Matt Westmore, Chief Executive
Health Research Authority
2 Redman Place, Stratford, London E20 1JQ

Dear Matt Westmore,

We are writing to you on behalf of various LGBT or trans-specific organisations who work to support transgender, non-binary and gender-diverse children and young people. A critical healthcare service used by our community is the Gender Identity Development Services (GIDS), which is currently under independent review by Dr Hilary Cass ('The Review'). Many of us are key stakeholders in this work, and have been involved in an advisory and advocacy role with the team at various stages. The Review has commissioned three pieces of research: a literature review, qualitative research and quantitative research, led by researchers at the University of York. We write today to express our concerns about the proposed quantitative research approach, and would appreciate you making this letter available to the relevant Research Ethics Committee and the Confidentiality Advisory Group as part of the materials for their upcoming meetings considering the applications for approval of the proposed research protocol.

Trans, non-binary and gender-diverse people in the UK are currently facing a difficult political and media context, where we see our basic rights under threat, including our rights to privacy and freedom from discrimination. This understandably makes us concerned when the legislation which protects our privacy is compromised, such as the Statutory Instrument introduced in June to relax protections under the Gender Recognition Act (2010) for the purposes of this research. Access to appropriate, timely healthcare for our community is also an increasing challenge, with waiting times for a first appointment at GIDS at 2.9 years, and even longer in adult services. The Care Quality Commission (CQC) concluded an inspection of GIDS in 2021 raising concerns over waiting times and access to services, echoing issues voiced by trans advocates for many years. As organisations which provide direct support to young people and their families navigating healthcare on a daily basis, we are wholly invested in the improvement and expansion of gender healthcare services - an aim we understand is shared by The Review and NHS England. Further, we see the value of community-informed research in this space, to improve best practice in supporting trans healthcare approach and to enable continuous improvement of NHS services. We value evidence-based approaches to healthcare, and also believe this must be conducted with the trust and consent of those being researched.

This background is important to contextualise the concerns raised by many in our community about the proposed quantitative research approach, outlined below:

- Accessing 9,000 sensitive GIDS records without individual consent: GIDS records are highly likely to include incredibly personal notes on the gender dysphoric and life experiences of patients. The research will also obtain records of those who went on to access adult Gender Dysphoria Services after GIDS, containing similarly sensitive information. Some of our service users and wider community have expressed distress at these notes being made available to other people without their consent, even if they are pseudonymised. Given the specific vulnerability and politicisation of this population, and the historical context in which our medical journeys have been exposed and sensationalised in the past, the non-consensual nature of this research is of critical concern for many. While appreciating the logistical difficulties of opt-in consent for this cohort, we think it is especially important and should be strived for. The researchers have not explained why this cannot be achieved and we therefore ask that the Confidentiality Advisory Group probe this particularly carefully.

- Lack of meaningful Patient and Public Involvement (PPI): while The Review team does engage with patient and advocacy groups, we have expressed concerns with the lack of involvement of transgender health research professionals in the project. Regarding the quantitative research, we believe the overall PPI has been inadequate to date. They conducted 4-6 small focus groups to discuss the research, where the Statutory Instrument plans were not mentioned, and where we understand participation was limited and consensus in supporting the approach was lacking. We have asked to view more detail of the research protocol, to help understand the detail and potentially assure our community, but have been denied this. We do not believe that there is any legitimate reason to withhold the protocol. As the HRA has pointed out to researchers, effective PPI improves the quality project design in many ways. Even if the level of PPI proposed by the researchers reaches minimum standards, the refusal to share the protocol has already led to community mistrust in the research process; this will likely lead to higher opt-outs in this specific project, and disengagement from The Review, compromising the validity of the obtained dataset by biasing whose records are included more than an opt-in active consent approach would. We would ask the Research Ethics Committee to defer its decision on the application until it receives evidence that the protocol has been shared with a substantial and representative sample of potential participants and that their feedback has been adequately taken into account.

- Data safety: while we appreciate that the data linkage and storage process has been further explained, it is critical that the research protocol and governance is especially clear on maintaining the security of this highly sensitive data. The plans for immediate destruction of the linked data following the research project is also critical, and needs to be communicated clearly. This data set cannot be used for an ever-growing list of research projects interested in scrutinising some of our most private medical documents. Further, given full anonymisation will not be possible, and the team is instead aiming for pseudonymisation, there should be especially robust safeguards in place to limit identifiability.

- Opt-out options must be specific and widely communicated: should the quantitative research team proceed without individual consent of those involved (see point 1), there must be an opt-out option that is specific for this piece of research, and it must be communicated widely and effectively. There is a risk that people will otherwise use the National Data Opt-Out option, hindering future public health data collection which is critical for such a marginalised population.

Thank you in advance for your consideration, and for sharing these views with the relevant committees. We are committed to working with The Review toward the best outcome for the trans, non-binary, gender-diverse and otherwise gender-questioning children and young people who need access to healthcare in England, and recognise the importance of research and data in achieving this. However, there are times when we must advocate for the direct engagement and involvement of those the research seeks to study, and convey the serious privacy and consent concerns held by many of our service users.

Kind regards,

Susie Green (she/her)
Chief Executive Officer

Dr Paul Martin OBE (he/him)
Chief Executive Officer

Helen Belcher (she/her)
Managing Director

Cat Burton (she/her)
Chair

Helen Bowie (she/her)
Head of Partnerships and Development

Lisa Harvey Nebil (she/her)
Chief Executive Officer

Heather Paterson (she/her)
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Chief Executive Officer