**BEC1 BIOBANK/DATABANK CHECKLIST 2025**

This checklist is designed to provide biobank/databank initiators or custodians with a summary of the recommendations included in the policy and audit and compliance documents of the Biobanks Ethics Committee.

Kindly complete and include this document with your submission. Please include an explanation where any response is “NO”

**Checklist**

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| 1 | Do you have a business plan?  | YES□/NO□ |
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2 | Has there been consultation with pertinent stakeholders, groups and communities? | YES□/NO□ |
| 3 | Is the information on the biobank/databank publicly available and easily accessible to stakeholders, including participants and the general public?  | YES□/NO□ |
| 4 | Do you have operational policies in place on all the biobank/databank contents, including policies regulating samples, data and equipment?  | YES□/NO□ |
| 5 | Have you developed criteria for sampling and participant selection to ensure data are representative of the targeted population? | YES□/NO□ |
| 6 | Have you developed an applicable governance structure?  | YES□/NO□ |
| 7 | Are the specific roles and responsibilities of those involved in the biobank/databank’s activities clearly identified?  | YES□/NO□ |
| 8 | Will participants be provided with detailed information prior to signing consent for storage in the biobank/databank? | YES□/NO□ |
| 9 | Have you specified which type of data and samples will be collected? | YES□/NO□ |
| 10 | Do you have a quality management process in place that maintains participant confidentiality? | YES□/NO□ |
| 11 | Do you have a system in place that allows all the biological material, data and any other information to be tracked? | YES□/NO□ |
| 12 | Are you in compliance with best practice guidelines? | YES□/NO□ |
| 13 | Have you ensured that privacy and confidentiality is protected? | YES□/NO□ |
| 14 | Have you ensured that the data contained within the biobank databank are protected in accordance with domestic law? | YES□/NO□ |
| 15 | Have you ensured that information that can readily identify an individual is separated from other data (eg. Genotypic data)?  | YES□/NO□ |
| 16 | Is there a robust infrastructure in place consisting of both hardware and software components, to prevent unauthorized access? | YES□/NO□ |
| 17 | Have you ensured that only a restricted number of authorized staff have access to information identifying participants and that information is monitored and documented? | YES□/NO□ |
| 18 | Have you ensured that there are policies in place on protection (samples/data)?  | YES□/NO□ |
| 19 | Have you ensured that there are policies in place on access to all samples and data? | YES□/NO□ |
| 20 | Have you ensured that researchers are provided access only to coded samples and data unless determined otherwise by an HREC? | YES□/NO□ |
| 21 | Have the terms of access for researchers been set out in an agreement? | YES□/NO□ |
| 22 | Have you developed a material/data transfer agreement or other appropriate agreement for samples and data access?  | YES□/NO□ |
| 23 | Have mechanisms been employed to ensure that researchers are not inadvertently provided access to potentially identifying data?  | YES□/NO□ |
| 24 | Have you ensured that national and international access to biobank/databank and samples are contingent on recipients being subject to the law and other binding requirements substantially similar to those applicable in South Africa?  | YES□/NO□ |
| 25 | Will international researchers who request access to data or samples have a collaboration agreement with the biobank/databank?  | YES□/NO□ |
| 26 | Have you ensured that participants will be informed whether or not samples and data will be accessible to third parties or law enforcement agencies and whether there are legal requirements to do so? | YES□/NO□ |
| 27 | Have you ensured that samples and data collected for health research purposes are not accessible to or disclosed to third parties for non-research purposes?  | YES□/NO□ |
| 28 | Will you ensure the general results of research conducted using the biobank/databank are made publicly available regardless of outcome? | YES□/NO□ |
| 29 | Will you ensure that aggregate results from research using the biobank/databank are not limited to academic publications and are made available in easily accessible forms?  | YES□/NO□ |
| 30 | Will you ensure an annual progress report and report at the completion or termination of a health research project is released and is made publicly available? | YES□/NO□ |
| 31 | Will researchers using the biobank/databank be provided with detailed guidance on the manner in which the biobank/databank wishes to be acknowledged in publications and/or patents?  | YES□/NO□ |
| 32 | Have you ensured that there are policies in place on benefit sharing?  | YES□/NO□ |
| 33 | Have you ensured that there is a system where benefit sharing agreements can be negotiated before a study begins? | YES□/NO□ |
| 34 | Have you ensured that participants are informed of commercial products that may arise from research conducted using the biobank/databank? | YES□/NO□ |
| 35 | Have you ensured that there is a plan for a situation where the biobank no longer meets a continued scientific need? | YES□/NO□ |
| 36 | Have you considered a possible end date for the biobank/databank? | YES□/NO□ |
| 37 | Have you ensured that there are policies relating to the closure of the biobank/databank including the manner in which the samples and data will be dealt with?  | YES□/NO□ |