcoming challenges **MUST** be reported quickly and fully

- **Management**
  - must **establish a trustful and close relationship with each site**
  - must **know and optimize workflows**, and reduce admin challenges to a min.
  - should be ready and able to react promptly
  - should ensure a **close monitoring** of recruitment numbers at all sites
  - must have **strategies in place** to compensate for lower than expected patient numbers, reaching the original targets in the original timeframe with the fixed budget

Monitoring

- **Official reporting in H2020**:
  - **every 18 months**, with the possibility of additional monitoring activities as the coo/management team sees fit to optimize implementation (e.g. interim reports)

- **Additional specific requirements for monitoring/reporting CS**:
  - three **mandatory deliverables** (EC)
  - **closer monitoring** and much more (basic) **reporting back** of information is definitely needed (e.g. monthly reporting of recruitment numbers, monthly TCs with all clinical partners,…)

Concluding remarks

- in H2020, CS are a **central issue in Health calls** (SC1)

- if CS is the main activity of the project
  → core CS expertise needs to be available within the consortium
  → provide comprehensive info on the CS during proposal stage (CS template!)

- be **realistic** with regards to: time planning, patient numbers, no. of recruiting centers (feasibility check), budget for the study
  → project extensions are not generally granted in H2020
  → max. EC contribution per project is fixed!

- **comply with** ethical principles, applicable international, EU and national law

Info and support

Sources of advice and support:

- FFH 2.0 support (FFH 2.0 CT factsheet, webinars, FAQs on CT,..)
- National Contact Points
- FAQs concerning the H2020 SC1 *Health, demographic change & wellbeing*

  https://ec.europa.eu/research/participants/portal/doc/call/h2020/sc1-pm-03-2017/1730125-faqs_v5_august2016_en.pdf

  Clinical Study Template
- Commission Decision C(2016) 7553 on Unit Costs
- EU IPR Helpdesk: www.iprhelpdesk.eu

Thank you!

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