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**FUND TERMS AND CONDITIONS**  
**'PIONEERS IN HEALTH CARE INNOVATION FUND'**  
**VERSION 20240909**

This document contains the Terms and conditions and obligations applicable to applying for a voucher from the Pioneers in Health Care (PIHC) Innovation Fund (hereinafter "Fund") and implementing the Project after a voucher is honoured.

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## 1 DEFINITIONS

<b>Award Letter</b>	Letter stating the Fund's decision to allocate budget to the Project proposal according to the Fund Terms and conditions and confirming this to the Project Leader.
<b>Fund</b>	The Pioneers in Healthcare Innovation Fund
<b>Fund Terms and conditions</b>	Conditions and obligations established by the Fund for the submission of a Project proposal, the assessment procedure, the responsibilities of the Fund and the Project parties, the implementation of the Project and the Invoicing, version 20240202 as published on the website <a href="http://www.utwente.nl/pioneersinhealthcare">www.utwente.nl/pioneersinhealthcare</a> .
<b>Other Party</b>	Party involved in the Project, which is not a PIHC party
<b>PIHC coordinators</b>	Staff at UT's TechMed Centre responsible for coordinating and managing the day-to-day operations of the Fund.
<b>PIHC Party</b>	Party that is part of the PIHC Fund (UT, Saxion, MST, ZGT or DZ) and is also involved in the PIHC Project.
<b>Project</b>	The research that is partly funded by the Fund and that will be carried out as further specified in the Project proposal and Project budget.
<b>Project budget</b>	Personnel, material and other costs relating to the implementation of the Project, shown per Party involved
<b>Project leader</b>	The Project Leader, as described in the Fund Terms and Conditions, is ultimately responsible for the content of the Project and monitors expenditure as defined in the Project budget.
<b>Project members</b>	All researchers and clinicians involved in the implementation of the Project
<b>Project parties</b>	The PIHC Party(ies) and/or Other Party(ies) involved in a Project.
<b>Project proposal</b>	The proposal submitted to the Fund
<b>Project results</b>	All results, including but not limited to data, know-how, software, information, materials, conclusions and findings generated under the Project by or on behalf of a Party, and all intellectual property rights relating thereto.
<b>Project team</b>	Project leader and project members
<b>Voucher</b>	An entitlement to a financial contribution from the Fund to be spent on the honoured Project proposal.

## 2 THE PIHC FUND

- 2.1. The University of Twente (UT) and the hospitals Medisch Spectrum Twente (MST) and Ziekenhuisgroep Twente (ZGT) launched the Pioneers in Health Care (PIHC) Innovation Fund in 2014. In 2017, the Fund was expanded to include Deventer Ziekenhuis and Hogeschool Saxion as partners.
- 2.2. The mission of the PIHC Innovation Fund (hereinafter "Fund") is to accelerate the introduction of innovative technology into clinical practice through bottom-up collaboration between the world of new technology and medical practice.
- 2.3. A call for proposals is published annually for researchers from UT and Saxion and medical specialists MST, ZGT and Deventer Hospital. Together, the Parties provide an annual budget of €600,000 for the Fund, from which 10 Projects can receive a contribution of up to €60,000 (including any VAT due).

## 3 SUBMISSION OF A PROJECT PROPOSAL

### 3.1 Formats and method of submission

- 3.1.1. The PIHC Fund Terms and conditions, proposal and budget formats, timeline and latest information are posted on the PIHC website ([www.utwente.nl/pihc](http://www.utwente.nl/pihc)).
- 3.1.2. Applicants use the proposal format and follow the guidelines. Applicants can choose between a Dutch or an English format. The title, keywords and abstract will be included in Dutch and English.
- 3.1.3. The Project proposal is submitted by the lead applicant via the submission page on the PIHC website, not via e-mail.
- 3.1.4. The deadline for submission is listed on the website. A Project proposal submitted after the deadline will not be considered for evaluation.
- 3.1.5. For questions, lead applicants can contact the PIHC coordinators at [PIHC-fund@utwente.nl](mailto:PIHC-fund@utwente.nl).

### 3.2 Applicants

- 3.2.1. The Project proposal is a joint effort of at least 1 researcher from UT or Saxion and 1 clinician from MST, ZGT or Deventer Hospital. Other parties may be involved in a Project proposal, but this is not a prerequisite.
- 3.2.2. The applicants designate 1 lead applicant, who is employed by 1 of the PIHC parties. The other applicants are co-applicants.
- 3.2.3. The lead applicant has demonstrable experience in conducting and supervising scientific and/or clinical research. For UT researchers, this means a completed PhD thesis.
- 3.2.4. The lead applicant is the first point of contact for the PIHC coordinators, e.g. for providing a presentation for during the PIHC Award ceremony.
- 3.2.5. Researchers or clinicians who have previously received a PIHC voucher can only apply for a new voucher if they start a new collaboration, develop new technology or focus on a new application, and if they can prove that the previous Project was successfully executed.

### 3.3 Project proposal

- 3.3.1. The research is innovative at the intersection of medicine and technology, answers a clear clinical need and is technological-scientific challenging and has an impact on healthcare.
- 3.3.2. The Project proposal indicates for which type of voucher the Project proposal is submitted:
  - a. The 'Technological pioneering in healthcare' (PIHC-TECH) voucher is for projects with a focus on the (further) development of a new technology for a specific clinical challenge. Clinicians provide essential knowledge and input from medical practice. When assessing Project proposals submitted under 'Technological pioneering in care', the technological-scientific challenge will weigh more heavily.
  - b. The voucher 'Applying technology in healthcare' (PIHC-APPL) is for projects investigating how technology with a proven track record (within or outside healthcare) can be used for a new application, such as a different condition, a different target group, or a different use situation. Because the technology is already further developed, the results can be meaningful in healthcare practice in a relatively short period of time. When assessing Project proposals submitted under 'Applying technology in care', the clinical impact will weigh more heavily.

- 3.3.3. If a grant or other financial contribution has been applied for from third parties for the same research described in the Project proposal, this will be stated in the Project proposal, indicating the status of the assessment of that application. As soon as the same research receives a contribution from another source, the lead applicant (or Project leader) informs the Fund so that it can be discussed whether to withdraw or amend the Project proposal (or Project).

### 3.4 Project budget

- 3.4.1. The Project proposal includes a Project budget according to the PIHC format with a maximum requested budget of €60,000 (including any VAT due).
- 3.4.2. Only project-specific costs can be entered in the Project budget.
- 3.4.3. The budget is not intended to fund staff members (personnel with a permanent (research) appointment) of UT, Saxion or hospitals (also no vacancy fees).
- 3.4.4. Guidelines Project budget:
- a. List the expected costs for each partner in the cost types personnel, material and other. Briefly explain the costs, and broadly tick in the schedule when the costs will be incurred.
  - b. Take into account any VAT due, which will be at the expense of the requested budget of €60,000.
  - c. Aim to distribute the budget among the partners. Provide an explanation in the Project proposal if all or most of the budget is allocated to 1 partner.
  - d. Keep in mind that staff are generally assigned to 1 employer (instead of 0.4 FTE for partners 1 and 2 and 0.2 FTE for partner 3).
  - e. Roughly maximum 10% of the budget may be budgeted at Other parties.
  - f. Additional budget or co-financing can be included in the Project budget.
  - g. The maximum contribution from the PIHC fund is €60,000 per voucher (including any VAT due).
- 3.4.5. Other purely commissioned parties should be included in the Project budget of one of the PIHC partners. A total maximum of roughly 10% of the budget may be budgeted for other parties closely involved in the research project, and these other parties should sign the Project agreement with the associated rights and obligations.
- 3.4.6. Contact the relevant finance department for more information on personnel costs, or when VAT is due.

## 4 ASSESSMENT PROCEDURE AND ALLOCATION OF A PIHC VOUCHER

### 4.1 Assessment procedure

- 4.1.1. After submission via the PIHC website, receipt of the Project proposal will be confirmed by the PIHC coordinators. It will then be checked whether the Project proposal meets the general requirements regarding the composition of the Project team, the completeness and maximum length of the Project proposal and whether the Project budget meets the basic conditions (e.g. maximum budgeted budget, maximum 10% to other parties).
- 4.1.2. If a Project proposal or Project budget does not meet the Fund Terms and conditions, the PIHC coordinators may decide to
- a. giving the Project leader the opportunity to amend the Project proposal or Project budget within 2 working days.
  - b. not to submit a Project proposal to the Assessment committee, but to inform it about this
- 4.1.3. The Assessment Committee consists of professors or associate professors affiliated with UT's TechMed Centre, lecturers from Saxion, and representatives of the science offices and clinicians of MST, ZGT and DZ.
- 4.1.4. An assessor serves on the Assessment Committee for a maximum of five consecutive years.
- 4.1.5. If members of the Assessment Committee are personally involved in a Project proposal, the assessment form is completed by another person from their own organisation. The other members of the Assessment Committee must agree to the nomination of this person. During the meeting of the Assessment Committee, the committee member concerned should temporarily leave the room during discussion of the Project proposal in question.

- 4.1.6. The Evaluation Committee will evaluate and assess the Project proposals using established evaluation criteria (further explanation of these evaluation criteria can be found in Annex 1). Weights (factor 1 or 2) are attached to these criteria (score from 1 to 5 for weak to strong); the minimum total score per party for a Project proposal is thus 10, the maximum score 50:
- Clinical and societal relevance (factor 2)
  - Challenge (factor of 2 for PIHC-TECH or 1 for PIHC-APPL)
  - Synergy between technological and clinical partners (factor 1)
  - Plan of action (incl. study design, timeframe and budget) (factor 2)
  - Short term Project results (factor 1)
  - Sustainable collaboration, continuation of project (factor 1)
  - Impact on healthcare and long term outcome (factor 1 for PIHC-TECH or 2 for PIHC-APPL)
  - Valorisation and/or implementation (factor 1)
- 4.1.7. The assessment for PIHC-TECH and PIHC-APPL Project proposals differs in the weighting factor for the assessment criteria Challenge and impact on Healthcare, and the focus within the Valorisation and/or Implementation criterion.
- 4.1.8. For each Project proposal, 2 assessors per Party jointly complete 1 assessment form. In addition to the scores on the above assessment criteria, the evaluators also give 'Tops' and 'Tips'. Each Project proposal ultimately has 5 scores (1 per PIHC Party)
- 4.1.9. The 5 evaluation forms are processed into 1 form by the PIHC coordinators. The Project proposals are ranked by the PIHC coordinators based on the average scores and the mean ranking. Notable issues, such as large differences in scores between batches, are highlighted.
- 4.1.10. At a meeting, the Evaluation Committee makes a pre-selection of the submitted Project proposals based on the ranking and further discussion of the best Project proposals. The Evaluation Committee submits the preselection of the submitted Project proposals to the PIHC Steering Committee.
- 4.1.11. The Steering Committee consists of the scientific director of the UT Technical Medical Centre, chairman of the Saxion Executive Board, and the chairmen or members of the Executive Boards of MST, ZGT and DZ.
- 4.1.12. The Steering Committee makes a final decision on the allocation of vouchers based on the preselection and balanced distribution of research themes and involvement of PIHC partners. In case of changes in the allocations compared to the pre-selection, feedback to the Evaluation Committee takes place before the decision is made final.

#### 4.2 Allocation of a PIHC voucher

- 4.2.1. The vouchers will be awarded to the Project teams during the award meeting to which all applicants are invited. Until that date, the results are confidential and will not be fed back to the applicants.
- 4.2.2. All Lead applicants will receive a confirmation or rejection message via e-mail after the distribution of vouchers.
- 4.2.3. After it is announced which Projects have been honoured, summaries will be posted on the PIHC website. A press release will also be distributed describing the objectives of the Projects.

## 5 RESPONSIBILITIES AND OBLIGATIONS OF THE FUND AND THE PROJECT PARTIES

### 5.1 Project parties

- 5.1.1. Each Project party shall ensure that the Fund Terms and conditions are complied with in the implementation of the Project, and that the contribution from the Fund is spent efficiently for the purposes for which it is granted.
- 5.1.2. Each PIHC Party concerned and any Other party shall provide the basic facilities required for the implementation of the Project (e.g. research infrastructure such as laboratories and equipment, workplace including computer and internet connection) and shall ensure the supervision of staff assigned to the Project.

- 5.1.3. The Project parties, together with the Project leader, will ensure proper management and administration of the financial contribution from the Fund. The Project parties will keep the financial records relating to the Project for a period of at least fifteen (15) years after completion of the Project.
- 5.1.4. If and to the extent that the Project may lead to harmful consequences for third parties - such as, e.g., patients or test subjects - the Project party will adequately insure itself against the risks of relevant claims. Each Project party indemnifies the Fund against any liability in this regard.

## 5.2 The Project team

- 5.2.1. The Project members are jointly responsible for the execution of the entire Project.
- 5.2.2. The Project team must implement the Project as described in the Project proposal and according to the Project budget. If the Project team wishes to make changes from the Project proposal, these must first be approved by the Fund. When submitting a change, it is essential to state the progress of the Project at that time, what changes from the Project proposal are desired and how the changes will have a positive impact on the intended results of the Project.
- 5.2.3. The parties are required to inform the designated representatives of the Fund in writing without delay of any circumstance that impedes or threatens the successful execution of the Project or will delay it, whether in time or not.
- 5.2.4. Project members provide the necessary information so that the Project leader can report the efforts made and (interim) results of the Project in the update, progress report and final (financial) report.
- 5.2.5. The Project team agrees for the Fund to include data from the reports in public publications such as the PIHC website, unless the Project teams indicate that there are compelling interests (privacy, patent application) that require temporary confidentiality.
- 5.2.6. Parties will carry out the Project to the best of their knowledge and ability, taking into account the criteria and standards applicable to scientific and/or technological and/or clinical research. The Project to be carried out by Parties will take place in accordance with the relevant laws and regulations and codes of conduct, including but not limited to the Dutch Code of Conduct on Scientific Integrity, Medical Research Involving Human Subjects Act (Wmo) and Medical Device Regulation (MDR).
- 5.2.7. If data and/or personal data are exchanged between Parties, those Parties will comply with the legal requirements and relevant regulations thereon. If necessary, Parties will conclude the necessary supplementary agreements to lay down the rights, obligations and responsibilities arising for Parties from the General Data Protection Regulation.
- 5.2.8. If a data subject suspects a violation of the said scientific norms and standards in the implementation of the Project, the data subject shall immediately inform the Fund of this suspicion and submit all relevant documents to the Fund. The Fund may launch an investigation.
- 5.2.9. The engagement of any third parties by Project members shall not affect the obligations of Project members set out in this agreement. The Project proposal and the Project budget must accurately describe which activities will be performed by third parties and what costs are budgeted for them.
- 5.2.10. At relevant meetings of the Fund's partners, project teams are expected to participate in any presentation of their Project and Project results.

## 5.3 The Project leader

- 5.3.1. The main applicant is designated as Project leader and bears final responsibility for the Project in terms of content and finance. If another Project member is designated as Project leader, this will be announced to the Fund as soon as possible after the voucher is awarded.
- 5.3.2. The Project leader is the first point of contact for the Fund. This is without prejudice to the fact that the Fund may also address the other Project members directly.
- 5.3.3. The Project leader can contact the Fund at: [PIHC-fonds@utwente.nl](mailto:PIHC-fonds@utwente.nl).
- 5.3.4. The Project leader and Project members are themselves responsible for complying with the Fund Terms and conditions. The Project leader monitors this.
- 5.3.5. The Project leader participates in information meetings organised by or on behalf of the Fund with Project leaders of other Projects receiving a contribution from the Fund.

- 5.3.6. The Project leader is responsible for delivering the reports required by the Fund: the update, the progress report and the final substantive and financial report.
- 5.3.7. The Project leader will request approval from the Fund for any substantial deviation or modification of the project plan, Project budget or composition of the Project team honoured by PIHC.
- 5.3.8. A request for extension by the Project leader must be received by the contact persons designated by the Fund no later than three (3) months before the end of the Project's term, who will decide thereon within three (3) weeks of receipt.
- 5.3.9. The Project leader will preserve and keep the scientific source data accessible in accordance with the applicable scientific standards for this purpose, but in any case at least five (5) years after completion of the Project.

#### 5.4 The Fund

- 5.4.1. The Fund will jointly provide the parties with a contribution of (a maximum of) €60,000 (in words: sixty thousand euros) in the year of award, which will be paid out after the voucher has been awarded on the basis of a Project budget prepared by the Project members and approved by the Fund, taking into account any VAT due. At the Fund's request, the costs listed in the Annex may be adjusted by mutual agreement. The contribution made available will remain unchanged, unless there is a lower contribution or withdrawal of the grant.
- 5.4.2. Unless otherwise agreed, payments shall be made within thirty (30) days of receipt of the invoice. The Fund shall be entitled to suspend payment if:
  - a. there are or will be substantial deviations from the Project proposal;
  - b. the progress report(s), including the financial accounts, do not provide sufficient insight or give the Fund good reason to fear that the Project proposal, including the approved Project budget, will be deviated from;
  - c. Parties fail to fulfil their obligations or fail to do so on time.
  - d. Before suspending, the Fund will hear the Parties on their intention to do so. Such hearing may be in writing.
- 5.4.3. If the Project has not started within six (6) months of the Fund's award, the Fund is entitled to withdraw the awarded contribution and terminate this agreement by written notice to the Project leader.
- 5.4.4. The Fund is entitled to discontinue the Project with immediate effect if, in the opinion of the Fund, it is unacceptable on medical or ethical grounds to start or continue the parties' research activities. In that case, the Fund will decide on the consequences, on the basis that the costs incurred up to the time of discontinuation will be reimbursed.
- 5.4.5. The Fund provides formats for the update, progress report and final project content and financial report.

## 6 PROGRESS AND IMPLEMENTATION OF THE PROJECT

### 6.1 The launch of Project

- 6.1.1. An award letter is sent to the lead applicant confirming that an amount of up to €60,000 (including any VAT due) is available for the Project as applied for by the lead and co-applicants.
- 6.1.2. The Project leader considers how to incorporate the substantive feedback from the assessment committee into the Project proposal.
- 6.1.3. After award, there may be adjustment of the Project budget. The Project leader provides a Project budget that has been discussed with and approved by the financial contact persons of the Project parties. Any feedback from the Assessment Committee and the Steering Committee is included.
- 6.1.4. For each project, the lead applicant becomes the intended Project leader. The co-applicants become Project members.
- 6.1.5. The Project must have started within six (6) months of award.

## 6.2 Project agreement

- 6.2.1. Prior to the execution of the Project, agreements on the execution of the Project and the utilisation of the Project results are laid down in a Project agreement. This is done between all Project parties.
- 6.2.2. The Fund has prepared a format for a Project agreement that defines concrete agreements on, among other things, the Project and implementation, finances, guarantee, confidentiality, intellectual property and liability. In exceptional cases, it is possible to use a different agreement. This is subject to the condition that (i) the mutual rights and obligations to the Fund, as stipulated in the Project agreement, are not deviated from and (ii) the agreement declares the PIHC Fund Terms and Conditions to apply fully and unconditionally. If the unamended pre-formatted format of the Project agreement is used, the provisions contained therein are subject to VAT reconciliation with the Inland Revenue. The Tax Authorities have confirmed to UT that no VAT is payable in respect of the mutual collaboration between the PIHC Parties on the basis of those provisions.
- 6.2.3. The Fund encourages collaboration between and participation of Parties. In doing so, no contribution will be made if agreements lead or may lead to the granting of unlawful state aid or if, as a result, the provisions set by the Fund cannot be met.
- 6.2.4. If using the Project agreement prepared by the Fund, the PIHC coordinators support the drafting and signing of the Project agreement.
- 6.2.5. If the Project proposal qualifies as a medical-scientific research with humans to which the Medical Research with Human Subjects Act (Wmo) applies, the parties will conclude a Clinical Trial Agreement (CTA) with each other in accordance with the applicable model of the Dutch Clinical Research Foundation (DCRF), which can be found on the website [www.ccmo.nl](http://www.ccmo.nl). The provisions of that agreement on liability, publication and termination shall prevail over this Project agreement.
- 6.2.6. If the Project agreement prepared by the Fund is not used, this will be made known to the PIHC coordinators. Any modifications in the template must be immediately recognisable. The Fund will receive a copy of the Project agreement signed by all Project parties.

## 6.3 Progress and completion of the Project

- 6.3.1. The Parties shall take all reasonably necessary steps to start the Project within six (6) months of its award by the Fund and complete the Project within twelve (12) months of its start, unless otherwise agreed by the Project leader with the Fund. The parties are aware that if the Project has not commenced within six (6) months of its award by the Fund, the Fund is entitled to withdraw the voucher awarded.
- 6.3.2. The Project leader will provide a brief update no later than 6 months after the award of the voucher, a progress report 6 months after the start of the Project, and will submit a final project content and financial report to the Fund within eight weeks after the Project ends. The Fund will provide formats for these reports in a timely manner.
- 6.3.3. The progress and final reports should clearly show the efforts made. More specifically, the reports report the (interim) results of the Project and indicate which (interim) objectives have been achieved.
- 6.3.4. The final report will indicate what efforts have been and are being made to promote knowledge transfer, implementation and utilisation of the results.
- 6.3.5. To stimulate sustainable regional collaboration and clinical implementation in multiple hospitals, during and after the Project, other PIHC parties will be considered to join the (follow-up) research and benefit from the results obtained.
- 6.3.6. Renewal of a Project should be requested by the Project leader from PIHC-fonds@utwente.nl at least 3 (three) months before the scheduled completion of the Project.
- 6.3.7. The final report will indicate which Project member can be contacted after 2 years for an update on, among other things, publications and follow-up (funding) resulting from the Project. This information will be included with the final reports in the Fund's 2-year evaluation.

## 6.4 Publication and communication

- 6.4.1. The Fund is committed to Open Access of Project results funded by the Fund: the Project results should be freely available for sharing and reuse and freely accessible for new

scientific research, unless there are compelling interests (privacy, patent application) that require temporary confidentiality.

- 6.4.2. The Fund aims for FAIR data management: the data resulting from the Project will be stored in a findable, accessible, interoperable and reusable manner.
- 6.4.3. The Project leader or Project members may be invited by the Fund to make a presentation on the progress of the project.
- 6.4.4. If the Project research results in publications, such as articles, reports, dissertations, conference contributions, presentations, reports and the like, an acknowledgment will be included in the relevant publication(s) with one of the following Dutch or English sentences:
  - a) This publication was produced with financial support from the Pioneers in Healthcare Innovation Fund of the University of Twente, Saxion University of Applied Sciences, Medisch Spectrum Twente, ZiekenhuisGroep Twente and Deventer Ziekenhuis.
  - b) This study was financially supported by an unrestricted research grant from the Pioneers in Health Care Innovation Fund, established by the University of Twente, Saxion University of Applied Sciences, Medisch Spectrum Twente, ZiekenhuisGroep Twente, and Deventer Hospital.
- 6.4.5. In addition to the scientific dissemination of the results, the Project team should also publish purposefully on the results.
- 6.4.6. If the results of the Project are publicised, for example with a press release, in an (online) daily or weekly newspaper, radio or TV, the Project team will inform the Fund, and the Project team will indicate in the publication that the results were achieved with a contribution from the Fund.

## 7 CONTRIBUTION AND BILLING

- 7.1. The Fund will finance the Project with a maximum amount of €60,000 (in words: sixty thousand euros), taking into account any VAT due. The amount paid out will be used exclusively for the implementation of the Project in accordance with the Project proposal and the Project budget.
- 7.2. The Fund informs the PIHC Parties concerned about the distribution of budgets among the various Parties, including the Project budget. Each Party takes care of its own financial administration. The Project leader and the Project members ensure that the costs incurred are correctly processed in the financial administration.
- 7.3. Other parties may submit an invoice for their budgeted and realised activities in the year of award. The Fund will submit the necessary information for this purpose, such as the reference of the invoice and correct way of sending the invoice.
- 7.4. Where projects involve Other Parties that are part of the project application or are engaged separately and receive part of a voucher in return for their work, the starting point is that this is a service on which this Other Party is liable to pay VAT.
- 7.5. The Project leader may submit a request for approval of a budget change or budget shift to the Fund after all Parties have agreed to this adjustment of the Project budget. The request shall be accompanied by a justification and an adjusted Project budget. The Fund shall approve or disapprove such request within three (3) weeks. The Fund is entitled to discontinue the Project with immediate effect if, in the opinion of the Fund, it is unacceptable on medical or ethical grounds to start or continue the research activities of the parties. In that case, the Fund will decide on the consequences, on the basis that the costs incurred up to the time of discontinuation will be reimbursed.
- 7.6. If the Project is terminated early, Parties will be jointly and severally liable to repay the remaining budget to the Fund.
- 7.7. The financial justification, which is part of the final report, should show how the voucher has been used for the Project in accordance with the approved items in the Project budget. The accountability provides such insight that a responsible judgement can be formed about the use and expenditure of the voucher. Significant differences between Project budget and realisation must be explained in the final report. If it can be deduced from the financial accounts that the funds have been used for the Project, the Fund will inform the Project leader of the determination of the contribution.
- 7.8. If in the Project, at the end of the term, the full budget has not been spent, the Fund will decide to proceed to repayment, or in consultation with the Project leader, use the remaining contribution for additional research, including new budget and justification in a supplement to the final report.

- 7.9. If it cannot be deduced from the financial statements that the funds have been used for the Project, the Fund may decide to have all or part of the contribution repaid. In the event that the Fund decides to have all or part of the amount disbursed repaid by Parties, the internal carrying obligation will be determined by the extent to which the decision to repay can be attributed to each of the Parties.

## ANNEX 1 EVALUATION CRITERIA PIHC PROJECT PROPOSALS

Voucher “Technological pioneering in healthcare”	Voucher “Applying technology in healthcare”
<p><b>Clinical and societal relevance (2):</b> The clinical and societal question (from specialists/patients/institution) is clearly defined and the relevance is clear. The solution is better, more efficient, faster or cheaper than current practice. It is clear who will use the technology, and who will benefit from the solution.</p>	
<p><b>Challenge (2)</b></p> <ul style="list-style-type: none"> <li>– The technology is not yet (sufficiently) developed.</li> <li>– The challenge is in the development of new technology. The technology-scientific and pioneering aspects are clearly defined.</li> <li>– It is clear what the new and pioneering aspects are and why seed funding is required.</li> <li>– This technological challenge arises logically from clinical demand.</li> </ul>	<p><b>Challenge (1)</b></p> <ul style="list-style-type: none"> <li>– The technology is developed to the point where it is ready for application, or the technology is already being applied within or outside healthcare, but not yet for this clinical question.</li> <li>– The challenge lies in adapting and/or applying this existing technology in healthcare (for this clinical demand).</li> <li>– It is clear what the new aspects are and why seed funding is required.</li> <li>– This challenge arises logically from clinical demand.</li> </ul>
<p><b>Synergy between technological and clinical partners “1+1=3” (1):</b></p> <ul style="list-style-type: none"> <li>– Clinical and technological partners make contributions that are complementary within the Project proposal (1 + 1 = 3). The role for each partner is clearly defined.</li> <li>– Collaboration is necessary for a successful Project (e.g. hospital is more than just a supplier of blood samples).</li> <li>– It was indicated whether consideration was given to involving other PIHC partners in this Project, and why this has not happened (yet). For existing collaborations, more weight is given to whether new Parties are involved in the Project.</li> </ul>	
<p><b>Plan of action (incl. study design, timeframe and budget) (2):</b></p> <ul style="list-style-type: none"> <li>– The study design, study population size (including rationale), outcome measures, analysis methods, tasks per person and time frame are clearly described.</li> <li>– The Project budget matches the tasks per person and per partner and the solution is feasible within the amount of the voucher (60k€).</li> <li>– The mentioned milestones/results are realistic within the project period (1-1½ years).</li> </ul>	
<p><b>Expected (short term) results of the project (within 1-1½ years) (1)</b></p> <ul style="list-style-type: none"> <li>– The expected results are concrete realistic (development/adjustment of technology, prototype, patient study etc).</li> </ul>	
<p><b>Sustainable collaboration, continuation of project (1):</b></p> <ul style="list-style-type: none"> <li>– The collaboration as described in the proposal is a logical combination of expertise and research lines. For successful further development or implementation, the collaboration may be expanded with other parties during or after completion.</li> <li>– The next steps in case of the Project's success are described, for example follow-up research, follow-up funding and possible additional partners, and results will be applied in other hospitals.</li> </ul>	
<p><b>Impact on healthcare (1):</b></p> <ul style="list-style-type: none"> <li>– Expected impact upon further development of technology or implementation in healthcare.</li> <li>– In what timeframe can this impact be expected, for which target group will this impact be realised and what is the size of or importance for the target group (NB: a larger target group does not result in a higher score).</li> <li>– The possibility of a supplement/design of a (regional) clinical guideline.</li> </ul>	<p><b>Impact on healthcare (2):</b></p> <ul style="list-style-type: none"> <li>– Expected impact upon further development of technology or implementation in healthcare.</li> <li>– In what timeframe can this impact be expected, for which target group will this impact be realised and what is the size of or importance for the target group (NB: a larger target group does not result in a higher score).</li> <li>– The possibility of a supplement/design of a (regional) clinical guideline.</li> </ul>
<p><b>Valorisation and/or implementation (1):</b> Proposal has potential for value creation. The TR level at the end is higher than at the start of the project. Writing a businessplan has been considered, possibly with additional partners from SME/industry/healthcare. The developed technology is or can be protected through a patent application.</p>	<p><b>Valorisation and/or implementation (1):</b> The added value of implementing the technology in care over the current treatment is described. How will potential barriers be overcome, what conditions for implementation are met, including clinical trials and associated regulatory requirements, time and cost reduction and efficiency, acceptance by health insurers, healthcare providers and/or patients.</p>