**In awarding access to 1958 Birth Cohort resources, we ask all recipients to note the following stipulations:**

1. When publishing your work, you should acknowledge the use of the 1958BC biomedical resource (data and samples) using the statements provided at
http://www.metadac.ac.uk/acknowledging-1958-birth-cohort-resources-in-publications/
2. Data and samples from the 1958BC resource cannot be used for commercial purposes and any commercial involvement would breach the basis on which the access has been awarded.
3. Third party sharing of either data or biosamples is strictly prohibited. Any third party seeking to use the data, samples or derived variables or genotypes must apply directly to the METADAC access committee to obtain access permission in their own right. When your work is published, any journal seeking to provide access to the underlying data must provide links to the 1958BC resource and METADAC and not to the data itself.
4. The Principle Applicant is responsible for ensuring that novel data are returned to the study, in a format suitable for use by other researchers, and that meets 1958BC governance requirements. The Access Committee requires that, where possible, individual level data items created de novo are made available to other users in accordance with contemporary best practice and taking appropriate account of ethico-legal restrictions and recognising any potential risks of disclosures of summary level genotypes[[1]](#endnote-1). Data arising from the 1958BC resource cannot under any circumstances be posted in ‘open’ repositories, due to the need to ensure future research is in accordance with participant consent, and to oversee good management of any disclosure risk. When you have created novel data and are planning publication of your results, please contact the Secretariat who will arrange approval of your data return, including data format, IDs, linkage of gender/geographic information, documentation, and agreements on access governance for the new data. Any embargo periods must be pre-approved by the METADAC.
5. Following issue of 1958 data or samples, the METADAC requires annual reports until your project is concluded. Reports will be requested by *proforma* each November, for a return by the end of January. Reporting will usually end when publications are complete and all novel data have been appropriately returned: any data that is overdue for return will delay issue of further data or samples via METADAC until the issue is resolved.
6. For applications involving linked phenotype and genotype data it is important to note that once an award has been made, any future additions to the dataset (for example, if an additional linked phenotype variable is required) will have to be processed by the 1958 Birth Cohort Access Committee (Technical Review Team) and must comply with the original application. If you do need additional variables to be added, you should therefore inform the Secretariat of the METADAC.
7. Applicants are reminded that the Terms and Conditions for the cohort explicitly forbid any attempt to identify individuals or to compromise or otherwise infringe the confidentiality of information on data subjects and their right to privacy.
8. Incidental findings of clinical significance and potential benefit

In signing their original consent forms for inclusion in the 1958BC Biomedical Survey (2002-2003), consenting participants agreed that they would not receive feedback about any individual genetic results: *“...no information found in the DNA will be given to me”* (NCDS Medical Follow-Up, Consent Form 2 – blood samples)*.* In keeping with this wording the current policy is that *no* genotypic information (regardless of its nature) will be returned to cohort members.

To date, most informed commentators have seen this position as ‘good practice’ because nobody has really known how to interpret the clinical relevance of the genetic variants that have been identified: their effects have typically been rather small and there has been no agreed way in which to respond to the limited increases in risk they may convey. But in common with many of the world’s major cohort studies and biobanks, the 1958BC recognises that national and international views of what constitutes ‘best practice’ might be about to change. For example, as outlined by a senior international commentator in the field[2](#_ENREF_1), it is possible that in the future it may become mandatory to report genetic results to participants if they satisfy three key requirements:

 **(i) scientific validity** (the genotyping is of adequate quality);

 **(ii) clinical significance** (the disease or condition caused by the genetic variant is potentially serious) , and

 **(iii) potential benefit** (*i.e.* a valid approach exists to prevent or cure the condition/disease of concern and that early knowledge of the genetic risk to which an individual is exposed could enhance the efficacy of that prevention/cure).

At present a change in what is seen as best practice remains no more than a hypothetical possibility, but findings that satisfy the three stated criteria are likely to become more common as the global scientific focus moves to full sequencing of genes and/or longer segments of DNA. The METADAC therefore wishes to help contribute to the national and international evidence-base on which any future strategic decisions might be made regarding policy for feeding back genetic results.

For this reason, **the METADAC now *requires* that if in the course of any analysis of DNA from any participant in the 1958BC, a genetic variant is found that could potentially be viewed as meeting all three of the criteria stated above, that information must be transmitted to the METADAC Secretariat.**

At this stage this is no more than an exercise in collection of key data to assist us in developing an appropriate future strategy for the 1958BC – transmission of any information in this manner does not absolve the research group which generates the relevant finding from having their own internal policy to deal with this globally recognised problem. It is also important to ensure that your research group policy is consistent with the facts that: (1) at present NO genetic information can be returned to 1958BC participants; and (2) even if that policy were to change, all such contacts with cohort members would necessarily be undertaken by the Centre for Longitudinal Studies (contactable via the METADAC Secretariat). **These requirements are immutable under any circumstances** – even at the direction of an ethics committee that has reviewed your (the research group’s) project.

1. 1.. (Policy for Use and Oversight of Samples and Data arising from the 1958 Cohort at <http://www2.le.ac.uk/projects/birthcohort/oversight-committee>)

2. Knoppers BM, Joly Y, Simard J, Durocher F. The emergence of an ethical duty to disclose genetic research results: international perspectives. *Eur J Hum Genet* 2006;14(11):1170-8. [↑](#endnote-ref-1)