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5.2 Model informed consent

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INFORMOVANÝ SOUHLAS

Vážená paní, vážený pane, v souladu se Všeobecnou deklarací lidských práv, zákonem č. 101/2000 Sb., o ochraně osobních údajů a o změně některých zákonů, ve znění pozdějších předpisů, Helsinskou deklarací, přijatou 18. Světovým zdravotnickým shromážděním v roce 1964 ve znění pozdějších změn (Fortaleza, Brazílie, 2013) a dalšími obecně závaznými právními předpisy Vás žádám o souhlas s prezentováním a uveřejněním výsledků vyšetření a průběhu terapie prováděné v rámci praxe na kde Vás příslušně kvalifikovaná osoba seznámila s Vaším vyšetřením a následnou terapií. Výsledky Vašeho vyšetření a průběh Vaší terapie bude publikován v rámci bakalářské práce na UK FTVS, s názvem Získané údaje, fotodokumentace, průběh a výsledky terapie budou uveřejněny v bakalářské práci v anonymizované podobě. Osobní data nebudou uvedena a budou uchována v anonymní podobě. V maximální možné míře zabezpečím, aby získaná data nebyla zneužita. Prohlašuji a svým níže uvedeným vlastnoručním podpisem potvrzuji, že dobrovolně souhlasím s prezentováním a uveřejněním výsledků vyšetření a průběhu terapie ve výše uvedené bakalářské práci, a že mi osoba, která provedla poučení, osobně vše podrobně vysvětlila, a že jsem měl(a) možnost si řádně a v dostatečném čase zvážit všechny relevantní informace, zeptat se na vše podstatné a že jsem dostal(a) jasné a srozumitelné odpovědí na své dotazy. Byl(a) jsem poučen(a) o právu odmítnout prezentování a uveřejnění výsledků vyšetření a průběhu terapie v bakalářské práci nebo svůj souhlas kdykoli odvolat bez represí, a to písemně zasláním Etické komisi UK FTVS, která bude následně informovat řešitele. Místo, datum

5.4 Application for Approval UK FTVS Ethics Committee

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Application for Approval by UK FTVS Ethics Committee

of a research project, thesis, dissertation or seminar work involving human subjects

The title of a project: Case study of physiotherapy Early Phase Rehabilitation and Adaptation following Lower Limb Amputation

Project form: Bachelor Thesis

Period of realization of the project: January 2023 – February 2023

The research will be carried out in accordance with the valid epidemiological measures of the Ministry of Health of the Czech

Republic

Applicant: Lucie Fiala

Main researcher: Lucie Fiala

Co-researcher(s):

Supervisor (in case of student's work): Mgr. Michaela Stupková

Financial support:

Project description: I will be writing my bachelor thesis and working with a lower amputee patient at Nemocnice na Homolce, who has been amputated acutely after being hospitalized for 2 months with the attempt to save his leg. The case study will include examination such as goniometry, anthropometrics and posture amongst other examinations. The kinesiological examination will be followed by therapy and treatment in which the aims are to strength the lower limb, teach the patient to be able to independently transfer himself, lengthen shortened muscles, and to learn how to use a wheel chair and walk using crutches.

Characteristics of participants in research: One patient is involved, a male who is 68 years old and was assigned to me by my supervisor at Nemocnice na Homolce. Patients with acute (especially infectious) diseases do not participate in therapy.

Ensuring safety within the research: Non-invasive methods will be used and the patient will not be at risk as all techniques and methods used will not harm the patients' health. My supervisor at the hospital will be present to control my techniques and therapy at Nemocnice na Homolce. Risks of therapy and methods will not be higher than the commonly anticipated risks for this type of therapy.

Ethical aspects of the research: Data will be collected in line with the rules given by European Union no. 2016/679 and the Czech Act no. 110/2019 Coll. – on personal data processing.

The collected data will be anonymized within one week after the end of working with the patient. I understand that anonymization means that the text does not use any item of information or combination of Items that could lead to the identification of a person. I will be careful not to enable recognition of a person in the text of the thesis, especially within the anamnesis. After the text has been anonymized, any personal data still kept elsewhere will be deleted.

All collected data will be safely stored on a PC safeguarded by a keyword in a locked room, any data in paper form will be kept safely under lock and key in a locked room. The data will be processed, safely retained and published in an anonymous way in the bachelor thesis.

<u>Photographs:</u> Photographs of the participant will be anonymized within one week after being taken by blurring the face, parts of the body or any characteristics that could lead to identification of the person. After anonymization any non-anonymized photographs will be deleted. The non-anonymized photographs will be accessed only by the main researcher and supervisor.

No audio recordings or video recordings will be taken during the research.

I shall ensure to the maximum extent possible that the research data will not be misused.

Informed Consent: attached

It is a duty of all participants of the research team to protect life, health, dignity, integrity, the right to self-determination, privacy and protection of the personal data of all research subjects, and to undertake all possible precautions.

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Responsibility for the protection of all research subjects lies on the researcher(s) and not on the research subjects themselves, even if they gave their consent to participation in the research. All participants of the research team must take into consideration ethical, legal and regulative norms and standards of research involving human subjects applicable not only in the Czech Republic but also internationally.

I confirm that this project description corresponds to the plan of the project and in case of any change, especially of the methods used in the project, I will inform the UK FTVS Ethics Committee, which may require a re-submission of the application form.

In Prague, 17.01.2023

Applicant's signature: Lucied

Approval of UK FTVS Ethics Committee

The Committee: Chair:

Doc. PhDr. Irena Parry Martínková, Ph.D.

Prof. PhDr. Pavel Slepička, DrSc. PhDr. Pavel Hráský, Ph.D. Members:

Prof. MUDr. Jan Heller, CSc. Mgr. Eva Prokešová, Ph.D.

Mgr. Tomáš Ruda, Ph.D.

MUDr. Simona Majorová

The research project was approved by UK FTVS Ethics Committee under the registration number: ...

Date of approval: 14.1. 2023

UK FTVS Ethics Committee reviewed the submitted research project and found no contradictions with valid principles, regulations and international guidelines for carrying out research involving human subjects.

The applicant has met the necessary requirements for receiving approval of UK FTVS Ethics Committee.

UNIVERZITA KARLOVA Fakulta Manpor vic FTVS a sportu José Martíno 31, 162 52, Praha 6 – 20 –

Signature of the Chair of **UK FTVS Ethics Committee**