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SECTION III: USE CASES

Challenge Title: Data in the Healthcare sector	
Use Case Author	*Adrián Palma Ortigosa and Sara Lorenzo Cabrera, Universidad Sevilla*
Topic	*Privacy in Health*
Overview	*The Hospital "Virgen del Rocío" of Sevilla is made up of a staff of more than 300 healthcare professionals and has a unit specialized in the study and treatment of patients suffering from severe headaches, migraines and sleep-related problems.* *In the last year, this unit has received European funding to carry out researchs that seeks to link certain eating habits to certain types of headaches. The management team has decided to collect a number of personal data to start the investigation. In particular, the following documents shall be used:* *– Medical records of those patients who have been treated in the hospital for research-related illnesses.* *– Up to a total of 10,000 clinical records of patients with the same symptoms of the rest of the hospitals of the public health service in Andalucía.* *– Up to a total of 5000 medical records from other hospitals in the European Network to which the hospital belongs.* *Clinical tests of patients (hospital users or not) suffering from any of the diseases described above. The clinical trials will bring together a segment of the population ranging from 14 to 50 years old.*
1. Engage	
Big idea	*Medical research in the health sector.*

Essential Question	*Is the research that the hospital carries out viable from the point of view of data protection?*
Initial resources	*Students will be given a document specifying the complete research project and the personal data to be collected.* *In addition, the students will be able to watch two videos on health research and data protection that are proposed as initial resources:* *– https://renovatiobiomedica.com/2018/02/08/nrd- proteccion-datos-ue-bigdata-sanitario-evaluacion-impacto- una-herramienta-proteccion-la-privacidad/.* *– http://www.comda.tv/video-296_novedades-del- reglamento-general-de-proteccion-de-datos-en-la-asistencia-e-investigacion-sanitaria-·-1-de-marzo-de-2018.html-*
Guiding Questions	*Students must act as if they were the DPO of the hospital. Before going deeper into the subject, they have to analyse what personal data are they going to collect and process, for what purpose, what will be the legal basis, who will be the unit responsible for the processing, etc.* --- *To this end, students will carry out a briefing room exercise, in which they will decide what questions or information to ask the unit responsible for the research to begin framing the task.* *The brain storming exercise will be completed with the elaboration of a mental map, which will be of great help for the students (for example, they can use the following tool: https://coggle.it/).* *Questions asked by students:* (…)
Reflections	*According to the list of questions:* *– Would you classify the questions in priority order or according to any other criteria?* *(We think that a different classification can raise new information and knowledge)* *– Would you change the priority order of the questions?* *– Would you remove any question from the list because you think it is not necessary?* *– Would you introduce into the list any question that you feel is missing?*

	– Do you think that this exercise is useful as a starting point? *– Can you think of another way to initially address the problem?* *– Do you believe that the given list of questions takes into account the complexity of the legal problem?* *– (...)* *Individual reflections on the process* *– (...)*
Other notes	*Suggestions for dealing with the brainstorming exercise:* *1. The teacher is the driver of the brainstorming exercise.* *2. The teacher has to create an understanding atmosphere in which the students can express their ideas freely and confidently.* *3. The teacher and students have to respect others ideas, because all ideas, although it can be initially seen as nonsense, have value to address the suggested problem.*
2. Investigate	
Activity Description	*Encourage students to map out a process of investigation for answering the questions above.*
Resources	*• Working Document on the processing of personal data relating to health in electronic health records (EHR). Adopted on 15 February 2007. Article 29 Data Protection Working Party. Available in: https://www.apda.ad/system/files/wp131_es.pdf* *• Guidance on HIPAA and Individual Authorization of Uses and Disclosures of Protected Health Information for Research. Available in: https://www.hhs.gov/sites/default/files/hipaa-future- research-authorization-guidance-06122018%20v2.pdf* *• Web site. ICO. Information Commissioner´s Office https://ico.org.uk/for-organisations/resources-and-support/health-sector-resources/*
Synthesis	*In order to understand the main data protection implications of this project, the research management team asks you to write a short report. (2-3 pages). ---* *The students should not explain the concrete measures, but only refer to them, relating them to the project proposed by the management team.*

Reflections	*Please provide a reflection on the process:* *1. What are the key problems to overcome in this challenge?* *2. How did you organise the work involved in the investigation?* *3. How did you collect additional data? What worked well about this? What information gaps were still present at the end?* *4. How successful was the investigation process?*
Other notes	*None.*
3. Act	
Solution Proto-types	*Prepare a full legal report analyzing all the legal consequences you consider appropriate related to the implementation of the research project to which the research team refers. Please, take into account any implication that may affect the right to data protection of patients.*
Solution	*Please, indicate your key recommendations to the Direction Team here:* *(…)*
Implementation plan	*Please, develop a plan for the implementation of the legal report.*
Evaluate	*Please develop a journal entry which answers the following questions:* *1. What measure(s) do you consider necessary to implement since the design stage?* *2. What measures do you think will generate the most rejection from the management team?* *3. What were the strengths and weaknesses of your overall legal report?*
Other notes	*None.*
4. Reflection and documentation	

Case notes	*Students must assess the legal suitability of this project in relation to data protection. Among the items that must be taken into account:* *– Legal bases that allow the processing of data.* *– Regarding consent: That consent must be informed, need to inform about the possibility of withdrawing such consent, consent without a clearly defined purpose.* *– Processing of minors' personal data.* *– Data conservation period.* *– Implementation of security measures (encryption, pseudonymization)* *– Possibility of anonymizing personal data.* *– Personal Impact Assessment.* *– Contingency plan for possible security breaches or incidents.*