IRB | EK Application Online Form - MedUni Wien
EK Medical University of Vienna
Template and Instructions | Fill-in Aid

(Prepared by Eva Schernhammer, Reviewed by Thomas Waldhör and Jürgen Zezula)

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First step: Prepare a study protocol, specific format following Helsinki Declaration (see also templates here under "Vorlage retrospektive Studien")
Anything that is classified as „retrospective analysis" will primarily be reviewed by the statistician members of the EK (which is a good thing, as they are more familiar with PH projects) therefore it is ALWAYS recommended to check the box and include in the title that it is a retrospective analysis.

Second step: create your EK application in the EK online portal under "Neuer Antrag" (to be found under tab "Studien")

Fill-in Aid:

GERMAN	**Tab number (Reiter)**	**ENGLISH**	**Commentary, sample text (in red)**
Tab "ECKDATEN"		Key data	
Art des Projektes	2.1.x	Project type	Retrospektive (explorative/deskriptive) Datenauswertung [2.1.12] (applies if no new data will be collected as part of the project) Biobank [2.1.11] If samples are newly collected as part of a project Note: Registers, just like biobanks, refer simply to a collection of data without any research hypotheses or analyses. E.g., register can refer to a compilation of health data many times this is e.g., in the clinical context, such as a cancer register

			AKIM, RDA are common registers in the AKH as other examples Side note: Which box you check does not have to be set in stone; as it is meant to direct IRB members Fragebogen Untersuchung [2.1.13]
AMG/MPG Studie einreichen als		Study in accordance with the Medicinal Products Act or the Medical Devices Act	nicht zutreffend These are usually clinical studies conducted by or with a pharmaceutical company. Largely does not apply to observational studies.
MPG Studie nach neuem Medizinproduktegesetz		MPG study in accordance with the new Medical Devices Act	nicht zutreffend
Sonstige Kategorien	2.1.7.	Other categories	Here is an opportunity to denote other aspects of the study that were not provided as specific categories under 2.1.x For example, you can indicate here that yours is a: Epidemiologische Untersuchung Prospektive Kohortenstudie
Zusatzinformation	2.1.8/9/19/20/21	Additional Information	Only meant for students: specify the type of dissertation/report
Fachgebiet	2.2	Specialty area (of project's research)	e.g., Neuroscience; Epidemiologie
Klinische Phase	2.5.	Clinical phase of study	nicht zutreffend Usually only needed if AMG/MPG study, so not for observational studies
Tab „TEILNEHMER“		Study Participants	

Geplante Anzahl der Prüfungsteilnehmer/innen gesamt	2.9	Planned total number of study participants	In all participating centers worldwide (if there are any)
Mindestalter	2.10.1	Lowest (minimum) age of participants	Should always be noted; usually 18 (below age 18, consent of the legal guardian is required in most cases)
Mindestalter Einheit	2.10.1	How is age defined (which unit)?	Specify whether in years, months, hours; e.g., In Jahren In Monaten (for infants)
Höchstalter	2.10.2	Maximum age of participants/patients	If there is no maximum age, i.e. if the maximum age is undefined, or there is no upper age limit, or an age specification may not be meaningful (e.g. study of archived material, anatomical corpses...), fill in 999
Höchstalter Einheit	2.10.2	How is age defined?	In years, months, hours, e.g., In Jahren In Monaten (for infants)
Männliche Teilnehmer	2.10.4	Male participants	Pick Ja/Nein (yes/no) (whichever applies)
Weibliche Teilnehmerinnen	2.10.4/5	Female participants	Pick Ja/Nein (yes/no) (whichever applies)
Divers	2.10.4	Participants who classify themselves as diverse	Pick Ja/Nein/Nicht definiert (yes/no/not defined) (whichever applies)
Dauer der Teilnahme der einzelnen Prüfungsteilnehmer/innen an der Studie	2.11	Duration of participation of the individual participants in the study	Describe in own words (e.g., 25 mins to fill out survey) Provide a total count of time of all activities of the participant that are related to the study. This could mean e.g., 15 Minuten (for blood draw, or for measuring blood pressure if that's the only study-related activity), or 4 Tage if multiple surveys had to be filed out over 4 days. In cases where it does not make sense to specify the duration of study participation (e.g. archived material etc.), the note "nicht zutreffend " should be used.

Aktive Phase	2.11.1	Active phase	Same as above
Nachkontrollen	2.11.2	Follow-up check	Either clinical follow-up (do they exist, and if so, how many, how often) or could be also understood as longitudinal follow-up (is follow-up planned, if so, how frequently and when) as it commonly occurs in prospective cohort studies, repeat survey etc.
Voraussichtliche Gesamtdauer der Studie	2.12	Likely total duration of study	Here, one should indicate the total duration of the planned study (in months, or years). For example, if there is a baseline survey and a follow-up survey after 6 years, then the study duration is 6 Jahre; or, if enrolment of a total of say 1,000 participants takes one year, and no follow-up is planned, then the duration is 1 Jahr. Note: This is more important for clinical studies as it will help assess for how long insurance of e.g., patients will have to be provided.
Nicht-persönlich-Einwilligungsfähige	2.10.3	Non-personally consenting persons	Cross off whichever applies (if any) The term "women of childbearing potential" should not be confused with "pregnant women". The term "incapable of personal consent" does not refer to minors. Rather, it refers to subjects who are temporarily (e.g. emergency) or permanently (e.g. dementia) unable to give their personal consent to participate in the study.
Tab „KURZFASSUNG“			
Projekttitel (Deutsch)	7.1.		Provide project title in German
Projekttitel (Englisch)	1.1.		Provide project title in English

Zusammenfassung des Projektes (Rechtfertigung, Relevanz, Design, Maßnahmen und Vorgehensweise)	7.2.	Summary of the project (justification, relevance, design, measures and approach)	The summary contains a short version in German with the most important contents understandable for medical laypeople. Please do not make any references to the protocol, most EC members do not have access to the protocol and other uploaded documents. Nonetheless, as this should serve as a quick overview/guidance for all EC members, it is desirable if this is not too long. Half a A4 page or even only a few sentences would be perfectly fine. Brevity is of essence and will be conceived with friendliness by the EC. Main points should be mentioned, such as number of participants, whether samples/surveys/clinical exams will be performed, follow-up planned, which country/countries participating. Any details will be looked up by concerned EC members in the English protocol.
Ergebnisse der präklinischen Tests oder Begründung für den Verzicht auf präklinische Tests	7.3.	Results of the preclinical tests or justification for waiving preclinical tests	Preclinical refers to the laboratory and animal studies required for the development of medicinal products or medical devices. For other studies, enter "nicht zutreffend " in the input field.
Primäre Hypothese der Studie	7.4	Primary study hypothesis (if relevant, also secondary hypotheses)	If it is a study that does not have a hypothesis due to its nature (e.g.: the creation of a biobank, pilot study), enter " nicht zutreffend " under this point.
Relevante Ein- und Ausschlusskriterien	7.5.	Relevant inclusion and exclusion criteria	This concerns the selection of data; e.g. if I use a large cohort study but only those who are cancer free at baseline, I should state this here. Most commonly, age will be a relevant criterium, e.g. Nur Personen im Alter von 18+ Jahren werden eingeschlossen Or: define whom you consider as a healthy participant (e.g., no history of cancer, CVD, etc)

			If not applicable, enter „ nicht zutreffend “ Note: this tends to be very clearly defined in clinical studies/ RCTs. In observational studies it more often refers to whom one considers a health participant, or a control subject.
Ethische Überlegungen	7.6	Ethical considerations	Identify and describe any problems that may arise. Describe the potential knowledge gain to be achieved by the study, its significance, and possible risks of harm or distress to the subjects. Explain your own assessment of the risk-benefit ratio → short example, e.g. if risks are minimal and no gains to the participants, could read like this: Retrospektive Datenauswertung von anonymisierten Datensätzen, keine Einwilligung erforderlich. Die Studie wird unter Einhaltung der GCP Regeln durchgeführt.
Begründung für den Einschluss von Personen aus geschützten Gruppen	7.7	Justification for the inclusion of persons from vulnerable groups and individuals	Fill in only if applicable e.g., minors, temporarily or permanently non-consenting persons including a description of the direct benefit to the individual or group otherwise nicht zutreffend
Beschreibung des Rekrutierungsverfahrens	7.8	Description of the recruitment process	All materials intended for use, e.g. advertisements including layout, must be enclosed This is an important section, especially if any form of monetary incentive (beyond mere imbursement for expenses related to commute to the study site e.g.) for the participant is intended. Any form of Euro amount intended to incentivise participation should be avoided. There are work-arounds, e.g., provide a QR

			code in the recruitment flier for more information, which brings you directly to the informed consent form with the amount of compensation. While Euro amounts/numbers should not be on the recruitment flier/poster, a voucher (without Euro amount) may be on the poster. Also, no blatant advertising should be involved; instead, briefly state what it is about, who to get in touch with, time required for being a part of the study. Example statement here, in case of completed data collection at study start and no new recruitment will be conducted: Anonymisierte Datensätze von Stellungspflichtigen werden vom …(xxBundesministeriumxx)... zur Verfügung gestellt Important to be as precise as possible under this tab here, as the EC will need to know this in order for them to be able and approve
Vorgehensweise an der Prüfstelle, zur Erlangung der informierten Einwilligung	7.9	Procedure at the recruitment/inspection site to obtain informed consent	Indicate here who discusses the patient or subject information with the participants (including parents or legal representatives, if applicable) and obtains their written consent, and at what time this takes place. If applicable, the procedure for persons temporarily unable to give consent must also be described. who will inform and when, requirement for legal representation, witnesses, etc Sample text could read: Nicht zutreffend, Retrospektive Auswertung anonymisierter Daten

			Arzt/Psychologin oder Diätassistentin – hinsetzen, erklären, consent form (24 Std. Zeit). Qualifizierte Mitarbeiterin bei Epi Studien geht auch
Risikoabschätzung	7.10	Risk assessment	Here, the risks, burdens, inconveniences, pain and injuries to the integrity of the participants should be indicated, as well as the measures to prevent and/or care for unforeseen/adverse events. Sample text could be: Die Risiken sind minimal, da keine invasiven Maßnahmen (Blutentnahme, Röntgen, CT, Biopsien usw.) vorgesehen sind.
Voraussichtliche Vorteile für die eingeschlossenen Prüfungsteilnehmer/innen	7.11	Likely advantages for included participants	Only benefits of purely study-related measures can be stated. Measures that are part of the usual routine cannot be cited as a benefit of study participation. If not applicable, state "keine"
Relation zwischen Prüfungsteilnehmer/in und Prüfer/in	7.12	Relationship between study participant and examiner/PI	To describe the relationship between study participant and examiner/PI, simple state who they are, e.g. patient - doctor, student - teacher, employee - employer, etc. Possible answers could be: Nicht zutreffend or Arzt-Patient or Student:in – Lehrer, or qualifizierte Mitarbeiterin-Teilnehmerin
Verfahren an der/den Prüfstelle/n, zur Feststellung, ob eine einzuschließende Person gleichzeitig an einer anderen Studie teilnimmt oder ob eine erforderliche Zeitspanne seit einer	7.13	Procedure at the trial site(s) to determine whether a subject to be included is concurrently participating in another study or whether a required period of time has elapsed since	Of particular importance when healthy subjects are included in drug studies. Most of the times not relevant for observational studies, as these are not "Prüfungen gemäß AMG" i.e. RCTs (e.g., conducted by the pharmaceutical industry) – this question targets primarily drug studies.

Teilnahme an einer anderen Studie verstrichen ist		participation in another study	Therefore, typically this is answered with nicht zutreffend
Methoden, um unerwünschte Effekte ausfindig zu machen, sie aufzuzeichnen und zu berichten	7.14	Methods to identify, record and report undesirable effects	Describe methods that were used to identify/record/report undesirable/side effects, state when, by whom and how, these will be recorded. E.g. free questioning and/or using lists Most typically however, for observational/epidemiological studies, here one would reply “nicht zutreffend”
Statistische Überlegungen und Gründe für die Anzahl der Personen, die in die Studie eingeschlossen werden sollen	7.15	Statistical considerations and reasons for the number of people to be included in the study	Optional: refer to additional information on details in the Biometrics tab, if required. These might be necessary; if more complex calculations, then refer here to section 8.2. and the protocol. If the study is retrospective, then point that out and give details, sample text could be: All eligible persons between 2015 and 2019 were selected… Sample text e.g., for existing large data sets, where the sample size cannot be influenced anymore, could be: Es ist eine retrospektive Studie welche die Grundgesamtheit aller österreichischen Männer beinhaltet. Aus der Fallzahl von ca. 2.4 Millionen Personen folgt eine große Mächtigkeit von statistischen Tests Oder: Alle Männer mit Bluthochdruck die in meiner Ordination zw. 2016-2023 aufscheinen. Oder: Fallzahlkalkulation wie im Protokoll

Verwendete Verfahren zum Schutz der Vertraulichkeit der erhobenen Daten, der Quelldokumente und von Proben	7.16	Procedures used to protect the confidentiality of collected data, source documents and samples	Essentially describe here who has access to the data and how these are protected from unauthorized access. Access should be restricted to the PI only, or other/multiple persons; but anyone with access should also been mentioned in the study protocol. Describe that the office is locked in which the PC for data access is hosted; and that access to the PC is password protected. Sample text could read: „Es werden nur vollkommen anonymisierte Datensätze verwendet, Rückverfolgung nicht möglich auf Grund der verwendeten Merkmale. Die Daten werden auf einem Passwort geschützten Rechner auf einer verschlüsselten Festplatte in einem verschlossenen Raum abgespeichert“ Oder „Die Eingabe der Daten erfolgt im RDA-System der MedUni Wien (siehe auch https://www.meduniwien.ac.at/web/mitarbeiterinnen/it-hilfe-support/it4science/plattformen/rda/)
Plan zur Behandlung oder Versorgung nachdem die Personen ihre Teilnahme an der Studie beendet haben (wer wird verantwortlich sein und wo)	7.17	Plan for treatment or care after individuals have completed their participation in the study (who will be responsible and where)	This only applies to some of the studies (e.g. trials of medicinal products) after the persons have ended their participation in the study. Otherwise, and more typically, “nicht zutreffend” should be used
Betrag und Verfahren der Entschädigung oder Vergütung an die Prüfungsteilnehmer/innen	7.18	Amount and method of compensation or remuneration to examination participants	Description of the amount paid during participation in the examination and for what, e.g. travel expenses, loss of income, pain and inconvenience, etc.

			Indicate the amounts paid to participants as travel expenses, expense allowances or fees to the examination participants. If not applicable, simply state “trifft nicht zu” If amount paid is very unclear, then inquire first with EC members as there are limits to the top amount of amounts paid/compensations.
Regeln für das Aussetzen oder vorzeitige Beenden der Studie an der/den Prüfstelle(n), in diesem Mitgliedstaat oder der gesamten Studie	7.19	Rules for suspension or early termination of the study at the trial site(s), in that Member State or of the study as a whole	If not a trial, simply state „trifft nicht zu“
Vereinbarung über den Zugriff der Prüferin/des Prüfers/der Prüfer auf Daten, Publikationsrichtlinien, etc.	7.20	Agreement on the access of the examiner(s) to data, publication guidelines, etc.	State here who your likely co-authors will be on any resulting papers Sample text: Dr. …., Mag. …. Vom … sind als Ko-Autoren/innen in einer Publikation vorgesehen
Finanzierung der Studie und Informationen über finanzielle oder andere Interessen der Prüferin/des Prüfers/der Prüfer	7.21	Funding of the study and information on financial or other interests of the investigator(s)	The primary reason for this question 7.21 is to determine whether it is ensured that data sovereignty (i.e. who has the final say over the use of study data) remains with the Medical University of Vienna; which typically would be the case if money comes from a peer-reviewed third party funded project; but if (partial of full) funding comes e.g., from a (pharmaceutical) company, then this issue becomes relevant. If not applicable state “trifft nicht zu”
Weitere Informationen wenn erforderlich	7.22.	Additional information (if needed)	Note: Remains practically always empty

Tab „SPONSOR“		Der die Datenhoheit hat darum geht es hier (zb AMZ Studie, Pharmafirma)	For projects that we (e.g., OE ZPH) carry out, typically, the the Meduni Wien (MUW) is usually the sponsor. (De facto, however, the decision-making power remains with the PI.) This becomes relevant, for example, if the PI changes institution during the project; however, data sovereignty always remains with the Medical University of Vienna (although copies can be taken along).
Firma/Organisation	1.5.1	Company/organization	If the sponsor is identical to the invoice recipient, enter the sponsor details. If the sponsor is not the invoice recipient, activate the relevant checkbox. This allows you to enter the address and contact details for the sponsor and invoice recipient separately. Example: Medizinische Universität Wien Nicht zutreffend if no company (e.g, pharma) is involved.
Adresse	1.5.2		
Postleitzahl	1.5.2	Zip code	
Stadt	1.5.2	city	
Länderkürzel	1.5.2	Country code (e.g., AT for Austria)	
Anrede der Kontaktperson	1.5.3		
Vorangestellter Titel der Kontaktperson	1.5.3		
Nachgestellter Titel der Kontaktperson	1.5.3		
Vorname der Kontaktperson	1.5.3		
Nachname der Kontaktperson	1.5.3		

Telefon	1.5.4		
Fax	1.5.5		
Email	1.5.6		
UID Nummer	1.5.7	For pharma companies	Sample text: Keine Angaben
Tab „ANTRAGSTELLER“ (EK Antrag)		Applicant to EC (not to funder) This is more important for pharmaceutical companies if they outsource who has filled out the EC	The system distinguishes between the applicant and the person submitting the application. These may or may not be identical. The applicant here is the person who has primary access to the EC-System and is usually identical to the PI; this could be changed by the EC to another person if e.g., the applicant/PI leaves the institution Note: This is about who is legally responsible for what was entered into the mask. Becomes relevant in case of disputes. It tends to be safer if the PI is also the person who enters data into the mask and is the only one having access to her/his EC account (i.e. not sharing passwords with colleagues). What disputes/mistakes could arise? Very rarely a dispute over participation in the project (e.g. diploma thesis)
Tab „MASSNAHMEN“		Measures	Not relevant if retrospective analyses in a sense of using only existing data; however, if collecting any new data/specimen, then anything that would not take place outside of the clinic (e.g. anything beyond routine diagnostics/interventions/blood draws, etc) should be mentioned here When taking blood samples, etc., indicate the quantity; note duration of filling out questionnaires; etc

			List what is routinely collected in point 6.2.
Ausschließlich studienbezogene Maßnahmen	6.1	Exclusively study-related measures Provide information on -type e.g., survey - number and dosage 1 survey with 74 questions - duration (from when to when) Survey is implemented between January 1 and January 10 2024 - total (per participant) Takes 30 minutes to fill out	Exclusively study-related measures are all measures that would not take place without the study. Note: If more blood is taken than for routine lab, it is study-related. If a case-control blood sample is subsequently taken, this is study-related A complete list of all measures (e.g. administration of medication, examinations, questionnaires, tests, blood samples, ...) that are carried out for study reasons is required. Measures that are also carried out without conducting the study are not to be listed here. Example: In a study of patients with a knee endoprosthesis, their quality of life six months after the operation is to be assessed using a questionnaire. The patients are called in for a short appointment. Study-related measures: Calling the patient, questionnaire survey. The knee operation is not related to the study. If the patients are interviewed as part of a routine follow-up that is carried out anyway, only the completion of the questionnaire would be the study-related measure.
Invasive/strahlenbelastende Maßnahmen im Rahmen der Routineversorgung während der Studiendauer	6.2.	Invasive/radiation-inducing measures as part of routine care during the study period	Mention only invasive measures here (blood tests, spinal tap, skin punches, biopsies; etc.) or measures involving radiation (Rx or CT, but not MRI) Do NOT mention questionnaires here.
Ergänzende Informationen zu studienbezogenen	6.3.	Supplementary information on study-	Fill in only if applicable

Maßnahmen und alle erforderlichen Abweichungen von der Routinebehandlung		related measures and any necessary deviations from routine treatment	
Tab „BIOMETRIE“			Mark those fields that do not apply to your study as „nicht zutreffend“
Offen/blind/doppelblind	8.1.13, 8.1.14, 8.1.12, 8.1.11., 8.1.10., 8.1.7., 8.1.6., 8.1.2, 8.1.3	Open/blind/double-blind	Not applicable for observational studies
Sonstiges	8.1.15	Other	If not an RCT, sample response could be: Retrospektive, explorative, epidemiologische Studie
Anzahl der Gruppen	8.1.16.	Number of groups	Not applicable (if not RCT)
Stratifizierung (Kriterien)	8.1.17	Stratification (criteria)	Not applicable (stratification here refers to randomization or when conducting the analyses)
Messwiederholungen (Zeitpunkte)	8.1.18.	Repeat measurements (time points)	Identical to prior point 2.11.2: Repeat measurements during either clinical follow-up (if they exist, and if so, how many, how often) or could be also understood as longitudinal follow-up (is follow-up planned, if so, how frequently and when) as it commonly occurs in prospective cohort studies, repeat survey etc.
Hauptzielgrösse	8.1.19	Main outcome measure	If none exists, come up with a hypothetical outcome measure Sample text could be: Klinisch diagnostizierte Depression
Nullhypothesen	8.1.20	Null hypothesis	If none exists (survey), sample text could be: Explorative Studie, keine a priori Hypothese
Alternativhypothesen	8.1.21	Alternate hypothesis	state nicht zutreffend if none exists

Nebenzielgrössen	8.1.22	Secondary outcomes	For example: Haupt=overall mortaliy, secondary=disease free duration state nicht zutreffend if it does not apply
STUDIENPLANUNG		Planning of the study	Important: Refers ONLY to the sample size calculation, no description of the statistical analysis per se. If none because retrospective, then state nicht zutreffend
Alpha	8.2.1	Alpha	Most typically: Alpha=0.05 (and 2-sided tests) Many times, no concrete hypothesis exists e.g., in pilot studies, or explorative, or retrospective studies. Or if the purpose of the study is to generate hypotheses (exploratory studies) – then indicate nicht zutreffend
Power	8.2.2	Power	Most typically: aim for minimum 80% (or: same as above i.e. nicht zutreffend)
Stat. Verfahren	8.2.3	Statistical tests	State on the basis of which statistical tests the sample size is calculated. Example: Chi-square test. Comparison: p1=25% versus p2=40%. Must fit the main hypothesis and its evaluation as a rule. Chi-square test must also be included in the analysis.
Korrekturverfahren	8.2.4	Correction measure	In the case of statistical tests, make sure to include how/if you adjust for multiple testing; to do so you could 1) Either add Explorative to title, and in (methods/publication) something like "…No adjustment for multiple tests was applied, p-values are to be interpreted exploratorily only". 2) Or: State method for adjusting (Bonferroni etc.) and define number of tests before analysis is done.

			E.g.: The total number of tests is 3, the significance level is set to 5%/3=1.66% using Bonferroni correction. 3) If no stat. test/p-values will be applied at all, call it "descriptive" study.
Erwartete Anzahl von Studienabbrecher/inne/n (Drop-out-Quote)	8.2.5	Drop-out quota	This applies only to RCTs, so if not an RCT, state: trifft nicht zu
GEPLANTE STATISTISCHE ANALYSE	8.3.1 8.3.2 8.3.3	Which one? Intention to treat, per protocol, interim evaluation	If your study is observational/retrospective, then ITT etc. is irrelevant, but be sure to still include a brief description of your statistical analysis. A sample text could read: Beschreibende Statistiken wie Lagemaße, Streumaße oder auch Korrelationskoeffizienten werden abhängig vom Skalenniveau der zu untersuchenden Merkmale verwendet. Zusammenhänge mit dem Outcome Mortalität werden univariat mit Werkzeugen der Überlebensanalyse beschrieben wie z.B. Kaplan-Meier Kurven, Kumulative Inzidenz. Multivariable Verfahren wie Cox-Regression, Fine-Gray competing risk model, cumulative incidence function sind für Modelle angedacht mit mehreren unabhängigen Merkmalen. Für einfachere Prävalenz-Fragestellungen mit einem fixem Zeitabstand nach der Stellung sind auch logistische Regressionsmodelle eine Option Could also provide identical text as in 7.15 (or refer to the BIOMETRIE tab in general: siehe Biometrieteil
Abbruchkriterien	8.3.3	Termination Criteria	Nicht zutreffend for observational studies etc.

Geplante statistische Kriterien **?Verfahren?**	8.3.4	Planned statistical criteria	For retrospective studies typically “nicht zutreffend”
DOKUMENTATIONSBÖGEN / DATENMANAGEMENT			
Angaben zur Datenqualitätsprüfung	8.4.1	Information on the data quality check	Sample text here could be: Die Daten werden seitens des (z.B. Statistik Austria) bereits bei der Dokumentation geprüft“ Or: Daten werden von 2 verschiedenen Personen eingegeben und auf Unterschiede geprüft
Angaben zum Datenmanagement	8.4.2	Information regarding data management	Sample text here: Die bereits vom … anonymisierten Daten werden nur auf der Abteilung für Epidemiologie, ZPH, MUW auf einem Computer verwendet.
VERANTWORTLICHE UND QUALIFIKATION			
Wer führte die biometrische Planung durch (ggf. Nachweis der Qualifikation)?	8.5.1	Who carried out the biometric planning (proof of qualification if applicable)?	Write here the name of a real person, not "MUW statistician". If completely unknown, any minimum qualification (Epidemiology PhD student, statistician, bioinformatician, etc) should be described. Not so important for retrospective studies.
Wer wird die statistische Auswertung durchführen (ggf. Nachweis der Qualifikation)?	8.5.2	Who will carry out the statistical analysis (proof of qualification if necessary)?	Same as above
DATENSCHUTZ			
Die Datenverarbeitung erfolgt:	8.6.1 Personenbezogen Pseudonymisiert Vollstaendig anonymisiert	Personalized Pseudonymized Completely anonymized	Options: Personenbezogen Pseudonymisiert (most often) Vollständig anonymisiert (would be ideal)

Begründung	8.6.2	Justification	Sample text: Keine Angaben
Wie erfolgt die Pseudonymisierung oder Anonymisierung?	8.6.3.	How is this done?	Sample text could be: Die Daten werden auf Seiten von Statistik Austria anonymisiert
Zentren im Inland die Gegenstand der Einreichung sind			Trifft nur für MPG Studien mit Leit-EK Prinzip zutreffend
Prüfzentrum	10.2	Test center	This is the Department that carries out the work, so for example Abt. f. Epidemiologie, Zentrum für Public Health
Teilnehmer/innen an diesem Zentrum	11.	Participants in this center	Number of persons to be included in the research project at this center. Sample text: 2400000 für Gesamtpopulation
Prüfer	10.1	"Examiner"	The Prüfer is the name of the PI; e.g.; Thomas Waldhör
Zentren im Inland, die nicht Gegenstand der Einreichung sind		Domestic centers that are not the subject of the submission	This point must be completed primarily so that the EC can determine who is responsible for determining the first EC approval (if several national centers are involved, each of them must obtain its own approval). The lead EC may be the MUW; then the other ECs in the national centers usually follow suit. Overall, it may be best to contact the EC office beforehand, they can advise you on where best to start; but as I said, basically for us the MUW is the first EC to which the application must be submitted.

https://ekmeduniwien.at/help/für-einreichende/neuer-antrag/#biometrie

A **consent form template** can be found here under the Hyperlink “Musterinformation für klinische Studien”

AMP MPG are for medical/clinical applications
KAKUG and UOG2022 are the laws after which IRB is executed in Austria
Medicinal products are e.g., vaccinations, drugs, …
Medical devices are e.g., Veganscreener, …
NON-Interventional study is without taking blood or without any other invasive measures
If it is not medical research then do not need IRB; Para 37 exempts (Helsinki)
Medical research vs. non-medical research: With Lifestyle It can be a grey zone whether this is medical or not

Non-clinical = healthy study participants