DIRECT Consortium

Publication Policy

Version 8, April 2019

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1. Brief and Objectives

The brief

Recognizing that the dissemination of research findings through peer-reviewed publications is an important obligation of academic scientists, the DIRECT consortium has developed this publication policy. The purpose of the policy is to guide DIRECT consortium members in the development and submission of publications and other reports arising from the work performed within the DIRECT consortium.

The objectives of this publication policy are:

- To ensure that research outputs are prepared and curated in a way which helps maximise their value to the DIRECT consortium, the individuals working within the consortium, and the partner institutions.
- To promote the scientific and technical accuracy and clarity of publications and oral presentations involving DIRECT results.
- To increase the visibility of research publications and oral presentations produced by investigators connected to the DIRECT consortium.
- To provide a guide for the review and approval of publications or oral or poster abstracts prior to submission.
- To provide guidance on the expected ethical standards associated with publication and oral or poster presentations.
- To ensure that fair credit is given to the authors and to other individuals who have contributed significantly to the work that is described in each publication, report, or presentation.

2. Types of publication

For the purposes of this policy, there are five publication types:

2.1 Presentations about DIRECT to external partners containing unpublished information on DIRECT, e.g. parts of the Description of Work, etc.

2.2 Abstracts submitted to scientific meetings for publication only, poster or oral presentation

Invited oral presentations at conferences or seminar series where unpublished DIRECT data may be presented

2.3 Primary DIRECT consortium manuscripts:

Manuscripts that address a research question of DIRECT *and* utilise DIRECT resource, including samples and data or personnel. See "DIRECT research questions" in the annexe to data access policy (DAP) protocol.

Any manuscript that utilises a substantial contribution of DIRECT generated data as its major data source should be considered a primary DIRECT manuscript.

2.4 Other manuscripts (non-primary DIRECT manuscripts):

Manuscripts that do not address a research question of DIRECT but where DIRECT resources, including samples, data, methods, or personnel are utilised.

2.5 Patent Applications

Where it is unclear whether a manuscript is primary or not, this should be discussed with the Managing Board prior to manuscript submission. Examples of non-primary DIRECT papers could be analyses that are collaborative, where DIRECT data is pooled with other data to address a question that is not the main focus of DIRECT, or papers that are undertaken only on a single centre's DIRECT-generated data.

3. Publications Review Committee (PRC)

This consists of the PRC chair ([redacted]) and its core members ([redacted]). The WP9 member ([redacted] will ensure specifically that data governance requirements have been met.

The remit of the Committee is to oversee the implementation (and revision) of the DIRECT publications policy and to coordinate the appropriate review process for all potential DIRECT publications (abstracts and primary manuscripts) prior to submission to ensure scientific rigour and to assess against the following criteria:

- Is the publication, report or presentation abstract in line with the intended use of DIRECT data?
- Is there overlap with other known DIRECT analyses?
- Is the authorship appropriate?
- Are all authors included who should be?
- Are there any intellectual property filings required before disclosure?
- Is the DIRECT consortium acknowledged appropriately?

All potential publications will be submitted to the PRC members (see contact details below). *Members of the PRC, who are also a named author on the abstract or manuscript under review, should not be involved in its review, though they can still assist in the coordination of the review process*. If necessary, another scientific

member of the consortium may be temporarily co-opted onto the PRC in order to help avoid any conflict of interest.

4. What information should be included in an IMI DIRECT Presentation / Abstract / Poster / Manuscript

The following section *does not* apply to patent applications:

4.1 Title text

Where allowed within the abstract submission rules, the title should be suffixed "…: An IMI DIRECT study" e.g. "Biomarker x predicts progression to diabetes: An IMI DIRECT study". The reason for this is to aid the identification of IMI DIRECT studies and to promote the brand of the consortium.

4.2 A Standardised Acknowledgement of DIRECT

All manuscripts utilising DIRECT-funded data, methods or personnel should acknowledge DIRECT by stating the relevant grant number, using the EXACT text below:

"*The work leading to this publication has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n°115317 (DIRECT), resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution*."

The reason for this is that it is a requirement of IMI-JU. If necessary, this text can be inserted in the supplementary online material.

4.3 A reference to the website

All manuscripts utilising DIRECT-funded output should include a reference to the DIRECT website in the acknowledgement section: http://www.direct-diabetes.org/

4.4 Appropriate logos

All posters need to include the EC, EFPIA, DIRECT and IMI-JU logos. Please contact [redacted] for the relevant logo files if you do not have them already. Presentation template slides are available in the members' area.

5. Process for Submission, Review and Approval of Presentations, Abstracts, Primary DIRECT manuscripts, other manuscripts and Patent Applications

5.1 DIRECT presentations

Presentations about DIRECT to external partners containing non-published consortium information require a Confidentiality Disclosure Agreement (CDA) between the DIRECT participant and the external partner. Presentations should be submitted together with the signed CDA to [redacted] at least 7 calendar days

prior to the planned date of presentation who will acknowledge receipt and circulate the presentation to the DIRECT Directorate The DIRECT Directorate members will be asked to respond within 5 calendar days. Lack of response will be assumed to signal agreement for presentation. In the event that [redacted] is out of the office, the presentation should be submitted to [redacted] and [redacted] who will deputise in [redacted] absence.

5.2 Abstracts

Abstracts should be submitted to the Chair of the PRC via [redacted] at least 14 calendar days prior to planned submission, who will acknowledge receipt. In the event that [redacted] is out of the office, the abstract should be submitted to [redacted] and [redacted], who will deputise in [redacted] absence.

Abstracts should be submitted along with *2 - 4 suggested Reviewers* from among the post-doctoral scientific members of the DIRECT consortium.

On approval by the PRC, the abstract will be sent to all DIRECT scientific members for information and to ensure no one has any objection to the publication, or any authorship dispute. Scientific members will be asked to respond within 5 calendar days. Lack of response will be assumed to signal agreement for submission. A negative response should be justified and will prompt further discussion, and this may delay or prevent submission of an abstract.

The corresponding author is responsible for ensuring that all co-authors have seen and approved the abstract prior to submission to the PRC; it is the responsibility of all co-authors to consider whether intellectual property should be protected. If a co-author is an EFPIA member then the relevant EFPIA company approval process will need to be followed; this process can be pursued in parallel with submission to the PRC.

5.3 Primary DIRECT manuscripts/reports

The final draft of the manuscript, with tables and figures, should be submitted to the Chair of the PRC ([redacted]) via [redacted] at least 30 calendar days prior to planned submission, who will acknowledge receipt. In the event that [redacted] is out of the office, the manuscript should be submitted to [redacted] and [redacted], who will deputise in [redacted] absence. A completed manuscript submission pro-forma (see appendix) must also accompany the manuscript. This pro-forma shall also include up to 4 suggested Reviewers from among the post-doctoral scientific members of the DIRECT consortium and who are not co-authors on the manuscript. The manuscript will be forwarded to the Chair of the PRC and, in parallel, to all DIRECT scientific members (to enable objection to publication or authorship disputes to be considered by the Publications Review Committee (PRC), and to allow internal approval from EFPIA partners, if required). The PRC will be responsible for forwarding the draft manuscript to the suggested Reviewers. Response from selected Reviewers should be made via the PRC members within 14 calendar days of receipt. Lack of

response will imply approval. Response from scientific members should be directed to [redacted]. Lack of response will imply approval after 30 calendar days.

The PRC Members will provide content and context review of the manuscript as outlined above and coordinate Reviewers' responses with the corresponding author, where necessary. If a revision is deemed necessary then, as is the norm in peer-review, the same Reviewers will be given the chance re-review the revised version of the article. Articles will be considered ready for submission only once this internal review process has been completed satisfactorily. Please note that any accepted manuscripts should be sent to [redacted] for deposition on the DIRECT website.

5.4 Other manuscripts

Non-Primary DIRECT manuscripts only require review and approval of the PRC prior to submission, this to be completed within 14 calendar days of receipt. All manuscripts should include the acknowledgement text outlined above to acknowledge the contribution of the DIRECT resource, and accepted manuscripts should be sent to [redacted] for deposition on the DIRECT website.

5.5 Patent Applications

Patent applications should be submitted to [redacted] for circulation to the Management Board, members of which will either agree to the patent application within 14 days or feed objections back to the patent developer.

6. *What to do after your presentation, abstract or manuscript has been accepted*

Following acceptance for publication, please inform the PRC members and provide the name of the journal/ meeting and the publication reference, so this can be recorded in the DIRECT publication tracker. Copies of all presentations, abstracts, posters and manuscripts, except patent applications, should be provided to [redacted] for deposition in the members' area of the website.

6.1 What to do after your patent application has been filed

Please notify [redacted] that your application has been filed.

7. Notes about Manuscript Authorship

7.1 All DIRECT-related work planned for publishing should be based upon results gleaned from previously submitted analysis plans. Once key results are finalised, the writing group for the project in hand (membership of which is to be determined in the early stages of the proposed analysis plan) should ensure the appropriate authorship positions for *all* members of the consortium involved. Authorships should include the appropriate data providers (e.g. clinical site staff, data QC, etc.), writers and analysts associated with the planned manuscript.

Prior to drafting of the manuscript proper, a brief framework, including key findings/results, should be submitted to *all members of the PRC* in the form of an 'Abstract of Intent'. This document shall also include an initial list of

proposed authors. The PRC will check that the authorship list is appropriate before the Abstract of Intent is then circulated to the whole consortium; any interested parties not yet aware of the ongoing work will then have 7 working days to inform the writing group of their intent to contribute.

Please note that all authors should be proactive in their role, be able to take public responsibility for the content of the publication and defend its criticism. It is suggested that preference be given to an institution's more junior contributors, who have been most active in the research being reported. The author list may also include non-DIRECT co-authors, who have contributed significantly to the work.

7.2 For manuscripts produced outside of an approved DIRECT Analysis Plan, the instigating author and the relevant PI will be responsible for coordinating a working group to prepare the manuscript. The PI will announce the intended plan for the manuscript via email to other members of the Work Package (WP) and, where relevant, to the consortium. The PI will also invite WP members to volunteer to contribute, by submitting a clear justification for their inclusion in the paper, including details of exactly how and what they will contribute (no more than 1/2 A4 page of text). This invitation will include a deadline for response of 10 working days after it is sent out. Non-response within this timeframe will be interpreted as unwillingness to take part. In instances where more than one person volunteers for a similar role, or where the writing group exceeds a reasonable number (i.e. 10 members), the leading author and PI will work with other potential authors to reach an agreement on the final author list. Note: final authorship should be decided by members of the writing group most involved in designing and drafting the manuscript; all authors should be able to take public responsibility for the content of the publication and defend its criticism.

7.3 Authorship lists shall include the suffix ": *for the IMI DIRECT consortium*" or, if this is not allowed by the journal, then embed "The IMI DIRECT consortium" in the author list. All scientific members of the consortium are to be listed in the supplementary online appendix; those not listed as co-authors in the actual author list should be listed as collaborators in Pubmed indexing.

For non-primary DIRECT manuscripts, authorship should include all scientific members who have contributed to sample collection, sample and data analysis (including QC of data).

Should an authorship list be disputed this should be referred in the first instance to the PRC. If their guidance is not accepted then the matter should be referred to the Management Board for resolution. In the unlikely event that authorship cannot be agreed, the key areas of dispute should be outlined and the IMI JU coordinator will arrange for independent review. Unless conflicted, this will be the role of the PRC WP9 member ([redacted]) and the legal representative(s) of [redacted] If necessary, other members of the Management Board will be co-opted. A majority decision will be final. All authorship assignment needs to be in line with journal policies.

8. Other considerations:

8.1 Impact maximisation

To maximise the impact of peer-reviewed research publications there is a need to make such publications as widely available as possible. Where possible, the findings from the research funded by the DIRECT consortium should be made freely available to the broader scientific community as soon as possible by deposition in an open-access repository.

8.2 Quality of written publications

It is necessary to ensure high standards of writing, editing and production consistent with the international status of the DIRECT consortium and the exceptional staff who work within the Consortium.

8.3 Audiences

The DIRECT consortium recognizes the following audiences for information dissemination through its publications:

(a) The international scientific community

(b) The extension personnel in the DIRECT consortium and the participating organisations

(c) Policy makers, and IMI-JU officials

(d) The general public and specifically, the patients and volunteers who have participated in DIRECT studies

8.4 Publication Ethics

Scientific publication is governed by certain ethical principles that should be followed by authors, editors, manuscript reviewers, and publishers. Of these, a few key principles, adapted from the Council of Biology Editors Style Manual {CSE (Council of Science Editors) manual, *Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers*}, are described below.

Authors have three main ethical responsibilities in presenting their work for publication:

(a) honest and full reporting, which implies accurate and complete description of the observations made and data collected,

(b) honest relation of their work to that of others allowing the reader to evaluate their report objectively

(c) follow DIRECT (and institutional) procedures for the approval of their manuscripts.

(d) ensuring that, where data have appeared in a prior publication, this is appropriately acknowledged within subsequent manuscripts, presentations, or reports that cite those data

(e) that emphasis is placed on the inclusion of all relevant available data within a single publication (i.e., avoid salami slicing the data)

Unpublished data drawn from other sources should be identified as such and be appropriately credited, with indication that such acknowledgement is with the consent of the person or entity being credited.

Unless the data have been updated and the conclusions modified, the same manuscript should not be published in more than one outlet. For example, a paper published in the proceedings of a workshop should not be published as such in a journal, but it may be offered to a journal if its content has substantially changed since it appeared in the workshop proceedings. All reviewers must treat unpublished manuscripts as confidential communications and not divulge their contents without the written consent of the author/s. Reviewers are responsible not only for unbiased, objective critical analysis of manuscripts but also for completing their task within the time-frames outlined in this policy.

8.5 Competing Interests Statements:

Some publications, such as PLoS ONE, require a Competing Interests Statement to be declared by authors in situations where a commercial funder has had involvement with the study – such as the role of EFPIA in the DIRECT consortium. Accordingly, a statement to the effect that this does not alter our adherence to all the journal's policies on sharing data and materials may be requested and should be readily given. This should read:

IMI DIRECT has received funding from EFPIA members, including companies X, Y and Z. Authors A, B and C [insert author initials] are employees of company X / Y / Z.. This does not alter our adherence to [the publishing journal's] policies on sharing data and materials.

8.6 Use of pilot data in support of Grant Applications

It is permissible to use pilot data arising from DIRECT in support of grant applications but only on the following conditions:

The preliminary data to be used must be circulated to all contributors together with an outline of the grant application

The Management Board must also be sent a copy of the data to be used and an abstract of the grant. The MB will have 5 working days in which to raise any objections.

9. PRC Members' contact details

For DIRECT PRC Members as mentioned in this policy:

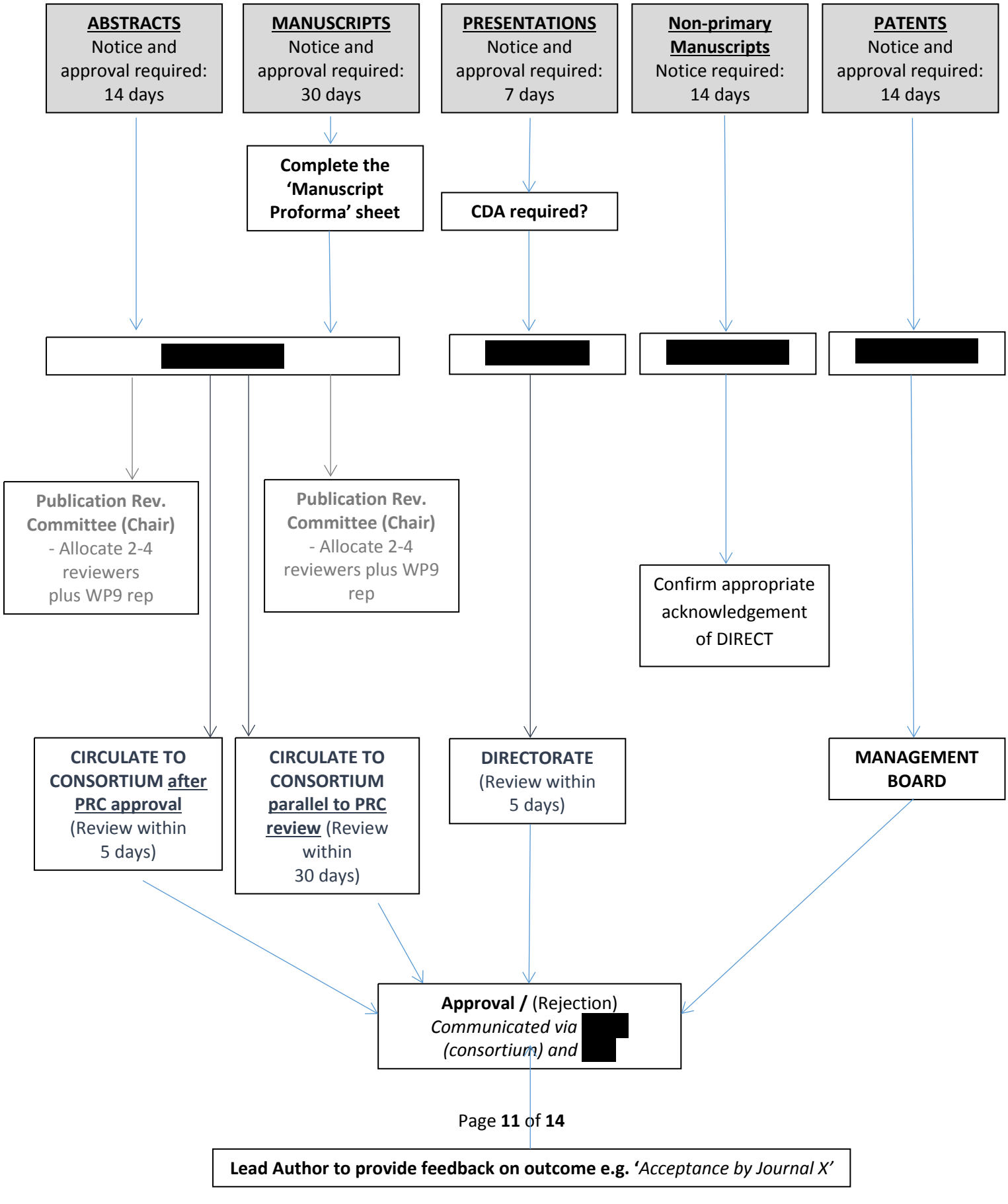
[redacted]

10. Summary of Revisions: Changes from previous version of this Policy

- Revision of PRC chairperson, members and inclusion of their contact details
- Introduce use of all post-doctoral scientists within DIRECT as a pool of potential reviewers
- Reduction in time for reviewing and responding to abstracts
- Insertion of contents page, numbered sectioning, competing interests statements, use of pilot data and 'summary of changes' section

- Clarification of non-primary DIRECT manuscripts
- Other minor edits

ANNEX: Publications Flow Chart



DIRECT Consortium Manuscript / Patent Submission Proforma

Title of Manuscript/Patent:

Authors of Manuscript/Patent (in order planned):

This Manuscript/Patent will be submitted to {planned journal/Patent office}:

Complete for manuscript only: Does this manuscript include (tick those which apply): Title text Acknowledgement to DIRECT Website link Logos

Complete for manuscript only: Describe any intellectual property protection which has been secured ahead of the manuscript submission or which is in progress:

Complete for manuscript only: List all historical samples used and their originating studies: *Complete for manuscript only*: Have appropriate acknowledgements been included for these studies according to the MTA? (Y/N)

Suggested Reviewers from the DIRECT consortium (Min 2, max 4 for abstracts; Min 4 for manuscript). No Co-authors

Date of submission to DIRECT consortium manager:

Proposal for authorship of manuscripts arising from pre-diabetes and diabetes cohorts (WP2)

1. Authorship for each manuscript will be determined by the writing group, with analysts who have contributed directly to the analysis and manuscript being positioned in the first few and last few authorship slots.

   All DIRECT participants not included in the author list will be listed as collaborators on PubMed and in a supplementary document in the manuscript.

In addition, the following authors should be included in the author list:

2. Core – for all DIRECT primary papers arising from pre-diabetes and diabetes cohorts

*Clinical study centre authors **
[redacted]- study coordination and phenotype definition;
[redacted]- study design and coordination;
[redacted]– contributed to diabetes study design and coordination (for diabetes cohort)
[redacted]- study design;
[redacted]- Data curation, computation environment, study design;
[redacted]- QC (incl.. sample swaps);
[redacted]- Sample processing/analysis;
[redacted]– ethico-legal input.

3. ***Plus the following authors***, depending on data/focus of the manuscript:

Progression models – [redacted]

OGTT derived parameters - [redacted]- already included

GLP-1, Glucagon - [redacted]

MRI derived parameters - [redacted]

Diet - [redacted]

Accelerometry – [redacted]- already included, [redacted]

GWAS - [redacted](already included)

RNA Seq – [redacted]- already included

Metabolomics – [redacted]- already included, [redacted]

Proteomics – [redacted]– already included), [redacted]

Metagenomics - [redacted]- already included

Ethico-legal/governance – [redacted]

** Study centres (where authors are to be rotated, clinical centre to decide)*

Prediabetes:

[redacted]

Diabetes:

[redacted]