

DUC profile completion tool guide.

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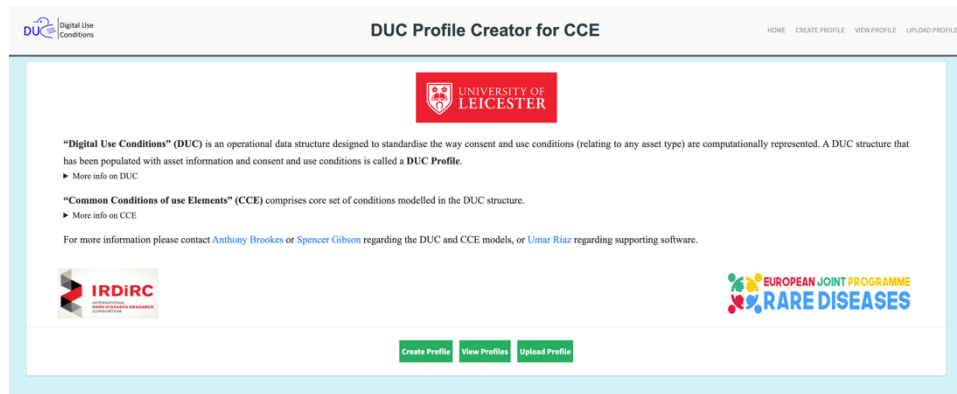
1.0 Introduction

The Digital Use Conditions (DUC) structure provides a convenient way to store a summary of use conditions alongside some basic details of the asset 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 compatible condition terms to construct use statements for their asset.

An asset is the entity (either physical or digital) to which the profile refers. This could for example be a collection such as a biobank, an online database, or a single record or sample.

2.0 Using the DUC profile tool.

The tool can be accessed at duc.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). Further information on Digital Use Conditions and the DUC tool can be found by clicking the “Learn More” button.



2.1 Creating a new profile.

Clicking the “create profile” button takes the user to the 6 profile creation pages. These can be navigated through either by using the next or previous buttons, alternatively the user can navigate directly to any page 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. While it is not necessary to complete this section to use the tool, completion is required to enable saving of profiles and custom lists of use condition terms. To access the form and complete this section, please click the green plus button. The Email of the user is used to store and retrieve saved profiles and custom use conditions but **is not** included in the profile itself. The First and Last Name are optional fields. The red X button can be used to delete the user information.

The screenshot shows the 'DUC Profile Creator' interface. At the top, there is a navigation bar with the logo 'Digital Use Conditions' and the title 'DUC Profile Creator'. To the right of the title are links: 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE'. Below the navigation bar is a progress indicator with six steps: 1. USER (highlighted in green), 2. PROFILE, 3. ASSET, 4. SELECT USE STATEMENTS, 5. USE STATEMENTS, and 6. SUMMARY. The main content area is a white form titled 'User Information' with the subtitle 'If you want to save profile in our server (to use later), Please enter user details.' The form contains a '+ User info' button, a red 'X' button, and input fields for 'Email: *', 'First Name:', and 'Last Name:'. A green 'Next' button is at the bottom of the form.

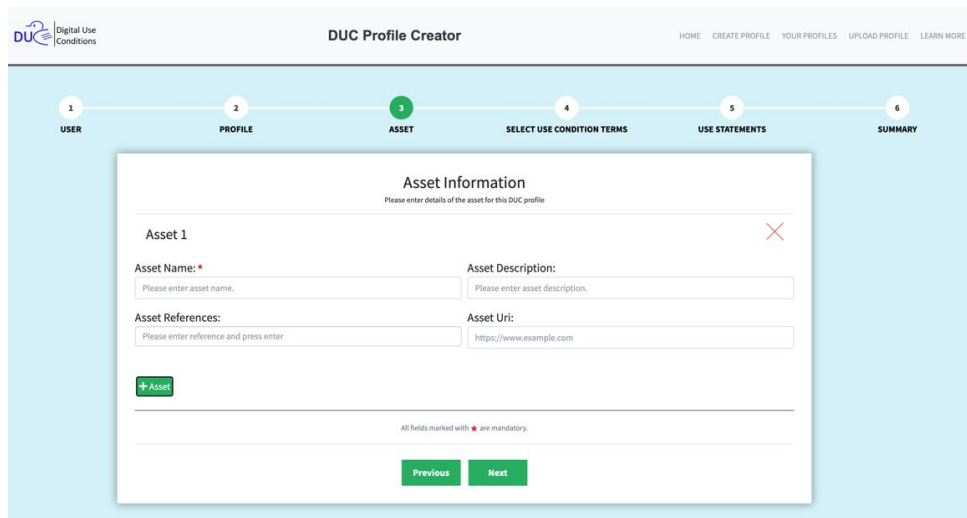
2.1.2 Section 2 - Profile information.

The user can assign a name to the profile as well as a version number, should the user wish to provide one. For tracking purposes, the tool will automatically log the creation date and the last update date. However, these fields are not able to be edited by the user and so are shown but greyed out. The permissions mode allows the user to set a default for all unstated use condition terms (i.e., all unstated conditions are either permitted or forbidden). It should be noted that this field is not required and can be left unselected. Finally, the user can define the language used in the profile's free text sections from the drop-down list.

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2.1.3 Section 3 – Asset Information.

This section is used to collate information regarding the asset itself. It is only necessary to enter the asset name in this section. However, the user can choose to provide the information shown in the screen shot below for the asset to which the CCEs relate.



The screenshot shows the 'DUC Profile Creator' interface. At the top, there is a navigation bar with the logo 'DUC Digital Use Conditions' on the left and links for 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE' on the right. Below the navigation bar is a progress indicator with six steps: 1. USER, 2. PROFILE, 3. ASSET (highlighted in green), 4. SELECT USE CONDITION TERMS, 5. USE STATEMENTS, and 6. SUMMARY. The main content area is titled 'Asset Information' and contains a form with the following fields: 'Asset Name' (marked with a red asterisk and a red 'X' icon), 'Asset Description', 'Asset References', and 'Asset Uri'. A green '+Asset' button is located at the bottom left of the form. At the bottom of the form, there are 'Previous' and 'Next' buttons. A note at the bottom of the form states 'All fields marked with * are mandatory.'

It should be noted that this entire section is optional, as a profile can be generated and used outside of the tool. If the user does decide to provide asset information, then only the Asset Name is compulsory, with the other sections being optional. The remaining fields are as follows: the asset description allows the user to provide a short free text description of the asset; the asset references box allow the user to enter a URL to publications or other online information that provide more details about the asset and finally, the asset URI box allows the user to enter the URI link to the asset itself. The user can enter details of more than one asset per profile using the green +Asset button.

2.1.4 Section 4 – Select Use Statements.

This section allows the user to select from different sets of predefined use condition terms or to define a list of their own for use in section 5.

The tool has predefined terms from Common Condition of Use (v1), Data Use Ontology and Informed Consent Ontology. These can be selected using the appropriate check box and will cause the tool to pre-populate the drop-down list in section 5. Alternatively, the user can define their own terms. To do this they must provide an Email address which is used to identify returning users and provide access to any lists of use condition terms that they have defined previously. After entering an Email address, the user is given the options on the right of the screen to either use saved terms or create new terms, which can be selected via the appropriate button.

The screenshot shows the 'DUC Profile Creator' interface. At the top, there is a navigation bar with the logo 'DUC Digital Use Conditions' on the left and the title 'DUC Profile Creator' in the center. On the right side of the navigation bar are links: 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE'. Below the navigation bar is a progress indicator with six steps: 1. USER, 2. PROFILE, 3. ASSET, 4. SELECT USE CONDITION TERMS (highlighted with a green circle), 5. USE STATEMENTS, and 6. SUMMARY. The main content area is a white box titled 'Select Use Condition Terms' with the instruction 'Please select use condition terms group or define your own.' The box is divided into two sections: 'System Terms' and 'User Defined Terms'. Under 'System Terms', there are three checkboxes: 'CCE terms v1', 'DUC compatible DUO terms', and 'DUC compatible ICO terms', each with a blue information icon. Under 'User Defined Terms', there is a text input field with the placeholder 'username@email.com' and a label 'Please enter a valid email to use/create your own Terms:'. To the right of the input field are two green buttons: 'Use Saved Terms' and 'Create New Terms'. At the bottom of the white box are two green buttons: 'Previous' and 'Next'.

Clicking the create new terms button will open a pop-up window (please ensure that your browser is not blocking pop-up windows), where the user must define a term group name and a term (descriptive name) for each term that they wish to define. Optionally, they can define a description of the meaning of the term in the description box. Although this field is optional, it is highly recommended that the user completes a description for each new terms to facilitate their re-use in a uniform manner. New terms can be added using the green +Term button. Once, all the new terms have been entered then the list can be saved by clicking on the green disk icon in the bottom right of the popup window. This will save the list to the system, allowing the user to retrieve the list for use later.

The screenshot displays the 'Create Condition Terms' pop-up window. The window title is 'Create Condition Terms'. It features a 'Term Group Name' field with a red asterisk and a placeholder 'Please enter name of term group'. Below this is a 'Term 1' section with a 'Term' field (red asterisk, placeholder 'Please enter use condition term') and a 'Description' field (placeholder 'Please enter use condition term description'). There are three checkboxes below the term fields, a green '+ Term' button, a green 'Terms' button with a disk icon, and a grey 'Close' button. At the bottom, there is an email input field with the placeholder 'Please enter a valid email to use/create your own Terms:' and the value 'sg307@leicester.ac.uk'. Below the email field are 'Previous' and 'Next' buttons. The background shows a navigation menu with '1 USER' and '6 SUMMARY' and a top bar with 'FILES', 'UPLOAD PROFILE', and 'LEARN MORE'.

Once the lists are saved the user will receive a passcode to the email that they provided before making the list. This passcode will need to be entered to access their previous lists of terms when the user clicks the "Used Saved Terms" button.

To proceed to section 5, the user must pick at least one set of terms (either from the tool pre-defined terms or the user defined terms) but it is permissible to choose as many sets of terms as needed to complete a DUC profile.

2.1.5 Section 5 - Use Statements.

This section permits the user to define individual use statements. Each statement must consist of at least the core statement (a use condition term, rule and scope) but may optionally include a free text condition parameter to expand or clarify this.

The screenshot shows a web interface for defining use statements. At the top, there is a navigation bar with the logo 'DUe Digital Use Conditions' and links for 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE'. Below the navigation bar is a progress indicator with six steps: 1. USER, 2. PROFILE, 3. ASSET, 4. SELECT USE CONDITION TERMS, 5. USE STATEMENTS (highlighted in green), and 6. SUMMARY. The main content area is titled 'Condition of Use Statements' and contains the following text: 'Create at least one Condition of Use Statement using the following format: Regarding [conditionTerm], this form of use is [rule], and applies to the [scope] for which the details are [conditionParameter]'. Below this text is a form for 'Statement 1' with three mandatory fields: 'Use Condition:' (text input), 'Rule:' (dropdown menu), and 'Scope:' (dropdown menu). There is also an optional 'Condition Parameter:' text input field. A green '+ Use Statement' button is located below the form. At the bottom of the form, there is a note: 'All fields marked with * are mandatory.' and two green buttons: 'Previous' and 'Next'.

To define a use condition statement in section 5 the user should first select a use condition term from the drop-down menu, which will have been pre-populated with the terms specified in section 4. The user must then select the rule and scope. The rules that can be associated with any use condition term are:

- **FORBIDDEN** – The stated use/requirement *must not* occur.
- **PERMITTED** – The stated use/requirement *may occur*.
- **OBLIGATED** – The stated use/requirement *must occur*.
- **NO REQUIREMENTS** – There are *no conditions* associated with this CCE term for some or all of the asset. This rule can be used to explicitly state that this is the case (as opposed to not making any statement about a given use condition). This may be particularly useful when conditions would normally be expected to apply.

SCOPE

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

- **WHOLE OF ASSET.**
- **PART OF ASSET.**

If the user also chooses to provide a condition parameter, then they **must** only clarify the core statement and not introduce any exemptions or duality, nor make any interdependencies with other use condition statements in the DUC profile. Where this would occur, the user is advised to split the use statement into two or more statements.

An acceptable example would be.

Use condition: Commercial Use, Rule: Permitted, Scope: Whole of asset.

Condition Parameter: Subject to participant consent.

The following example would not be acceptable.

Use condition: Commercial Use, Rule: Forbidden, Scope: Whole of Asset

Condition Parameter: Except for non-profit research purposes.

This statement should be split, as exemplified below.

Use Condition: Commercial Use, Rule: Forbidden, Scope: Whole of Asset

Condition Parameter: For profit generating purposes.

Use Condition: Commercial Use, Rule: Permitted, Scope: Whole of Asset.

Condition Parameter: For non-profit research purposes, subject to approval by the asset provider.

Although there is no logic between “use condition statements” in the same profile, profiles can still become complex to unravel. 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 permitting the CCE term for “use by a commercial entity in the first profile and forbidding it in the second). 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 how probable it is that this could be correctly determined by someone unfamiliar with it.

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

2.1.6 Section 6 - 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 tool 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

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

Profile Information

Profile Name	Test 1
Profile Version	0.1
Creation Date	2023-04-20
Last Update Date	2023-04-20
Permission Mode	All unstated conditions forbidden
Language	eng

Resource Information

Asset No	Name	Description	References	URI
1	Test database	Dummy database		Undefined

Use Statements

Statement No	Use Condition	Rule	Scope	Condition Parameter
1	Clinical care	Obligated	Whole of Asset	Only where the patient has consented to treatment.
2	Genetic research	Forbidden	Whole of Asset	
3	Publication	Obligated	Whole of Asset	This is a patient sample biobank and their consent to use their data must be obtained before any results are published.

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

PLEASE NOTE

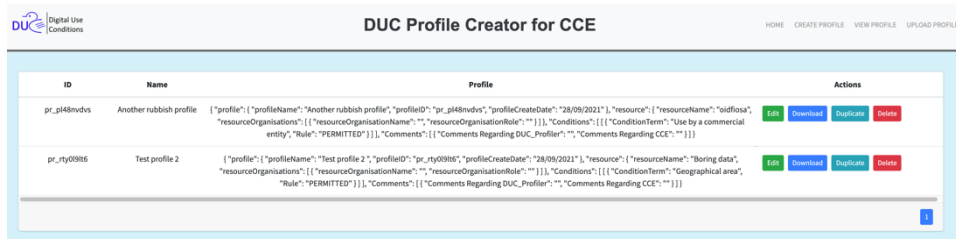
Currently, it is the responsibility of the end user to check the final profile generated for inconsistent or contradictory use condition statements.

3.0 Reviewing a previously created profile

This section assumes that you have created at least one DUC profile 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 tool 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' interface. At the top, there is a navigation bar with 'HOME', 'CREATE PROFILE', 'VIEW PROFILE', and 'UPLOAD PROFILE'. Below this is a table with the following columns: ID, Name, Profile, and Actions. The table contains two rows of profile data.

ID	Name	Profile	Actions
pr_pi48nvds	Another rubbish profile	{ "profile": { "profileName": "Another rubbish profile", "profileID": "pr_pi48nvds", "profileCreateDate": "28/09/2021", "resource": { "resourceName": "oldfosa", "resourceOrganisations": [{ "resourceOrganisationName": "", "resourceOrganisationRole": "" }] }, "Conditions": [{ "ConditionTerm": "Use by a commercial entity", "Rule": "PERMITTED" }] }, "Comments": ["Comments Regarding DUC_Profiler": "", "Comments Regarding CCE": ""] }	Edit Download Duplicate Delete
pr_rty09t6	Test profile 2	{ "profile": { "profileName": "Test profile 2", "profileID": "pr_rty09t6", "profileCreateDate": "28/09/2021", "resource": { "resourceName": "Boring data", "resourceOrganisations": [{ "resourceOrganisationName": "", "resourceOrganisationRole": "" }] }, "Conditions": [{ "ConditionTerm": "Geographical area", "Rule": "PERMITTED" }] }, "Comments": ["Comments Regarding DUC_Profiler": "", "Comments Regarding CCE": ""] }	Edit Download Duplicate Delete

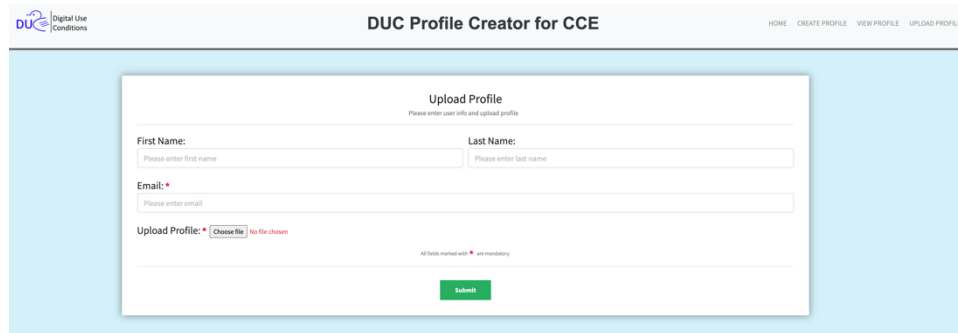
The “Edit” button takes the user to the same summary page as described in the create profile section, with the same ability to review and edit the profile (by clicking the green pencil icon).

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 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 JSON format**. Once uploaded a profile can be modified (see section 2.1.6) 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' and includes a sub-header 'Please enter user info and upload profile'. It contains the following fields and elements:

- First Name:** A text input field with the placeholder text 'Please enter first name'.
- Last Name:** A text input field with the placeholder text 'Please enter last name'.
- Email:** A text input field with the placeholder text 'Please enter email' and a red asterisk indicating it is mandatory.
- Upload Profile:** A file upload field with a 'Choose file' button and the text 'No file chosen'.
- Submit:** A green button at the bottom of the form.

At the bottom of the form, there is a small note: 'All fields marked with * are mandatory.' The application header includes the 'DUC Digital Use Conditions' logo and navigation links for 'HOME', 'CREATE PROFILE', 'VIEW PROFILE', and 'UPLOAD PROFILE'.