### Examples of good practice on Research (GxP)

<table>
<thead>
<tr>
<th>Title</th>
<th>Type of example</th>
<th>Country</th>
<th>Brief description/ details</th>
<th>How does this exemplify GxP?</th>
<th>Contact: Organisation</th>
<th>Contact: Address</th>
<th>Contact details: E-mail</th>
<th>Contact details: Post Code, Place</th>
<th>If a detailed description has been published, please give bibliographical details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical review</td>
<td>Policy</td>
<td>NL</td>
<td>Departmental policy requires all research with humans to undergo ethical review, even when this is not required by national law (e.g. observation and retrospective research). By Dutch law, all animal research must be approved by an ethics board, so additional policy is not needed.</td>
<td>assures that all departmental research is ethically sound</td>
<td>Erasmus MC Department of Radiology</td>
<td>s Gravendijkwal 230</td>
<td>3015 CE Rotterdam</td>
<td><a href="mailto:research.radiology@erasmusmc.nl">research.radiology@erasmusmc.nl</a></td>
<td></td>
</tr>
<tr>
<td>Research Support Office</td>
<td>Support Services</td>
<td>NL</td>
<td>The department funds personnel to provide wide ranging support to researchers. With the motto &quot;Researchers should do research, the Research Office will take care of the rest&quot;, the Research Office liaises with attorneys, provides constructive criticism of (methodology of) research proposals, arranges ethics submissions, includes subjects, collects data and inputs it into databases, monitors milestones and deliverables, centrally archives necessary paperwork, and prepares financial accounting, all according to standardised, approved protocols.</td>
<td>(1) provides a standardised means of data acquisition and storage, (2) provides a centrally archived, transparent paper trail, (3) assures proper use of grant funds</td>
<td>Erasmus MC Department of Radiology</td>
<td>s Gravendijkwal 230</td>
<td>3015 CE Rotterdam</td>
<td><a href="mailto:research.radiology@erasmusmc.nl">research.radiology@erasmusmc.nl</a></td>
<td></td>
</tr>
<tr>
<td>Research Committee</td>
<td>Quality control</td>
<td>NL</td>
<td>Comprised of all full professors in the department, the Research Committee must approve all new research lines and all projects that are not part of an approved research line. The Research Committee also monitors the progress of all departmental graduate students.</td>
<td>assures that all departmental research meets the departmental quality standard</td>
<td>Erasmus MC Department of Radiology</td>
<td>s Gravendijkwal 230</td>
<td>3015 CE Rotterdam</td>
<td><a href="mailto:research.radiology@erasmusmc.nl">research.radiology@erasmusmc.nl</a></td>
<td></td>
</tr>
<tr>
<td>Trial registration</td>
<td>Policy</td>
<td>NL</td>
<td>Departmental policy encourages registration of all clinical trials in an approved database.</td>
<td>increases global transparency on clinical trials being performed, reducing duplicate research</td>
<td>Erasmus MC Department of Radiology</td>
<td>s Gravendijkwal 230</td>
<td>3015 CE Rotterdam</td>
<td><a href="mailto:research.radiology@erasmusmc.nl">research.radiology@erasmusmc.nl</a></td>
<td></td>
</tr>
<tr>
<td>Research Support Office</td>
<td>Support Services</td>
<td>ES</td>
<td>The department selects grant and funding opportunities from national or international institutions, according to the research developed by the center. An annual schedule is then followed to control deadlines and application requirements.</td>
<td>it helps to find which research areas are more fundable, it provides good feedback and endpoints for research results (i.e. the need to provide periodical reports or annual results)</td>
<td>Radiology Department, Dr Peset University Hospital</td>
<td>Av Gaspar Aguilar 90</td>
<td>46017 Valencia</td>
<td><a href="mailto:rsanz.val@quiron.es">rsanz.val@quiron.es</a></td>
<td></td>
</tr>
<tr>
<td>Research Committee</td>
<td>Quality control</td>
<td>ES</td>
<td>As EIBIR advances a more multicenter research scenario is being built. This requires strong standardization and reliable quality controls to ensure reproducibility. In imaging devices with important variability, such as the MR equipments, it is necessary to perform regular image and signal (spectroscopy) quality assessments.</td>
<td>it ensures reliability and reproducibility in the results, especially in multicenter trials</td>
<td>Radiology Department, Dr Peset University Hospital</td>
<td>Av Gaspar Aguilar 90</td>
<td>46017 Valencia</td>
<td><a href="mailto:rsanz.val@quiron.es">rsanz.val@quiron.es</a></td>
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</table>
Trial registration Policy ES A friendly database is daily managed to include all information relevant to clinical trials. This database is usually managed by the same person, but it has been designed as an easy to use tool, so that anybody can follow it up if necessary.

Clinical Trial Path Policy BE 1. Registration in database of medical administration and financial department
Accomplishing overall transparency
Radiology Department, Dr Peset University Hospital
Av Gaspar Aguilar 90
46017 Valencia, rsanz.val@quiron.es

Clinical Trial Path Policy BE 2. Hospital policy requires personal contact with all departments involved in the clinical trial
Promoting communication between sponsor and departments involved, avoiding medical errors and duplicated research
Radiology Department University Hospitals Leuven
Herestraat 49
3000 Leuven
hilde.vandenhou@uzleuven.be
http://www.uzleuven.be/diensten/ec-toetsing
http://www.uzleuven.be/diensten/klinischestudies/opstarten/index.cfm?designmode=0#start

Clinical Trial Path Policy BE 3. Mandatory review of each clinical trial by the established ethical committee
Protection of patient's rights, overviewing financial agreement between partners involved
Radiology Department University Hospitals Leuven
Herestraat 49
3000 Leuven
hilde.vandenhou@uzleuven.be
http://www.uzleuven.be/diensten/ec-toetsing
http://www.uzleuven.be/diensten/klinischestudies/opstarten/index.cfm?designmode=0#start

Clinical Trial Path Policy BE 4. Registration of patients in clinical trials in the hospital database
Archiving and assuring global data availability
Radiology Department University Hospitals Leuven
Herestraat 49
3000 Leuven
hilde.vandenhou@uzleuven.be
http://www.uzleuven.be/diensten/ec-toetsing
http://www.uzleuven.be/diensten/klinischestudies/opstarten/index.cfm?designmode=0#start

Clinical report on MRI volunteers Patient Protection, Department Policy BE Research projects using healthy volunteers for MRI scanning are not required by law to provide a clinical report. The department strongly encourages a clinical report on the MRI outcome of the volunteers.
Avoiding false feelings of comfort for the patient, possible early detection of risks/diseases, collecting clinically relevant data of healthy volunteers for comparison with existing databases.

Working group conferences/courses Support and Quality Control Policy BE Committee comprised of medical staff deciding on financial support of assistant MD's with available assets using approved rules.
Encourage the number of research proposals and publications, research productivity, scientific presentations (oral and poster), etc.
Radiology Department University Hospitals Leuven
Herestraat 49
3000 Leuven
hilde.vandenhou@uzleuven.be
http://www.uzleuven.be/diensten/ec-toetsing
http://www.uzleuven.be/diensten/klinischestudies/opstarten/index.cfm?designmode=0#start

Monitoring of assistant MD's Quality Control Policy BE Evaluation of assistant medical doctors by full medical staff based on approved criteria including feedback from both parties.
Assessment of assistant MD's concerning their medical and research development for possible personal or teaching adjustments.
Radiology Department University Hospitals Leuven
Herestraat 49
3000 Leuven
hilde.vandenhou@uzleuven.be
http://www.uzleuven.be/diensten/ec-toetsing
http://www.uzleuven.be/diensten/klinischestudies/opstarten/index.cfm?designmode=0#start

2 March 2009
<table>
<thead>
<tr>
<th>Scientific research support office</th>
<th>Support Services</th>
<th>BE</th>
<th>Administration assistants providing a wide range of research services: collecting data and creating databases, correcting drafts of future publications or lectures and other paperwork.</th>
<th>Provides a clinical and research archive, creates time for researchers to focus on the job.</th>
<th>Radiology Department University Hospitals Leuven</th>
<th>Herestraat 49</th>
<th>3000 Leuven</th>
<th><a href="mailto:hilde.vandenhout@uzleuven.be">hilde.vandenhout@uzleuven.be</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pool of research personnel MRI</td>
<td>Support Services</td>
<td>BE</td>
<td>Availability of well-trained MRI personnel providing support with MRI scan acquisitions.</td>
<td>Decreasing scanning time; increasing scan quality</td>
<td>Radiology Department University Hospitals Leuven</td>
<td>Herestraat 49</td>
<td>3000 Leuven</td>
<td><a href="mailto:hilde.vandenhout@uzleuven.be">hilde.vandenhout@uzleuven.be</a></td>
</tr>
<tr>
<td>Radioprotection</td>
<td>Quality control</td>
<td>IT</td>
<td>Scientific research projects involving diagnostic and interventional procedures based on the use of ionizing radiations are monitored by a Board composed of the responsible radiologist, a medical physicist, and a chief technologist. The board has the task to propose and evaluate the quality of technical protocols with regard to patients’ exposure to ionizing radiations. Alternative imaging modalities are proposed - if necessary - to ensure that the overall exposure throughout the research activities can be set as low as reasonably achievable.</td>
<td>Increases awareness concerning radioprotection of the patients in medical research</td>
<td>Department of Radiology - University of Pisa</td>
<td>Via Roma 67</td>
<td>56100, Pisa</td>
<td><a href="mailto:caramella@med.unipi.it">caramella@med.unipi.it</a></td>
</tr>
<tr>
<td>Patient Anonymization</td>
<td>Policy</td>
<td>IT</td>
<td>Departmental policy dictates that all data potentially usable to determine the identity of the patient are to be permanently removed from the files archived for research purpose. These data include: surname, name, DoB, fiscal code, regional code, hospital code, radiological code and all other alphanumeric data of sensitive nature. Three-dimensional reconstructions of facial features are digitally edited to prevent recognition of the individual patient.</td>
<td>Avoids that departmental research may be detrimental to patients’ right to confidentiality and to privacy protection, taking into account also new areas of potential risk (temporary deletion, advanced 3D reconstructions)</td>
<td>Department of Radiology - University of Pisa</td>
<td>Via Roma 67</td>
<td>56100, Pisa</td>
<td><a href="mailto:caramella@med.unipi.it">caramella@med.unipi.it</a></td>
</tr>
<tr>
<td>High-Tech medical integration</td>
<td>Support Services</td>
<td>IT</td>
<td>Within the department an independent unit (EndoCAS: <a href="http://www.endocas.org">www.endocas.org</a>) is specifically devoted to the support of research in the area of image guided therapies, development of simulation environments for training and for therapy planning, and health technology assessment. HTA, in particular, is performed both in the framework of spontaneous research programs and as a service for the Toscana Regional Health Government.</td>
<td>(1) Support activities for multidisciplinary research involving different medical specialties and non-medical scientists</td>
<td>Department of Radiology - University of Pisa</td>
<td>Via Roma 67</td>
<td>56100, Pisa</td>
<td><a href="mailto:caramella@med.unipi.it">caramella@med.unipi.it</a></td>
</tr>
<tr>
<td>Monitoring of PhD student in radiology</td>
<td>Quality Control</td>
<td>CZ</td>
<td>Evaluation of PhD students of radiology by full professors of radiology based on approved criteria including feedback from both parties.</td>
<td>Assessment of PhD - MD's concerning their and research development</td>
<td>Department of Radiology - Charles University, Hradec Králové</td>
<td>Sokolská 581</td>
<td>506 05, Hradec Králové</td>
<td><a href="mailto:ledwik@yahoomail.com">ledwik@yahoomail.com</a></td>
</tr>
</tbody>
</table>

3 March 2009
## Monitoring and analyzing urgent MRI indication

Support and Quality Control, clinical good practice

Czech Retrospective and prospective evaluation of MRI indication done, their positive or negative result and establishing the limited list of indications and to decrease redundant so called "urgent" MRI indications.

Publishing the results and the review of literature, discussion of the list on Czech Congress of Radiology

Department of Radiology - Charles University, Hradec Kralove in cooperation with Department of Radiology in Umea, Sweden

Kokotská 581 500 06 Hradec Kralove niewy@zpl.cz

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## All new interventional devices must be CE marked before they can be evaluated in patient clinical trials

Good clinical practice

Czech Device companies must obtain CE marking before embarking on human clinical trials with new devices

Ensures patient safety

Department of Radiology, Beaumont Hospital, Beaumont Road d9 Dublin

nieec@di.ie

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## All new contrast agents to be used in clinical trials must be approved by the Irish Medicines Board

Good clinical practice

IRE Irish medicines investigate new contrast agents for use in clinical trials during the ethics review process

Ensures patient safety

Department of Radiology, Beaumont Hospital, Beaumont Road d9 Dublin

nieec@di.ie

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## Ethical review

Support Services

AT The application of study protocols to the local ethic committee is a prerequisite for pro- and retrospective research activities. The study protocol contains all aspects of methods planned to use for the study, even a detailed description of statistical analysis. This might be a barrier for some investigators. Therefore, an internal Research Board of the department reviews not only the technical details of data acquisition and patient inclusion, but also the fidelity of data post-processing.

assures (1) that researchers get help for the editing of applications and (2) that the used methods are suited for a planned study

Department of Radiology 1, Innsbruck Medical University Anichstrasse 35 6020 Innsbruck

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## Research Committee

Policy

AT The internal Research Board of a department must not be confounded with the local ethic committee. Firstly, the internal Research Board helps the investigators by giving advices for editing applications and reviewing study designs. However, the internal Research Board is also challenged to prove the fidelity of data post-processing and evaluation.

warrants a correct post-processing and evaluation of data

Department of Radiology 1, Innsbruck Medical University Anichstrasse 35 6020 Innsbruck

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## Research Training for Young Investigators

Support Services

AT The internal Research Board is requested to give helpful advices concerning study design, data collection and evaluation including statistical analysis and manuscript preparation. Thus, young academics get used to principles of good practice at the begin of their careers.

Young academics will be early introduced to principles of good scientific practice

Department of Radiology 1, Innsbruck Medical University Anichstrasse 35 6020 Innsbruck

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## Data Review

Quality Control

AT The quality of data sampling, post-processing and evaluation must be proved by the internal Research Board.

warrants a correct presentation of study results

Department of Radiology 1, Innsbruck Medical University Anichstrasse 35 6020 Innsbruck

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## Internal Research Board

Policy and Quality Control

AT An internal Research Board should comprise the most active researcher of a department, who are experienced in conducting clinical and experimental studies, data processing and statistical evaluation. Each member is requested to respect the current standard of scientific practice and to act in a fair manner.

assures an adequate performance of the internal Research Board

Department of Radiology 1, Innsbruck Medical University Anichstrasse 35 6020 Innsbruck

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Young researchers are often very busy with their residency program and need help for designing studies, for sampling and evaluating data as well as for editing manuscripts and applications. Therefore, member of the internal Research Board should act as a mentor for a group of assigned young academics. The young academics will be advised in periodical meetings.

Boosts the scientific education of young academics

Department of Radiology 1, Innsbruck Medical University
Anichstrasse 35
6020 Innsbruck,

Projects including personal data on patients must be carried out in correspondence with the Danish law on personal data. From this law, the department must not collect and/or handle personal information carelessly.

Provides patients with an assurance of correct handling of sensitive data

Department of Radiology Copenhagen University Hospital Herlev
Herlev Ringvej 75
2730 Herlev
sacskat1@regionh.dk

All project participants must have access to and be able to understand the original research results including their work up and interpretation. Data must be available on a long term, so that they can be reevaluated or used for further research.

Assurance of all participants gaining access to information about a project

Department of Radiology Copenhagen University Hospital Herlev
Herlev Ringvej 76
2730 Herlev
sacskat1@regionh.dk