Orientation Workshop for CEC CAH Ethical Evaluation Process
Regular Fondecyt and Postdoc Projects

**Social Sciences, Arts and Humanities Area
UC Research Ethics and Safety Unit
April 2020**

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How to present a project for ethical evaluation by the Committee?

Upload general information of the project to the evaluation platform:

https://evaluacionetica.uc.cl

Once notified:

Upload Protocols and supporting documentation

Formal entry to the CEC

CEC Decision

Suppor Resources

http://eticayseguridad.uc.cl/comite-etico-cientifico-en-ciencias-sociales-artes-y-humanidades.html

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CEC Schedule

COMITÉ ÉTICO CIENTÍFICO EN CIENCIAS SOCIALES, ARTES Y HUMANIDADES

Calendario Sesiones 2020

El Comité de Ciencias Sociales, Artes y Humanidades sesiona de manera regular dos veces al mes, con excepción de febrero, mes en que no sesiona.

En este link encontrará la calendarización de las sesiones y las fechas límite en que los investigadores deben presentar su documentación para ser evaluada en determinada sesión. Es fundamental que tenga en consideración este calendario en su planificación.

N° de sesión	Fecha limite para recibir documentos	Fecha de sesión
1	15 de diciembre 2019	8 de enero 2020
2	30 de diciembre 2019	22 de enero 2020
3	15 de enero	11 de marzo 2020
4	30 de enero	25 de marzo 2020
5	15 de marzo	08 de abril 2020
6	30 de marzo	22 de abril 2020
7	15 de abril	06 de mayo 2020
8	30 de abril	27 de mayo 2020
9	15 de mayo	10 de junio 2020
10	30 de mayo	24 de junio 2020
11	15 de junio	08 de julio 2020
12	30 de junio	22 de julio 2020
13	15 de julio	05 de agosto 2020
14	30 de julio	26 de agosto 2020

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Required documents for the ethical evaluation

- Social Sciences, Arts and Humanities Protocol.

- Researcher's commitment

- Original Project

- Informed consent and / or assent forms (CI / AI).

- Data-collection instruments.

- Institutional authorization sample letters.

- Collaboration agreements, terms of reference or contracts associated with the proposal.

Parts of the evaluation protocol

Social Sciences, Arts and Humanities Ethical Evaluation Protocol

Internal use

Assigned number	
Presentation date	
Presented version	

I. RELEVANT BACKGROUND FOR PROTOCOL PRESENTATION

The main mission of this Committee is to protect the dignity and well-being of the people and communities that participate in a scientific research, their rights and freedoms, and their sociocultural and heritage environment.

1. Criteria to be evaluated by the CEC: According to General Technical Standard 151 n° 7.2, updated in 2016 with circular A15 / 01, which establishes the self-evaluation guidelines for the accreditation of CECs, these Committees must consider **at least** the following criteria when evaluating a protocol:
   - ✓ Scientific validity of the research
   - ✓ Social utility of the research
   - ✓ Researchers competence
   - ✓ Risk-benefit ratio
   - ✓ Fair selection of people researched
   - ✓ Procurement process of informed consent and, where appropriate, informed assent.
   - ✓ Process of obtaining authorizations from individuals and institutions, when appropriate.
   - ✓ Documents for informed consent, informed assent, authorizations to individuals and / or institutions, depending on the case.

   - ✓ Protection of vulnerable groups.
   - ✓ Protection of privacy and confidentiality.
   - ✓ Provision for compensation in the event of adverse events that harm the person, when appropriate.

2. Minimum documentation required: In order to evaluate the criteria listed up above, and others that the CEC may consider pertinent in specific cases, only the proposals that upload the following documents, as a minimum, to the platform will be reviewed:
   - ✓ The Social sciences, Arts and Humanities ethical evaluation protocol
   - ✓ The copy of the original research project awarded or the thesis project approved by the study program (justify if this copy of the original project does not exist).
   - ✓ Commitment of the researcher in charge with all the required signatures.

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Parts of the evaluation protocol

Social Sciences, Arts and Humanities Ethical Evaluation Protocol

PONTIFICIA UNIVERSIDAD CATÓLICA DE CHILE

3.Formal aspects of the protocol:

✓ All sections of the protocol should be considered, except where explicitly stated otherwise. In case one or some of them are not pertinent, you must state "Doesn't apply" or another justification for the omission of information.

✓ The protocol must state the information in terms understandable to anyone (not an expert in a discipline).

✓ The protocol must be careful and rigorous in its presentation and writing, since it is an eventual public document.

✓ The content of the entire protocol must be written in a **single language**, Spanish or English.

✓ Additional documents (CI, AI, authorizations to individuals or institutions, instruments, etc.) must be presented in the language of the participants. If not Spanish, a translation must also be included.

II.- RESEARCHERS' BACKGROUND

Title of the research	

Research Team						
Rol	Name	ID number	Academic Status	Institution	Email	Research Ethics Training

III.- BACKGROUND FOR THE EVALUATION OF THE SCIENTIFIC VALIDITY AND SOCIAL UTILITY OF THE INVESTIGATION

Objetivo general del proyecto.

✓ **Indicate that you have the CITI certification**
✓ **Upload certification**

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Parts of the evaluation protocol

III. Background for the evaluation of the scientific validity and social utility of the research

> **- Objectives**
> *Clear and differentiated*
>
> **- Summary**
> *Synthesis of the study as a whole*
> *Understandable to the common citizen*
>
> **- Scientific justification**
> Main scientific arguments that support the research
> Mention the literature

Parts of the evaluation protocol

Methodology

- ***Schematic description of the research design and its stages***

Detail study stages

- ***Person responsable and criteria for the selection of people, participating communities, work areas or study materials***

Who is the one responsible for the selection?
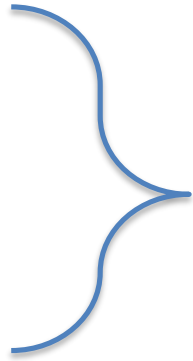
What are the inclusion and exclusion criteria?

- ***Recruitment and selection strategy***

State how will you recruit.

Institutions and participants sequence.

Direct access to the participants.

How? When? Who?

✓ **Consider:**
✓ Invitations
✓ Posters
✓ Authorization letters sample
✓ Data access authorization letters.

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Parts of the evaluation protocol

Methodology

- ***Intervention and data-collecting instruments***

They are presented in the particpant's language.

They are individually presented to be evaluated.

If you don't have them, you must:

Account for variables or dimensions

Commit to present the instruments when you have them for the approval of the CEC.

- ***Data-collecting proceedings***

Describe in detail

When, how, where and with who

- *Use of the collected data*

- *Estimation of key dates*

✓ **The examiners must understand what it is that you will undertake in the realization of the proposal.**

✓ **Safeguard the consistency between what is indicated in these sections and what is indicated in the IC/ IA.**

✓ **Consider:**
    Confidentiality agreements.

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Parts of the evaluation protocol

IV. Background for the evaluation of the care of participats and communities and their sociocultural and heritage environments

a) *Cost-benefit relation.*

b) *Aspects associated with vulnerable people.*

c) *Aspects associated with the protection of the privacy and confidentiality of participants.*

d) *Aspects associated with voluntariness of people's participation in the research and use of informed consent (IC)*

e) *Aspects associated with voluntariness of the participation of children and young people, minors and the use of informed consent.*

f) *Aspects associated with the participation of members of indigenous or native peoples in the research.*

g) *Specific considerations for studies with cultural heritage.*

h) *Other ethical considerations.*

V. **Annexes**

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CEC Resolutions

- ✓ **Approved:** an approval certificate is issued and is valid for one year.

- ✓ **Approved with minor changes:** the principle researcher must make adjustments and present the changes. They are reviewed. If they are correct, the approval certificate is issued immediately.

- ✓ **Approval subject to major changes:** the principle researcher must make the adjustments and present the changes. The project re-enters the committee and is reassessed in a regular session. Can continue with comments or approved.

- ✓ **Not approved**

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Subsequent to the Committee meeting

- According to the CEC Regulations at PUC, there is a period of **20 working days** to deliver the resolution to researchers.

- Usually we take 1 week, a week and a half to send the resolutions.

- After the resolution is sent, the time in which the project is approved depends largely on the researcher, since, as in the case of minor observations, it is not required to review by a committee meeting again.

- The improvements submitted by researchers are reviewed every Tuesday at a board meeting, attended by: the President, Vice President and Executive Secretary.

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Renovations

- Ethical approvals are valid for 1 year, beginning from the date they are discussed in session.

- Researchers must pay attention to the expiration date of the ethical approval, so they can request a renewal on time to the CEC.

- On the platform, select "Amendment" (there is no specific option for renewal) and attach a renewal letter.

- The letter format can be downloaded from: http://eticayseguridad.uc.cl/comite-etico-cientifico-en-ciencias-sociales-artes-y-humanidades/cec-sociales-2/solicitud-de-renovacion.html

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Amendment

- The ethical approval of a project includes all of its elements such as: financing, research team, sample, recruitment, data-collecting procedures, instruments, analysis and chain of custody, among other things.

- Any modification to the research must be reported to the CEC prior to its implementation, in the form of an amendment letter, which enters the next session immediately for discussion.

Amendment

- It is important that researchers are attentive to inform the Committee of the changes in advance, in order to avoid delays in the execution of their studies.

- As in the case of renovations, the option "amendment" must be selected via the platform and be attached to the corresponding letter.

- The letter format can be downloaded from: http://eticayseguridad.uc.cl/comite-etico-cientifico-en-ciencias-sociales-artes-y-humanidades/cec-sociales-2/solicitud-de-enmienda.html

- Both requests for renewals and requests for amendments are the sole responsibility of the researchers.

Monitoring

- In addition to ethical approval, Fondecyt requires researchers to have an ethical monitoring, which is performed once during the execution of the study.

- Thus it is usually done at the end of the research, but it can also be done at the end of the first or second year of implementation.

- It is the responsibility of the researchers to request CEC monitoring, since the CEC does not currently have the capacity to keep track of the dates by which they must be carried out.
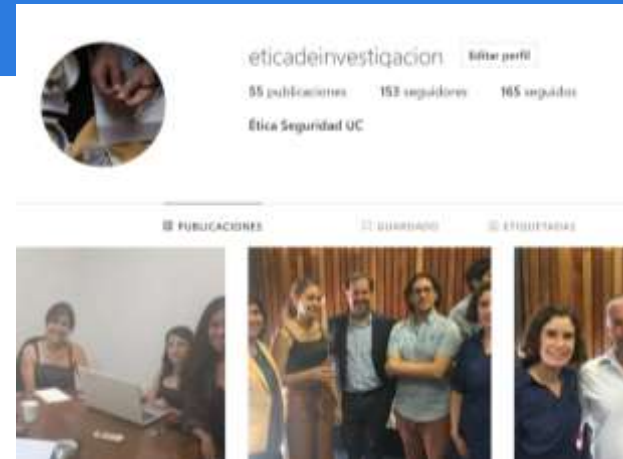
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Support resources
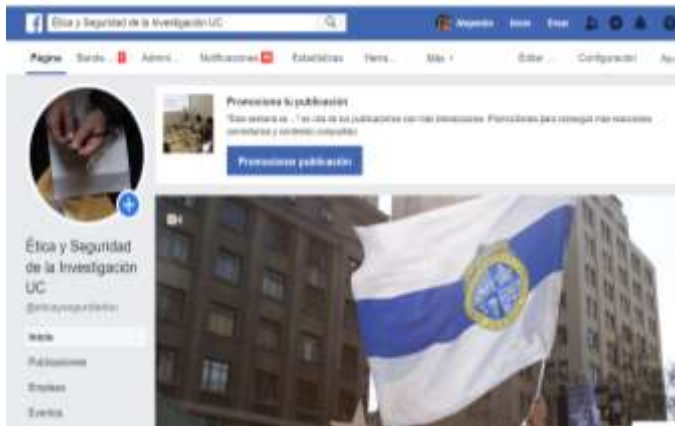
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