JDRF International
200 Vesey Street, 28th Floor
New York, NY, USA 10281

July 20, 2022

Elise Gamertsfelder
London School of Economics and Political Science
Houghton Street
London, UK
WC2A 2AE

RE: Response to Clinical Trial Transparency Assessment

Dear Ms. Gamertsfelder:

We sincerely thank you for your interesting and revealing analysis on clinical trial transparency based on information available on our website jdrf.org. We appreciate the opportunity to comment on your assessments. In this letter response, we will respond to your three questions: 1) whether your team has overlooked any items; 2) if we believe consideration of re-scoring is appropriate and if so, why; and 3) if we have forward plans to adjust our policies and practices.

We have organized our response according to the line items in your spreadsheet, "Rating_JDRF.xls". We have provided responses for Lines 5, 7, 8, 11, 14, 16, 17. For those line items not mentioned, we thank you for your informative perspective.

Line 5: Prospective Trial Registration

1. *Has our team overlooked any relevant items, links or documents?*

   Yes. We gather that your team focused your assessment on this page:
   https://grantcenter.jdrf.org/information-for-awardees/admin-resources/
   which is under the category "For Awardees" on JDRF's Grant Center. This includes a link to our **JDRF Terms and Conditions, the most recent version being at this link**:
   https://grantcenter.jdrf.org/wp-content/uploads/2022/03/JDRF-Terms-and-Conditions-3.25.2022.pdf
   This is the most current updated copy of the JDRF Terms and Conditions, we would appreciate your confirming use of this copy for your assessments.

   We would like to point out that there is additional information on the "For Applicants" page, https://grantcenter.jdrf.org/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements/ which leads to a key document, the

JDRF Clinical Guidelines for applicants:

https://grantcenter.jdrf.org/wp-content/uploads/2022/06/JDRF-Clinical-guidelines-13Jun2022.pdf

Please note that this copy of the JDRF Clinical Guidelines was uploaded to our website on June 30, 2022, prior to our receiving your request. However, this requirement has remained stable from prior versions of the JDRF Clinical Guidelines.

In relation to Prospective Trial Registration, The JDRF Clinical Guidelines include the following on page 4:

> "Clinical trial registration. JDRF requires all applicable clinical trials [including all non-exempt human subjects research] be registered in a clinical trial registry [country specific or international] e.g., Clinicaltrials.gov database to ensure information is freely available on JDRF funded trials within the T1D community. The registration should be no later than 21 days after the first subject is enrolled."

Registration of clinical trials is of particular importance to JDRF. We have a clinical trial matching tool for the T1D community at the link below that draws upon data from clinical trial registries like ClinicalTrials.gov. Our Clinical Trial Connector (CTC) tool matches people with type 1 diabetes to potential clinical trials based on their selections including for geography and age.

Clinical Trial Connector https://www.jdrf.org/impact/research/clinical-trials/

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   With this clarification, we respectfully request that the scoring be adjusted from "Some Trials (yellow)" to "Full (green")" as JDRF requires this for all trials.

3. *Is your foundation planning to introduce any new or additional policies or monitoring systems that are salient to this assessment? (If yes, please provide details on their content, plus the date at which the new policies/systems are expected to be put into place.)*

   Yes. To ease the finding of the JDRF Clinical Guidelines, we plan to cross-link the document to both the "For Applicants" and the "For Awardees" sections by end of Q3-2022.

Line 7: Results onto registry in 12 months; and

Line 8: Protocol onto registry in 12 months

1. *Has our team overlooked any relevant items, links or documents?*

Please see above, the **JDRF Clinical Guidelines** requiring registration were overlooked.

Additionally, we have in our grants portal, RMS360, documents with questions which address this topic. Your team did not overlook these, because the documents are not publicly-facing; however,

they are required for all applicants wishing to submit a clinical trial proposal and we refer to these documents on our website under "For Applicants" and in our special Requests for Applications.

We would like to draw attention to our **human subjects research plan (HSRP**) (referenced as a requirement in our **JDRF Application Guidelines**, https://grantcenter.jdrf.org/information-for-applicants/how-to-apply/application-guidelines/) which includes the following questions for applicants:

> "A. Describe the potential for disseminating and implementing the results of this research in settings like conferences, workshops, clinicaltrials.gov, etc.
>
> B. Describe how you will make study results available to study participants after you complete your analyses.
>
> C. Describe your plans on data sharing on clinical trial registries i.e., CT.gov (individual patient level data (IPD)), etc."

Additionally, JDRF strongly encourages investigators to publish data and there is a requirement for grantees to send pre-prints of manuscripts prior to publication **(JDRF Terms and Conditions, Section 5.7, Publication Requirements).**

> "5.7 Publication Requirements. The Grantee Institution is expected to publish in relevant scientific journals and to provide information to the public on objectives, methodology, and findings resulting from their JDRF-supported research activities. The Grantee Institution must notify JDRF Grant Personnel of any publication relating to JDRF-supported research. Copies of abstracts and journal articles (preprints and reprints) should be included as a component of the Grantee Institution's yearly grant renewal, or may be submitted anytime during the grant year through RMS360. The Grantee Institution is required to submit all full-length peer-reviewed publications resulting from JDRF funding to JDRF prior to the publication date. JDRF will honor all embargos."

In addition, **JDRF Terms and Conditions Section 5.8** reference our **Public Access Policy** which requires awardees to deposit manuscripts publicly in PubMed Central within 12 months of publication.

> "5.8 Public Access Policy To ensure the scientific knowledge generated by JDRF funding can be accessed, read, applied and built upon in fulfillment of our organizational goals, JDRF expects its researchers to publish their findings in peer- reviewed journals. It is a condition of JDRF funding that all peer-reviewed articles supported in whole or in part by its grants be made available in the PubMed Central online archive in accordance with the following conditions:
> • Authors are to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication.
> • The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication.
> • An author must acknowledge JDRF support in every article arising from such funding. The acknowledgement statement must include the applicable JDRF grant number. This

will enable JDRF to link the published outputs of research to the support it has provided. PubMed Central is a database of full-text biomedical journal articles available online without a fee. It is hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated within the context of other research findings, making it easier for scientists worldwide to pursue T1D research. Equally important, families, clinicians, patients, educators, funders, and students reap the benefits of information arising from funding by accessing publications on PubMed Central at no charge. An author must acknowledge JDRF support in every article arising from such funding. The acknowledgement statement must include the applicable JDRF award number. This will enable JDRF to link the published outputs of research to the support it has provided. Resources regarding JDRF's public access policy can be found within JDRF Administrative Resources."

Along with these requirements, standard operating practices encourage JDRF staff to remain in contact with an awardee even after a grant is concluded. It is common practice to discuss dissemination of the results at the time of manuscript preparation, and topics such as sharing results on a registry such as clinicaltrials.gov are often discussed at this time.

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   With this clarification, we respectfully request that the scoring be adjusted from "No/None (red)" to "Non-binding (orange)" for both categories, "Results onto registry in 12 months" and "Protocol onto registry in 12 months"

Line 11: Trial ID in publications

1. *Has our team overlooked any relevant items, links or documents?*

   The JDRF Clinical Trial Guidelines (see response to Line 5), the Publication Requirements (see response to Lines 7 and 8) and the Public Access Policy (see response to Lines 7 and 8)

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   When grant awardees comply with our Publication Requirements and supply a pre-print prior to publication, our staff have the opportunity to comment on the manuscript and request the inclusion of Trial ID. With challenges in enforcing the publication requirements, it would be fair to say our requirement is non-binding.

   With this clarification, we respectfully request that the scoring be adjusted from "No/None (red)" to "Non-binding (orange)"

Line 14: PIs' past reporting record

1. *Has our team overlooked any relevant items, links or documents?*

Biosketches are a requirement for all applications received by JDRF, per the JDRF Application Guidelines (https://grantcenter.jdrf.org/information-for-applicants/how-to-apply/application-guidelines/)
JDRF's scientific staff, and the peer review, include review of the biosketches for PIs' past publication and reporting records

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   With this clarification, we respectfully request that the scoring be adjusted from "No/None (red)" to "Non-binding (orange)"

Line 16: Monitors trial registration

1. *Has our team overlooked any relevant items, links or documents?*
   As above in the response to Line 5, in particular the JDRF Clinical Trial Guidelines that requires registration on clinicaltrials.gov

   In addition to the above requirement to register trials, we have had on staff at JDRF for nearly 10 years, specialized clinical trial management (CTM) staff. These staff are responsible for monitoring active clinical trials via the evaluation of progress reports, as well as through communications via teleconferences which typically occur quarterly. We ensure that the trial registration is kept updated via these regular check-ins.

   Furthermore, JDRF standard practices entail that we fully activate clinical trial funding only after all ethical and regulatory documents have been received. We monitor clinical trials using progress milestones, which may include requirements such as updating trial information on ClinicalTrials.gov. Progress milestones considered confidential information between JDRF and the investigator, so this information is not public. However, progress milestones are considered binding, with payment withheld if the milestone is not met.

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   With this clarification, we respectfully request that the scoring be adjusted from "No/None (red)" to "Some Trials (yellow)"

Line 17: Monitors results reporting

1. *Has our team overlooked any relevant items, links or documents?*

   As above in the response to Lines 7 and 8, in particular the Publication Requirements and the Public Access Policy

2. *Does our team's scoring of any individual item award a score that your foundation considers too low or otherwise misguided?*

   As described in the response to Line 16, JDRF manages all clinical trials via milestones and deliverables. We use the milestones to monitor results reporting, which may be included as a progress milestone. Milestones are considered binding, with payment withheld if the milestone is not met.

With this clarification, we respectfully request that the scoring be adjusted from "No/None (red)" to "Some Trials (yellow)"

Thank you again for allowing JDRF to consider your assessment and to provide a response. Your assessment has stimulated positive discussions within our Research team on how we might improve our policies, practices, and Grant Center web presence. While it will not be possible to finalize these enhancements in the short timeframe you require for your assessment, please know that you have encouraged consideration of these important topics.

If we can assist with further questions, please do not hesitate to contact us. Otherwise, we look forward to news of your publication. We would appreciate receiving notification on when the paper and press release are expected to be public, along with copies of the documents if possible.

Lastly, a general request: please use our legal name, "JDRF International." We no longer use the long-form, Juvenile Diabetes Research Foundation. Thank you.

Sincerely yours,

[redacted]

CC: [redacted]