Memorandum: Radboud Biobank scientific autonomy.

1. The Radboud Biobank is a central facility within the Radboud university medical center (Radboudumc) for the collection, storage and management of biomaterial and the corresponding clinical data for scientific medical research. In order to make this possible a catalogue of available samples is published on the Health-RI website.
2. If one wants to conduct research with biomaterial from a collection and the initiation of the collection has already been approved by the Institutional Review Board (IRB; CMO Radboudumc), one only needs to submit this to the IRB for assessment in certain cases (see also the memorandum Scientific and Ethical review at the Radboud Biobank). Research initiated, performed and financed from within an academic setting follows the same procedure as research initiated and financed by a private enterprise.
3. It is assumed and documented in the delivery contract, i.e. material and data transfer agreement (MDTA), that investigators will (eventually) make their findings public in a scientific journal. If an external applicant does not take the initiative to publish the Radboudumc partner involved in that project has the right (after a given time) to publish.
4. The Radboud Biobank has a differentiated fee for delivery. On payment of the fee the applicant acquires the right to use the biomaterial (and the corresponding clinical data) only for the research described in the application. The payer/applicant may not claim exclusive rights to the use of the remaining biomaterial from these patients; in other words, the Radboud Biobank may distribute the remaining biomaterial to other researchers according to the standard procedure and without consultation.
5. Should a private party wish to fully finance a Radboud Biobank collection in order to obtain exclusive rights to use of that biomaterial, a request can be made to the Radboud Biobank. If the IRB agrees that the purposes of medical science and innovation are served, such a request may be granted.
6. In order to maintain autonomy, management should ensure that the core funding for the Radboud Biobank is not dependent on such “exclusive” contracts. The net benefit will enable investments that will improve the Radboud Biobank.
7. In the instance of such ‘exclusive’ contracts the Radboud Biobank standards remain in force:
   - Review by the IRB at the initiation of the collection (Note: should the proposed research fall under the Dutch “Medical Research Involving Human Subjects Act” the application will be forwarded to the Medical Research Ethics Committee; CMO region Arnhem-Nijmegen);
   - Some requests for distribution of the biomaterial should be reviewed by the IRB;
   - Participation of a Radboudumc researcher;
   - A signed contract with the head of a department / health chain / consortium;
   - The usual procedures apply for the inclusion, collection, preparation, storage and distribution of the biomaterial and corresponding clinical data.
8. For such contracts an invoice will be drawn up based on the comprehensive costs for the Radboud Biobank (including overhead) and with a surcharge (of maximum 25%) for exclusive rights.
9. On payment of this fee exclusive rights will be acquired for the use of the biomaterial. For this reason the collection will not appear in the catalogue and requests for delivery to a third party will only be granted on approval by the sponsor.
10. The Radboud Biobank will mention these exclusive contracts, including the name of the sponsor, in the Annual Report.