

## ARISE task 2.1 – Nigeria

Within the ARISE project, particularly in the framework of the task 2.1 “Governance, Ethics and Law” the analysis of the applicable rules to be considered and respected to conduct research activities was performed.

The analysis advises in planning and executing research activities to be performed within the ARISE project, such as questionnaire-based studies, retrospective and prospective clinical studies as well as research involving the secondary use of data (e.g. Electronic Patient Registry) and samples.

These studies might involve human subjects, including also vulnerable populations (such as children) and in many cases the studies might imply also the transfer of data and samples between non-European and European countries.

The table below includes relevant information on the applicable official documents, particularly laws, regulations, and guidelines, in Nigeria, ruling the following items:

- Protection of personal data and confidentiality, including primary and secondary use of data
- Processing and protection of healthcare data, including also genetic data
- Handling of biological samples, including primary and secondary use of samples
- Requirements for minors and vulnerable populations

Title	Last update	Regulatory Authority releasing the document	URL
Constitution of the Federal Republic of Nigeria	1999	Federal Republic of Nigeria	<a href="http://www.nigeria-law.org/ConstitutionOfTheFederalRepublicOfNigeria.htm">http://www.nigeria-law.org/ConstitutionOfTheFederalRepublicOfNigeria.htm</a>
Child's Rights Act	2003	National Assembly of the Federal Republic of Nigeria	<a href="https://www.refworld.org/docid/5568201f4.html?_cf_chl_jschl_tk_=46cbdfae036cc91c78409366195f14169e01923c-1581082966-0-ATX0HzghRXgftXuL2_m7plgxYuzWFCFr7EyCSiIMVPD_lkwus3_mF7nJX-qMfw34HIHbvmWwRsm4mWEIZI0KhZ5qhULI8K94fQIJynQW5cb-Zk_4VYy-NTVv-wRsot8cJHj6ZIHHTWygcd4igAUdDf3OUo3LVo90xVtJaPbVJgH7NEr6DiVsvbK4XM23p_FkxPh0PMrer8-ise4VHwPspJLpvum5y5CCeF8EuJAWRw1ec3CWQOcGjecBEQiOypogyUfZJ6L4-YdZfnfpfjhac4sle1doYzvYQKAq55p7M-yn">https://www.refworld.org/docid/5568201f4.html?_cf_chl_jschl_tk_=46cbdfae036cc91c78409366195f14169e01923c-1581082966-0-ATX0HzghRXgftXuL2_m7plgxYuzWFCFr7EyCSiIMVPD_lkwus3_mF7nJX-qMfw34HIHbvmWwRsm4mWEIZI0KhZ5qhULI8K94fQIJynQW5cb-Zk_4VYy-NTVv-wRsot8cJHj6ZIHHTWygcd4igAUdDf3OUo3LVo90xVtJaPbVJgH7NEr6DiVsvbK4XM23p_FkxPh0PMrer8-ise4VHwPspJLpvum5y5CCeF8EuJAWRw1ec3CWQOcGjecBEQiOypogyUfZJ6L4-YdZfnfpfjhac4sle1doYzvYQKAq55p7M-yn</a>
National Code of Health Research Ethics	2007	Federal Ministry of Health	<a href="http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf">http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf</a>



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Code of Medical Ethics in Nigeria	2008	Medical and Dental Council of Nigeria	<a href="http://www.mdcnigeria.org/Downloads/CODE%20OF%20CONDUCTS.pdf">http://www.mdcnigeria.org/Downloads/CODE%20OF%20CONDUCTS.pdf</a>
Freedom of Information Act	2011	National Assembly of the Federal Republic of Nigeria	<a href="https://www.cbn.gov.ng/FOI/Freedom%20Of%20Information%20Act.pdf">https://www.cbn.gov.ng/FOI/Freedom%20Of%20Information%20Act.pdf</a>
National Information Systems and Network Security Standards & Guidelines	2013	National Information Technology Development Agency	<a href="https://nitda.gov.ng/wp-content/uploads/2018/07/National-Information-Systems-and-Network-Security-Final-Draft.pdf">https://nitda.gov.ng/wp-content/uploads/2018/07/National-Information-Systems-and-Network-Security-Final-Draft.pdf</a>
Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (PS1.02013)	2013	Federal Ministry of Health and National Health Research Ethics Committee of Nigeria	<a href="http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf">http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf</a>
National Health Policy	2016	Federal Ministry of Health	<a href="https://naca.gov.ng/wp-content/uploads/2019/10/National-Health-Policy-Final-copy.pdf">https://naca.gov.ng/wp-content/uploads/2019/10/National-Health-Policy-Final-copy.pdf</a>
National Health Act	2014	Federal Ministry of Health	<a href="https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01_-Official-Gazette-of-the-National-Health-Act-FGN.pdf">https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01_-Official-Gazette-of-the-National-Health-Act-FGN.pdf</a>
National Guideline for the Control and Management of Sickle Cell Disease	2014	Federal Ministry of Health	<a href="https://www.medbox.org/nigeria/listing?q=NATIONAL+GUIDELINE+FOR+THE+CONTROL+AND+MANAGEMENT+OF+SICKLE+CELL+DISEASE%2BNIGERIA&amp;sort=&amp;language=">https://www.medbox.org/nigeria/listing?q=NATIONAL+GUIDELINE+FOR+THE+CONTROL+AND+MANAGEMENT+OF+SICKLE+CELL+DISEASE%2BNIGERIA&amp;sort=&amp;language=</a>
Policy Statement Regarding Enrolment of Children in Research in Nigeria (PS2.1016)	2016	Federal Ministry of Health and National Health Research Ethics Committee of Nigeria	<a href="http://nhrec.net/nhrec/Final%20NHREC%20Policy%20Statement%20on%20Enrollment%20of%20Children%20in%20Research.pdf">http://nhrec.net/nhrec/Final%20NHREC%20Policy%20Statement%20on%20Enrollment%20of%20Children%20in%20Research.pdf</a>
Patients' Bill of Rights	2018	Consumer Protection Council and Federal Ministry of Health	<a href="http://fccpc.gov.ng/uploads/files/patients-bill-of-rights-full-version.pdf">http://fccpc.gov.ng/uploads/files/patients-bill-of-rights-full-version.pdf</a>
Nigeria Data Protection Regulation	2019	Nigerian Information Technology Development Agency	<a href="https://nitda.gov.ng/wp-content/uploads/2019/01/Nigeria%20Data%20Protection%20Regulation.pdf">https://nitda.gov.ng/wp-content/uploads/2019/01/Nigeria%20Data%20Protection%20Regulation.pdf</a>



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