WELL LIVING LAB GOOD PUBLICATION PRACTICES

PURPOSE

This document outlines the way the Well Living Lab generates and disseminates scholarly work (e.g., manuscripts, abstracts, presentations) resulting from its research, collaborations, and other activities, with a concentration on:

- How selection of topics and distribution channels for publications, presentations, etc. are made;
- How authorship and the order of authors is determined;
- How each publication and presentation is planned and how its preparation, review, and approval is kept on a reasonable timeline;
- What internal and external reviews and approvals are needed; and
- When and in what form data, manuscripts, and presentations, or portions thereof, are shared with sponsors, collaborators, or other third parties.

GOALS

This document helps to ensure:

- The highest integrity in the Well Living Lab's scholarly work, with the proper and timely report of research results in a complete, responsible, accurate, and transparent manner and pursuant with any related agreements.
- The proper interactions with sponsors, collaborators, and other relevant third parties as well as the conduct of internal legal reviews to ensure alignment of scholarly work with related agreements and internal marketing/communications reviews to ensure proper dissemination.
- The proper protection, sharing, and use of the data generated or otherwise collected by Well Living Lab as part of its research or collaboration with others in addition to the identification of intellectual property.
- The alignment of Well Living Lab's scholarly endeavors with the broader needs of Well Living Lab and those of its parent company Delos Living LLC.

SOURCES

This document has been generated and will continue to evolve based upon well-established good publication practice guidelines and advice from groups such as:

- The International Society for Medical Publication Professionals (ISMPP) "Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3." (link)
- The International Committee of Medical Journal Editors (ICMJE) "Awareness and Enforcement of Guidelines for Publishing Industry-Sponsored Medical Research among Publication Professionals: the Global Publication Survey." (link)
- The Well Living Lab Research Committee.
- The Well Living Lab Scientific Advisory Council.

This document is not meant to be all-encompassing given the established good publication practices that have been written and agreed to within the scientific community. The most notable of these good publication practices are identified and linked to above.

PUBLICATION AND PRESENTATION PROCESS AND PLANNING

The Well Living Lab Lead Scientist for each specific study will facilitate the drafting of a publication plan following the drafting and finalization of a study protocol for any IRB or non-IRB study. All members of the Study-Specific Research Team will be invited to contribute to the plan for each of the prospective publications. For each publication proposed, the following should be included in the respective publication plan:

- Tentative manuscript title/short internal title (e.g., Res IAQ Methods or place main study question as title);
- Tentative author list, with first and senior author defined;
- Tentative timeline broken into deadlines for each section, when possible, and an overall deadline, with the dates listed accounting for all potential contingencies that might alter the dates set forth for the publication plan;
    - The Well Living Lab Senior Project Manager and Research Lead will work collaboratively to document all tentative manuscript timelines with the Lab's project management tool. These individuals will assist in ensuring workloads that are balanced enough to facilitate study completion and later manuscript drafting in a manner commensurate with the tentative manuscript(s) deadline(s).
- Tentative potential journal and conference outlets;
- Study rationale and main study questions/hypotheses;
- Projected study design and manuscript-specific data analysis; and
- Relevant literature review borne from extensive investigation of prior studies on a given topic(s).

The Well Living Lab will strive for at least one primary publication to be generated as a result of each study completed - ensuring data are reported as completely as possible and commiserate with all relevant data sharing approvals, privacy laws, collaborative or sponsorship agreements, etc. Secondary publications for secondary, exploratory, and/or post-hoc analyses will also be considered. Each publication should be outlined as completely as possible within the publication plan for the associated Well Living Lab stud(ies).

The Well Living Lab strives to publish in peer-reviewed journals regardless of whether study results are positive, negative, or inconclusive. However, cases will be considered where study data are not publishable when study data are limited in scientific/clinical value, when a study has been rejected numerous times by multiple peer-reviewed outlets, or when other constraints on publishing the study data exist. (ISMPP's GPP3 in Section 1.3 (link)).

In general, the Well Living Lab will not publish the same data in multiple peer-reviewed publications (i.e., redundant or duplicate publications). Potential exceptions exist, however, are outlined in the ISMPP's GPP3 (link) in Section 1.5 of the Appendix. Desire to use the same data in a second paper would need to be reviewed and approved by the Well Living Lab Research Committee.

The Well Living Lab does not tolerate plagiarism, and each co-author is expected and required to take appropriate steps to avoid plagiarism.

When relevant, the Well Living Lab will register its studies in clinical databases such as ClinicalTrials.gov. The Well Living Lab will also consider submission of study protocol to preregistration databases like Open Science and AsPredicted, among others, for original research and to PROSPERO and others for systematic or meta-analytic reviews. Delos Legal will be consulted prior to the preregistration of trials and reviews to ensure protection of intellectual property.

PUBLICATION AND PRESENTATION PROCESS AND PLANNING (CONT'D)

The Well Living Lab adheres to the ICMJE Authorship Criteria when making decisions regarding authorship.

Briefly, the ICMJE Authorship Criteria specify that an author is anyone who meets ALL of the following four criteria (also available at above link):

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it critically for important intellectual content;
- Final approval of the version to be published;
- 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; and
    - These criteria apply equally to collaborators as well as members of the Well Living Lab team. Anyone who does not meet ALL of the above for criteria, but who still contributed to otherwise supported the relevant study or the publication, can be acknowledged per the specifications of the journal to which a manuscript is being submitted. Per the ICMJE Authorship Criteria: “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.”
- Members of study-specific research team that are drafting a manuscript will evaluate each team member’s contribution to the project and manuscript drafting to discern whether said individual’s contributions rise to the level of authorship. The study-specific research team will make recommendations to the project lead (e.g., the lead scientist) who will then make the final decision regarding authorship.

The Well Living Lab will adhere to all applicable standards as applicable in the reporting of their research observations. This includes CONSORT for trial reporting, STROBE for observations studies, and PRISMA for systematic or meta-analytic reviews, among others.

Conflicts of interest:

- The Well Living Lab will properly deal with potential conflicts of interests that may impact publications including, but not limited to, the following ways:
    - Via study design, with actions including, but not limited to:
        - Properly evaluating all technology and intervention options available to conduct a study rather than choosing that offered by any sponsoring entity.
        - Ensuring the study design is completed independently of the sponsor and by the Well Living Lab Team only.
    - Via strategic choice of collaborators who have no real or perceived conflicts of interest, currently or within the last three (3) years, with any of the sponsoring entities or their technology.

If the Well Living Lab cannot address conflicts of interests via the above strategies, the Well Living Lab will disclose any real or perceived conflicts of interest, be they financial or non-financial, that might be created by the sponsor and/or collaborators on the study. The ICMJE disclosure form will be preferred as a manner by which to determine potential conflicts of interest ahead of time.

ROLES/RESPONSIBILITIES, DATA SHARING, AND MANUSCRIPT REVIEW WITH SPONSORS AND COLLABORATORS

All Well Living Lab studies should have related written agreements with sponsors and collaborators as follows:

- For each sponsor, a Sponsored Research Agreement (SRA) will be in place, identifying, among other things, what access the sponsor may have to data, manuscripts, and presentations, how the sponsor may use and share such data, manuscripts and presentations, and any rights to review and approve any manuscript and presentation that the sponsor may have.
- For each collaborator, a Collaboration Agreement (CA) will be in place identifying, among other things, what access the collaborator may have to data, manuscripts, and presentations, how the collaborator may use and share such data, manuscripts and presentations, and any rights to review and approve any manuscript and presentation that the collaborator may have.
    - In some cases, it is possible that an entity can be both a sponsor and collaborator. In that case, the entity would need to sign both an SRA and CA or a combined single agreement, with these documents explicitly clear on the access this sponsor and collaborator has to all data, manuscripts, and presentations.

The Well Living Lab will make every reasonable effort to provide the results or data to a sponsor or collaborator in a manner pursuant with their role and in accordance with any agreement with such sponsor or collaborator.

Some example situations:

- Sponsors: If an entity is sponsoring a study but did not participate in study development and is not involved with the day-to-day execution of the study, the entity can be provided study results in the form of presentations and/or research briefs/updates, but they will not be privy to study data in any form unless otherwise provided for in an agreement with the entity. If, during submission for peer-reviewed publication, the Well Living Lab is requested to upload its study data to a journal-specific data repository, the sponsoring entity will have access to those data given that they are publicly available. However, unless otherwise provided for in an agreement, the Well Living Lab is under no obligation to notify the sponsoring entity as to the fact these data will be or have been published or to get approval from the sponsoring entity prior to such uploading of the data.
- Collaborators: A collaborating entity that is not sponsoring a study, but is instead serving in a collaborative role with the Well Living Lab to develop a study design, assisting with the day-to-day execution of the study, and/or conducting any analysis or review of data from or other results generated by the study, will have access to some or all of the aggregated and de-identified raw data when a scientifically valid reason is provided or such access is provided for in an agreement with the collaborating entity. The Study-Specific Research Team will have the discretion to make this data sharing decision without needing to bring the request to the Well Living Lab Research Committee, but will engage the Legal to confirm that any data-sharing related decision aligns with any requirements of a relevant agreement, privacy, or other laws, etc.
- Note on Data Privacy: Relevant participant privacy laws (e.g., HIPAA, HIPCO) and other laws will be adhered to when responding to any type of data access request from a collaborator, sponsor, publisher, etc. If providing any entity access to any form of aggregated de-identified raw data would violate any relevant participant privacy laws, the Well Living Lab will not share these data regardless of the entity's role and any specified agreement with said entity. If aggregated de-identified raw data can be shared without breaking relevant participant privacy

ROLES/RESPONSIBILITIES, DATA SHARING, AND MANUSCRIPT REVIEW WITH SPONSORS AND COLLABORATORS (CONT'D)

laws and in a manner pursuant with the entity's role and in accordance with any relevant agreement, these data must be shared via acceptable electronic mediums (e.g., only using encrypted servers, transmission in an encrypted format) and in a manner that, as greatly as reasonably possible, minimizes the ability of the entity to store data on their personal computer or other device and aligns with any relevant agreement.

- The Well Living Lab has clear, concise statements regarding data security and management (link).

The Well Living Lab will engage in a reasonable process of abstract, presentation, and manuscript review with a sponsor or collaborator in a manner pursuant with their role and in accordance with any relevant agreement.

Some example situations:

- Sponsors: If an entity is sponsoring a study but did not participate in study development and is not assisting with the day-to-day execution of the study, the entity will only be provided the opportunity to review select passages from manuscripts relevant to it for approval (e.g., when an industry sponsor's product is mentioned) unless and to the extent an agreement with the sponsoring entity requires otherwise. To the extent required or requested, the Well Living Lab then will make changes as necessary and to the extent possible to assure product accuracy, remove confidential information of the sponsoring entity, avoid disclosure or use of intellectual property, and satisfy all obligations of the Well Living Lab in the agreement. Unless required by the agreement, the sponsoring entity will not be provided the full manuscript for review and comment. However, the sponsoring entity will be provided an opportunity to review content that discloses any of its confidential information or uses its intellectual property when the Well Living Lab includes this information as part of abstracts or presentations, with the Well Living Lab again making changes necessary to protect the entity's confidential information, avoid disclosure or use of intellectual property, and satisfy all obligations of the Well Living Lab in any relevant agreement. Regarding final reports for sponsors, which can take the form of a manuscript or separate study report, the Well Living Lab will provide this report to a sponsor no earlier than when a study is submitted for peer-reviewed publication unless otherwise required differently in any relevant agreement. Individuals from these entities will not be listed as coauthors on any manuscript submitted for publication as unless they would meet the ICMJE authorship criteria discussed above. The sponsoring entity will be acknowledged as the funding source.
- Collaborators: Collaborating entities who are not sponsoring a study and are only serving in a collaborative role to develop the study design, assist with the day-to-day execution of the study, and/or conduct any analysis or review of data from or other results generated by the study may be given access, as appropriate or as required by a relevant agreement, to some or all of the abstracts, presentations, and manuscripts for review and comment. Individuals from these entities who participate in the drafting of these items will be listed as coauthors if they meet the ICMJE authorship criteria discussed above linked previously.