FIMABIS

FUNDACIÓN PUBLICA ANDALUZA
PARA LA INVESTIGACIÓN DE MÁLAGA
EN BIOMEDICINA Y SALUD

ibima

The FIMABIS-Methodological, Statistical and Scientific Advise Unit (FIMABIS-AMEC Unit) services

Internal Regulations

RED DE FUNDACIONES GESTORAS
de la investigación del SSPA

INDICE

1. FIMABIS policy on the Health Units research governance frameworks

FIMABIS supported research must comply with the RCE (Red de Comités de Ética de Universidades y Organismos Públicos de investigación (http://www.ub.edu/rceue/index2.htm) guidelines to ensure work is of high scientific standard, is conducted safely and respects the wishes and integrity of any patients or volunteers involved.

2. FIMABIS-AMEC Unit framework

FIMABIS benefits from an Integral Assesment Unit with a multidisciplinary conception that brings together the expertise of statistics and epidemiologists with that of research scientists and clinicians and technology tranasfer units and bridge those expertise with that of project and data management. Within this frame, the area of methodology, statistical and scientific assessment is what the AMEC Unit particularly supports.

The research in the Clinic Units to generate crucial data to detect and to solve and to prevent problems related to patient health has a great potential. The AMEC Unit has the aim of recruiting and supporting investigators into this area of research to facilitate the generation of therapeutic and biotechnological solutions into the Public Health System. The AMEC Unit services abides by the FIMABIS regulations.

3. FIMABIS Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship

These are our requirements for FIMABIS supported research under the Health Units Research Governance Frameworks. These requirements cover FIMABIS supported research carried out by any Research Group, Clinical Unit and Institution under the IBIMA organization. They apply to all the clinical research that FIMABIS support.

FIMABIS abides by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals recommended by The INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS (ICMJE) (http://www.icmje.org/) (provided below). Following these requirements FIMABIS requests the corresponding author of any scientific publication to acknowledge the activity or activities carried out by the AMEC Unit as appropriate based on the following criteria:

- To identify as an **author** that FIMABIS employee who meet the four criteria stated by The ICMJE that designate authorship in the publication.

- To include in **the Materials and Methods** section the **technical service** provided by the AMEC Unit when this service implies the Statistical Analysis of the data shown in the manuscript either as a whole or as part of the analysis or it implies the sample size calculation and to identify the FIMABIS AMEC Unit as the provider of such service. The following text should be included as part of the description of the specific analysis performed:
    - "The Statistical Analysis was performed by the FIMABIS AMEC Unit, Málaga (Spain) with xxxxxx software (version X.Y)."
    - "The sample size calculation was performed by the FIMABIS AMEC Unit, Málaga (Spain) with xxxxxx software (version X.Y)
- To **acknowledge** individually the contribution and to specify the contribution of the AMEC Unit using the appropriate text from the following suggestions:
    - "We thank name (FIMABIS) for assistance on the statistical analysis (methodology design) or for helpful scientific discussion".
    - "We are grateful to name (FIMABIS) for support on the statistical analysis (methodology design) or for critical reading of the manuscript (critical reading the study proposal)".

4. FIMABIS AMEC Unit Standard Operational Procedures in the Support of the research in the Health Units

The AMEC Unit services are based on the following main processes and proceedings:

- **Statistical advice** comprising the following proceedings:
    - Definition of the objectives of the study and identification of appropriate variables and statistical analysis to achieve them
    - Data base purge and statistical analysis
- **Methodology advice** comprising the following proceedings:
    - Project evaluation comprising its maturation and improvement
    - Project design comprising the inception of the methodology
- **Scientific advice comprising the following proceedings**:
    - Identification within de Clinical Units of:

      a) new research groups and/or initiatives

b) research groups and/or initiatives suitable for establishing inter-Units, inter-Centre or international collaborations.

- Identification and support in the implementation of new research plans
- Advice on the development of research plans or strategic research plans in the Clinical Units with the aim of achieving an international projection.
- Collaboration with the OTT Unit to pursuit:

a) the development of innovative projects

b) the identification of research groups and/or companies with a common interest to establish public-private collaborative enterprises

- **Professional training** comprising the following proceedings:
  - To identify training necessities in clinical research
  - To carry out training sessions in clinical research
  - To tailor design training sessions for the researches of the clinical Units

*See Spanish version of these regulations for specificities in the proceedings of the AMEC Unit.

Uniform Requirements for Manuscripts Submitted to Biomedical Journals (The ICMJE)

*The ICMJE recommends that **authorship** be based on the following 4 criteria:*

1. *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
2. *Drafting the work or revising it critically for important intellectual content; AND*
3. *Final approval of the version to be published; AND*
4. *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.

***Those who do not meet all four criteria should be acknowledged**—see Section below*

Non-Author Contributors. Acknowledgement

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed

*as authors, but they should be **acknowledged**. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and*

writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").