# Completing the ethics process (Undergraduate and Post graduate students)

Professor Dave Walsh, BAL Faculty Research Ethics Chair

## The Ethics Process

- The process, guidance and forms can be found from this webpage
- <a href="http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/bal.aspx">http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/bal.aspx</a>
- Necessary to complete an application for all primary research
- Primary research that which involves humans (or indeed animals!)
- Are you planning to do primary research?
- First, you'll need to complete then in ALL cases a triage form to see whether you will need to go onto complete an ethics application form

This is a copy of the triage form

Applicant Name:	lore comm	encing your study if y		sure if ethical	appro	val is re	quire	d.	
Applicant Name.				sor name.	Ц,		_		_
Email Address:			Start Date:			End Date:			
Course and Module Title:									
Project Title:									$\neg$
Ethical Considerat	tions							YES	NO
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		administration of a q					_		Н
		observation of huma							$\Box$
		gathering of informa							
		ring in normal physio							Ш
		earching into illegal a	ctivities th	at are previo	usly ur	iknown	to		
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October 2018

Slide 3

See next slide for notes on how to complete these sections BAL Ethics approval form - last updated September 2018



2c End Date:

Research Question(s) or aim(s)

Tracking No:
Date approved:
Initials:

#### Faculty of Business and Law

#### **Application to Gain Ethics Approval for Research Activities**

Undergraduate/Postgraduate Taught Students

(PGR students and staff to complete other form – see http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-rethics-procedures.absx)

Students should complete this form in consultation with their supervisors.

Form to be completed electronically only and uploaded to the module on Blackboard in line with module leader's advice (manually completed forms not accepted). **Do not submit through Turnitin.** 

+‡+	Please also see footnotes on Page 11	
	SECTION 1. Applicant	
	Please complete all sections	
	Last Name:	
	First Name:	
	Student number:	
	DMU Email address:	
	Programme of Study (Course title)	
	Module (name): Module (code):	
	Supervisor's Name:	
	Co-Applicants Name(s) if applicable:	
Ì		
	SECTION 2. The Research	
	2a Title:	
	2b	
- 1	Start Date:	l .

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#### 2e

Please provide a description of your research and the methods you will use to gather data

#### IMPORTANT: Please include the following details

- 1. Who your sample will include (not names but job roles, positions in civic society etc)
- 2. How will they be selected and recruited?
- 3. Provide details of your principal data collection methods (e.g. questionnaires, interviews, observation, social media sites, documents be as specific as possible but ensure that you submit a copy of your questionnaire or your schedule of research questions with this application.
- Where will you be collecting the Data? (please provide details of the sites/locations where data collection will take place- and what times of day i.e. during normal working hours i.e. 9am till 5 pm)
- 5. If you are collecting data at a primary or secondary school/work premises/police stations/law courts etc. (but not the NHS) have you obtained, or will you obtain, written permission from the organisation <u>before</u> you start your research? If your answer is 'No' please state the reasons why.
- 6. If you are collecting data off DMU campus will a member of DMU Staff or responsible adult such as a relative or friend be made aware of the locations you intend to undertake research, dates and times and when you are expected to return? Please state the name and contact details of the DMU member of staff or responsible adult (Please see the Suzy Lamplugh Foundation Guidelines on lone working: <a href="https://www.suzyilemplugh.org/">https://www.suzyilemplugh.org/</a>)
- Give details as to whether your project being funded by a third party? (this includes if funding has been applied for but not yet given)
- 8. If you are collecting data overseas, will you also obtain ethical approval within the host country? If not, please explain. Have you identified and complied with all local requirements in that country complied ethical approval & research governance and data protection\*? Please also give contact details of a local person identified to field initial complaints locally so the participants can complain without having to write to or telephone the UK

"Please note that many countries require local ethical approval or registration of research projects, further some require specific research visas. You must also ensure you are aware of and abide by the national data protection legislation including legal requirements around research using data and transfer of data to and from the UK. If you do not abide by the local rules of the host country, you will invalidate your athical approval from DMU, and may run the risk of legal action within the host country.

Slide 4

- 1

**Section 1 and 2 a to 2d** – Just your details, supervisor details, the module details and the title of your research - so it should be easy to do

**Section 2e** – Please tell us what you are planning to do.

Go through the items 1 to 8 and supply those details. If they do not apply please advise accordingly. Where any of items 1 to 8 do apply please tell us how they apply.

For example, 2e. 7 Give details as to whether your project being funded by a third party? (this includes if funding has been applied for but not yet given). Most of you will not be funded. So a simple sentence to say "This research is not being funded" will be sufficient and will ensure that item 2.e 7 has been covered. Likewise if you are not doing research overseas, just provide a sentence to that effect "I am not doing research overseas".

If you are doing research off campus please read the note about having your research risk assessed

#### Section 4.1

Participation in your research should be voluntary and based on informed consent so it is expected that you will answer 'yes' to both these questions. If you answer 'no', explain why

> See next slide for guidance on section 4.2

SECTION 3. Conflict of Interest

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	Yes	No
3a Do you have any connection with the external organisation(s) being researched? Such as through personal, financial or family connections		
If 'Yes' please give details If you are employed by the external organisation please advise if you will receive any financial or in-kind benefits or payments for undertaking the research from the organisation		

#### SECTION 4. Research Ethics and the Protection of Participants' Interests

NB. Participants should suffer no harm as a result of participation in the research

#### 4.1 Please provide details here as to whether participation by those in your sample will be

- a) Voluntary
- b) Based on informed consent

(Please provide copies of the participation sheet and consent form -Templates available on BAL Ethics website http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-

#### 4.2 Please also provide details as to how your

- a) Participants' identities will be protected with regard to
- b) Confidentiality with respect to the data
- c) Anonymity in terms of any reported findings from the research
- research process will avoid emotional harm or upset to those taking part d) Data that has been gathered will be kept securely? (For example, will files and data sticks be encrypted? Or data stored on password protected computers?)
- If using a recording device for interviews please advise when the original recording will be erased (e.g. immediately upon uploading to a secure device such as your password protected computer)
- 4.3 What steps you will undertake to avoid/minimise emotional harm or upset to those taking part (including measures signposting individuals should they become distressed later e.g. To staff welfare services)

SECTION 5. Sensitive Research

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If your research topic is concerned with the following 'sensitive research' areas: illegal activities, including the collection of source data, e.g. access to web sites normally prohibited on university servers, or extremism and radicalisation please complete the questions below. (For more information

5a Does the intended research include research into	Yes	No
llegal activities? (This may include, but is not limited to,		
esearch into hate crime <sup>1</sup> , theft, fraud, or harmful and illegal	5a	
ultural practices",		
Please note: the university does not permit any crime to be committed for research purposes, such as accessing images of paedophilia or child abuse, unless special permission has been granted by the Home Office.		
b Does the research involve deception? Are the	5b	
articipants fully informed of the nature of the research? If not,		
thy not?		
ic Will the research require the use of sites	5c	
isually prohibited on university computers (e.g.		
ornography or the sites of these prohibited organisations)?"		
Does the intended research fit into any of the	Yes	No
ollowing categories? If you are unsure as to whether your		
esearch will involve any of these categories in 5d to 5h you are		
dvised to answer 'Yes'		
od Terrorism, extremism, terrorist or extremist	5d	
organisations or groups, extremist ideologies,		
adicalisation, de-radicalisation		
	5e	
Se Has the research been Commissioned by the		
military or GCHO		
and the same		
	5f	
of Has the research been Commissioned under		
an EU / US security call or similar		
5g Does the research involved the viewing,	5g	
isage or transfer of sensitive personal data as		
lefined by relevant Data Protection Regulations		
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	Eb.	
ih Does the research involve the acquisition of	5h	
in Does the research involve the acquisition of security clearances (including the Official Secrets sect)	5h	

Slide 6

Section 4.2 – Relates to how you protect the anonymity and confidentiality of your participants (and the data – or information – they give you). For a survey you could answer for example by not asking or revealing the names of participants

But also tell us how you are keeping the information securely – for example, will you store digital data on a password protect computer (or an encrypted USB drive that only you know the password to?

If you have recorded an interview what are you doing with the original recording once you have uploaded it to a secure storage space? It needs erasing immediately after uploading so tell us that you will do just that.

If your research involves collecting hard copy questionnaires where will you store them? Are they securely kept? How is it secure (e.g. Locked drawer that you only have access to?)? Remember you should have promised research participants that the information they give is being kept securely so tell us how you will keep that promise.

See next slide for guidance on Section 4.3

	Yes	No
Ba Do you have any connection with the external organisation(s) being researched? Such as through personal, financial or family connections		
If 'Yes' please give details If you are employed by the external organisation please advise if you will receive any financial or in-kin benefits or payments for undertaking the research frothe organisation		

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5a Does the intended research include research into llegal activities? (This may include, but is not limited to,	Yes	No
research into hate crime", theft, fraud, or harmful and illegal cultural practices",	5a	
Please note: the university does not permit any crime to be committed for research purposes, such as accessing images of paedophilia or child abuse, unless special		
permission has been granted by the Home Office.		
5b Does the research involve deception? Are the	5b	
participants fully informed of the nature of the research? If not, why not?		
5c Will the research require the use of sites	5c	
usually prohibited on university computers (e.g.		
cornography or the sites of these <u>prohibited organisations</u> )?"		
Does the intended research fit into any of the	Yes	No
following categories? If you are unsure as to whether your research will involve any of these categories in 5d to 5h you are advised to answer 'Yes'		
5d Terrorism, extremism, terrorist or extremist	5d	
organisations or groups, extremist ideologies, radicalisation", de-radicalisation"		
	5e	
5e Has the research been Commissioned by the military or GCHQ		
	5f	
5f Has the research been Commissioned under an EU / US security call or similar		
5g Does the research involved the viewing, usage or transfer of sensitive personal data as defined by relevant Data Protection Regulations	5g	
5h Does the research involve the acquisition of	5h	

Slide 7

Do you really need to ask those and not others?

would cause harm.

If you avoid asking them about their personal experiences this might well avoid harm.

If you feel your questions are essential but might cause harm what can you do if your participant becomes distressed (or might become distressed later).

For example, if your participant is a student you might give them the contact details of student welfare. So you'll need to show us that you know these contact details so you can (in turn) advise the participant.

See next slide for Guidance on section 5 SECTION 3. Conflict of Interest

3a Do you have any connection with the external organisation(s) being researched? Such as through personal, financial or family connections

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If 'Yes' please give details

If you are employed by the external organisation please advise if you will receive any financial or in-kind benefits or payments for undertaking the research from the organisation

SECTION 4. Research Ethics and the Protection of Participants' Interests

NB. Participants should suffer no harm as a result of participation in the research

#### 4.1 Please provide details here as to whether participation by those in your sample will be

Yes

No

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- b) Based on informed consent

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- d) Data that has been gathered will be kept securely? (For example, will files and data sticks be encrypted? Or data stored on password protected computers?)

  If using a recording device for interviews please advise when the original recording will be erased (e.g. immediately upon uploading to a secure device such as your password protected computer)

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research into hate crime <sup>1</sup> , theft, fraud, or harmful and illegal	5a	
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research will involve any of these categories in 5d to 5h you are		
advised to answer 'Yes'		
advised to district 165		
5d Terrorism, extremism, terrorist or extremist	5d	
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military or GCHQ		
	5f	
5f Has the research been Commissioned under		
an EU / US security call or similar		
5g Does the research involved the viewing,	5g	
usage or transfer of sensitive personal data as		
defined by relevant Data Protection Regulations		
Sh Door the recearch involve the acquisition of		
5h Does the research involve the acquisition of	5h	
security clearances (including the Official Secrets	5h	
· · · · · · · · · · · · · · · · · · ·	5h	

Slide 8

### Sections 5, (also 6,7 and 8 – see next slide).

There are a number of questions but if you examine these one by one you'll see that they need you to answer 'yes' or 'no'.

If you answer 'yes' then tell us the details.

If you answer 'yes' to any question in section 8 then see the note in bold below Section 8 (regarding other people helping you to conduct the research – and details of Disclosure and Barring checks).

My advice here is that all questions between Sections 5 to 8 should be answered 'no' unless it is absolutely essential that you need these participants. But even then, you might consider recruiting other participants. For example, professional groups who deal with offenders rather than offenders themselves

# SECTION 3. Conflict of Interest Yes No 3a Do you have any connection with the external organisation(s) being researched? Such as through personal, financial or family connections If 'Yes' please give details If you are employed by the external organisation please advise if you will receive any financial or in-kind benefits or payments for undertaking the research from the organisation

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Does the intended research fit into any of the	Yes	No
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5d Terrorism, extremism, terrorist or extremist organisations or groups, extremist ideologies, radicalisation°, de-radicalisation"	5d	
5e Has the research been Commissioned by the military or GCHQ	5e	
	5f	
5f Has the research been Commissioned under on EU / US security call or similar		
5g Does the research involved the viewing, usage or transfer of sensitive personal data as defined by relevant Data Protection Regulations	5g	
5h Does the research involve the acquisition of security clearances (including the Official Secrets Act)	5h	

Slide 9

See the notes on previous slide for guidance on sections 6, 7 and 8

	Yes	No
a Will your research involve visits to websites that night be associated with radicalisation or errorist/extremist organisations or groups?		
you answer 'Yes' to Q8a you are advised that such sites may be ibject to surveillance by the police and accessing those sites ight lead to police enquiries. It is strongly recommended that you so your university network address, once you have received hical approval, which will ensure these activities are flagged as a gitimate part of your research. Whilst acquiring ethical approval or this project and adhering to University guidance on accessing ebsites and storing related materials securely will allow the inversity to verify the legitimacy of you accessing these websites, cannot guarantee legal protection.		
b		
Please acknowledge that you understand this risk by putting an 'X' in the 'I Agree' box.		
Agree SECTION 7. Storage and Transmission of Research	h Materials	
	Yes	N
.1 Does your research involve the downloading and		
torage on a computer of any materials relating to		
torage on a computer of any materials relating to xtremism or radicalisation (for example, records,		
torage on a computer of any materials relating to extremism or radicalisation (for example, records,		
7.1 Does your research involve the downloading and storage on a computer of any materials relating to extremism or radicalisation (for example, records, statements or other documents)?  If you answered 'Yes' to Q7.1, you should request a secure file share from ITMS to be created for your project, with access restricted to you, or if absolutely necessary, any internal comvestigator(s). The research materials should not be kept on a personal computer, and all online research in this area should be fone on university servers". Physical data should be scanned and uploaded to the passivord-protected server; where this is not possible, it should be kept in a locked filing cabinet or similar on university premises.		
storage on a computer of any materials relating to extremism or radicalisation (for example, records, statements or other documents)?  If you answered 'Yes' to Q7.1, you should request a secure file thare from ITMS to be created for your project, with access restricted to you, or if absolutely necessary, any internal convextigator(s). The research materials should not be kept on a personal computer, and all online research in this area should be fone on university servers". Physical data should be scanned and uploaded to the password-protected server; where this is not possible, it should be kept in a locked filing cabinet or similar on		

7.2 Might your research involve the electronic transmission of such materials to project Co-Investigators? Yes/No Note: The Terrorism Act (2006) and the Counter-Terrorism and Security Act (2015) outlaw the dissemination of terrorist publications if the individual concerned has the intention to encourage or induce others. Publications disseminated for the purposes of an approved and clearly defined research project should not amount to an offence, because the requisite intention is unlikely to be present. However, you are advised to exercise caution and avoid dissemination of raw research materials where possible. You will need to agree to only transmit these materials to Co-Investigators after they have been passwordprotected and that you will only use 'Zend'ii', which encrypts materials in transmission. Please confirm you understand the risks in disseminating publications and that you will only transmit these materials to collaborators after they have been password-protected and via 'Zend'. (see footnote at end of form) I Agree Section 8. Additional Questions Yes No 8.1 Are you specifically recruiting pregnant women 8.2 Will persons from any of the following groups be participating in the study 8.3 Adults without capacity to consent 8.4 Those with learning disabilities 8.5 Prisoners 8.6 Adults at risk If yes please give details of a) the protection procedures you propose to adopt should there be any evidence of or suspicion of harm (physical, emotional or sexual) to a adults at risk. Include a referral protocol, identifying what to do and who should be contacted. b) of how you propose to ensure the well-being of adults at risk, particularly with respect to ensuring that they do not feel pressured to take part in the research and that they are free to withdraw from the study without any prejudice to themselves at anytime. You should indicate how you intend to ascertain that person's views and wishes.

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See the notes on previous slide for guidance on section 8

Section 9. - Your module leader or supervisor will give you these details

Section 10. - Don't forget to submit copies of these forms!

Remember!
No primary
research can
be undertaken
until
authorisation
has been given

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8.7 Young offender	s (16-21 years)	
particular depende	uld be considered to have a nt relationship with the ose in care homes, students, ues)	
	ruiting (as participants) or have any children under the age of	
propose to adopt suspicion of harm child/young perso	s of the child protection procedures you should there be any evidence of or (physical, protional or sexual) to a n. Include a referral protocol identifying no should be contacted.	
being of the child/ ensuring that they research and that	s of how you propose to ensure the well- young person, particularly with respect to y do not feel pressured to take part in the they are free to withdraw from the study dice to themselves at any time	

If you have answered yes to ANY question in Section 8 please give details

- a) of any staff or students who will have contact with adults at risk and/or will have contact with young people (under the age of 18)
- b) of current Disclosure and Barring check for you (and also for those staff or students named above at a)

	ce/faculty-specific-pr		v.dmu.ac.uk/resea ss-and-law-ethics	
Name:			Web address:	
SECTION	10. Supporting Do	cuments		
SUPPOR Compuls		all documents s	hould have a vers	ion number and date)
	A (for all applicants) search proposal (sugg	ested headings	are listed in subm	ission guidelines)
For those	whose research invol	ves human part	icipants (Appendi	es B, C and D required)
Appendix Da	B ta Collection tools (e.d	draft interview	schedule, survey	questionnaire)
Appendix	С			
Pai	ticipant information s	heet (see submi	ission guidelines f	or example)
Appendix	D			
<b>=</b> c-	nsent form (see subm	ission auidelines	s for example)	

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You'll find a list of these from the web link

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#### SECTION 11. Declaration and Signatures

I confirm that I have read the **Responsibilities of the Researcher** guidelines at http://www.dmu.ac.uk/research/ethics-and-governance/responsibilities-of-theresearcher.aspx and I will comply with them.

I have considered my own personal safety and a separate Risk Assessment has / has not been completed (please delete as appropriate).

11a Signature of Applicant		Date:
11b Signature of workplace supervisor (if applicable)	*Support/non-support (please give reasons for non-support)	Date:

#### Please upload to the relevant module on Blackboard. Please do not upload through Turnitin.

MODULE LEADER ONLY: Supervisor and Module Leader to each review ethics application (unless the Supervisor and Module Leader is one and the same person- in which case the Supervisor and the Programme Leader should review the application. However, if the Supervisor, the Module Leader, and the Programme Leader are all one and the same person, then the Supervisor needs to find an academic colleague to also review the form).

Once each has reviewed the application, please sign Section 11e and scan the form and upload to Blackboard (or if preferred use a digital signature and upload to Blackboard). Note: if the other Reviewer does not have access to that particular module on Blackboard, the application form once authorised etc (and signed) should be forwarded to the supervisor by email for them to upload on Blackboard.

#### 11c Risk Level Assessment

#### I determine the risk level of this application to be;

Please refer to FREC Guidelines at:

http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/businessand-law-ethics-procedures.aspx

Note for Supervisor: For MEDIUM and HIGH risk applications, please notify FREC of the Module name, number and student name by emailing: BALResearchEthics@dmu.ac.uk
Low risk cases should be logged and filed.

Low risk cases should be logged and filed.

Low Risk Medium Risk High Risk

11 d Please confirm that the applicant has addressed each of the following issues to your satisfaction (if applicable).	Yes	No	N/A
The study design is appropriate and within ethical parameters			
The research questions are clear and within ethical parameters			
Recruitment method is explicit, fair, free from duress and data protection is not breached			
Sample and sampling method is appropriate and ethical			
Participants are fully informed about the research in writing			
Participation is voluntary with informed consent?			
Vulnerable people have additional interventions to ensure informed			
consent (e.g. parents, guardians, carers, advocates etc)			
Participants are given details of how to complain			
DMU consent form template has been used			
Data will be stored securely, and for the appropriate duration			
Permission has been, or will be, sought from external host organisation (where applicable)			
Confidentiality, anonymity and privacy will be ensured and maintained			
Possible adverse outcomes to participants are identified and suggestions			
to minimise or			
deal with these are presented			
Risks to the researcher are identified and suggestions to minimise or deal			
with these are presented (in the laboratory or off campus)			
Do the procedures identified necessitate formal assessment by another ethical			
committee? If yes, which one?			

SECTION 11e. Outcome of review		Please tick one box only
I recommend this study is given ethical approv required)	al (no changes	
I do not support this application (please give r	easons)	
I recommend the applicant addresses the char reviewed by a Reviewer or the Chair	ges listed below and the	resubmission is re-
Please list the <u>specific changes</u> the applicant	must make to obtain eth	ical approval
Please write any additional comment you may	have (optional)	

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After
authorisation
please take
these steps, if
you are
planning to
undertake
your research
off-campus

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#### SECTION 12. Chair of Faculty Research Ethics Committee (For Medium and High Risk Cases Only)

For applications identified as Medium or High Risk ONLY to be reviewed by the FREC Chair.

#### Chair of the Faculty Research Ethics Committee

Approval /Rejection/Referral (please delete which does not apply)

"This is the final approval from the Chair of the BAL faculty Research Ethics Committee that this Ethical Approval application has been approved as outlined in the application.

- This Ethics application is rejected for the following reasons
- This Ethics application is referred back to applicant
- \* This Ethics application is referred to FREC/UREC for further consideration

Chair's Comments (if applicable)

BAL FREC Chair's Name:

BAL FREC Chair's Signature:

Date:

#### SECTION 13. HEALTH AND SAFETY – FOR THE APPLICANT AFTER AUTHORISATION!

Are you planning to undertake your research off- campus? Yes/No (please delete as appropriate)

If yes, if you are planning to undertake research off-campus then you must contact Tracey Lee-Adams by sending her a copy of this AUTHORISED ethics application form explaining to her that you propose to undertake research off-campus and as such you recognise that a risk assessment is required

(Tracey's email address is Tlee-Adams@dmuac.uk).

In most cases it is anticipated that Tracey will send you a signed risk assessment form advising you how to remain safe and well while undertaking your research. In exceptional cases Tracey will meet with you to assess risks.

Once you have received your authorised risk assessment from Tracey please attach it your authorised ethics application.

#### Footnotes

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Hate Crimes are those committed against someone because of their disability, genderidentity, race, religion or belief, or sexual orientation.

Harmful and illegal cultural practices: these include violence against women and girls, Fernale Genital Mutilation (FGM), forced marriage, child sexual exploitation and honour-based violence.

Accessing prohibited websites: You will need to seek permission from ITMS; advice on how to gain permission is available from the ITMS helpdesk.

Y Radicalisation refers to the process by which a person comes to support terrorism and forms of extremism leading to terrorism

De-radicalisation usually refers to activity aimed at a person who supports terrorism and in some cases has engaged in terrorist related activity, which is intended to effect cognitive and/or behavioural change leading to a new outlook on terrorism and/or disengagement from it.

Secure File Share: You will need to ask ITMS to create a Secure File Share for your project, with access restricted to yourself, or if absolutely necessary, any internal co-investigator(s). Advice is available from the <a href="ITMS helpdesk">ITMS helpdesk</a>.

Zend: advice on using Zend is available from the ITMS helpdesk.

IMPORTANT: A COPY OF THIS COMPLETED DOCUMENT IS RECOMMENDED TO BE SUBMITTED WITH THE DISSERTATION/INDEPENDENT STUDY AS AN APPENDIX ITEM

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<sup>&</sup>lt;sup>1</sup> Illegal activities incorporates any illegal activity; for example, trespassing, theft, or online piracy.

# Specimen forms

- Participant Information sheet
- Verbal version of the participant information sheet (for say focus groups or brief face to face interviews)
- Participant Consent From
- Examples can be found on the webpage
- <a href="http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/bal.aspx">http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/bal.aspx</a>

# After authorisation

Need to amend your proposed activity?

- Amendment form found from here
- http://www.dmu.ac.uk/research/ethics-and-governance/facultyspecific-procedures/bal.aspx

• See also next slide

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#### De Montfort University Faculty of Business and Law Faculty Research Ethics Committee

#### AMENDMENT/EXTENTION APPLICATION FORM

#### PLEASE READ SUBMISSION GUIDELINES BEFORE COMPLETING THIS FORM

Further information and application forms are available at : <a href="http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx">http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx</a>

For further information or advice please contact the Research and Innovation Office by email: BALResearchEthics@dmu.ac.uk

Amendments may include changes to the terms of the FREC application, the protocol or any other supporting documentation for the trial. Applicants should consider;

- a) Any change in the research proposal
- b) The safety or physical or mental integrity of the subjects of the trial
- c) The scientific value of the trial
- d) The conduct or management of the trial
- e) The quality or safety of any investigational medicinal product used in the trial

1. Applicant name:		2. Email address:
3. Supervisor(s) or co-appli	cants:	4. Programme (if applicable):
5. Title of Research Project		
6. Original Approval Reference number;	7. Start date for the p	roject 8.Expected end date for the project: (FREC must be advised upon completion)
Netereine Humber		grace make we advised upon compretion)

10. R	ationale for the amendment		
	lease list each potential ethical is de potential risks to participants	ssue relating to your study and state how and research staff	these will be addressed:
	ORTING DOCUMENTS (all documents)	nents should have a version number and d	ate)
	Research proposal (suggested	headings are listed in submission guidelin	es)
When	e applicable		
When	e applicable  Permission from external orga	inisation	
Wher			
	Permission from external orga Consent form (see submission		
	Permission from external orga Consent form (see submission Participant information sheet	guidelines for example)	
Author By sig	Permission from external orga Consent form (see submission Participant information sheet Data collection tools (eg draft prisation pring this form, you confirm that	guidelines for example) (see submission guidelines for example)	
Author By sig guide	Permission from external orga Consent form (see submission Participant information sheet Data collection tools (eg draft prisation pring this form, you confirm that	guidelines for example) (see submission guidelines for example) interview schedule, survey questionnaire) you have read, understood and will comple	

Please submit this form to: BALResearchEthics@dmu.ac.uk

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