Ethics Application Form for Non-Invasive Research on Healthy Adults

When preparing your ethics application, please take care to ensure that it reads well and is free from typographical and other errors. While this might seem a bit pedantic, it is worth bearing in mind that the ethics application form is an official document that may, in exceptional circumstances, need to be produced and scrutinized by others. A useful way of thinking about this might be to imagine what might happen if the document was being scrutinized by someone with a complaint about your study: is there anything in it that seems unprofessional or a bit sloppy, or that could be used, inadvertently or otherwise, to harm your reputation, or the reputation of the department or university?

For program applications, the limits of the approval sought should be made clear. That is, what are the key inclusion and exclusion criteria by which a study can be undertaken within this program approval. Please also provide a clear indication of the duration of studies (how long they will take each participant) permitted under the program application (e.g., 'no individual study will take longer than 1 hour').

SECTION A APPLICATION DETAILS

A1 Project details

Project title: Exploring the training provision and clinical care for Body Dysmorphic Disorder in the United Kingdom

Date of submission: 21/11/2023

Proposed start date: 01/02/2024

Proposed end date: 31/01/2029
(this can be up to 5 years from start date):

A2 Principal researcher

(Note: A student – undergraduate, postgraduate or research postgraduate – cannot be the principal researcher for ethics purposes).

Full name: Dr Georgina Krebs

Position held: Associate Professor

Research Department: Research Department of Clinical, Educational and Health Psychology

The principal researcher must read and sign (electronic signature or scanned pdf with signature are acceptable) the following declaration. Please tick the box next to each of the statements below to acknowledge you have read them and provided all required information.

▪ I will ensure that changes in approved research protocols are reported promptly and are not initiated without approval by the Departmental Ethics Committee, except when necessary to eliminate apparent immediate hazards to the participant.	x
▪ I have completed a risk assessment for this programme of research and hereby confirm that the risk assessment document will be discussed with any researcher/student involved in this programme of research (currently or in the future). I will ensure that all researchers/students sign the risk assessment form following this discussion.	x

Risk assessment forms for projects can be downloaded from the Ethics section of the PaLS Intranet.	
▪ I have completed the Information Governance training provided by ISG	x
▪ I have obtained approval from the UCL Data Protection Officer stating that this research project is compliant with the General Data Protection Regulation. My Data Protection Registration Number is: **Z6364106/2023/11/93** A Data Protection Registration number can be obtained by following the steps here: https://www.ucl.ac.uk/data-protection/guidance-staff-students-and-researchers/research/research-registration-guidance#data-protection-registration ***Note***: your data protection number could cover a whole programme of research. It is not always necessary to request a data protection number for each individual project.	x
▪ I have included examples of the Information Sheet and Consent Form for the proposed research. It will be made clear to the participants that they can withdraw from the study at any time, without giving a reason.	x
▪ I will ensure that all adverse or unforeseen problems arising from the research project are reported in a timely fashion to the UCL Research Ethics Committee.	x
▪ I will undertake to provide notification when the study is complete and if it fails to start or is abandoned.	x
▪ I have met with and advised students on the ethical aspects of this project/programme of research.	x
▪ I am satisfied that the proposed research complies with current professional, departmental and university guidelines.	x
▪ I consent to this application (and related documents) being shared as an example of good practice (please delete as appropriate): YES, I am happy for ethics chairs to share this with interested parties via email, but please don't post on the intranet.	x

Signature:  **Date: 21/11/2023**

A 3 Contact details

Principal Researcher

Full name: Dr Georgina Krebs

Position held Associate Professor

Research Department: Research Department of Clinical, Educational and Health Psychology

Email: g.krebs@ucl.ac.uk Telephone: 07968963857

Additional applicant 1

Full name: Dr Elizabeth Hogg

Position held: Staff (Clinical Research Fellow)

Research Department: Research Department of Clinical, Educational and Health Psychology

Email: e.hogg@ucl.ac.uk Telephone: 07791667034

Additional applicant 2 (n/a)

Full name:

Position held: *(undergraduate/taught master's/MRes/research student/postdoctoral/staff)*:

Research Department:

Email: Telephone:

(Add further details on a separate sheet if there are more applicants to be covered by this form)

A4 Approval from the Departmental Ethics Committee

(Approval cannot be given by the principal researcher of this project – if necessary the application must be sent to an Ethics Officer from a different Research Department, or to the College Ethics Committee, for approval)

Declaration by the Research Department Ethics Chair:

I have reviewed this project and I approve it. X

The project is registered with the UCL Data Protection Officer and a formal signed risk assessment form has been completed.

Allocated Departmental Project ID Number for the approved application:

_____ **CEHP/2024/595**

Name of the Research Department Ethics Chair (type in):
Jean-Baptiste Pingault

Date: 01/02/2024

SECTION B	PROJECT DETAILS

B1 **Summary of Research**

It is particularly important to provide sufficient detail of the research protocol and the measures that will be used, to enable evaluation of the application on ethical grounds. It is also important to clearly demonstrate that the proposed measures are 'innocuous' and fall within PaLS Ethics remit.

Please provide a brief summary of the project/programme of research including

- Background
- Aims
- Participants and recruitment
- Procedure (including whether face-to-face or online study)
- Measures
- Examples of measures (tests, questionnaires, interviews etc.) as per RD guidelines

NB When providing examples of each measure you plan to use, please select the most emotive/distressing examples so that the Ethics Chair can judge the potential for causing any distress.

Background and Aims:

Body dysmorphic disorder (BDD) is characterised by an intense, impairing, and distressing preoccupation with perceived flaw(s) in one's own physical appearance that are not visible or appear slight to others. This preoccupation is associated with participation in time-consuming, repetitive behaviours aimed at checking, camouflaging, or correcting the perceived flaw(s). Despite research showing that BDD can have a devastating impact on quality of life, with concerningly high rates of suicidality evident, the disorder is strikingly underdiagnosed and there are substantial barriers to individuals with BDD accessing evidence-based treatment. A key obstacle to individuals with BDD receiving an accurate diagnosis and evidence-based treatment in the United Kingdom (UK) is a lack of training among therapists. Many mental health professionals in the UK do not receive any teaching on the diagnosis or treatment of BDD during their professional training.

Therefore, the overarching aim of the proposed programme of research is to investigate training provision and clinical care for BDD in the UK.

Studies included in the programme will utilise survey designs to obtain information from clinicians and UK mental health professional training providers. Participants will be informed of what participation in the study entails and sign a consent form before taking part.

Participants, recruitment, procedures, and measures for proposed studies within the programme:

<u>Study 1: The Identification and Psychological Treatment of Body Dysmorphic Disorder in Youth and Adults: Understanding and Enhancing Clinical Practices</u>

Participants
We aim to recruit 500 participants who will be clinicians working in Child and Adolescent, and Adult Mental Health Services in the NHS. We conducted a series of power analyses to determine this sample size. For example, with regards to exploring whether identification of BDD and treatment recommendations vary according to the clinician's experience, a power calculation conducted in G*power indicated that a sample size of 464 participants would have 80% power to detect a small effect size (Cohen's $\omega = 0.15$), using a Chi-squared test and a Bonferroni-corrected alpha level of 0.017 (i.e. 0.05 / 3).

Recruitment
Recruitment will take place via several routes, including contacting NHS Trusts directly and contacting Child and Adolescent and Adult training programme directors (e.g. Improving Access to Psychological Therapies [IAPT], Children and Young People's IAPT [CYP-IAPT]). We will contact NHS organisations across the UK in order to ensure representation from all geographical areas. If 'gatekeepers' agree to support the study, they will be asked to forward an email to their clinical staff distribution lists, containing an information sheet and link to the online consent form and

questionnaire, which can be completed anonymously. In order to reduce the risk of gatekeepers pressuring staff to participate, we will ask gatekeepers to forward the email without amending the wording and we will emphasise that it is up to individual staff members to decide whether or not they would like to participate. We will also include the research team contact details in the email so staff members can contact the team with any questions or concerns. There will be separate information sheets for CAMHS clinicians and adult mental health clinicians. The information sheet for CAMHS clinicians is attached to this application.

To note, Health Research Authority (HRA) approval will be required and applied for given we will be recruiting staff working in the NHS, through NHS services.

Procedure and measures
An online questionnaire will be designed specifically for this project, based on previous similar studies focussing on clinical practices related to panic disorder and PTSD (Baker & Waite, 2020; McGuire et al., 2022). Study materials will refer to understanding and treating 'emotional difficulties' in young people and will not mention BDD specifically so as to avoid experimental demand effects. Participants will be able to complete the questionnaire anonymously, but will be asked to provide demographic information and their professional background (e.g. psychology, psychiatry, nursing etc.), years spent as a qualified/practicing clinician, and their service context (e.g. child community, child specialist, child inpatient, adult inpatient, adult community etc.). The response format for professional background and service context will be categorical to ensure participants do not provide specific details, and subsequently reduce the risk of participants being identifiable. Participants will then be randomly assigned to one of two clinical vignettes describing a typical presentation of BDD (the age of the person in the vignettes will dependent upon the service context of the clinician I.e. child or adult mental health service). The two vignettes will be identical, with the exception that one will be cisgender male and the other cisgender female. The information provided in the vignette will be consistent with a DSM-5 diagnosis of BDD and not any other disorder. After reading the vignette, participants will be asked to select a) what they thought the main diagnosis or primary presenting problem was and b) what treatment the person should be offered. Following the completion of the vignette questions, clinicians will also be asked questions explicitly relating to BDD, including their training in assessing and treating BDD, their experience of working with people with BDD, and their impression of how BDD is treated in their service context. The online survey will be administered via Qualtrics, a secure and widely-used platform for survey-based studies. It is anticipated that the survey will take 20-30 minutes to complete. Participants will have the option to provide an email address in order to receive a £10 electronic voucher to thank them for their time (see C2). Email addresses will be immediately deleted after sending the voucher.

<u>Study 2: An exploration of Current Training on Body Dysmorphic Disorder Provided to Mental Health Practitioners on Professional Psychological Therapy Courses in the United Kingdom</u>

Participants
Participants will be course or curriculum directors of professional training courses in psychological therapies in the UK, such as the Doctorate in Clinical Psychology, IAPT and CYP-IAPT.

Recruitment
We will contact psychological training courses in the UK, including Doctorate in Clinical Psychology, Doctorate in Counselling Psychology, IAPT and CYP-IAPT courses. Should the first point of contact agree to support the study, they will be asked to forward an email to their course and/or curriculum director, containing an information sheet and link to the online consent form and questionnaire.

Procedure and measures
A brief online questionnaire will be designed specifically for this study. Participants will be asked to provide the name of the course they work for, select whether the course provides teaching on BDD within their core curriculum, and note any barriers to providing teaching on BDD within the curriculum (e.g. time constraint, lack of available expertise). If the course does deliver BDD teaching, participants will be asked to provide details such as duration of training and the unit/module the teaching is part of (e.g. child and adolescent mental health or adult mental health). Participants will also be asked to share the same details about teaching provided on related disorders, such as Obsessive Compulsive Disorder and Eating Disorders, which will provide a point of comparison. The online survey will be administered via Qualtrics, a secure and widely-used platform for survey-based studies. It is anticipated that it will take approximately 10 minutes to complete.

Study 3: Mapping Health Service Provision for Children and Young People with Body Dysmorphic Disorder in the United Kingdom

The aim of this study is to better understand the current state of play with respect to specialist service provision for children and young people with BDD, and to compare this with obsessive-compulsive disorder (OCD).

BDD and OCD are closely related conditions and are categorised together under the same NICE guidelines (2006). The NICE guidelines specify a stepped-care model and state that "effective treatments for OCD and BDD should be offered at all levels of the healthcare system" (from primary care teams to multidisciplinary teams with expertise in OCD/BDD). In step 3 to 5 of the stepped-care model, the guidelines state that children and young people with OCD with mild functional impairment should receive guided self-help alongside support and information for family or carers, and for children and young people with OCD with moderate to severe functional impairment and those whom guided self-help has been ineffective or refused, CBT (including exposure and response prevention; ERP) should be offered. For children and young people with BDD, the guidelines for step 3 to 5 of the model state that "all children and young people with BDD should be offered CBT (including ERP)". The guidelines further state that "each primary care trust, mental healthcare trust and children's trust that provides mental health services should have access to a specialist OCD/BDD multidisciplinary team offering age-appropriate care".

The extent to which these guidelines are reflected in current services and care provision for children and young people across the UK presenting with BDD and OCD is unclear. We therefore aim to provide a geographical overview of BDD service provision and access to specialist care, and to compare this with OCD service provision and access to specialist care. Whilst there is some overlap in the phenomenology and treatment of BDD and OCD, there is a substantial difference in the training offered for mental healthcare professionals on the two disorders. Therefore, we will draw comparisons between BDD and OCD service provision, to understand whether differences exist in access to specialist care. We hope that mapping service provision will support our understanding of the extent to which NICE guidelines are adhered to in current practice

Participants
Participants will be Child and Adolescent Mental Health Service (CAMHS) service leads from NHS mental health trusts across the UK.

Recruitment
Recruitment will take place via directly contacting CAMHS service leads. Initial emails contacting potential participants will include an information sheet and link to the online consent form and questionnaire. We will approach service leads from mental health trusts across the UK to ensure adequate geographical mapping of service provision.

Procedure and measures
A brief online questionnaire will be designed specifically for this study. Participants will be asked to provide demographic information, including their professional role and the NHS Trust and service they work for. Participants will be asked the same series of questions related to BDD service provision and OCD service provision. Participants will be asked whether their service provides treatment for BDD/OCD, and if it does, what treatment is offered (e.g. CBT, SSRI medication). The survey will ask participants to state the care pathway for children and young people with BDD/OCD in their service. Participants will be provided with a list of existing specialist services for children and young people with BDD/OCD. Participants will be asked which of the services they are aware of, whether they refer to these services. An open-ended question will ask them about any perceived barriers to accessing these specialist services. And lastly, participants will be invited to add details of any other specialist services they refer young people with BDD/OCD to.

Study 4: Establishing Core Knowledge and Competency Standards for Specialised Cognitive Behaviour Therapy for Body Dysmorphic Disorder: a Delphi Study

The aim of this study is to establish knowledge and competency standards for delivery CBT for BDD, which will directly inform training provision.

Participants

Participants will be clinical or clinical academic experts in BDD.

Recruitment
First, second, last, and corresponding authors of international peer-reviewed papers on CBT for BDD published since 2010 will be invited to participate. In addition, existing collaboration networks of specialist BDD clinicians and snowball sampling will be used.

Procedure and measures
This study will involve a Delphi consensus study using three rounds of online surveys (*see Wahid et al 2021*)

- Round 1: open-ended questionnaire asking participants to detail all the knowledge and competency standards recommended for delivering specialised cognitive behaviour therapy with for BDD. Participants will also be asked to provide demographic information, including their role, experience, and range of expertise.
- Round 2: Participants will be asked to rank finalised items from round 1.
- Round 3: Summary results from round 2 will be shared with participants. The table will indicate items that reach consensus and those that do not. Participants will be asked if they would like to reconsider their rankings at this stage.

<u>Additional studies within the research programme</u>

Additional studies focused on training provision and clinical care for BDD may be included in this programme of research. The key inclusion and exclusion criteria by which a study can be undertaken within this programme are:

- Inclusion
    - The aim of the study is to improve understanding of clinical care for BDD, encompassing professional training, clinical practices, and perspectives on diagnosis and treatment.
    - Participants are clinicians working in mental health services in the UK, course staff on professional training courses in psychology in the UK, or clinical/clinical academic experts in BDD.
    - The study utilises a survey design which participants can complete anonymously (i.e. they do not have to report their name).
- Exclusion
    - The study includes clinical measures (e.g. BDD, OCD, depression).
    - Clinical samples e.g. individuals with a diagnosis of BDD/elevated BDD symptoms.

No individual study will take participants longer than 1 hour 30 minutes to complete.

B2 **Will the results be disseminated outside the standard academic outlets?** **Yes** **No**
If you answered 'yes', please specify:

Websites e.g. The BDD Foundation

B3 **Please outline any ethical issues that might arise from the proposed study and explain how they will be addressed.**

The proposed programme of research raises minimal ethical issues. Study 1 will use a clinical vignette which will include presenting difficulties of emotional symptoms. The participants will be practicing clinicians within mental health services and will therefore be very used to these clinical presentations, and experienced in supporting people with psychological difficulties. Furthermore, the vignette will not include any reference to potentially more distressing content, such as suicide attempts or childhood abuse. Details of BDD charities (e.g. the BDD Foundation) and mental health organisations will be provided in the debrief following completion of the online questionnaire, as sources of further information.

	All studies described in the programme, and any additional studies that could be conducted under the programme, do not raise ethical concerns. Participants will provide informed consent, receive a debrief after participation in the study, deception will not be utilised, and data will be collected anonymously and processed confidentially. Participants will be clinicians and academics in the field of mental health who will not be asked to disclose any details about their own mental health/complete clinical measures. Furthermore, although we will collect some personal data (age in years, gender, and ethnicity) in order to report demographic characteristics of the sample and any relationships with variables of interest, overall, the risks to privacy are low given the anonymous completion of the surveys. To mitigate the risk of data breaches, the research programme will invite all participants to complete surveys anonymously, implement robust encryption protocols for datasets, and enforce strict access controls limiting access to research members involved in the specific study only. All data files will be password protected and stored on the UCL Data Storage Service. Data will be accessed only by researches directly involved in the project and will not be transferred. Data for each study will be deleted ten years following publication, in accordance with the UCL Research Data Policy.

SECTION C PARTICIPANT DETAILS

C1 Participants to be studied

Number of volunteers:	Approx. 1000
Upper age limit:	80
Lower age limit:	18

C2 Payment

Will payment or any other incentive (e.g. a gift voucher or free services) be made to any research participant?

Yes **No**

Participants in study 1 will receive a £10 voucher (e.g. Amazon voucher) as reimbursement for their participation in the study. We have received approval from Prof Adam Harris and John Draper to pay each participant £10 for their participation (please see attached email). Furthermore, we have received a grant for study 1 from the British Academy/Leverhulme Small Research Grants, and of this secured funding £5,000 is for reimbursing participants for their time.

For studies 2-4, funding is not currently in place. It is possible that these studies will be undertaken as student projects (e.g. DClinPsy projects), which would provide a source of a modest amount of funding (e.g. £350 per project). In this case, we would offer small incentives, such as the opportunity to enter a prize draw to win an electronic voucher (e.g. Amazon).

C3 Recruitment

(i) Describe how potential participants will be identified:
As outlined in section B1, and an example for one of the studies planned within the programme, participants for study 1 will be identified as clinicians working in Child and Adolescent, and Adult Mental Health Services in the NHS.

(ii) Describe how potential participants will be approached and recruited:
As outlined in section B1, and an example for one of the studies planned within the programme, participants for study 1 will be approached and recruited via several routes, including contacting NHS Trusts directly and contacting Child and Adolescent and Adult training programme directors (e.g. Improving Access to Psychological Therapies [IAPT], Children and Young People's IAPT [CYP-IAPT]). We will contact NHS organisations across the UK in order to ensure representation from all geographical areas. If 'gatekeepers' agree to support the study, they will be asked to forward an email to their CAMHS clinical staff distribution lists, containing an information sheet and link to the online consent form and questionnaire, which can be completed anonymously.

C4	**Will the participants participate on a fully voluntary basis?**	**Yes**	**No**
	Will UCL students be involved as participants in the research project?	**Yes**	**No**

C5 Deception

Will any form of deception be used that raises ethical issues? If so, please explain.

There will not be any form of deception used that raises ethical issues/concerns in the studies in the proposed research programme.

C6 **Will you provide a full debriefing to the participants?** **Yes** **No**

If 'No', please explain why below.

C7 Information Sheets And Consent Forms

You must attach the final information sheet and consent form for your participants with this application. This will already have received approval from the Data Protection Team. Templates are available on the PaLS intranet (please note that these changed at the end of 2017, so as to be compliant with new Data Protection regulations [GDPR]). The information sheet needs to contain sufficient detail to enable informed consent. However, the information must be provided in **lay language** and should look different from the summary of research provided in section B1.

The template information and consent forms should give you an idea of the level of detail required. NOTE THAT MAILING AND E-MAIL ADDRESS SHOULD BOTH BE INCLUDED IN RESEARCHER CONTACT DETAILS. All information sheets and consent forms should include a) Institutional headed paper, b) information regarding the RD Ethics Chair who approved your study, c) project ethics ID. N.B. Where consent will be obtained online, the information sheet and consent form should be accurate to reflect that.

When applying for an ethics approval for a broader research programme, you should provide an example information sheet and consent form for a representative study/experiment. You do not need to provide further examples, unless future studies/experiments substantially depart from the proposed programme of research.

Please see attached the example information sheet for CAMHS clinicians and consent form for Study 1. ***To note, within study 1 there will be separate information sheets for CAMHS clinicians and adult mental health clinicians.***

If your research includes analysis of secondary data, please complete Section D.

Not applicable

SECTION D ACCESSING/USING PRE-COLLECTED DATA

D1 Access to data

If you are using data or information held by third party, please explain how you will obtain this. You should confirm that the information has been obtained in accordance with the General Data Protection Regulation 2018.

D2 Accessing pre-collected data

Does your study involve the use of previously collected data?
No ☐ - There is no need to complete the rest of this section.
Yes ☐ - Complete all parts of this Section. **Note**: If you ticked any boxes with an asterisk (*),ensure further details are provided above in Section B3: Ethical Issues.

D3	**Name of dataset/s:**

D4	**Owner of dataset/s (if applicable):**

D5	**Is the data in the public domain?**	**Yes** ☐	**No** ☐
	If not, do you have the owner's permission/license?	**Yes** ☐	**No*** ☐

	Is the data anonymised?	**Yes** ☐	**No** ☐
	If not:		
D6	**Do you plan to anonymise the data?**	**Yes** ☐	**No*** ☐
	Do you plan to use individual level data?	**Yes*** ☐	**No** ☐
	Will you be linking data to individuals?	**Yes*** ☐	**No** ☐

D7	**Is the data sensitive?**	**Yes*** ☐	**No** ☐

D8	**Will you be conducting analysis within the remit it was originally collected for?** **Yes ☐ No* ☐**

D9	**If not, was consent gained from participants for subsequent/future analysis?** **Yes ☐ No* ☐**