Radboud Biobank Regulations

1 January 2018

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The Executive Board,

in consideration of the importance of regulating the constitution of the Radboud Biobank,
has defined the following Radboud Biobank Regulations.

Article 1.
The terms in these Regulations are understood to mean:

a) Sub-biobank: a biobank that qualifies for inclusion in the Radboud Biobank.

b) Head of a sub-biobank: the department head / head of a Health Chain / head of a consortium who is ultimately responsible for the sub-biobank.

c) Biomaterial: all human specimens collected and stored in the Radboud Biobank for research purposes.

d) Patient data: medical and clinical data – including imaging – and other donor details relevant to research, as well as details derived from the donor's biomaterial.

e) Donor: a person who donates or has donated biomaterial and the accompanying data to, among others, the Radboud Biobank.

f) Researcher: a person, company, institution, business or organisation who conducts research compliant with the terms and conditions laid down in these Regulations.

g) Dean: the Dean/vice chairman of the Executive Board

h) Research Board: the Research Board of the Radboudumc, comprising the Dean and the directors of the Research Institutes (RIMLS, RIHS and DCMN).

i) Director: Radboud Biobank Director

j) Director RIHS: Scientific Director of the Radboud Institute for Health Sciences

Article 2
2.1 The Radboud Biobank is a central infrastructural provision of the Radboud university medical center (Radboudumc) for clinical scientific research whereby the biomaterial and accompanying data are collected, prepared and stored for research purposes.
2.2 The aim of the Radboud Biobank is to improve the health of patients and to strengthen biomedical research in particular within the Radboudumc.
2.3 The Radboud Biobank is positioned as a technology center within the Radboud Institute for Health Sciences.

Article 3
3.1 The Dean appoints the members of the Radboud Biobank Advisory Council. The Academic Hospital Client Advisory Commission (CRAZ) and the Patient Advisory Council (PAR) have the opportunity to designate a patient representative, as a member and concurrently chairperson, of the Advisory Council.
3.2 The Dean appoints the chairperson of the Radboud Biobank Advisory Council.
3.3 The Radboud Biobank Advisory Council:
- advises the Dean
- develops the strategic plan

3.4 As a rule the Director attends the Advisory Council meetings.

Article 4
4.1 Radboud Biobank Strategic policies are discussed at least four times a year in the Research Board in the presence of theDirector. Advice from the Radboud Biobank Advisory Council is included in these discussions.
4.2 After discussion in the Research Board, as meant in 4.1 the Dean (chair of the Research Board) concludes in het governing capacity regarding Radboud Biobank policies and delegates the execution to the Director and the Director RIHS.
4.3 The day-to-day running of the Radboud Biobank is the responsibility of the Radboud Biobank Director who is appointed by the Dean. The Director is accountable to the Director RIHS for the operational management of the Radboud Biobank.

Article 5
5.1 The Director is supported by the Management Team (MT), comprising the CFO for the Radboud Biobank, an ICT co-ordinator, a biomaterial co-ordinator, a staff member management support and a biobank manager responsible for operational and quality management.
5.2 The Director appoints the MT members.
5.3 The Director appoints one of the MT members as a deputy director.

Article 6
The inclusion of biomaterial and the accompanying patient data into the Radboud Biobank via a sub-biobank will be determined conform the guidelines defined by the Director. These guidelines stipulate, among other things, the quality of the inclusion and collection of the biomaterial and the accompanying patient data.

Article 7
7.1 Each year the Director submits a budget to the Director RIHS. After approval the Director RIHS submits the Radboud Biobank budget to the Executive Board.
7.2 The head of the sub-biobank is responsible for the decentralised starting-up costs and the costs of the inclusion and collection of the biomaterial and the accompanying patient data.
7.3 The Director is responsible for the costs of preparatory work, freezing and storage of the biomaterial.
7.4 Researchers pay a contribution to the Radboud Biobank for issuance of biomaterial with accompanying patient data according to the tariff determined by the Director RIHS based on the proposal submitted by the Director.

Article 8
Both the Radboud Biobank and the sub-biobanks ensure that donor privacy is protected in agreement with legal provisions and codes of conduct pertaining to the use of biomaterial and patient data in the Netherlands.

Article 9
Patient participation in the Radboud Biobank is voluntary. The patient may withdraw consent at any time. Both the Radboud Biobank and the sub-biobanks ensure that the biomaterial and the accompanying patient data are collected, stored and used in observance of pertaining legal rights and existing codes of conduct.

Article 10
The Radboud Biobank will make public the use of biomaterial from its collection.

Article 11

In case of conflict between the Radboud Biobank and a sub-biobank, the Director or the head of the sub-biobank may present the case to an ethicist from the Department of IQ Healthcare for mediation. If, in this manner, no amicable agreement is reached the Director RIHS settles the matter or binding arbitration follows by an arbitration commission appointed by both parties.