UK LLC Confidentiality Due Diligence Panel Meeting – Minutes

19th November 2024, 12-1.30 pm

PANEL MEMBERS IN ATTENDANCE	
Name	**Position**
Yoav Ben-Shlomo (Chair)	Professor of Clinical Epidemiology, Bristol Medical School (PHS)
Laura Corbin (Deputy Chair)	Research Fellow, Bristol Medical School (PHS)
Henry Stuart	Information Governance Manager and Data Protection Officer, Legal Services and Secretariat Management Team
Adam Taylor	Head of Research Governance, Research, Enterprise and Innovation
Anya Skatova	Senior Research Fellow, Bristol Medical School (PHS)
Debra Hiom	Associate Director (Research & Scholarly Communication), Library Services
Kirsty Merrett	Research Support Librarian, Library Services
Zosia Beckles	Research Information Analyst, Library Services
4 public contributors	Public contributor
INTRODUCERS IN ATTENDANCE	
Name	**Position**
Jacqui Oakley	UK LLC, Head of Operations
Emma Turner	UK LLC Research Fellow
Abigail Hill	UK LLC Research Manager (Data)
OBSERVERS IN ATTENDANCE	
Name	**Institution**
Andy Boyd	UK LLC Director
Robin Flaig	UK LLC Co-Director

Agenda Number	Application Feedback and Outcome
1.	**Conflicts of interests:** None declared.
2.	**Review of Terms of Reference for the Panel** A. The Panel reviewed the Terms, and it was highlighted that it was not clear that the pool of public participants would be invited to every meeting, to ensure quorum membership of public participants was met. B. In addition to this, the Panel highlighted during the meeting that there would be a benefit in recording additional comments relating to restrictions/inclusions in LPS materials for future use (and to ease the burden on future panel considerations). In response, the ToR has been updated to clarify point A with an additional statement: *"To ensure that the quorum for the public contributors for each meeting is met, a greater number than the quorum will be invited from the pool of public contributors".* In response to point B, a term suggesting that members flag inclusions/restrictions noted (for posterity) (v1.1) was added. The updated ToR will be circulated with these minutes for approval.
3.	**Review of previous minutes and actions:** None (this was the first meeting of this Panel).
4.	**<u>Name of Longitudinal Population Study (LPS) applying:</u> United Kingdom Research study into Ethnicity And COVID-19 outcomes in Healthcare workers** (UK-REACH) (application presented by Emma Turner) **<u>Outcome:</u>** The Panel agreed that UK-REACH's consent materials sufficiently met all criteria assessed and agreed that reasonable expectations had been met. An ambiguity in the original fair processing materials for UK-REACH was noted. The original text includes a description of the study purpose being both: *"to better understand how social and work-related factors affect the risks of COVID-19 infection, the impact on physical and mental health outcomes from COVID-19 among healthcare workers, and how to help*

reduce differences in outcomes among healthcare workers from diverse ethnic groups."

And in the original consent materials specifically detailed that participant data:

"can be used in anonymous form for further research in the public interest".

Summary of mitigations:

4.1 Further communications to participants about UK LLC should include clarification in relation to the possible ambiguity between the retention period specified on the Participant Information Sheets (PIS) provided as part of the UK LLC application and the retention period outlined in PIS v2.0 for a qualitative sub-study on the website.

Guidance and Requirements:

4.2.1 The Panel recommended provisional approval to join UK LLC, subject to a satisfactory response to the clarifications requested.

4.2.2 It is suggested that further communications with participants should clarify the term "periodically" when describing how frequently participant data is linked and reinforce previous messaging that the data could be used for public good research.

Risk Assessment Criteria:

1. **Is it clear to participants that the research purpose is compatible with the UK LLC research purpose (for any public good research)?**

   The Panel acknowledged that the original remit of UK-REACH was described as a 'study of healthcare workers and people who work in healthcare settings' and aimed 'to better understand how social and work-related factors affect the risks of COVID-19 infection, the impact on physical and mental health outcomes from COVID-19 among healthcare workers, and how to help reduce differences in outcomes among healthcare workers from diverse ethnic groups.' and that the original consent wording had a broader permitted purpose.

   The Panel agreed that the Newsletter sent out to participants, detailing how 'approved researchers may apply for access to the de-identified linked data held in UK LLC in order to undertake additional research in the public interest', helps address any potential ambiguity in the purpose and makes clear to participants that their data is being used for a wider research purpose.

	2. Is it clear to participants that researchers from other organisations will be able to access data? The Panel agreed that PIS v1.1 clearly states that anonymous information from the study would be shared with researchers approved by the UK-REACH Steering Committee. It was agreed that the stated process is consistent with UK LLC's researcher application process, with UK-REACH still conducting a review of each research application. For the I-Care sub-study, there was discussion around missing statements 9,10,11 in consent form v1.1 (18-07-24). The Panel agreed that further information about why numbers 9-11 were missing from the consent form is required in case there is a risk that important information was not provided.
	3. Is it clear to participants that other organisations (beyond the study group/organisation) are to be involved with record linkage? The Panel agreed that the PIS (v1.1. and v2.1) specifically details the linkage process, including the involvement of TRE organisations other than the University of Leicester, such as the NHS and other partnering academic institutions and a reasonable expectation for this was established.
	4. Is the retention period of the data compatible with UK LLC processing of the LPS data? It was noted that there appeared to be a discrepancy between the retention period information provided on PIS v1.1, v2.1, and PIS v2.0 for a qualitative sub-study on the website. The Panel agreed that clarification was required on the discrepancy between the 25-year retention period stated in the PIS v1.1, v2.1 or for a maximum of 5 years as stated in REACH-OUT's PIS V2.0. The Panel noted that, in order to meet reasonable expectations for participants future communications should clarify to participants the wording of "periodically linking".
	5. Is it clear to participants how to opt out of the study? The Panel agreed that a suitable level of detailed information had been provided, making it clear that participants have the right to opt out at any time and the mechanism to do this.

5.	**<u>Name of Longitudinal Population Study (LPS) applying:</u>** Covid Symptom Study Biobank (CSS Biobank) (application presented by Jacqui Oakley) **<u>Outcome:</u>** The Panel agreed that CSS Biobank sufficiently met the reasonable expectation to join UK LLC, with a restriction applied to the research purpose and subject to the following mitigations being implemented. The original remit of CSS-Biobank was 'to understand the impact and effects of COVID-19 and how these may be linked with health conditions and other genetic and environmental factors'. Despite the consent form stating that the participants linked health records would be used in 'health research', the PIS stated that 'Data linkage allows us to access large volumes of high-quality data for COVID-19 research'. Therefore, the Panel advised that it is not clear to participants that their data would be used for any public good research. **<u>Summary of mitigations:</u>** 5.1 The research purpose criteria (1) was considered to be too restrictive to set a reasonable expectation for data to be provisioned for public good research. The following were seen as options for the study to join: 1. Subject to the research purpose being restricted to Covid-19 research. 2. To reconsent participants informing them of the broader research purpose. **<u>Guidance and Requirements:</u>** 5.2.1 The Panel recommended provisional approval to join UK LLC, subject to the communications materials covering all the key mitigations. 5.2.2 CSS-Biobank is advised to send a newsletter/email communications directly to participants explaining the partnership with UK LLC, clearly stating UK LLC as the linkage facilitator (rather than OPENSAFELY). The communication should be accompanied by a clear mechanism to opt out (email/telephone). 5.2.3 UK LLC will check communications have been sent and the relevant permissions are in place prior to the study's data being linked by NHS England.

	Risk Assessment Criteria:
	1. **Is it clear to participants that the research purpose is compatible with the UK LLC research purpose (for any public good research)?** The Panel noted that participants had agreed to the use of their data for health research (question 8 on the consent form), however, it was noted that the supporting materials that were provided at the time of consent (VIS 1.1), and all accompanying and subsequent materials (newsletters, website) stated that the purpose of the study was to understand the short term and long term impacts of Covid-19. The Panel advised that to join UK LLC the study had two options: 1. to join UK LLC subject to the research purpose being restricted to COVID-19 research. 2. To reconsent participants. The Panel noted that a further option would be to seek Section 251 support from the Health Research Authority's Confidentiality Advisory Group. Panel members queried whether the study would be eligible to seek s251 as because the study was established in 2020 reconsent may be practicable without the risk of bias. This may be an option the study could explore.
	2. **Is it clear to participants that researchers from other organisations will be able to access data?** The Panel agreed that the consent form clearly stated that data could be shared with 'bona fide researchers, nationally and internationally' (question 7 consent form). It was agreed that VIS 1.1 reiterates this message and states that researchers outside of Kings College London may request data and that this is a study-level approval process. It was agreed that these statements met criteria 2. There was some discussion around the ambiguity of the term 'may' but this was considered to be appropriate because applications could be declined.

	3. **Is it clear to participants that other organisations (beyond the study group/organisation) are to be involved with record linkage?** The Panel agreed that VIS 1.1 had detailed the linkage process well and how IDs and personal information are handled, including the involvement of organisations other than Kings College London. It was noted that OPENSAFELY was mentioned as the organisation that would facilitate linkages. Therefore, the Panel agreed that the current statements did not fully meet reasonable expectations, but that this might be expected when processes and technology rapidly develop over time. To meet reasonable expectations for participants, and future communications to participants, the wording of 'fair processing" should clarify that UK LLC is now the organisation that will facilitate the linkages. It was advised that these communications should either detail the organisations that UK LLC works with within its privacy notice or signpost to the information available on UK LLCs website and privacy notice.
	4. Is it clear to participants that the retention period of the data is compatible with UK LLC processing of the LPS data? The Panel agreed that it was clear that the information would be stored for future projects, with no end date stated.
	5. Is it clear to participants how to opt out of the study? It was agreed that detailed information had been provided, making it clear that participants have the right to opt-out at any time and the mechanism to do this. The Panel advised that this clear statement should be provided in the information accompanying communication around UK LLC to participants, with a direct line of contact provided (email/telephone).

6.	**<u>Name of Longitudinal Population Study (LPS) applying:</u> European Prospective Investigation into Cancer and Nutrition** (EPIC) Oxford (application presented by Abigail Hill) **Outcome:** There was insufficient information for the Panel to reach a consensus on whether EPIC Oxford meets a reasonable expectation to join UK LLC. The Panel advised that additional supporting evidence should be submitted by the LPS and the application re-reviewed. **<u>Summary of mitigations:</u>** 6.1 it was deemed that there was insufficient information to reach a consensus on whether the research purpose is restricted to diet-related research. There was discussion on the following points: - The possibility of the research purpose being restricted to diet-related research. - Data to be provisioned for public good research if the LPS can demonstrate evidence of sufficient active communications to participants of the broader research purpose. **<u>Guidance and Requirements:</u>** 6.2.1 Further information and evidence are required to demonstrate whether there has been 'active communication' (i.e., where materials are sent directly to participants, not just 'passive' web content) with participants (e.g. Newsletters) outlining that data will be used for a wider research purpose. 6.2.2 Further information is required to clarify whether non-postal participants were also informed about the other organisations (beyond the study group) that are involved in record linkage. 6.2.3 Further information is required to clarify whether there has been 'active communication' with participants (e.g. Newsletters) outlining that data will be shared beyond the 'research group'. 6.2.4 UK LLC will request the additional information from EPIC Oxford and resubmit the application for re-review.

UK Longitudinal Linkage Collaboration

	Risk Assessment Criteria:
	1. **Is it clear to participants that the research purpose is compatible with the UK LLC research purpose (for any public good research)?** The Panel queried whether the materials supported public good research. The PI Leaflets (V6 and V7) state that 'EPIC has been designed to provide the best information ever collected on the effects of food on long term health ', which could be seen to restrict the research purpose. There was a thorough discussion around wider information provided on the website, newsletters and publications which appeared to demonstrate more general-purpose research. However, there are too many outstanding questions for the Panel to reach a consensus. The Panel acknowledged that the Protocol document referenced on the website details the potential use of the LPS data in answering 'questions of public health importance' but the Panel did not deem a Protocol document to be an accessible format to the participants/public and to be more aimed at a research audience and passive in nature. The Panel agreed that additional evidence of lay 'active communications' is required.
	2. **Is it clear to participants that researchers from other organisations will be able to access data?** The Panel identified potential ambiguity between the information stated on the website and the PIS v6/v7. The Panel agreed that further information is required on whether more up-to-date materials eg. newer versions of PIS or Newsletters address any ambiguity as to who comprises the 'research group' who are permitted to access study data.
	3. **Is it clear to participants that other organisations beyond the study group/organisation) are to be involved with record linkage?** It was agreed that the website explicitly details that other third parties are involved in the linkage process including the involvement of NHS England and or similar bodies in Scotland and Wales. As stated on the website, the Panel acknowledged that the participants who received the Consent form 'vegetarian participant EPIC consent.pdf' asked if they consented to linkage via their NHS number. However, the Panel agreed that further information is required to determine whether participants who were recruited via a GP surgery were asked the same question on the Postal Consent form.

	4. **Is the retention period of the data compatible with UK LLC processing of the LPS data?** The Panel agreed that it was clear that the information would be stored for at least 25 years after the end date of the study, which is currently still active.
	5. **Is it clear to participants how to opt out of the study?** The Panel agreed that detailed information had been provided, making it clear that participants have the right to opt out, information about what they are opting out of and the mechanism to do this.
6.	**Precedence and learning:** The Panel acknowledged across all three applications that 'passive' updates should not be the sole method of updating participants, such as just updating the LPS website. Instead, 'active' communication' methods of updating participants (e.g., newsletter/email notifications) should be implemented in conjunction with 'more passive communications' updates.
7.	**AOB**

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Annex 1. Risk Assessment

Is it clear to participants that…	**Outcome** (Delete as appropriate)	**Evidence** (From consent materials and participant information sheets)	**Risks and mitigations (To be completed by UK LLC)**	**Panel comments**
1. the research purpose is compatible with the UK LLC research purpose (for any public good research)	**Yes/ Is not entirely compatible/No**		**Risks:** ***Mitigations:***	
2. that researchers from other organisations will be able to access data?	**Yes/ Is not entirely compatible as presented/No**		**Risks:** ***Mitigations:***	
3. that other organisations (beyond the study group/organisation) are to be involved with record linkage?	**Yes/ Is not entirely compatible as presented/No**		**Risks:** ***Mitigations:***	
4. Is the retention period of the data compatible with UK LLC processing of the LPS data?	**Yes/ Further communications with participants are required/ No**		**Risks:** ***Mitigations:***	
5. how to opt-out of the study?	**Yes/ Further communications with participants are required/ No**		**Risks:** ***Mitigations:***	

Panel overall outcome (to be completed by the panel):
Please follow Figure 1, Panel Decision Flow Diagram in the Guidance document to select one of the following overall outcomes:* *- **Consent materials are compatible with UK LLC processing LPS data.* *- **Is not entirely compatible**- Further communications are required to be compatible with UK LLC processing LPS data.* *- **Consent materials are not compatible** with UK LLC processing LPS data.*
Further actions:

Annex 2. Panel overall outcome flow diagram