CONTRACT

CONSENT IN A TRIAL & CARE ENVIRONMENT

SEVENTH FRAMEWORK PROGRAMME

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Call: FP7-HEALTH-2010-single stage

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Online Helpdesk Platform Publically Accessible

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Project Overview

Project Name: Consent in a Trial and Care Environment

Call Identifier: FP7-HEALTH-2010-single stage

Activity Code: HEALTH.2010.4.2-6 - Impact of EU legislation on health research

Contract No: 261412

Partners: Custodix (Custodix), Interdisciplinary Centre for Law & ICT– K.U.Leuven (KULeuven), Leibniz Universität Hannover (LUH), Technological Education Institution of Crete (TEIC), Universität des Saarlandes (USAAR)

Document History

Version	Date	Author/Editor	Description/Comments
0.1	14 Sept	Cédric Vansuyt	Initial Version
1.0	31 Sept	Brecht Claerhout	Final

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Table of Contents

1 Purpose of this Document

This document provides a short overview of the informed consent helpdesk platform that was made publicly accessible in September 2012. This helpdesk is the final deliverable for WP5 of CONTRACT: “D5.2 Online helpdesk platform publically accessible (M24)”.

The helpdesk platform is hosted on the website of the Center of Data Protection (CDP), an independent non-profit organisation founded by representatives of LUH and Custodix.

The helpdesk can be reached at http://www.privacypeople.org.

2 Description of the Helpdesk

2.1 Content

The homepage of the CDP-website (http://www.privacypeople.org) is shown in Figure 1.

Figure 1: CDP front-page with CONTRACT related "Informed Consent" resource-menu visible

The informed consent component consists of 5 components:

1. Basics of Informed Consent:
2. Guidelines
3. National Legislation
4. Case Studies
5. Informed Consent Generator

These components are briefly described below.

2.1.1 Basics of Informed Consent

In this section the background and history of informed consent is sketched. Also the different terms that are used in the context of informed consent are defined, and the preconditions for informed consent are listed.

2.1.2 Guidelines

Part of the CONTRACT project (WP3) was to gather information regarding the practical usage of informed consent, especially regarding good practices of acquiring informed consent, the content of the documents used in the context of informed consent and how to handle informed consent once it has been given or declined by the patient. This information is encapsulated in the guidelines-component on the helpdesk website.

The information is summarised in easily searchable online content, hereby forming a reference point for people/projects that have to deal with informed consent.

2.1.3 National legislation

This section contains national legal information of several countries on informed consent. It is described how the national legislation defines consent for care, trial participation and data processing.

2.1.4 Case studies

Case studies are examples of projects in which complex consent related issues have arisen. In this section future case studies will be described.

2.1.5 Informed Consent Generator

The informed consent (IC) Generator is a tool that helps the organisers of a clinical trial to compose IC forms for the intended patients of the trial (or their guardians). The user is guided through a wizard style questionnaire which captures the specific characteristics of the trial that influence the content of an IC form. The template IC forms, produced by the IC generator, are tailored to the specific needs of the end-user. They do not only contain template “legal text”, but also include guidelines and tips for creating correct (legal) IC form, ready to be used in the trial.

2.1.5.1 Questionnaire

The questionnaire is a list of questions, each providing one or more possible answers. For this, Custodix used modules from an in-house data capture product and extended them so that they can cope with conditional rendering, meaning that certain questions will only be asked (or shown) when a certain answer to a previous question was selected or not, hereby eliminating contradictions in the answers provided.

2.1.5.2 Results

The outcome of the generator is a list of XML- and RTF-documents (Figure 2) containing sections that have text fragments (tips, explanations, descriptions or form text) in them. XML (Extensible Markup Language) is a good starting point for a transformation into a final (usable by an end-user) document. This intermediary XML format allows the IC forms to be rendered into whatever document format needed without changing the core generator, leaving possibilities for the future. The provided RTF (Rich Text Format) document is rendered from this XML-document. Most word processing software implementations support RTF format importing and exporting and/or direct editing.

Appendix A shows a generated IC form in detail.

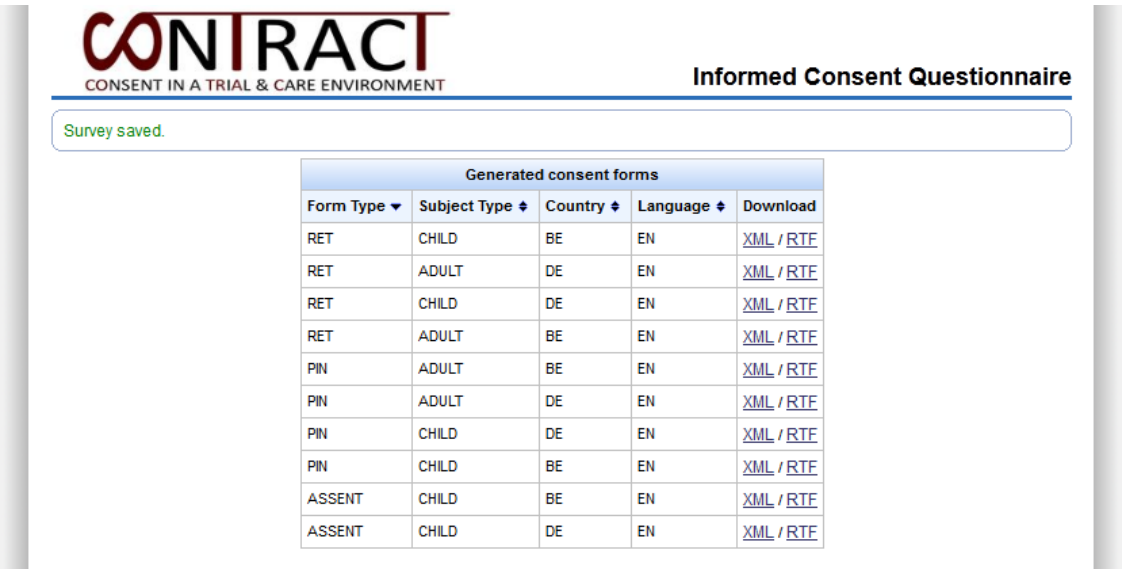

Figure 2: List of generated IC forms.

2.2 Sustainability

The helpdesk platform is a Content Management System (CMS) driven web application. Content within such a CMS can be managed with almost no technical skill or knowledge. Therefore the helpdesk can be easily updated and maintained by non-technical people.

The CMS-origin of Joomla! not only makes it easy to maintain the content of the website, so content can be added, moved and removed very effortlessly, but it also provides a complete user management system making it easy to give people different privileges regarding the access to certain pages, not just in the context of maintaining the website (i.e., editing the layout or the content), but also for using it.

The templates for the IC forms, generated by the IC Generator, are also easily modifiable. The rules defining which text fragments must be shown, where in the form and in which way, are contained in an Excel-file. Non-technical people are able to modify this file in order to change the text that will be generated by the IC Generator.

3 Summary

The final deliverable of WP5 of CONTRACT, D5.2, is a public informed consent helpdesk website. In order to guarantee sustainability beyond the CONTRACT project end, the informed consent helpdesk has been harboured at the Center for Data Protection, a Belgian non-profit organisation.

This document gives a very short overview of the different information sources and tools made available through that website, which can be visited on http://www.privacypeople.com/ .

Appendix A. Resulting IC Form

Depending on the given answers in the questionnaire, the IC Generator creates a set of IC forms. These forms are derived from a set of basic IC forms to which the IC Generator adds certain content that is defined by certain rules. These rules are of the form “when question A is answered with answer X, then add this paragraph in section Y”.

There are different types of paragraphs that can be added to the form:

- **Form text**: text that will be literally used in the final consent document (but could still need some editing).
- **Descriptions**: placeholders for descriptions that still need to be provided by the organisers (e.g. the purpose of the trial).
- **Explanations**: text that provides an explanation to why a certain section is in the final IC form. These could be excerpts from a law, or just additional information for the person that should sign the IC form. This text is displayed in a gray box in italic.
- **Tips**: these are guidelines or tips that inform the people issuing the IC forms about certain actions they might have to undertake in order for the form to be valid (e.g. when collecting data in a trial, this can require a notification to a national protection authority). These guidelines are displayed in a blue box.

When all rules are evaluated, the basic IC form is completed with a set of paragraphs, and the result is shown to the user. The resulting IC forms are returned to the user in two ways: in xml-format and as an rtf-file. The reason why these formats are chosen is simple: xml is a structured format that allows easy transformation to any given format, and rtf is a rich text format that can be opened in almost every text editor (e.g., Word).

Figure 3 shows a resulting IC form in XML-format. The tags surrounding the paragraphs indicate the paragraph-type.

```
<?xml version="1.0" encoding="UTF-8"?>
- <ICF name="PIN_ADULT-BE_EN">
  - <head>
      <section title="Informed consent for prospective interventional clinical trial" id="S.HEADER.TITLE"
        description="Document title"/>
      <section title="Informed consent form for participation in [name trial]" id="S.HEADER.SUBTITLE"
        description="Document subtitle"/>
    - <section title="Invitation" id="S.HEADER.INVITE" description="Invitation">
        <text>Dear Sir/Madam, You suffer from[...]. We would like to invite you to take part in our research study (=
          clinical trial) for treatment of [...]. The clinical trial has already been presented to you by [physician /
          counselor]. It has been developed by [investigator/sponsor/hospital]. It is coordinated by [physician /
          research centre / hospital]. Your decision to participate in this study is entirely voluntary. It is your choice
          whether to participate or not. If you choose not to consent, all the services you receive at this clinic will
          continue and nothing will change. You may also choose to change your mind later and stop participating,
          even if you agreed earlier, and the services you receive at the clinic will continue. In order for you to enroll
          in this trial, you need to sign the informed consent form which is attached to this information sheet as 'Part
          II: certificate of consent'. In addition, study staff will also discuss study participation with you. This leaflet
          has two parts: - The information sheet where you can find all information about the clinical trial you will
          participate in and the data of you that will be processed; - The actual certificate of consent where you are
          requested to sign if you agree to the participation in the trial. By signing the informed consent form you
          agree to 1) the participation in this trial and you confirm that you understand the goal of the trial, how it
          may impact you and what your rights are. 2) the collection and further processing of your personal data
          and you confirm that you understand the aims of processing and your rights as a trial subject. You do not
          have to decide today whether or not you will enroll in the trial. Before you decide, you can talk this through
          with any person of your choosing. When in the text or the oral explanations given certain terms or words
          are used which you do not understand, please do not hesitate to ask for more information or further
          explanation. If you have questions later, you can address them to the contact points as mentioned at the
          end of this information sheet.</text>
      </section>
    </head>
  - <body>
      <!-- PART 1: INFORMATION SHEET -->
    - <part title="Information sheet" id="INFORMATION_SHEET" description="information part of the informed consent
      form">
      - <section title="Participants to the trial" id="S.PART" description="Participant selection">
          <explanation>For vulnerable patients (minors, but also other persons legally incapable of consenting) you
            should explain why it is necessary to include them in a trial. Additionally you should emphasize that
            their participation is only approved because their personal benefits outweigh the risks of the trials. Only
            under exceptional circumstances the Clinical Trials Directive allows clinical trials where the personal
            benefits do not outweigh the risks. Such trials should always directly benefit the group of patients
            participating in the clinical trial and concern research essential to the validation of data obtained in
            clinical trials on persons able to give consent, not children, or to validate data obtained via other
            research methods. Additionally, it should always relate to either a clinical condition from which the
            minor suffers or be of such a nature that it can only be carried out on minors. In any case all
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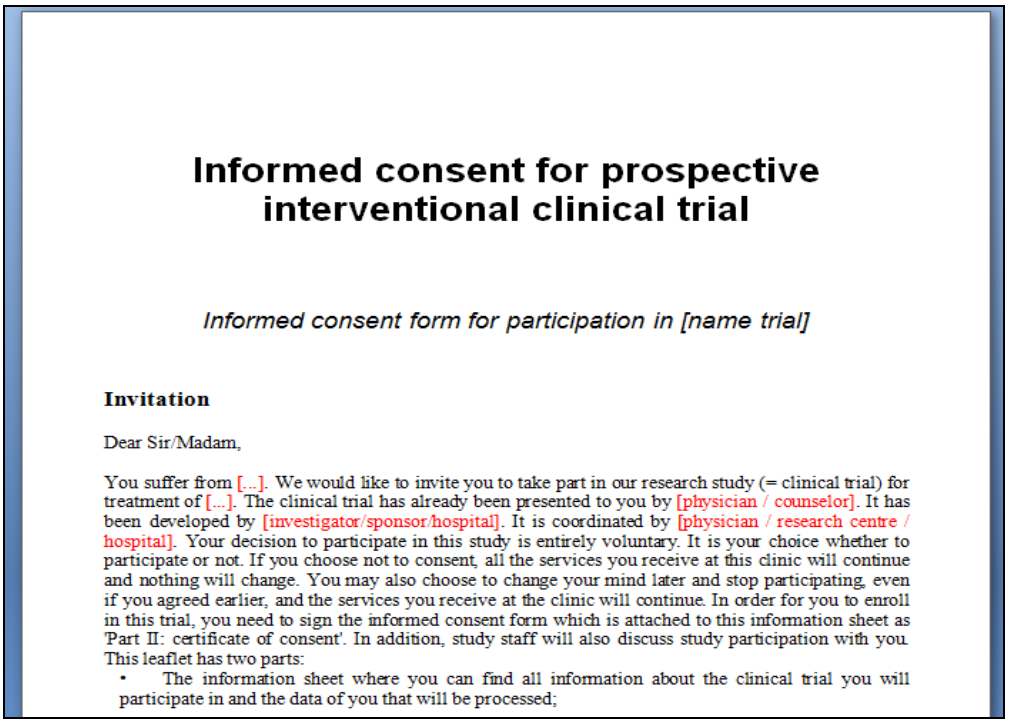
Figure 3: Resulting IC form in XML-format



Informed consent for prospective interventional clinical trial

Informed consent form for participation in [name trial]

Invitation

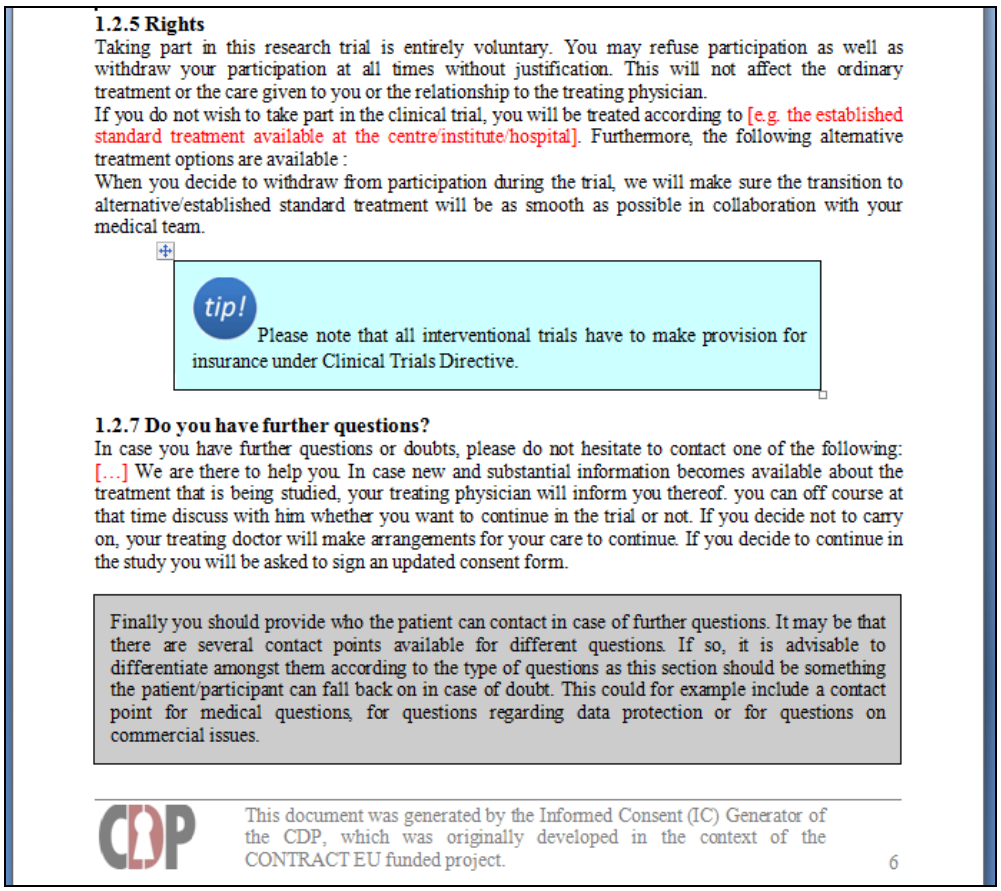
Dear Sir/Madam,

You suffer from [...]. We would like to invite you to take part in our research study (= clinical trial) for treatment of [...]. The clinical trial has already been presented to you by [physician / counselor]. It has been developed by [investigator/sponsor/hospital]. It is coordinated by [physician / research centre / hospital]. Your decision to participate in this study is entirely voluntary. It is your choice whether to participate or not. If you choose not to consent, all the services you receive at this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you receive at the clinic will continue. In order for you to enroll in this trial, you need to sign the informed consent form which is attached to this information sheet as 'Part II: certificate of consent'. In addition, study staff will also discuss study participation with you. This leaflet has two parts:

- The information sheet where you can find all information about the clinical trial you will participate in and the data of you that will be processed;

Figure 4: Example of an IC form in RTF-format

Additional styling can be indicated by using html-snippets, which the IC Generator is able to interpret. This way the RTF-file can be styled according to the user's preferences. Figure 4 shows the front page of a RTF-file. An example of explanations, tips and plain text is shown in Figure 5.



1.2.5 Rights

Taking part in this research trial is entirely voluntary. You may refuse participation as well as withdraw your participation at all times without justification. This will not affect the ordinary treatment or the care given to you or the relationship to the treating physician.

If you do not wish to take part in the clinical trial, you will be treated according to [e.g. the established standard treatment available at the centre/institute/hospital]. Furthermore, the following alternative treatment options are available :

When you decide to withdraw from participation during the trial, we will make sure the transition to alternative/established standard treatment will be as smooth as possible in collaboration with your medical team.

tip! Please note that all interventional trials have to make provision for insurance under Clinical Trials Directive.

1.2.7 Do you have further questions?

In case you have further questions or doubts, please do not hesitate to contact one of the following: […] We are there to help you. In case new and substantial information becomes available about the treatment that is being studied, your treating physician will inform you thereof. you can off course at that time discuss with him whether you want to continue in the trial or not. If you decide not to carry on, your treating doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Finally you should provide who the patient can contact in case of further questions. It may be that there are several contact points available for different questions. If so, it is advisable to differentiate amongst them according to the type of questions as this section should be something the patient/participant can fall back on in case of doubt. This could for example include a contact point for medical questions, for questions regarding data protection or for questions on commercial issues.

Figure 5: IC Form content in RTF-format