Radboud Biobank Regulations

Technology Centers
Radboudumc
Radboud Biobank

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The Research & Innovation 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) Collection: a structured and delineated collection of biomaterial and associated data intended for multiple scientific studies, which is facilitated by the Radboud Biobank.
b) Head of a collection: the department head / head of a Health Chain / head of a consortium who is responsible for the collection.
c) Biomaterial: all human specimens that are collected by collections, including tissue, blood, urine, feces, and their derivates, such as DNA, serum, and plasma.
d) Data: all data related to both the donor – including images – and the biomaterial belonging to a collection, i.e., data from electronic patient files, extra data, and sample data.
e) Donor: a person who donates or has donated biomaterial and the associated 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 chair of the Executive Board.
h) Research & Innovation Board (RIBO): the Research Board of the Radboudumc, comprising the directors of the Research Institute for Medical Innovation (RIMI) and the domain leaders.
i) Academic Deliberation: comprising the directors of the Research Institute for Medical Innovation and the dean.
j) Head: Head of Radboud Biobank.
k) Director RIMI: Director Operations of the Research Institute for Medical Innovation.

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 associated data are collected, prepared, and stored for research purposes.
2.2 The aim of the Radboud Biobank is to improve health and healthcare by enabling good quality biomedical research.
2.3 The Radboud Biobank is positioned as a technology center within the Research Institute for Medical Innovation.

Article 3
3.1 For the strategic policy of the Radboud Biobank, a User Council has been established in which (potential) users of the Radboud Biobank are represented and a donor representative who acts as chair of the User Council.
3.2 The User Council of the Radboud Biobank advises on the development of the strategic policy of the Radboud Biobank and supervision on its implementation.
3.3 The User Council meets at least twice a year. The chair has periodic contact with the Head to discuss current affairs.
3.4 As a rule the Head attends the User Council meetings.

Article 4
4.1 Radboud Biobank operations and developments are discussed with the Director RIMI each month.
4.2 If necessary, the Director RIMI will ask the RIBO to provide advice on a decision to be made.
4.3 After discussion in the Research & Innovation Board, as meant in 4.2 the Dean (chair of the Academic Deliberation) concludes in het governing capacity regarding Radboud Biobank policies and delegates the execution to the RIMI.

4.4 The day-to-day running of the Radboud Biobank is the responsibility of the Head Radboud Biobank. The Head is accountable to the Director RIMI for the operational management of the Radboud Biobank.

Article 5
5.1 The Head is supported by the Management Team (MT), consisting of a business manager, an ICT coordinator, a biomaterial coordinator, and a staff member management support responsible for operational and quality management.
5.2 The Head appoints the MT members.

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

Article 7
Researchers pay a graduated rate to the Radboud Biobank for issuance of biomaterial with associated data according to the financial policy of Radboudumc.

Article 8
Both the Radboud Biobank and the collections ensure that donor's privacy is protected in agreement with legal provisions and codes of conduct pertaining to the use of biomaterial and associated data in the Netherlands.

Article 9
Donor participation in a collection which is facilitated by the Radboud Biobank is voluntary. The donor may withdraw consent at any time. Both the Radboud Biobank and the collections ensure that the biomaterial and the associated 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 and the associated data from its collections.

Article 11
In case of conflict between the Radboud Biobank and a collection, the Head or the head of the collection may present the case to an ethicist from Radboudumc for mediation. If, in this manner, no amicable agreement is reached the Director RIMI settles the matter or binding arbitration follows by an arbitration commission appointed by both parties.