Grant Agreement no. 644956

RAIS

Scalable, point-of-care and label free microarray platform for rapid detection of Sepsis

INSTRUMENT: Research and Innovation Action

TOPIC: ICT-26-2014: Photonics KET

D8.1: Project Handbook

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Duration: 36 months

Lead partner for deliverable: iXscient

Revision: v1.0

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Document History

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<td>v0.1</td>
<td>First draft</td>
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<td>27\textsuperscript{th} February 2015</td>
<td>v1.0</td>
<td>Final version</td>
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Document Main Author(s): David Wenn (iXscient)

Document signed off by: Valerio Pruneri (ICFO)

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# Table of Contents

1. Introduction .............................................................................................................................................. 4  
2. Legal basis .................................................................................................................................................. 4  
3. Important Contacts ................................................................................................................................. 4  
   3.1. RAIS Coordinator ........................................................................................................................... 4  
   3.2. RAIS Project Manager ................................................................................................................... 4  
   3.3. RAIS Project Administrator ........................................................................................................... 5  
   3.4. RAIS EC Project Officer ............................................................................................................... 5  
4. Consortium Partners .................................................................................................................................. 5  
5. Management and Governance ................................................................................................................ 6  
   5.1. Project Coordinator ....................................................................................................................... 6  
   5.2. Project Manager (PM) .................................................................................................................. 7  
   5.3. Steering Committee ...................................................................................................................... 7  
   5.4. Workpackage Leaders .................................................................................................................. 8  
   5.5. Exploitation & Impact Sub-Committee (EIS) .............................................................................. 8  
   5.6. Industrial Advisory Group (IAG) ................................................................................................ 8  
6. Communications ......................................................................................................................................... 9  
   6.1. E-mail & E-mail Etiquette ............................................................................................................. 9  
   6.2. Mailbases .......................................................................................................................................... 9  
   6.3. Conference Calls ........................................................................................................................... 9  
7. Project Website .......................................................................................................................................... 9  
8. Project Filestore ....................................................................................................................................... 10  
9. Financial ..................................................................................................................................................... 11  
10. Project Reporting Requirements .......................................................................................................... 11  
   10.1. Reporting Periods ...................................................................................................................... 11  
   10.2. Certificates of Financial Statements & Cost Claims ............................................................... 11  
11. Deliverables and Milestones .................................................................................................................. 11  
   11.1. Approving Deliverables .............................................................................................................. 12  
12. File Naming Conventions & Version Control ..................................................................................... 12  
13. Conflict Resolution .................................................................................................................................. 13  
14. Grievance Procedure ............................................................................................................................. 13  
15. Publication Clearance Procedure ........................................................................................................ 13  
16. Procedure for IP Protection and Exploitation ..................................................................................... 14  
17. Minutes of Meetings ............................................................................................................................... 15  
18. Useful Links ............................................................................................................................................ 15
1. Introduction

The RAIS Project Handbook has two main functions. Firstly, it acts as a reference source for all Consortium members, covering many of the day-to-day activities and providing links to further information where required. Secondly, it aims to standardise various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

This Handbook is a living document and will be updated regularly throughout the project.

For the avoidance of doubt, the Grant Agreement and Consortium Agreement take precedence over this document.

2. Legal basis

The project operates within the Horizon 2020 Framework Programme.

The Grant Agreement with the Commission No. 644956 is in operation. The current version of the Grant Agreement is file “Grant Agreement-644956-RAIS.pdf” and is dated 21/11/2014 on the front page.

A Consortium Agreement has also been signed by all partners.

3. Important Contacts

3.1. RAIS Coordinator

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 Spain
 Tel. +34 93 554 2207
 E-mail: stewe.bekk@icfo.eu

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 European Commission
 DG CONNECT
 Unit A1-Photonics
 Av. De Beaulieu 31 5/37
 B-1049 Brussels
 Belgium
 Tel. +32 2 296 83 74
 E-mail: anna.pelagotti@ec.europa.eu

Please note that the details of the Project Officer are provided here for information. However, all contact with the Project Officer relating to the project should be through the Coordinator.

4. Consortium Partners
The following table shows the current RAIS partners. E-mail contact details for all partners can be found on the project filestore under “Mailbases”.

<table>
<thead>
<tr>
<th>No.</th>
<th>Partner</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Institute of Photonic Sciences (ICFO)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>2</td>
<td>École Polytechnique Fédérale De Lausanne (EPFL)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>3</td>
<td>WITHDRAWN</td>
<td>M0</td>
<td>M0</td>
</tr>
<tr>
<td>4</td>
<td>Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>5</td>
<td>Microtec Gesellschaft Für Mikrotechnologie MBH (microTEC)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>6</td>
<td>Trinean NV (Trinean)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>7</td>
<td>Institut Català De La Salut – Hospital Universitari Vall D’Hebron (ICS)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>8</td>
<td>Brahms AG (Brahms)</td>
<td>M0</td>
<td>M36</td>
</tr>
<tr>
<td>9</td>
<td>iXscient Ltd (iXscient)</td>
<td>M0</td>
<td>M36</td>
</tr>
</tbody>
</table>
5. Management and Governance
The following diagram illustrates the overall project management structures. Members of the various project bodies are listed below.

5.1. Project Coordinator
The Coordinator is Prof. Valerio Pruneri from ICFO. The primary responsibilities for the Coordinator are:

- Monitoring overall implementation of the project
- Acting as primary contact for the European Commission
- Chairing meetings of the Steering Committee
- Submitting reports and deliverables to Project Officer
- Collation and submission of cost claims and audit certificates
- Receiving and distributing payments from the European Commission
- Financial and contractual administration
- Interfacing with the Industrial Advisory Group, including participation at its meetings
- Acting upon decisions of the Steering Committee
- Producing financial reports as per H2020 reporting requirements
5.2. Project Manager (PM)
The Project Manager is Dave Wenn from iXscient. The primary responsibilities are:

- Acting as secondary contact for the European Commission
- Acting as Secretary for the Steering Committee meetings
- Collating WP reports to produce overall quarterly project reports
- Reviewing progress in conjunction with Coordinator and Steering Committee
- Checking that progress and deliverables are produced according to the work plan
- Advising the relevant bodies on delays, project issues and problems
- Risk Management
- Formulating project documentation and templates
- Providing advice and information to consortium partners
- Writing periodic management reports

5.3. Steering Committee
The top level of decision making within the consortium is the Steering Committee. This will be composed of one representative from each partner organisation and will be chaired by the Project Coordinator. The Steering Committee is responsible for reviewing and approving project reports and for making decisions regarding strategy, budgets and resource allocations. It will also be responsible for day-to-day decisions across WPs and will be strongly influential, having a major impact on the overall outcomes and success of the partnership, as decisions concerning the best technological developments to pursue in order to meet the needs of the end users will be taken here. The Steering Committee will meet at least on a six-monthly basis to review project status for the previous 6 months and plans for the following year. Intermediate communication may be held via e-mails and conference calls. Every partner is entitled to submit resolutions to the Committee for consideration.

The Steering Committee is currently made up of the following nominated representatives:

- Valerio Pruneri (ICFO)
- Hatice Altug (EPFL)
- Laura Lechuga (CSIC)
- Helge Bohlmann (microTEC)
- Ronny Bockstaele (Trinean)
- Rosa Bartolome (ICS)
- Volker Liebenberg (Brahms)
- Dave Wenn (iXscient)

However, any partner representative is able to attend meetings of the Steering Committee, subject to the limitation that each partner only has one vote. Each representative listed above shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.6 of the Consortium Agreement. The Consortium Agreement contains details of the working voting rules and procedures for the Steering Committee and should be used as the reference document. In summary:

- Decisions shall be taken by the representatives of at least two-thirds (2/3) of the consortium partners present or represented
- Each partner shall have one vote
- Defaulting partners may not vote
- Any partner may appoint a substitute or a proxy to attend and vote at any meeting
- Decisions shall be taken by a majority of two-thirds (2/3) of the votes of the partners present or represented
5.4. **Workpackage Leaders**

Each Workpackage has a nominated leader, as shown in the table below, who is responsible for the deliverables and milestones for that WP. They are also responsible for reporting to the Steering Committee primarily through the PM and they should hold reviews both with the WP partners and the product development / commercialisation leaders. As they are ultimately responsible for the delivery of the WP, they will be required to implement a project management regime consistent with this responsibility.

<table>
<thead>
<tr>
<th>WP</th>
<th>Title</th>
<th>WP Leader</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td>Clinical application scenarios, user requirements and system design</td>
<td>Rosa Bartolome, ICS</td>
</tr>
<tr>
<td>WP2</td>
<td>Microarray reader development</td>
<td>Valerio Pruneri, ICFO</td>
</tr>
<tr>
<td>WP3</td>
<td>Microarray plate for Sepsis biomarkers</td>
<td>Claudia Alcaro (Company to be confirmed)</td>
</tr>
<tr>
<td>WP4</td>
<td>Microfluidic cartridge and instrument integration</td>
<td>Mathieu Rabaey, Trinean</td>
</tr>
<tr>
<td>WP5</td>
<td>Laboratory validation</td>
<td>Laura Lechuga, CSIC</td>
</tr>
<tr>
<td>WP6</td>
<td>Validation and testing in real setting (clinical)</td>
<td>Rosa Bartolome, ICS</td>
</tr>
<tr>
<td>WP7</td>
<td>Dissemination and Exploitation</td>
<td>Volker Liebenberg, Brahms</td>
</tr>
<tr>
<td>WP8</td>
<td>Consortium Management</td>
<td>Valerio Pruneri, ICFO</td>
</tr>
</tbody>
</table>

5.5. **Exploitation & Impact Sub-Committee (EIS)**

An Exploitation & Impact Sub-Committee (EIS) will be setup to review both the technology within the consortium and the market drivers affecting its exploitation. Its role will be to identify potential areas of exploitation over and above those already identified and provide market guidance to steer the direction of work. This panel will include members encompassing the exploitation and industrial partners, knowledge management partners and the Coordinator.

The Exploitation Committee is currently made up of the following nominated representatives:

- Valerio Pruneri – ICFO
- Dave Wenn – iXscient
- Helge Bohlmann – microTEC
- Ronny Bockstaele – Trinean
- Volker Liebenberg – Brahms
- Claudia Alcaro (Company to be confirmed)

However, all other partners are welcome to join the committee and/or attend meetings.

5.6. **Industrial Advisory Group (IAG)**

The members of the IAG have been agreed as follows.

- Michael Helgert – Carl Zeiss
- Michel Prassas – Corning (To be confirmed)
- Peter Mouritzen – Exiqon
6. Communications

6.1. E-mail & E-mail Etiquette

When sending e-mails, it should be remembered that many people may be working on a number of different projects and are likely to receive numerous e-mails every day. This can make it difficult to quickly recognise the significance of an e-mail and also to find and segregate related e-mails. In order to ease this problem, RAIS related e-mails should always include in the subject title the name of the project (i.e. “RAIS”) followed by a more specific description of the subject.

When sending e-mails with file attachments, please consider the size of the attachment. Very large attachments may not be accepted by the recipient server and even modest size attachments (around several MB) might rapidly cause e-mail quotas to be exceeded, particularly where recipients are away from the office for an extended period. Therefore, consideration should be given to uploading the relevant file to the project filestore instead of attaching it to the e-mail. When replying to an e-mail with a file attachment, please ensure that you delete the attachment unless the attachment is still required (e.g. if the reply is copied to a new group of people).

Finally, as a courtesy, please include your contact details on every e-mail that you initiate.

6.2. Mailbases

To facilitate rapid e-mailing of different sub-groups within the consortium, the following e-mail reflectors have been implemented:

<table>
<thead>
<tr>
<th>Reflector name</th>
<th>Members</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL</td>
<td>All technical project participants</td>
<td><a href="mailto:all@rais-project.eu">all@rais-project.eu</a></td>
</tr>
<tr>
<td>MGT</td>
<td>Management team</td>
<td><a href="mailto:mgt@rais-project.eu">mgt@rais-project.eu</a></td>
</tr>
<tr>
<td>Admin</td>
<td>Partner administrative contacts</td>
<td><a href="mailto:admin@rais-project.eu">admin@rais-project.eu</a></td>
</tr>
</tbody>
</table>

In addition to these, an e-mail reflector for each Workpackage WP1 – WP7 has been set up, in the form of wpx@rais-project.eu (where x is the number of the Workpackage). Also, there is a reflector for each partner in the form name@rais-project.eu where name is the short name of the partner. Further e-mail reflectors may be set up on request. Any queries related to these mailbases, requests for additions or for new mailbases should be addressed to the Project Manager.

A current list of the members of each mailbase is maintained on the project filestore under “Mailbases”. Note that, if you send an e-mail to a mailbase that you are a member of, you will not receive a copy.

6.3. Conference Calls

It is recommended that all individuals who are able to do so should install an internet-based voice, video and chat facility for conference calls, e.g. Skype or WebEx, so that all members of the consortium are able to communicate freely and directly with each other. Skype provides a facility for limited conference calls (up to 25 users) with video and screen-sharing facilities. Skype can be downloaded from www.skype.com.

7. Project Website

A RAIS project website will be set up and will be regularly updated (see www.rais-project.eu). Partners are encouraged to add a link from their own website to the RAIS home page.
Every partner will be provided with one or more login accounts in order to access the secure pages on the website and to allow updating of their organisation details.

8. Project Filestore

A project filestore has been set up. This will act as a file transfer and archive facility. Access to the filestore is controlled via a username and password. These are notified to users separately and are not included here in order that this document may be widely disseminated.

Important project files will be stored and maintained on the filestore, e.g. the current version of the Grant Agreement, current budget allocation, formal deliverables, minutes of important meetings, etc.

The filestore includes a folder structure and most project related files will fit within this. Partners should not delete any of the existing folders. However, partners are encouraged to add further sub-folders where relevant, e.g. for each additional meeting or for technical WP information. Folders may also be created for storing temporary files where, for example, these are too large to circulate by e-mail. The filestore is accessed through WebDAV, not ftp. In order to do this, you will need to use Windows Explorer to map a network drive to “https://remote.ixscient.com/RAIS”. Instructions for how to do this are given below. Do not click on this link because it will open in Internet Explorer or other browser and you cannot access the filestore this way.

INSTRUCTIONS

In Windows Explorer, click the Alt key to see the menu, select Tools, Map Network drive and then fill in as follows, except instead of “Project1” type “RAIS”:-

![Map Network Drive](https://example.com/map.png)

You will be prompted to enter your username and password.

If you are using a Mac, from OS X, go to Finder, then “Go” and “Connect to server…”, enter “https://remote.ixscient.com/RAIS” (etc).
9. Financial
Details of the individual partner budgets are given on pages 200-201 of the Grant Agreement. A spreadsheet detailing the distribution of the payments to partners, including the pre-financing, is available on the project filestore under the “Financial” folder.

10. Project Reporting Requirements
All partners are required to complete a quarterly partner report detailing progress against each task. Templates will be provided for these quarterly reports which should be sent to the Project Manager and the relevant WP leaders by the 15th of the month following the end of the quarter.

The Project Manager will compile the quarterly partner reports into an overall quarterly project report. This will also include information on effort expended vs budget taken from the Annual Action Plan.

Copies of the relevant templates will be available on the project filestore under “Templates”. The templates will be designed to provide the information that is required for the Periodic Report for the Commission. This will simplify the reporting at the end of each period.

The consortium will submit a Periodic Report to the Commission (within 60 days after the end of each reporting period) containing the following:

- Publishable summary
- Project objectives for the period
- Work progress and achievements during the period
- Deliverables and milestones tables
- Details of Project Management activities
- Financial statement (Form C) from each partner including an explanation of use of resources
- Audit certificates (if required)

More details on the reporting requirements can be found in the H2020 Reporting Guidelines, a copy of which will be placed on the filestore under “EC Guidelines”.

10.1. Reporting Periods
The project has two formal reporting periods of 18 months duration, as follows:
1) 1st January 2015 – 30th June 2016
2) 1st July 2016 – 31st December 2017 (or end of project)

10.2. Certificates of Financial Statements & Cost Claims
Each partner must provide a Certificate of Financial Statements (CFS) for each period unless the financial contribution that they are claiming (for all periods for which a certificate has not been provided) is less than €325,000.

A guide to the CFS is available on the filestore under “EC Guidelines”.

11. Deliverables and Milestones
Deliverables and milestones should be completed on time. This means it should be submitted to the Project Officer on the last day of the month in which they are due. In order to achieve this, the near-final version of the deliverable should be completed at least one week before the deadline, in order to allow time for internal review (see below).
Progress on deliverables or milestones should be reported in the quarterly reports for the period in which they are due. If any deliverables or milestones due in the quarter are late, an explanation for this MUST be given, as well as any mitigation actions and the anticipated completion date. For deliverables which are not written reports (e.g. prototypes), a brief written summary should nevertheless be produced to accompany the deliverable. A template for the deliverable reports will be produced and will be available on the filestore under “Templates”.

11.1. Approving Deliverables

To ensure that deliverables are of an appropriate standard, all deliverables will be reviewed by someone who has not been part of the core team developing the deliverable. The prime responsibility of a reviewer is to ensure that the deliverable is complete and of an appropriate standard. Typically, the Project Manager or Coordinator will act as reviewer. Alternatively, the PM will nominate a reviewer. The reviewer will then receive the final draft of the deliverable and provide the partner responsible for the deliverable and the relevant WP leader with a written response by e-mail indicating that the deliverable is ready for release or that elements of the deliverable require further attention giving details. The reviewer may also make minor corrections and format adjustments directly. The reviewer should respond within 5 working days of receiving the draft deliverable. If revisions are required, then the above process is repeated. Once the deliverable has been accepted the date of sign off will be added to the cover page, together with details of the reviewer.

The review process is part of the preparation of the deliverable and WP leaders should take appropriate steps to ensure that the review is completed and the deliverable issued before the due date.

The Project Manager will circulate the final deliverable to the consortium and also place a copy on the project filestore. The Coordinator will submit all deliverables to the Commission.

If the author and the reviewer cannot agree to release the document, the matter will be referred to the Steering Committee for a binding decision.

12. File Naming Conventions & Version Control

It is essential that every document circulated to other partners in the consortium includes a version number and date. This will help to avoid the situation where partners are working with old or obsolete versions of documents.

In terms of file names, it is difficult to have a fixed file naming convention which can cover every situation. However, the guidelines below should be followed as much as possible:

1. The filename should be descriptive of the contents and should include the project name e.g. “RAIS_ICFO_SPIE_2015.pptx” for a presentation by ICFO at an SPIE conference in 2015.

2. Where a document is specific to a particular date, this date should be included in the filename in the form ‘dd-mm-yy’. For example, minutes of a WP4 meeting on 1st October 2015 will be called “RAIS_WP4 Minutes_01-10-15.docx”.

3. Where a document is likely to be produced in a similar format by various partners, the partner short name should be included in the filename e.g. “RAIS_Q1_Report_CSIC” for CSIC’s first quarterly partner report.

4. Where different versions of a document are used, e.g. for deliverables and reports, the version number should be included at the end of the filename. For draft documents, the version number should start at v0.1, and increment in 0.1 steps. Once the document is formally issued, the version should change to v1.0 and then increment in 0.1 steps for
minor changes. For a major change, the version will change to v2.0. For example, “RAIS_D2.1_v0.1.docx” will be used for the first draft version of deliverable D2.1.

5. When commenting on a document provided by another partner, the filename should be changed to include the initials of the person or short name of the partner making the changes e.g. “RAIS_D2.1_v0.1_dw.docx” if changes to D2.1 have been made by Dave Wenn or “RAIS_D2.1_v0.1_EPFL” if changes have been made by EPFL.

6. When suggesting changes to a document, the use of the track changes feature in Word is recommended to assist the document author/owner.

7. Only the originating author or owner of a document should increment the version number i.e. when the author has received and implemented all changes to the first draft version of deliverable D2.1, it becomes “RAIS_D2.1_v0.2.docx”.

13. **Conflict Resolution**

In the case of a technical, financial or procedural conflict arising among partners, there is a principle of amicable settlement whenever possible at the lowest decision making body. If there is a dispute within a Workpackage, the WP leader should in the first instance try and resolve the issue, with the aid of the Project Manager if necessary. Only if a resolution is not possible should the matter be raised with the Steering Committee. The Project Manager and the Coordinator should help in the conflict resolution as necessary. Failing such a resolution, the Steering Committee will discuss the issues and vote on a resolution to achieve a binding solution. If necessary, individual partners can seek to convene an extraordinary meeting of the Steering Committee, and all partners are able to put resolutions to that Committee.

14. **Grievance Procedure**

Should a partner wish to complain about any member of the Consortium, the first action should be to document, in detail, the grievance, communicating this in private to the Coordinator and the Project Manager. The individual concerned will then be given a right to reply to the complaint, again, in private. The Coordinator and Project Manager will then work to resolve the complaint to the satisfaction of both parties. Partners should refrain from making personal attacks or remarks against any individual.

15. **Publication Clearance Procedure**

Some information on the publication clearance procedure is contained section 8.3.1 of the Consortium Agreement. The preliminary procedure is detailed below.

During the course of the project many partners will disseminate information about the project through:

- presentations at public events
- posters at public events
- submission of articles for publication in professional and other journals
- other means

There is a duty within the consortium to ensure that information is not disclosed that partners would regard as proprietary, or that they may be using to prepare patent applications. If this type of information inadvertently becomes public, then any subsequent patent applications relying on this information would be invalid. Any information prepared for public dissemination must be made available for review by all partners in advance of its submission for publication, i.e. in good time to review it and make comments and changes if necessary.
The partner wishing to publish, present or disclose information about the project must follow the correct procedure as summarised below. This is specified in more detail in the Consortium Agreement, which takes precedence over this document.

- The partner wishing to publish shall forward an abstract and/or draft presentation to the whole consortium.
- As a general rule, the time-limit for prior notice of any such dissemination activity to be given to the other partners shall be forty five (45) days.
- Following receipt of the aforementioned notification, any of the partners may object to such dissemination activity within thirty (30) days from the date on which they received such notification.
- Should any partner fail to reply within the said period, it shall be deemed that such partner does not object to the relevant publication.

An objection is justified if:

- The objecting Party’s legitimate academic or commercial interests are compromised by the publication; or
- The protection of the objecting Party's Foreground or Background is adversely affected; or
- The proposed contribution includes the Foreground, Background or Confidential information of the objecting Party.

The objection has to include a precise request for necessary modifications. If an objection has been raised, the involved partners shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication).

Please note that all publications MUST acknowledge the funding from the EU. A suitable form of words is “The research leading to these results has received funding from the European Union's Horizon 2020 Framework Programme under grant agreement no. 644956”.

16. Procedure for IP Protection and Exploitation

Intellectual Property protection and access rights are detailed in the Grant Agreement and the Consortium Agreement, both of which can be found on the project filestore.

Any partner within the consortium has the right to protect knowledge it has generated within the project. Partners should however declare their intention of seeking protection for IP generated within the RAIS project to the consortium. Partners must also take into account the contributions of other partners in the generation of such knowledge and come to an amicable and reasonable decision on its sole or joint ownership.

Partners wishing to seek IP protection should follow this procedure:

- Partners should initially discuss their intention to seek protection with partners that have been involved with the generation of that knowledge.
- After this the partner must inform the consortium by e-mail of the intention to seek protection, giving as much detail as possible without compromising the application.
- A minimum of 45 days prior notice of application shall be given by the party wishing to seek protection.
- Any partner may object within 30 days of receipt of the notice on the grounds that it has a legitimate claim to be included in the application or for some other good reason.
- The partner wishing to seek protection should address the concerns of the objecting partner and, if the claim is legitimate, negotiate a reasonable solution.
17. Minutes of Meetings

The keeping of minutes for all project related meetings is extremely important as they are a record of decisions taken and actions required by partners in the project. It is the responsibility of the chair of the meeting to organise the taking of minutes.

A template for minutes is located on the project filestore under “Templates”. The template has space for attendees, minutes, actions from the meeting and for the meeting agenda to be attached. The minutes are to be written up and circulated to all members of the meeting for comment and correction as soon as possible after the meeting. The author should set a deadline for response e.g. 5 working days. After this period the minutes can be circulated to other relevant partners and uploaded to the filestore as a permanent record of the meeting. Minutes of all meetings should also be sent to the Coordinator and Project Manager.

18. Useful Links

Project Website: www.rais-project.eu

General information from the Commission including contractual documents and guidelines is available on the Participant Portal at: