3D Pathology

Developing 3D Digital Pathology with Spectroscopy

DELIVERABLE D6.5

Reference document: Patient safety issues – Hospitals

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HISTORY

Document version #	Date	Remarks
V0.1	May 30, 2017	Starting version, template
V0.2	June 1, 2017	Added input from contributors
V0.3	June 15, 2017	Additional input from contributors
V1.0	June 20, 2017	Final version

Deliverable review procedure:

- **3 weeks before due date**: deliverable owner sends deliverable – approved by WP leader – to Project Manager.
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable
- **1 week before due date**: co-reviewer provides input to deliverable owner.
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer.

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1 Executive summary

This reference document gives a number of Guidelines for sharing patient' data in e-research and e-diagnosis activities. The referred to web links provide regulation for ensuring patient anonymity in web-accessible data (meta-coding…) and tissue samples handling protocols.

2 REFERENCES

Dutch reviews, laws and guidelines

Wet medisch-wetenschappelijk onderzoek met mensen (WMO)
http://wetten.overheid.nl/BWBR0009408/2017-03-01

Wet Openbaarheid van Bestuur
http://wetten.overheid.nl/BWBR0005252/2016-10-01

Algemene bestuurswet
http://wetten.overheid.nl/BWBR0005537/2017-06-12

Wet bescherming persoonsgegevens
http://wetten.overheid.nl/BWBR0011468/2017-03-10

Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen
http://wetten.overheid.nl/BWBR0035881/2015-07-01

Verklaring van Helsinki
http://www.ccmo.nl/nl/nieuwsarchief/verklaring-van-helsinki-herziene-versie

European reviews, laws and guidelines

Ethics on new health technologies and citizen participation
https://ec.europa.eu/research/ege/pdf/opinion-29_ege.pdf#view=fit&pagemode=none

Statement on the formulation of a code of conduct for research integrity for projects funded by the European Commission
https://ec.europa.eu/research/ege/pdf/research_integrity_ege_statement.pdf#view=fit&pagemode=none

2013 EGE Statement on Clinical Trials
https://ec.europa.eu/research/ege/pdf/statement_of_the_ege_on_the_clinical_trials_directive_revision.pdf#view=fit&pagemode=none

Ethical standards and procedures for research with human beings
http://www.who.int/ethics/research/en/

Ethics for researchers
http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf