

## Examples of DUC/CCE profiles

### Simple Condition profiles

This section gives examples of how to use CCE statements in isolation or combination to reflect some “simple” use cases. Even taking these examples into account, it quickly becomes apparent when used correctly a profile made using CCE statements can be a powerful tool. However, it should be noted that in the current form there is no logic assumed between each CCE statement and as such each CCE statement in a profile should be treated independently. While it is possible to combine statements, care must be taken not to do so in a way that would exclude an intended use. CCEs are not intended to be a definitive statement on what uses are possible for a given resource but making them too stringent may preclude a given resource from the search results for a given discovery context.

In basic terms, the CCE statements take the same form:

Considering the stated [\[conditionTerm\]](#), for which the details are [\[conditionParameter\]](#), this form of use is set by [\[rule\]](#), and applies to the [\[scope\]](#) of the asset.

CCE statements can be encoded in section 4 of the tool using the interface shown below.

The screenshot displays the 'DUC Profile Creator Using CCE' web application. At the top, there is a navigation bar with the 'DUC' logo and links for 'HOME', 'CREATE PROFILE', 'YOUR PROFILES', 'UPLOAD PROFILE', and 'LEARN MORE'. Below the navigation bar is a progress indicator with five steps: 1. USER, 2. PROFILE, 3. RESOURCE, 4. CCE STATEMENTS (currently active), and 5. SUMMARY. The main content area is titled 'CCE Statements' and includes instructions: 'Create at least one CCE Statement using the following format: Considering (CCE Term), this use is/has (Rule), and applies to the (Scope), for which specifically (Condition detail) applies. The same CCE Term can be used in multiple statements and terms omitted if not relevant to the resource.' The form for 'CCE Statement 1' contains three dropdown menus: 'CCE Term', 'Rule', and 'Scope'. Below these is a 'Condition Detail' text input field. A green '+ Condition' button is located below the text field. At the bottom of the form is a 'Comments Regarding CCE' text area. A note at the bottom states 'All fields marked with \* are mandatory.' and there are 'Previous' and 'Next' buttons.

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 so that the exceptions are defined clearly in a separate CCE statement(s) that states use(s) that are forbidden. The “Comments Regarding CCE” box, is available for the user to leave general comments about the CCE Framework as a whole and is completely separate to the profile.

## Commercial Entity

This use condition is intended to set use conditions for use by a commercial entity. It has been separated from the concept of “for-profit use” as some commercial entities may undertake not-for-profit work when using a resource.

Considering the stated [Commercial Entity], for which the details are [for non-commercial use only], this form of use is set by [Permitted], and applies to the [Whole of resource] of the asset

This approach permits use by a commercial entity for non-commercial use only. However, as it is a Condition Detail, it is specific to use by a commercial entity, rather than forbidding commercial use using the “for profit purposes” CCE term.

## Geographical Area

The Geographical area can be used to simply confine use to a specific region. For example, in the case of French personal medical data, use is usually limited to France, as in the example below.

Considering the stated [Geographical Area], for which the details are [in France], this form of use is set by [Permitted], and applies to the [Whole of resource] of the asset

Alternatively, use outside of France could be forbidden for greater clarity.

Considering the stated [Geographical Area], for which the details are [outside of France], this form of use is set by [Forbidden], and applies to the [Whole of resource] of the asset

Care must be taken when using this CCE term not to confuse or combine it with a regulatory jurisdiction, which is a separate CCE term listed below. As such a geographical area is intended to represent a physical area that is treated as a single entity, for example the UK, even if it does not consist of a single land mass. For Europe, the European Union would represent a Regulatory Jurisdiction while the term Europe would represent the geographical region that contains all the countries that are part of the continent of Europe.

## Regulatory Jurisdiction

This CCE term is intended to be used to restrict use to only those regions that conform to a given law, regulation or formal oversight (i.e., an international agreement or standard). A prime example would be the use of EU data only where the EU General Data Protection Regulation is applied.

Considering the stated [Regulatory Jurisdiction], for which the details are [only in regions subject to GDPR or with an adequacy agreement], this form of use is set by [Permitted], and applies to the [Whole of resource] of the asset

## Research Use

This CCE term is used to stipulate conditions that apply to the use of a resource in the context of research. An example could be that the use of a resource is forbidden for an area that the provider is actively researching themselves, as was the case with the use of *Taq* polymerase initially in relation to HIV

Considering the stated [Research Use], for which the details are [for research into or involving HIV], this form of use is set by [Forbidden], and applies to the [Whole of resource] of the asset

## Clinical Care Use

This CCE term is intended to apply to permissions for use with direct patient care, such as diagnosis or treatment. An example could be where a biobank supplied a tissue sample with the explicit requirement that it is not used for treatment.

Considering the stated [Clinical Care Use], for which the details are [use as a treatment], this form of use is set by [Forbidden], and applies to the [Whole of resource] of the asset

## Clinical Research Use

This CCE term relates specifically to research that is performed to development of diagnostics and treatments. Hence, an example could be where a sample has been consented for use to improve general treatments for medical conditions.

Considering the stated [Clinical Research Use], for which the details are [research to improve diagnostics and treatments], this form of use is set by [Permitted], and applies to the [Whole of resource] of the asset

## Disease Specific Use

As the name suggests this CCE term relates to uses that concern a specific disease. One use case for this could be to obligate use to a given disease or group of diseases, where biosamples had only consented for that specific use case. Alternatively, the Forbidden rule could be used to preclude a use relating to a specific disease or disease area if it was not consented to or the supplying institution was imposing a moratorium on a specific disease(s).

Considering the stated [Disease specific use], for which the details are [relating to Parkinson's disease], this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Use As Control

If a given biosample could only be used as a control in research, then there are multiple possibilities to encode this using the CCE term "Use as Control". The first would be to use "Use as Control" and the Condition Detail "for research use only" and make this Obligatory. However, this would mean the resource would **have** to be used in that context whenever it was used. However, the resource may be able to be used for other purposes other than as a control, which would be precluded in the above example. A more representative Use Condition Statement would be "Use as control" with the Condition Detail stating non-research use and setting this to Forbidden. Hence, the resource could only be used in research when used as a control, BUT other uses where the resource is not being used as a control could be allowed.

Considering the stated [Use as control], for which the details are [non-research use], this form of use is set by [Forbidden], and applies to the [Whole of resource] of the asset

## (Re-)Identification Of Individuals Without Involvement Of The Resource Provider

This CCE term is specifically intended to refer to the re-identification of participants within resources that have been supplied in an anonymised or pseudonymised format, without the involvement of the resource provider. In most circumstances it is expected that such a use would be forbidden, however, there are some use cases where the providing institution may wish to explicitly state that this should not occur and use the condition parameter to specify safeguarding measures to ensure that it does not, such as the prohibition of using profiling technologies on biological samples.

Considering the stated [(Re-)Identification Of Individuals Without Involvement Of The Resource Provider], for which the details are [the use of profiling techniques on the supplied biological material or derivatives of it], this form of use is set by [Forbidden], and applies to the [Whole of resource] of the asset

## (Re-)Identification Of Individuals Mediated By The Resource Provider

This CCE term is specifically intended to refer to the re-identification of participants within resources that have been supplied in an anonymised or pseudonymised format, where the resource provider performs the reidentification. This is the more typical approach to re-contacting participants for involvement in further studies, for additional samples or to feedback on important findings (where the participant has consented to this). Again, the free text can be used to give an overview of the process or to state safeguards.

Considering the stated [(Re-)Identification Of Individuals Mediated By The Resource Provider], for which the details are [for the purpose of recontact], this form of use is set by [Permitted], and applies to the [Whole of resource] of the asset

## Time Period

This CCE term is self-explanatory and should be used to state any obligatory restrictions on the time period of use. An example is shown below. The free text condition parameter can be used to expand of the CCE term. While this could be a specific period of time, it could also be used to state conditions that would define a time period.

Considering the stated [Time Period], for which the details are [The recipient is permitted to use the data for no more than 1 year after the agreed completion date; to permit the preparation of the results for publication], this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Collaboration

This CCE term is intended to state where there is a requirement to collaborate with the supplying organisation of the resource. This may be used to require collaboration when the intended use overlaps with a current use that the resource provider is already performing.

Considering the stated [Fees], for which the details are [The recipient agrees to collaborate with the supplying institution whenever the use relates to Parkinson's disease], this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Fees

This CCE term is again self-explanatory, with the condition detail being used to give further information when they are not uniformly applied (such as for commercial use only) or where the resource provider wishes to give an overview of the fees concerned.

Considering the stated [Fees], for which the details are [use for commercial or for-profit purposes. Fees are £50 per sample for each aliquot], this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Return Of Results

This CCE term relates only to the requirement on the recipient to return the results that they intended to generate as part of the stated use, to the resource provider. The resource provider may wish to limit the obligation to only those results that pertain to uses that they themselves are performing.

Considering the stated [Return Of Results], for which the details are [in areas that overlap with the supplying institution's uses (these would normally be explicitly stated or referenced), this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Return Of Incidental Findings

This CCE term relates to findings that were not expected to be generated from the stated/intended use. In the case of results that may have medical implications, where a participant has not consented to being informed, some institutions may forbid the return of such findings to avoid the moral conundrum or conflicting responsibilities they would face if the results were returned.

Considering the stated [Return Of Incidental Findings], for which the details are [] this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Publication Moratorium

This Use Condition is intended for the supplying institution to stipulate a time period or conditions, during which the results of any work using the resource they provide may not be published. A prime example would be where the requester proposes a use that is overlapping with the use the supplying institution is currently using the resource for. Hence, they may wish to place a moratorium on publication until the supplying institution has published their finding, from using the resource.

Considering the stated [Publication Moratorium], for which the details are [recipient must not publish their results until the supplying institution has published their initial findings.] this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Publication

This CCE term is intended to be used to place a requirement on the recipient, to publish the results from their use of the resource. This may not necessarily be in the form of a peer-reviewed article, it could just be submitting their results to a database where they can be accessed. This is sometimes a requirement for resources that are themselves in the public domain or funded using public money.

Considering the stated [Publication], for which the details are [The recipient agrees to make the results of their use available in a public form, after any moratorium placed on doing so has been met. For example, as a result of publishing in a peer-reviewed journal.] this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## User Authentication

This CCE term is intended to allow the resource provider to state that there is some form of authentication step the requester must complete to either request access to or access the resource. An example could be providing proof from their employer that they work at a recognised research institution in a researcher capacity.

Considering the stated [User Authentication], for which the details are [The recipient must provide proof that they are employed by a recognised research organisation, in the capacity of a researcher, to request access.] this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Ethics Approval

This CCE term is intended to allow the provider to request proof that the use proposed by the recipient has received the appropriate ethics and governance approvals from their host organisation.

Considering the stated [Ethics Approval], for which the details are [The recipient must provide proof of sponsorship and/or ethics approval for the proposed use, before requesting access] this form of use is set by [Obligated], and applies to the [Whole of resource] of the asset

## Combining statements

Each CCE statement is intended to be true with no implied dependency or logic with other statements in the profile. However, the meaning of a profile can be easily lost if too many CCE statements are made in a single profile covering a variety of intended uses of a resource to which it is linked. It is down to the end user to review profiles to ensure that the individual permitted, or forbidden uses remain clear. However, it is recommended that different profiles are produced for each intended use case. For example, there may be a profile outlining permitted uses when a resource is used by a commercial entity and another that outlines a separate set of conditions when the resource is used by non-commercial entities. This can be achieved by having one profile where the “use by a commercial entity” is permitted and a second where that CCE term is forbidden.