**FORM FOR PROJECTS THAT DO NOT INVOLVE DATA COLLECTION**

**Thesis Dissertation**

|  |
| --- |
| **ATTENTION**  **- If your proposal is approved by the Publications Committee, the analysis plan of the paper should be presented at the monthly meeting of cohort researchers.**  **- After approval by the Publications Committee, you will have six months to submit the article for publication.**  **- Verify that the acknowledgments section of the article complies with Annex B of this form. If relevant, do not forget the special funding from FAPERGS, CNPq, etc.**  **- Based on the follow-ups, of which the variables will be used in the article, check the names in Annex C of the potential proposal co – authors.**  **- It is mandatory to fill in the Confidentiality and Secrecy Terms, found in Annex D, and submit them to the Publications Committee along with the proposal.**  **- The publications database funded by the Wellcome Trust,UK, shall be deposited in PMC (open-access), with charge to the applicant.**  **- Prior to the submission to the journal, the results should be submitted to the Statistical Commission for approval.**  **- The database used should be destroyed upon acceptance for publication of the final article.**  **- New variables (created for the analysis) should be delivered to the corresponding cohort, with their respective formula development notes.**  **- New articles with data from the available bank should be submitted as a new proposal to the Publications Committee.** |

1. **Identification**

Principle Author Name:

Institution:

Email:

Phone:

Address:

Co-authors From the cohort:

Names: Cesar Victora

Fernando Barros

External to the cohort:

Names:

1. **Provisionary article title**:
   1. Start date \_\_ \_\_/ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_
   2. Finish date \_\_ \_\_/ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_

**(6 months to present the complete draft to the Publications Committee)**

1. **Financing**

The Project has financing:\* (1) Yes (2) No

What is the deadline for the submission of project: \_\_ \_\_ /\_\_ \_\_/ \_\_ \_\_ \_\_ \_\_

List of sources of financing

\***Proposals must be revised by the Publications Committee at least three weeks before being submitted to a promotion agency and the financing agency**

1. **Variables**

Select the source of variables that will be used in this proposal with more details in the proposal summary section

Existing databases:

* + 1. Interviews ( )
    2. Biological Samples ( )
    3. Measurements ( )
    4. DNA\* ( )

**\*All analysis involving DNA will need to be submitted to the Ethics Committee of UFPEL in Portuguese for approval**

1. **Justification for the use of the Pelotas cohorts in the study (100 words max)**
2. **Ethics Committee approval**

The study hasbeen approved by the ethics committee

( ) Yes ( ) No ( ) Unknown

If YES please attach copy of the opinion from the Ethics Committee

**For analysis that do not involved DNA, it is not necessary to submit the proposal the Ethics Committee**

1. **Summary of the proposal**

In a maximum of two pages, describe your proposal clearly indicating the data that will be obtained from the Pelotas cohort. In the case that the analysis will be using biological data, clearly indicate the necessary volume or quantity of each specimen and the size of the sample. For new collections or visits to the cohort participants it is important to indicate the size of the sample and how they will be visited, stating all of the procedures (interview, measurements, collections of biological material). The summary should also indicate the results of the already published studies on the subject, with data on the cohorts, objectives, plan of analysis and dummy tables.

1. **Counterpart budget (clearly list the counterpart of the Project for the cohorts)**
2. **Terms of commitment**

The information collected in any stage of the Pelotas cohorts is highly confidential. It is essential that the applicant reads and follows the rules for using the databank.

**Rules for using the databank**

1. Confidentiality of the databank should be maintained and there will be no access to the identification of the participants of the study.
2. All of the scientific articles or summaries based on the Pelotas cohort should be sent to the Cohort Publication Committee, for approval at least two weeks from the submission date.
3. The provided data from the Pelotas cohort should be used only for approved analysis through a proposal.
4. New analyses should be only be realised after approval by the Publication Committee.
5. At the end of the proposed analysis, the databank should be destroyed. The instructions needed for the creation of new variables used in the analysis wil be sent to the management database team involved**.**
6. The databank should not be provided to other researchers who are not involved in the Project proposal.
7. The applicant will have 6 months, starting from the approval date by the Publication Committee, to submit the article to publish. Failure to do this results in the Publications Committee being able to approve the same analysis requested by another researcher.
8. The resulting publications of this request will be published in open access magazines, with the charge to the applicant.
9. The use of the variables in other analysis resulting in the publication of other articles without the consent of the Publications Committee will be considered a serious impediment that could impede future applications to the Publications Committee.

□I read the agreement

1. **Location, date and signature of the primary applicant**

**11 -Annex A**

References with information about the methodology of each cohort.

**1982 Cohort**

* [Barros FC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Barros%20FC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Victora CG](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Victora%20CG%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Horta BL](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Horta%20BL%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Gigante DP](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Gigante%20DP%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus). Methodology of the Pelotas birth cohort study from 1982 to 2004-5, Southern Brazil. Revista de Saude Publica 2008;42(suppl 2):7-15.
* Victora CG, Barros FC. Cohort profile: the 1982 Pelotas (Brazil) birth cohort study. International Journal of Epidemiology 2006;35:237-42.

**1993 Cohort**

* [Victora CG](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Victora%20CG%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Hallal PC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Hallal%20PC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Araújo CL](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Ara%C3%BAjo%20CL%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Menezes AM](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Menezes%20AM%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Wells JC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Wells%20JC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus), [Barros FC](http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=Search&Term=%22Barros%20FC%22%5BAuthor%5D&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus). Cohort profile: the 1993 Pelotas (Brazil) birth cohort study. International Journal of Epidemiology 2008;37:704-709.
* Victora CG, Araújo CLP, Menezes AMB, Hallal PC, Vieira MF, Neutzling MB, Gonçalves H, Valle NC, Lima RC, Anselmi L, Behague D, Gigante DP, Barros FC. Methodological aspects of the 1993 Pelotas (Brazil) Birth Cohort Study. Revista de Saúde Pública 2006;40:39-46.

**2004 Cohort**

* Barros AJD, Santos IS, Victora CG, Albernaz EP, Domingues MR, Timm IK, Matijasevich A, Bertoldi AD, Barros FC. Coorte de nascimentos de Pelotas, 2004: metodologia e descrição. Revista de Saúde Pública 2006;40:402-413.

**12 - Annex B**

Acknowledgements of the articles should be in the following format

**Coorte 1982**

This article is based on data from the study "Pelotas Birth Cohort, 1982" conducted by Postgraduate Program in Epidemiology at Universidade Federal de Pelotas with the collaboration of the Brazilian Public Health Association (ABRASCO). From 2004 to 2013, the Wellcome Trust supported the 1982 birth cohort study. The International Development Research Center, World Health Organization, Overseas Development Administration, European Union, National Support Program for Centers of Excellence (PRONEX), the Brazilian National Research Council (CNPq), and the Brazilian Ministry of Health supported previous phases of the study.

*Note: Check with the Researchers of the 1982 Pelotas Birth Cohort if any of the data you used at the analyses was funded by specific grants from the Brazilian National Research Council (CNPq) or from the Research Support Foundation of the State of Rio Grande do Sul (FAPERGS) that need to be acknowledged.*

**Coorte 1993**

This article is based on data from the study "Pelotas Birth Cohort, 1993" conducted by Postgraduate Program in Epidemiology at Universidade Federal de Pelotas with the collaboration of the Brazilian Public Health Association (ABRASCO). From 2004 to 2013, the Wellcome Trust supported the 1993 birth cohort study. The European Union, National Support Program for Centers of Excellence (PRONEX), the Brazilian National Research Council (CNPq), and the Brazilian Ministry of Health supported previous phases of the study.

*Note: Check with the Researchers of the 1993 Pelotas Birth Cohort if any of the data you used at the analyses was funded by specific grants from the Brazilian National Research Council (CNPq) or from the Research Support Foundation of the State of Rio Grande do Sul (FAPERGS) that need to be acknowledged.*

**Coorte 2004**

This article is based on data from the study "Pelotas Birth Cohort, 2004" conducted by Postgraduate Program in Epidemiology at Universidade Federal de Pelotas, with the collaboration of the Brazilian Public Health Association (ABRASCO). From 2009 to 2013, the Wellcome Trust supported the 2004 birth cohort study. The World Health Organization, National Support Program for Centers of Excellence (PRONEX), Brazilian National Research Council (CNPq), Brazilian Ministry of Health, and Children’s Pastorate supported previous phases of the study.

*Note: Check with the Researchers of the 2004 Pelotas Birth Cohort if any of the data you used at the analyses was funded by specific grants from the Brazilian National Research Council (CNPq) or from the Research Support Foundation of the State of Rio Grande do Sul (FAPERGS) that need to be acknowledged.*

**13 - Annex C**

Consult the potential co-authors in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **1982** | **1993** | **2004** |
| **Perinatal** | Cesar / Fernando\* | Aninha / Ricardo Halpern / Beth Weiderpass / Bernardo / Jura / Elaine Tomasi / Elaine Albernaz  \* | Aluísio / Iná / Alicia\* |
| **1 mês** | X | Aninha / Ricardo H / Elaine T / Elaine A / Beth W / Jura | X |
| **3 meses** | X | Aninha / Ricardo H / Elaine T / Elaine A / Beth W / Jura | Aluísio / Iná / Alicia |
| **6 meses** | X | Aninha / Ricardo H / Elaine T/ Jura / Bernardo / João Amaral / Paula Guimarães | X |
| **12 meses** | Cesar / Fernando | Aninha / Ricardo H / Elaine T/ Jura / Bernardo / João Amaral / Paula Guimarães / Elaine A\*\* | Aluísio / Iná / Alicia |
| **2 anos** | Cesar / Fernando / Cintia | X | Aluísio / Iná / Alicia |
| **4 anos** | Cesar / Fernando / Cintia /Magda (sub-estudo 400 mães e crianças - teste Griffiths) | Aninha / Moema / Denise G / Silvia Fonseca / Duda (sub-estudo) / Luciana e Vânia (na estatística) | Aluísio / Iná / Alicia |
| **5 anos** | X | X | Aluísio / Iná / Alicia / Marco e Karen (oral) |
| **6-7 anos** | X | Aninha / Moema | Aluísio / Iná / Alicia  Ulf Ekelund (artigos acelerometria)  Isabel Oliveira (artigos DNA) |
| **11-12 anos** | Fernando / Carmen Duarte / Bernardo | Aninha / Cora / Pedro / Fátima / Marilda / Helen / Duda | X |
| **15 anos** | Fernando / Cesar/ Duda (?) /  Paulo Orlando (caso-controle: obesidade) | Aninha / Cora / Pedro / Fátima / Marilda / Helen / Duda / Noal / Samanta / Samuel  Isabel Oliveira (artigos DNA/laboratório) | X |
| **18 anos (quartel)** | Cesar / Rô /  Paulo Post (Sangue) | X | X |
| **18-19 anos** | Cesar / Denise / Helen / Dominique /  Angela Maas e Pedro cubano (Oral) | Aninha / Cecília / Helen/Pedro/Fernando Wehrmeister  Ulf Ekelund (acelerometria)  Isabel Oliveira (artigos DNA/laboratório) | X |
| **22-23 anos** | Denise / Bernardo /  Isabel e Vera (sangue) | X | X |
| **24-25 anos** | Anaclaudia (Trabalho) / Marco e Karen (Oral) / Aydin (CRP) / David (Barriga) / Helen e Dominique (violencia) | X | X |
| **30 anos** | Denise/Bernardo/Helen  Ulf Ekelund (acelerometria)  Ricardo Pinheiro/Luciana Quevedo (Saúde Mental)  Isabel Oliveira (laboratório e DNA) | X | X |
| **Etnográfico** | Helen / Dominique |  |  |
| **Mortalidade** | Alicia, Bernardo, quem trabalhou nos primeiros anos (?) Ana Borges,  CINTIA? | Aninha (mortalidade infantil) |  |

\* FCB e CV em todos os acompanhamentos

\*\* Elaine Albernaz foi árbitro para mortalidade infantil e para morbidade

**14 - Annex D**

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| --- |
| Centro de Pesquisas Epidemiológicas |
| **UNIVERSIDADE FEDERAL DE PELOTAS** |

**Terms of Confidentiality and Secrecy**

<I …….., with nationality….., state civil, profession, identification documents and complete address > assume the commitment to maintain confidentiality and secrecy on all technical and other information related to the study ... . <cohort(s) whose data was applied for> ... that belongs to the study of Pelotas Birth Cohort. I promise to comply to this confidentiality and secrecy with regard to all items stated.

‘Confidentiality’ is to ensure the safeguarding of personal information given in confidence and protection against its unauthorized disclosure concerning your privacy.

1. Data from studies of Pelotas Birth Cohort are the property of the Graduate Program in Epidemiology (PPGE), Federal University of Pelotas. There will be no transfer or transfer of license or license rights data (s) of the Pelotas Cohort Birth Study (s) including any intellectual property rights. This term does not restrict the rights of PPGE to distribute the data to other institutions or publish any document relating to any of the data from these studies.
2. The individual signing will be responsible for the safeguarding of the data and will not allow them to become the possession or control of another organization or individual. The individual signing will not transfer the data in its entirety or in part to third parties without permission of PPGE. The individual signing will keep the data confidential and will not attempt to identify study participants , nor bind the data provided by PPGE other study data held by different parties or by the same signer for different projects
3. The individual signing will use the data only for analyzes previously authorized by the Publications Committee of PPGE. The individual signing warrants that he or she will not use the data or parts of the data for any commercial purpose or any other purposes . All future correspondence related to data and research should be directed to the Publication Committee of the Center for Epidemiologic Research.
4. The individual signing will use all reasonable endeavors to ensure that the data available should as soon as possible , be returned or destroyed upon ( i ) the application of PPGE , or ( ii ) upon the termination of this Agreement , or ( iii ) in a case where the individual signing is in violation of any condition of this Agreement, or ( iv ) upon termination of this Agreement . If the signer is obliged to destroy the data he/she will confirm in writing to the Committee on Publication PPGEA to return the original (and new variables , if any) as well as their destruction.
5. The individual signing will keep PPGE informed about the results (s) review (s) within the period set by the Commission for publication. All results, including results of chemical and biological variables and other clean or derived or directly related to study participants, will be incorporated into the study database Pelotas Birth Cohort and will be the sole property of PPGE. The results generated by the processing of data will be the responsibility of the individual signing when the publication of any analysis, according to the abovementioned Commission. The undersigned will provide the documented PPGE a copy of the full results before publication and submission of any bank with all the new variables created , documented , namely the variable definition and code (s) corresponding (s ) and statement (s) used for its creation .
6. PPGE and the study/ studies will be given the opportunity to review and give approval for all papers intended for publication at least 14 days before submitting the manuscript to a scientific journal and/ or press. The undersigned recognize the PPGE and authors include researchers as identified by the institution and coordination of studies Pelotas Birth Cohort.
7. The individual signing will undertake to publish any and all result obtained data from the studies of Pelotas Birth Cohort in periodic free or as open-access article, and be responsible for any cost resulting from the publication.
8. The PPGE are not responsible for misuse of the data. The PPGE cannot ensure that (i) the data are of satisfactory quality or suitable for any particular purpose, or ( ii ) the use of the data is free of infringement of third party rights , including intellectual property rights .
9. Any data held or transferred from internal servers from the cohort studies of PPGE must be encrypted and password protected.
10. This Agreement shall be governed by the laws of Brazil, especially Law 9610 of February 19, 1998, and subject to the jurisdiction of national courts. The Court of Pelotas will be responsible for resolving any disputes arising from this disclaimer.

This is the term agreed between the individual signing and PPGE.

Pelotas, \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ .

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_