GPPAD Publications and Presentations Policy

The Publications and Presentations Committee is set up to oversee and monitor the dissemination of GPPAD data and biomaterial to outside audiences.

GOALS:

The Publications and Presentations (P&P) Committee is designed to operate with the following goals and objectives:

1. Assure and expedite the orderly and timely release of information generated by GPPAD to various audiences, including, but not limited to:
    a. scientific and medical journals, conferences and meetings
    b. news media and other public information sources
    c. national, state and local government organizations and regulatory groups that are not part of the GPPAD group.
2. Assure that all members have the opportunity to participate and be recognized in the study- wide presentation of GPPAD data.
3. Establish and monitor procedures for timely review of proposed GPPAD publications, presentations, and other release of information.
4. Assure that press releases, interviews, presentations, and publications related to GPPAD are accurate, objective, and do not compromise the scientific integrity of the platform.
5. Maintain a complete up-to-date list of GPPAD presentations and publications.
6. Assure that studies and projects utilizing GPPAD resources (biomaterial or data) appropriately acknowledge and cite GPPAD as the source of information.
7. Assure that GPPAD publications follow the recommendations of the International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE).

ROLES AND RESPONSABILITIES:

Role of the Publication and Presentation Committee

The GPPAD P&P Committee acts as the principal group to oversee the public release and publication of data and other information generated by GPPAD. The P&P Committee sets the GPPAD presentations and publications policy, and mediates any disputes arising over the publication or presentation of GPPAD results

The recommendations of the P&P Committee are reported to the GPPAD Steering Committee. All Clinical Centers and the Coordinating Center (GPPAD CC) will have a representative on the P&P Committee at all times. Appointment of other P&P committee members will be made by the GPPAD Steering Committee.

Role of the GPPAD Coordinating Center (GPPAD CC)

The GPPAD CC at the Institute of Diabetes Research, Helmholtz Munich coordinates the approval of information related to GPPAD that is released into the public domain, including publications, abstracts, presentations, and press releases. All such material must be submitted to the **GPPAD Publications** (publications@gppad.org) for inclusion in the central GPPAD database.

GPPAD Publications will maintain a list of manuscripts in preparation that will be available on the Membersite of the GPPAD website. GPPAD publications (publications@gppad.org) will serve as the initial site for submission of all manuscripts, abstracts, presentations, and press releases for P&P committee review.

PROCEDURES:

Request for Data and Submission of Manuscript Proposal

The request of GPPAD data is organized via submission of a manuscript proposal. The proposals serve to reduce overlap between papers and will follow a standard format, including a description of the hypotheses of the paper, a one- or two-page paper topic description including a list and description of variables, and the general statistical approach, as well as the list of writing group members. Any requests for data access must be made at the time of manuscript proposal submission. The completed manuscript proposal shall be submitted electronically to GPPAD Publications (publications@gppad.org) for review.

The P&P Committee will review the manuscript proposal:

1. To ascertain that the formal manuscript proposal format has been followed
2. To determine that a clear and accurate analysis plan is included in the proposal.
3. To determine if there is inappropriate overlap between the proposed manuscript and any other papers proposed or in progress. In such cases the investigator will be encouraged to collaborate on the existing proposal/manuscript.
4. To confirm that each site has had a reasonable opportunity to participate and that the proposed writing group is appropriate for those paper categories.

The procedure from manuscript proposal to submitting to a journal involves the following steps:

1. GPPAD Publications will notify the Lead Author, and provide comments concerning the manuscript proposal. It is the responsibility of the Lead Author to integrate any

modifications required by the P&P Committee for proposal acceptance.

2. A revised version of the manuscript proposal needs to be sent to GPPAD publication (publications@gppad.org) for reference
3. As part of the process, once the manuscript draft is completed, it should be submitted electronically to GPPAD Publications (publications@gppad.org) for review. The P&P committee will carefully assess the manuscript and provide feedback.
4. The Lead Author needs to incorporate any modifications or revisions suggested during the review process.
5. After finalizing the manuscript, it is crucial to submit the completed version to GPPAD Publications (publications@gppad.org) again before proceeding with the submission to a journal. This step ensures that all necessary checks and revisions have been addressed, guaranteeing the manuscript is in its best form for publication.

Request for Data & Biomaterial

The request of GPPAD data & biomaterial for ancillary studies is organized via the GPPAD Data and Material Transfer Agreement. The GPPAD Data and Material Transfer Agreement can be found on the GPPAD website www.gppad.org. The review and approval process are otherwise identical to the above described data request via manuscript proposal.

AUTHORSHIP:

The authorship criteria for GPPAD are adapted from criteria for authorship currently in use at International Committee of Medical Journal Editors (ICMJE) and JAMA.
The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or reviewing it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- 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.

All persons listed as authors must meet ALL 4 of these conditions.

In accepting data, or biomaterial, or other material assistance from GPPAD, investigators agree to abide by the GPPAD Publications and Presentations Policy with regard to all manuscripts, abstracts, presentations, and press releases that incorporate any information obtained through the use of these resources and to acknowledge the role of GPPAD in their provision.
For ALL manuscripts using GPPAD data or biomaterial, at least one Investigator from each clinical

site will be included as co-authors, other contributing authors, “and the GPPAD Study Group.” All manuscript proposals and project applications must adhere to this requirement. The comprehensive information regarding the "GPPAD Study Group" will be provided by GPPAD Publications following the approval of the manuscript by the GPPAD P&P. The GPPAD Study Group should be included in the author list as “and the GPPAD Study Group,” alternatively “for the GPPAD Study Group” or “on behalf of the GPPAD Study Group” (depending on the requirements of the journal). Group authorship may be recommended, particularly, if the number of authors exceeds the specified journals’ maximum. “GPPAD Study Group” will be listed as the group author with all of the investigators and staff members listed in the appendix or acknowledgements per journal specifications. In addition to having all members of this group listed in the appendix, the authors should always aim for having all group members recognized on “Pubmed”-searches for the article.

TYPES OF PUBLICATIONS AND PRESENTATIONS THAT REQUIRE REVIEW AND APPROVAL

GPPAD policy recognize several classes of publications and presentations that report findings generated with the use of GPPAD resources:

- Manuscripts submitted for publication in electronic or print journals
- Abstracts submitted to meetings and conferences for either oral or poster presentation

Additionally, we strongly encourage the submission of the following by the GPPAD P&P:

- Oral presentations that may, or may not, involve the prior submission of an abstract
- News media and public information releases
- Releases to federal, state, and local governmental agencies and organizations
- Student dissertations and/or theses

Publications, presentations, news media, and other information that are written in a language other than English will need approval by the local site Principal Investigator and P&P member only.

ACKNOWLEDGEMENT OF GPPAD SUPPORT

All presentations that report findings obtained through the use of GPPAD resources must acknowledge GPPAD as the source of those resources and the agencies that supported their development.

For manuscripts, the comprehensive information regarding the "GPPAD Study Group" will be provided by GPPAD Publications following the approval of the manuscript by the GPPAD P&P.

Oral presentations and posters do not have to adhere to this exact language, but must acknowledge GPPAD and the listed funding agencies. A GPPAD logo has been produced in print and electronic format and this logo should appear in posters, electronic presentations and similar media (by contacting the GPPAD Coordinating Center (cc@gppad.org)).

PRESS RELEASES

Press releases related to publications, important new developments or findings from GPPAD will be reviewed by the P&P Committee and, upon approval, released from the GPPAD Coordinating Center or from a local site. Individual centers may wish, in some cases, to personalize GPPAD press releases to highlight their role in the study.
The P&P Committee has developed standard language/boilerplates that can be appended to GPPAD press releases to acknowledge the role of specific institutions as follows:

"The **Global Platform for the Prevention of Autoimmune Diabetes (GPPAD)** is a European platform that identifies children at increased genetic risk for type 1 diabetes and conducts studies on primary prevention. The aim of the studies is to reduce the occurrence of islet autoimmunity and type 1 diabetes in children. GPPAD research centers are located in Belgium (Leuven), Germany (Dresden, Hannover, Munich), Sweden (Malmö), and the United Kingdom (Cambridge, Newcastle, Oxford). The research platform is financed by the Leona M. and Harry B. Helmsley Charitable Trust."

„POInT (Primary Oral Insulin Trial) is a randomized, placebo-controlled double-blind study recruiting infants aged four to seven months. Children with an elevated genetic risk for type 1 diabetes receive a small daily dose of insulin powder or placeboorally together with a meal until age 3. The goal is to introduce immune tolerance to insulin, as insulin and the cells that produce insulin in the pancreas are the primary targets of the destructive autoimmune reaction that characterizes type 1 diabetes. Previous studies have shown that oral administration of insulin is safe and does not affect plasma glucose levels."

"SINT1A (Supplementation with B. Infantis for Mitigation of Type 1 Diabetes Autoimmunity) is a randomized, placebo-controlled double-blind study recruiting infants aged four to six weeks. Half of the children receive a daily dose of Bifidobacterium infantis (B. infantis EVC001) and half will receive a placebo. The aim of the study is to determine whether daily administration of B. infantis EVC001until age 12 months to children with elevated genetic risk for type 1 diabetes reduces the cumulative incidence of beta-cell autoantibodies in childhood."

"AVAnT1A (AntiViral Action against Type 1 diabetes Autoimmunity) is an investigator initiated, randomised, controlled, multicentre, multinational, primary prevention trial, recruiting infants up to age of six weeks. The study investigates whether vaccination of children with elevated genetic risk for type 1 diabetes against COVID-19 from 6 months of age reduces the cumulative incidence of islet autoantibodies or T1D in childhood. Children will be administered three vaccinations from age 6 to 7 months, 3 to 6 weeks after 1st vaccination and 8 weeks after the 2nd vaccination."

"Funded by The Leona M. and Harry B. Helmsley Charitable Trust"

Further editing of GPPAD press release text requires P&P Committee review and approval prior to

releases.