

DUC profile (using CCE statements) completion tool guide.

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1.0 Introduction

Common Conditions of use Elements (CCEs) are intended to be a summary profile (or “access policy”) for a resource, regarding the conditions placed on its’ use. There are 20 “CCE Terms” intended to cover common areas. By refining these broad categories, using free text and setting permissions, a profile (or “access policy”) can be generated that allows screening of proposed uses of a resource for compatibility with those permitted. While it is possible to use the CCE statements by themselves, the Digital Use Conditions (DUC) structure, provides a convenient way to store them alongside some basic details of the resource to which they relate. The tool that this user guide relates to, is intended to assist the user in constructing such a DUC profile using CCE statements for their resource.

2.0 Using the DUC profile (using CCE Terms) profile tool

The tool can be accessed at <https://ducejprd.le.ac.uk>. The home page gives the user the option of either creating a new profile (via the create profile button) or reviewing a previously constructed profile (using the view profile button).

The screenshot shows the homepage of the 'DUC Profile Creator Using CCE'. The header includes the 'DUC' logo and navigation links: HOME, CREATE PROFILE, YOUR PROFILES, UPLOAD PROFILE, and LEARN MORE. The main content area is titled 'Welcome to the Digital Use Conditions Profile Creator' and explains the tool's purpose. It features two columns: 'Digital Use Conditions (DUC)' and 'Common Conditions of use Elements (CCE)'. Below these columns are buttons for 'Create Profile', 'Your Profiles', 'Upload Profile', and 'Learn More'. At the bottom, there are logos for IRDiRC, University of Leicester, and the European Joint Programme on Rare Diseases.

2.1 Creating a new profile

Clicking the “create profile” button takes the user to the 5 profile creation pages. These can be navigated through either by using the next and previous buttons or by clicking the number in the white circle at the top of the screen corresponding to the required page.

In each page, mandatory fields are marked by a red asterisk next to the respective information box. Each one of these **MUST** be completed to generate a valid profile.

2.1.1 Section 1 – User Information.

This section collects information regarding the user who is responsible for the profile. The Email section records the Email of the user, which is used to store and retrieve saved profiles but **is not** included in the profile itself. The First and Surname are optional fields.

The screenshot shows the 'User Information' form, which is the first step in the 5-page profile creation process. The form is titled 'User Information' and includes a sub-header 'Please enter details of the person creating the DUC profile'. It contains three input fields: 'Email:' (marked with a red asterisk), 'First Name:', and 'Last Name:'. Below the fields is a note: 'All fields marked with * are mandatory.' and a green 'Next' button.

2.1.2 Section 2 - Profile information.

The user can assign a name to the profile as well as a version number, should the user wish to provide one. However, only the profile name is mandatory.

The screenshot shows the 'Profile Information' form, which is the second step in the five-step process (1. USER, 2. PROFILE, 3. RESOURCE, 4. USE STATEMENTS, 5. SUMMARY). The form has two main input fields: 'Profile Name: *' with a placeholder 'Please create a name for this profile' and 'Profile Version:' with a placeholder 'Please create a version for this profile e.g. 6.8.1'. A note below the fields states 'All fields marked with * are mandatory.' At the bottom of the form are two green buttons: 'Previous' and 'Next'.

2.1.3 Section 3 – Resource Information.

This section is used to collate information regarding the resource itself. It is only necessary to enter the resource name in this section. However, the user can choose to provide the following additional information for the resource to which the CCEs relate.

The screenshot shows the 'Resource Information' form, which is the third step in the five-step process. The form includes several input fields: 'Resource Name: *' (placeholder: 'Please enter resource name.'), 'Resource Description:' (placeholder: 'Please enter resource description.'), 'Data Level of Resource:' (a dropdown menu with a blue 'i' icon and placeholder: 'Please select resource data level'), and 'Points of Contact:' (placeholder: 'Please enter contact email and press enter.'). Below these is a section for 'Organisations related to Resource:' with two input fields for 'organisation name' and 'organisation role', and a plus button labeled 'Add More Organisations'. A note at the bottom states 'All fields marked with * are mandatory.' At the bottom of the form are two green buttons: 'Previous' and 'Next'.

The description allows the user to provide a short free text description of the resource. The data level of a resource provides a drop-down menu allowing the user to assign the resource to the predefined data types. The different resource types are defined in the CCE explanations document, or alternatively, descriptions can be accessed by clicking on the blue “i” icon. The point of contact box should be used to record the Email of the person who is the best person to contact for further details about the resource and its use. This may not be same person, as the user who has entered the profile. The user can also optionally enter the name of one or more organisations that are related to the resource and assign their roles in the bottom two boxes. Multiple organisations can be added using the plus button to the right of the organisation’s role box.

2.1.4 Section 4 - Common Conditions of use Elements

This section collects an overview of the use conditions for the resource, which any potential user must comply with. These are not intended to be a detailed representation but rather a summary that can be used to screen resources where the “queriers” proposed use is fundamentally incompatible with those permitted. For example, a user wanting to use a resource in a prohibited geographical area. The user must add at least one CCE statement per profile, although multiple conditions can be entered.

The screenshot displays the 'DUC Profile Creator Using CCE' web application. The interface features a top navigation bar with the 'DUC' logo and links for 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE'. Below this is a progress indicator with five steps: 1. USER, 2. PROFILE, 3. RESOURCE, 4. USE STATEMENTS (currently active), and 5. SUMMARY. The main content area is titled 'Condition of Use Statements' and includes a sub-header: 'Create at least one Condition of Use Statement using the following format: Considering the stated [conditionTerm], this form of use is set by [rule], and applies to the [scope] of the asset.' The form contains two statement entries. 'Statement 1' has 'Use Condition' set to 'Geographical area', 'Rule' set to 'Obligated', and 'Scope' set to 'Whole of Resource'. Its 'Condition Detail' is 'UK'. 'Statement 2' has 'Use Condition' set to 'Use by a commercial entity', 'Rule' set to 'Permitted', and 'Scope' set to 'Whole of Resource'. Its 'Condition Detail' is 'Research use only'. A green '+ Condition' button is located below the statements. At the bottom, there is a 'Comments Regarding CCE:' text area, a note stating 'All fields marked with * are mandatory', and 'Previous' and 'Next' buttons.

The “CCE Statements” box has a drop-down menu containing the CCE terms covering broad topics of use commonly used to describe the permitted use of resource. The CCE Conditions of Use are defined in the CCE explanations document

Once a specific CCE term has been chosen then a “RULE” must be selected from the drop-down menu. The system will present the applicable rules from the 4 stated on the next page, based on the CCE term.

THE RULE SHOULD APPLY TO THE CCE ONLY AND NOT ANY ASSOCIATED CONDITION ELEMENTS.

For example, a use may be permitted but **not** have compulsory use conditions that apply if a resource is used in that way. The “PERMITTED” rule should be used in this instance as the resource may be used in that fashion but it is not compulsory. The “OBLIGATED” rule should be used where a resource **must** be used in a certain way, for example, a resource **must** only used in relation to a specific disease, hence the CCE term “disease specific use” would be selected and the “OBLIGATORY” rule would be set.

CCE RULES

- **FORBIDDEN** – The stated Use/Requirement **must not** occur for some or all of the resource (as per the Scope).
- **PERMITTED** – The stated Use/Requirement is **may** occur for some or all of the resource (as per the Scope).
- **OBLIGATED** – The stated Use/Requirement is **must** occur for some or all of the resource (as per the Scope).
- **NO REQUIREMENTS** – There is **no obligation** to meet this CCE term during use.

SCOPE

Once a CCE term and its RULE has been defined for a resource, then the user must define the “SCOPE” (or extent) to which the CCE term applies to that resource. They can select from the following two self-explanatory options.

- **WHOLE OF RESOURCE.**
- **PART OF RESOURCE.**

USE CONDITION PARAMETER.

The condition parameter box is a free text box that allows the user to add additional information that relates to the CCE term selected that is not able to be captured as part of another combination of “CCE Term”, RULE” and “SCOPE”. For example, a “PROFIT MOTIVATED USE” may be subject to participant consent. As “participant consent” is not a CCE term in its own right but is a condition detail of the whole CCE statement (“profit motivated use is permitted for part of the resource, subject to participant consent”)

It should be noted that adding a condition detail via free text **must not** introduce a duality in a CCE statement, for example use inside the EU is permitted but use outside the EU must be subject to GDPR. Similarly, the free text **must not** introduce any exceptions, for example use as a control is permitted “except for clinical care”. Such terms should be split such that the exceptions are separated out into CCE statements that state uses that are forbidden.

The combination of a CCE Term (conditionTerm), RULE and scope plus any additional “CONDITION PARAMETER” forms one complete “USE STATEMENT”. Although there is no logic between “USE STATEMENTS” in the same profile (such as all conditions should be met), profiles can still become complex to unravel and in such circumstances, the user is advised to produce two or more simpler profiles with fewer conditions. An example may be producing one profile for commercial users and another for non-commercial users (by forbidding the CCE term for “use by a commercial entity in the latter profile and permitting it in the former). Where this is the case then the user should complete separate profiles for each combination of “USE STATEMENTS”. Although each use statement in a profile is intended to be independent, the user is advised to consider the difficulty in determining the

intended meaning from a profile, and as such they should consider how probable it is that this could be determined by someone unfamiliar with the profile.

N.B. It should be noted that the user only needs to define a “use Statement” for “CCE Terms” they choose to. They may choose to complete one or more use statements per CCE term, or alternatively make no statement at all regarding a given CCE term

2.1.5 Section 5 - Summary

This section allows the user to check the profile in its entirety. A summary of the inputted data is shown on a section-by-section basis and any sections where compulsory information has not been entered are highlighted red. These can be edited by clicking on the respective green pencil in a box icon. Once all the required information has been entered and the user has reviewed the profile, they can submit the information and the system will generate a summary file that can be saved or downloaded. If the user chooses to download the profile, they can choose to do so in either Excel or JSON format. In the event the user chooses to download the profile, it will not be saved on Leicester’s servers and no record will be kept. Only if a user chooses to save a profile, will it be available to them later when they log back in with the same email address they entered when they made the profile.

Summary
Please review your DUC profile.

User Information [Edit]

Email	sg307@le.ac.uk
First Name	Spencer
Last Name	Gibson

Profile Information [Edit]

Profile Name	Test 1
Profile Version	0.1

Resource Information [Edit]

Resource Name	Test 1
Resource Description	Metatdata relating to the Leicester medical data sources
Data Level of Resource	Dataset
Points of Contact	sg307@le.ac.uk

Use Statements [Edit]

Statement No	Use Condition	Condition Detail	Rule	Scope
1	Geographical area	UK	Obligated	Whole of Resource
2	Use by a commercial entity	Research use only	Permitted	Whole of Resource

[Previous](#) [Submit](#)

PLEASE NOTE

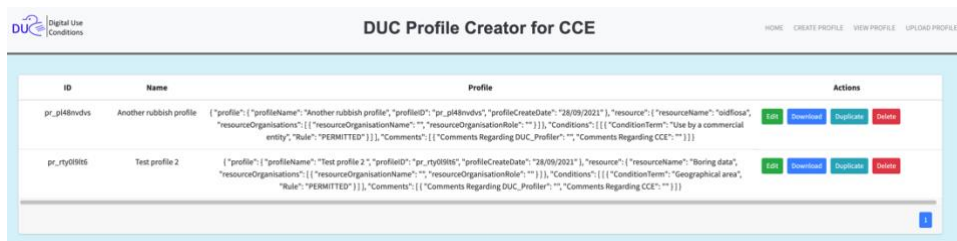
Currently, it is the responsibility of the end user to check the final profile generated for inconsistent or contradictory CCE Statements.

3.0 Reviewing a previously created profile

This section assumes that you have created at least one DUC profile (using CCE statements) previously and have chosen to save it in the tool. To do this you will need to have provided an Email address, which you will use to retrieve your previously stored profiles. You will need to choose view profile from the home page and enter the email address exactly as you typed it when you saved the profile. The system will send you a hyperlink via email that you can use to access your saved profiles. Please note that this may be re-directed to your Spam/Junk Email box.

Once you have the link, you should be able to access your previously stored profiles simply by clicking it. ***Please note that as no further user validation is performed after clicking this link, anyone with it will be able to access the stored profiles and will have full editing rights.***

Clicking the link will open the profile viewer screen. This will present a brief overview of all the profiles associate with the user. This view will show you a unique ID associated with each profile, the name associated with that profile, a computer readable summary of the profile and buttons that will allow you to “Edit”, “Download”, “Duplicate” and “Delete”. These buttons can be clicked to access the stated functions.



The screenshot shows the 'DUC Profile Creator for CCE' web application. At the top, there is a navigation bar with links: HOME, CREATE PROFILE, VIEW PROFILE, and UPLOAD PROFILE. Below the navigation bar is a table with four columns: ID, Name, Profile, and Actions. The table contains two rows of profile data. The first row has ID 'pr_p48mdivs', Name 'Another rubbish profile', and a JSON-like profile summary. The second row has ID 'pr_ry0986', Name 'Test profile 2', and another JSON-like profile summary. Each row has four action buttons: Edit (green), Download (blue), Duplicate (teal), and Delete (red).

ID	Name	Profile	Actions
pr_p48mdivs	Another rubbish profile	{ "profile": { "profileName": "Another rubbish profile", "profileID": "pr_p48mdivs", "profileCreateDate": "28/09/2021", "resource": { "resourceName": "soilflow", "resourceOrganisation": { "resourceOrganisationName": "", "resourceOrganisationRole": "" }, "Conditions": { "ConditionTerm": "Use by a commercial entity", "Rule": "PERMITTED" } }, "Comments": ["Comments Regarding DUC_Profile", "", "Comments Regarding CCE", ""] } }	Edit Download Duplicate Delete
pr_ry0986	Test profile 2	{ "profile": { "profileName": "Test profile 2", "profileID": "pr_ry0986", "profileCreateDate": "28/09/2021", "resource": { "resourceName": "Boring data", "resourceOrganisation": { "resourceOrganisationName": "", "resourceOrganisationRole": "" }, "Conditions": { "ConditionTerm": "Geographical area", "Rule": "PERMITTED" } }, "Comments": ["Comments Regarding DUC_Profile", "", "Comments Regarding CCE", ""] } }	Edit Download Duplicate Delete

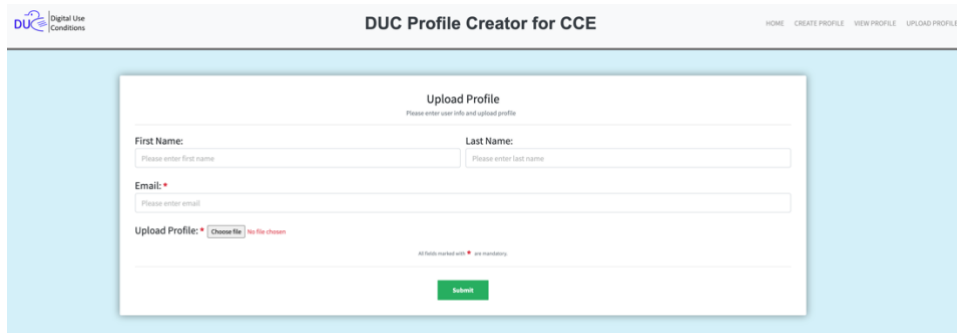
The “Edit” button takes the user to the same summary page as described in the create profile section, with the same ability to review and edit the profile (by clicking the green pencil icon).

The “Download” button creates a computer readable version of the profile that can either be copied directly from the pop-up window or saved using the “download” button. Again, the profiles can be downloaded in either JSON or Excel format.

The “Duplicate” and “Delete” buttons are self-explanatory. The duplicate function is useful when using one profile as a template to construct another (similar) profile, which can then be and saved under a different name

3.1 Uploading a Previously generated profile.

Finally, it is possible to “upload” a previously generated profile using the “upload profile” button. This requires the user to enter their Email, to allow any profile to be saved and retrieved later. From this screen it is possible to upload a profile previously generated by the tool that is in either JSON or Excel format. Once uploaded a profile can be modified (see section 2.1.5) as with any other profile created on the system.



The screenshot shows the 'Upload Profile' form within the 'DUC Profile Creator for CCE' application. The form is titled 'Upload Profile' with a subtitle 'Please enter user info and upload profile'. It contains four input fields: 'First Name' (placeholder: 'Please enter first name'), 'Last Name' (placeholder: 'Please enter last name'), 'Email' (placeholder: 'Please enter email', marked as mandatory with a red asterisk), and 'Upload Profile' (placeholder: 'Choose file', marked as mandatory with a red asterisk and a red message 'No file chosen'). A green 'Submit' button is at the bottom. A note at the bottom of the form states 'All fields marked with * are mandatory'. The top navigation bar includes links for 'HOME', 'CREATE PROFILE', 'VIEW PROFILE', and 'UPLOAD PROFILE'.