

Memorandum: Radboud Biobank scientific autonomy.

1. The Radboud Biobank is, as infrastructure for scientific medical research, a Radboud university medical centre (RUMC) public provision intended for use by researchers from the Radboud UMC and other research organisations throughout the world. In order to make this possible a catalogue of available samples will be published on the website.
2. Each application for the use of samples is reviewed by the CMO-light (see also the memorandum Scientific and Ethical review at the Radboud Biobank) for scientific relevance and quality and for validity regarding the Informed Consent. 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 that investigators will (eventually) make their findings public in a scientific journal. If an external applicant does not take the initiative to publish the Radboud UMC partner involved in that project has the right (after a given time) to publish.
4. The Radboud Biobank has a differentiated tariff for delivery. On payment of the fee the applicant acquires the right to use the biomaterial (and the accompanying patient 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 sub-biobank of the Radboud Biobank in order to obtain exclusive rights to use of that biomaterial, a request can be made to the Radboud Biobank. If the CMO-light and the Advisory Council agree that the purposes of medical science and innovation are served, and the business proposal is advantageous for the Radboud Biobank, 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 CMO-light at the establishment of the sub-biobank (N.B. should the proposed research fall under the Dutch “Medical Research Involving Human Subjects Act” the application will be forwarded to the CMO);
 - Each request for distribution of the biomaterial will be reviewed by the CMO-light;
 - Participation of a Radboud UMC 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 accompanying patient details.
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 at least 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 sub-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.