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Norway

att: Pål Halvorsen

Oslo, 29.05.2018

Enquiries to:

Trond Knudsen
+4722037527
tk@forskningsradet.no

Application received: 11.10.2017

Our ref.: 282315/O90

Contract dispatched

Project Title: AutoCap: Automatic Anomaly Detection in Video Capsule Endoscopy

Project No.: 282315

Project Manager: Pål Halvorsen

Project Administrator: Pål Halvorsen

With reference to the application for funding for the above-mentioned project, the programme/activity Brukerstyrt Innovasjonsarena at the Research Council of Norway has at its meeting of 31.01.2018 granted an allocation to the project for 2018. Pledges for subsequent years, if any, as well as the terms that apply to the allocation, are specified in the attached contract.

The project has been assigned the following project number 282315. Please use this number on all enquiries to the Research Council relating to the project.

Contacts at the Research Council:

Nanna Amundsen, na@forskningsradet.no for all reporting and
Trond Knudsen, tk@forskningsradet.no for subject-specific questions.

The contract is comprised of the following documents:

- R&D Project Agreement Document,
- Project description,
- General Terms and Conditions for R&D Projects.
- Any other documents specified in the agreement document.

The contract is based on information provided in the revised grant application of 28.05.2018. If any of the partners who are state aid recipients have received other public support to this project in the period after submission of the revised grant application but prior to the signing of the contract, the Research Council must be notified of this immediately. The attached contract is not to be signed until it has been clarified whether the Research Council must change the amount and/or conditions for its support to the project in light of the allocation of other public support.

All project partners who are state aid recipients must provide information about their funding from the Research Council in connection with any subsequent applications for funding under other support schemes, including the SkatteFUNN Tax Incentive Scheme. A funding provider that grants state aid in the wake of the Research Council's allocation must ensure that the sum of the support to the project does not cumulatively combine to a total that exceeds the level of maximum aid intensity.

Please read through the attached contract documents carefully and sign or reject them electronically via "My RCN Web" as soon as possible and at the latest within three months. If you choose to reject the contract documents, please provide your reasons.

Please check to ensure that all the data are correct and contact the Research Council immediately if you discover any errors or missing information.

Collaboration agreements with partners must be marked with the assigned project number and uploaded on "My RCN Web". This must be done before the contract may be signed.

The contract will not formally enter into force and disbursement of funding will not take place until the Research Council has received and approved the signed contract and copies of the collaboration agreements with partners.

The Research Council reserves the right to withdraw the dispatched contract or amend the provisions of the contract if it has not received the signed contract documents within the deadline.

In addition to the reporting obligations that are set out in the General Terms and Conditions for R&D Projects, the Project Owner is required to keep the Research Council apprised of the following:

- the Project Owner's enterprise number (now: 913968026);
- organisational changes carried out at the Project Owner;
- the Project Owner's current mailing address, telephone number, and email address;
- the party to whom the specifications regarding potential automatic disbursement of funds are to be sent: name and email address;
- the bank account number to be used for the Research Council's disbursements.

If the Project Owner has already supplied the above information in connection with other projects, it is not necessary to repeat them in connection with this project. The project administrator should send any new or updated information to the Research Council at okonomi@forskningsradet.no.

If disbursements to the project do not take place as agreed, please notify the Research Council's contact person for the project (see above). The Project Owner is not permitted to send reminder letters to or claim interest from the Research Council of Norway.

All changes to and deviations in the project framework must be reported to the Research Council as soon as possible via "My RCN Web > Projects/Reports > View / Change project"

This letter has been sent in electronic form to Pål Halvorsen, who has been authorised by the Project Owner to sign the contract with the Research Council on "My RCN Web".

If the Project Owner has chosen to centralise the responsibility for signing all R&D contracts with the Research Council to a single contract administrator within the organisation, then Pål Halvorsen as project administrator and Pål Halvorsen as project manager have been included as secondary recipients with read access to the available contract documents on "My RCN Web".

The Project Owner is responsible for informing the other parties involved in the project about the contract with the Research Council.

The project administrator is responsible for ensuring that all project documents of archival value are stored internally within the organisation. All contract documents may be downloaded from "My RCN Web".

More information about Research Council's general terms and conditions for R&D projects may be found on the Research Council's website at: www.forskningsradet.no.

Project no.: 282315

Sincerely yours,

The Research Council of Norway

Sander John Tufte

Director

Trond Knudsen
Seniorrådgiver

Approved and expedited electronically

Attachments

R&D Project Agreement Document

Article 1: Contracting parties

Between

The Research Council of Norway

Enterprise number: 970141669

(hereafter also referred to as the **Research Council**)

and

FORZASYS AS

Enterprise number: 913968026

(hereafter referred to as the **Project Owner**)

a contract has been signed for the following project, described below (hereafter referred to as the **project**).

The following partners will participate in the project:

Organization no.	Partner Institution	From date	To date
	Institutt for informatikk, UNIVERSITETET I OSLO	01.02.2018	
993467049	OSLO UNIVERSITETSSYKEHUS HF	01.02.2018	
984704461	SIMULA RESEARCH LABORATORY AS, SIMULA RESEARCH LABORATORY AS	01.02.2018	
974757486	UNIVERSITETET I TROMSØ - NORGES ARKTISKE UNIVERSITET UIT CAMPUS TROMSØ, UNIVERSITETET I TROMSØ - NORGES ARKTISKE UNIVERSITET	01.02.2018	

The Project Owner is under obligation to draw up collaboration agreements with the partners pursuant to Section 2.2 of the General Terms and Conditions for R&D Projects.

Article 2: The project

2.1 Project title: AutoCap: Automatic Anomaly Detection in Video Capsule Endoscopy

2.2 Project no.: 282315

Please specify the project number in connection with all enquiries directed to the Research Council, including on payment documents.

2.3 Objective of the project

The primary objective is to provide existing video capsule endoscopy (VCE) systems with an automatic disease detection technology by researching accurate, efficient and scalable solutions for automatic analysis and processing of GI tract videos. This will save endoscopists' time (as the doctor does not need to manually analyse the 4-12 hour video), reduce the need for intrusive colonoscopies or gastroscopies, consequently reduce patient discomfort, and improve the scale (needed for the planned nation-wide screening).

Secondary objectives include:

1) Generate public VCE datasets for learning and big-data analytics;

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- 2) Improve the state-of-the-art methods for detecting irregularities and abnormalities in GI videos;
- 3) Research an end-to-end solution VCE systems; and
- 4) Validate both system performance and detection accuracy

2.4 Project description and project summary

The **project description** for project no. 282315 is provided in the document dated 28.05.2018.

Changes in the project description must be approved by the Research Council. Requests for changes must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “View / Change project”.

The following project summary may be published by the Research Council:

Gastrointestinal (GI) diseases are largely influencing quality of life with almost 3 million new GI cancers per year. The mortality is about 65%, but it is heavily influenced by early detection of neoplasia, where a 1% increase in detection can decrease the risk of cancer with 3%. For example, colon cancer is the third most common cause of cancer mortality, and it is a condition where early detection is important for survival, i.e., going from a low 10-30% 5-year survival probability if detected in later stages (III-IV) to a high 90% survival probability in early stages (I-II). Screening on a regular basis is therefore recommended, and the Norwegian Government has therefore decided to implement a national bowel screening program for 55 year old citizens starting from 2019 and providing full coverage by 2024. Colonoscopy will be a cornerstone in this program. This is a very important goal, but hard to reach with the current personnel and equipment.

Some parts of the GI system is hard to reach with traditional endoscopy examinations like the small intestine, existing procedures does not properly scale to the recommended screening program, gastro- and colonoscopy examinations introduce discomfort for patients and the cost per examination is high. In this respect, several manufacturers now provide video capsules (pills) where the medical experts analyse the video of (parts of) the GI tract offline. This analysis, however, takes long time and going fast forward increase the probability to overlook important anomalies. Therefore, automatic analysis and anomaly detection in VCE videos will be crucial for success.

The goal of this project is to develop such a system, combining latest video technologies with different types of artificial intelligence, able to detect multiple diseases with a high accuracy enabling a more efficient public health care system in order to reach the required scale and cost efficiency.

Article 3: Contract documents and rules of interpretation

The contract includes this signed agreement document and as a minimum the following documents:

- **The General Terms and Conditions for R&D Projects** (attached)
- **Project description** (see reference in Article 2.4)

This project will be carried out in collaboration with partners, and a copy of the signed collaboration agreement(s) must be attached to this agreement document.

In the event that the provisions of the various contract documents conflict with one another, they shall apply in the order of precedence listed above.

Amendments agreed between the parties in writing subsequent to the signing of the contract are also part of the contract and will take precedence over other contract documents.

Article 4: Project management – administrative and scientific

4.1 The Project Owner has appointed the following project management:

Project administrator

Name: Pål Halvorsen

Title: CEO

Project manager

Name: Pål Halvorsen

Title: CEO

Any change of project administrator shall be immediately reported to the Research Council. Notification must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “Change of role”.

Changes of the project manager must be approved by the Research Council. Requests for changes must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “Change of role” and must include the CV of the desired project manager as well as the desired date of commencement of duties.

Research performance site at the Project Owner:

FORZASYS AS, Organization number: 913968026

4.2 The responsible division/unit of the Research Council is:

The allocation is granted under the following programme/activity: BIA

Article 5: Project period and progress plan

The project period is to be:

From the starting date: 01.02.2018

To the date of completion: 31.12.2020

The Project Owner is under obligation to carry out the activities listed in the progress plan:

Main activity	From year	Quarter	To year	Quarter
M1: collected rich VCE dataset	2018	1	2018	4
M2: first data enhancement algorithms impl.	2018	1	2018	4
M4: developed data enhancement algorithms	2018	1	2019	2
WP1: Medical Knowledge Transfer	2018	1	2018	4
WP2: Data preparation and enhancements	2018	1	2019	2
WP3: Anomaly detection	2018	1	2019	4
WP5: Searchable storage system of GI diseases	2018	1	2020	4
M3: first detection algorithms tested	2018	2	2018	4
M5: tailored the video backend	2018	3	2019	2
M6: developed anomaly detection algorithms	2018	3	2019	4
WP4: Compare human and machine detection	2019	1	2020	3
M7: performed detection accuracy study	2019	2	2020	3
M8: an end-to-end VCE video analysis prototyp	2019	2	2020	4

Article 6: Project budgets and funding

6.1 Cost plan

6.1.1 Distribution of project costs by cost category (amounts in NOK 1 000)

The project is to be implemented in accordance with the following cost plan:

	Amount	2018	2019	2020
Payroll and indirect expenses	10 787	3 470	3 569	3 748
Procurement of R&D services	993	321	331	341
Equipment	100	40	30	30
Other operating expenses	240	80	80	80
Total amount	12 120	3 911	4 010	4 199

Changes in the cost plan must be approved by the Research Council. Requests for changes must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “View / Change project”.

6.1.2 Distribution of project costs by cost code (in NOK 1 000)

Project costs are to be distributed by cost code as follows:

	Sum	2018	2019	2020
Trade and industry	11 127	3 590	3 679	3 858
Research institutes	993	321	331	341
Universities and university colleges	0	0	0	0
Other sectors	0	0	0	0
Abroad	0	0	0	0
Total amount	12 120	3 911	4 010	4 199

Changes in the distribution between cost codes must be approved by the Research Council. Requests for changes must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “View / Change project”.

6.2 Funding plan (amounts in NOK 1000)

The project is to be implemented in accordance with the following funding plan:

	Amount	2018	2019	2020
The Research Council	4 245	1 365	1 415	1 465
Own financing	7 875	2 546	2 595	2 734
Public funding	0	0	0	0
Private funding	0	0	0	0
International funding	0	0	0	0
Total amount	12 120	3 911	4 010	4 199

The allocation from the Research Council is limited to 35% of the approved actual project costs. The allocation is granted subject to further conditions from the Research Council, cf. Article 8. Changes in the funding plan must be approved by the Research Council. Requests for changes must be submitted to the Research Council via “My RCN Web” > “Projects/Reports” > “View / Change project”.

Changes in the funding plan require the written approval of the Research Council, and will be treated as amendments to the contract, cf. Section 14 of the General Terms and Conditions for R&D Projects.

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6.3 Specification of the Research Council's allocations for 2018 and pledges for upcoming years

Year	Up to NOK	Limited to percent of approved actual costs
2018	1 365 000	34.9 %
2019	1 415 000	35.3 %
2020	1 465 000	34.9 %

6.4 Disbursement

The Research Council's allocation for the first year and any pledges for subsequent years will be disbursed in accordance with the conditions set out in this agreement and the General Terms and Conditions for R&D Projects.

The Research Council will initiate automatic disbursement subsequent to the approval of the first project account report.

Once the first project account report has been approved, funds will be disbursed automatically at four-month intervals during the first and second interims in the calendar year provided that the project is in compliance with the progress and funding plans set out in the contract. Disbursement for the third interim will be subject to approval of the project accounts report.

Article 7: Reports

The following reports shall be submitted to the Research Council:

7.1 Project account reports

The Project Owner is to submit project account reports for each calendar year. The reports are to show the total project costs in relation to the total project funding.

The following cost categories are to be used in the Project Owner's accounts:

- Payroll and indirect expenses
- Procurement of R&D services (from universities, university colleges, research institutes)
- Equipment
- Other operating expenses

The first project account report is to be delivered at the end of the first full four-month interval after project start-up, if possible, and at the latest by the end of the first year of the allocation. For subsequent years, the project account report for each year shall be submitted at the latest by **20 January** of the following year.

Forms to be used: Project account report and Cost specification.

7.2 Progress reports

The Project Owner is to submit progress reports semi-annually.

Deadline: **1 June and 1 December**.

The progress report is to be submitted electronically via "My RCN Web".

Otherwise, please see Section 5 of the General Terms and Conditions for R&D Projects.

7.3 Final report

Deadline: **1 month after the conclusion of the project period**.

The Project Owner is to submit the final report electronically via "My RCN Web".

Otherwise, please see Section 5 of the General Terms and Conditions for R&D Projects.

7.4 Other reports

Reports and publications that are not compulsory that have been drawn up on the initiative of project management shall not be submitted to the Research Council, unless specifically agreed upon. The Project Owner is required to store all technical reports and publications for at least 10 years after conclusion of the project period. The Project Owner shall assign an ISBN/ISSN number to the reports and/or publications, where so required, and ensure that these are sent to the National Library in Mo i Rana.

Article 8: Other special terms of contract and deviations from the General Terms and Conditions for R&D Projects

The following special conditions shall apply to this project:

Limitations ensuing from the state aid rules

1. Funding from the Research Council is granted under Article 25 (Aid for research and development projects) of the General Block Exemption Regulation for state aid, and is awarded in compliance with the terms and conditions and limitations set out in the state aid rules. For more details, please refer to the information on the state aid rules on the Research Council website. The funding amount awarded and the aid intensity (stipulated in Article 6.2) are based on the budget table in the project description (cf. Article 2.4). This table shows the distribution of the main activities of the project among the R&D categories “industrial research” and “experimental development” and the distribution of the project costs for each main activity among the project partners that are considered state aid recipients. Any changes will require the prior written approval of the Research Council.
2. The collaboration agreement(s) that are to be signed between the partners in the project (cf. Section 2.2 of the General Terms and Conditions for R&D Projects) must be based on, and refer to, the budget table in the project description (cf. point 1 above).
3. The Project Owner is the recipient of the entire funding amount from the Research Council on behalf of the project partners that are state aid recipients. The funding is to be distributed in accordance with the agreed distribution of project costs and within the limits of the aid intensity stipulated in the state aid rules. Distribution of funding to each state aid recipient is to be based on the project’s maximum aid intensity of ForzaSYS AS, cf. Article 6.2.
4. The Project Owner is to keep a regularly updated overview showing how funding from the Research Council is being used. This overview must indicate the amounts that have been
 - paid out to cover costs for external deliverables to the project, including the cost category “Procurement of R&D services”;
 - transferred to state aid recipients other than the Project Owner, specified by the individual state aid recipient;
 - used by the Project Owner to cover own project costs.
5. The Project Owner is to ensure that all project partners who are state aid recipients are familiar with the content of the contract with the Research Council, particularly the limitations in connection with the maximum aid intensity and the distribution of project costs among the categories of R&D activity. Like the Project Owner all project partners who are state aid recipients are to keep a separate project account specifying project funding and project costs. Project funding and project costs must appear in the partners' formal accounts, with reference to General terms, item 4.

Other project specific terms:

- Significant deviations, including deviations in project description, progress plan, project income and cost shall be reported in writing to the Research Council via My RCN without undue delay.
- The procurement of all external R&D shall be in accordance with the approved project description.
- The Research Council reserves the right to participate as an observer in any steering committee established to manage the project.
- It is required that a special report be submitted that provides updated information about the project with regards to the potential for value creation, the plans for realization/utilization of the results and the risk factors involved in the realization (see Part 1 section 3 and Part 3, sections 12-13 in the project description). The special report must be submitted together with the mandatory progress report due on the 1st of June each year. Significant deviations or changes in the plans or prerequisites for utilization of the results may impact the Research Council's continued funding of the project.
- The Project has defined 8 project specific milestones and these will be monitored through steering group meetings and status meetings. Special attention will be given to milestone M2 and M3 which is due by the end of 2018, milestone M6 due by the end of 2019, and M7 by the end of 3rd quarter of 2020. If the project fails to meet its milestones, The Research Council will consider whether the project may continue after a revision of the project description, or whether it shall be terminated.
- A meeting shall be held no later than 4th February 2019 to review the status of the project. The meeting will also review the project and the contract- and affiliated partners' plans for utilisation of the project results. Based on this meeting, The Research Council will consider whether the project may continue after a revision of the project description, or whether it shall be terminated.
- Direct costs associated with obtaining, validating and defending patents are not eligible as project costs. This includes costs associated with patentability searches, patent drafting and filing, as well as maintenance and renewal fees.
- It is assumed that Oslo University Hospital (OUS), Department of Computer Science, UiT the Arctic University of Norway and Department of Computer Science at University of Oslo, The Cancer registry of Norway and Vestre Viken Hospital Trust participate in the project as defined in the project description. If any of these are prevented from participating in the project, The Research Council will consider whether the project may continue after a revision of the project description, or whether it shall be terminated.
- The approved project costs include travel expenses related to participation in conferences. Participation in conferences requires presentation of the paper/poster on behalf of the project by the traveller. The journey should be carried out in a cost-effective manner.

Required submission of data management plans for projects that generate research data

Starting in 2018, all projects that have applied for and been granted research funding will, as a general rule, be required to submit a data management plan if the project collects or in some other way produces research data. The Project Owner is use its own internal guidelines for data management to assess whether the project requires a data management plan.

Information about the archives and/or data infrastructure(s) where the data are to be stored is to be provided in the data management plan and in the final project report.

In the case of projects that generate research data but have not drawn up a data management plan, information regarding the archives and/or data infrastructure(s) where the data are to be stored must be provided in the final project report.

Archiving of research-generated data

The Project Owner is responsible for ensuring that research-generated data/result data generated in connection with projects, and all the necessary documentation for reuse of the data (metadata) are stored in secure archives. The data are to be transferred for storage at the earliest possible stage, and no later than three years after completion of the project.

This contract has been approved and expedited electronically.

For the Research Council of Norway

Oslo, 29.05.2018

Sander John Tufte

Director

For the Project Owner:

Pål Halvorsen

Attachments:

- **General Terms and Conditions for R&D Projects** (valid at date of received application: 11.10.2017)
- **Project description**
- **Copy of signed collaboration agreement(s)**