

OPERATIONAL GUIDELINES FOR RESEARCH SERVICES STAFF INVOLVED IN ACCEPTING RESEARCH AND RESEARCH RELATED AGREEMENTS - IN ACCORDANCE WITH THE ETHICS CODE

1. Introduction

The Ethics Code, introduced in Nov 2013, has been established to provide an overarching code of practice for the College which compliments existing policies relating to ethics. The Ethics Code, and its Relationship Review Policy, provide a number of key principles and behaviours which the College expects of its members and provides a route to escalate ethical matters which cannot be resolved under existing review procedures.

The Relationship Review policy requires that the ethics due diligence process be documented, together with the necessary approvals, before all research proposals are accepted. These guidelines set out this process, including the responsibilities for research services and the associated due diligence checks required.

These guidelines apply to all proposals for externally funded research and research-related agreements to be undertaken by the College including, but not limited to, all externally-funded research grants and contracts, collaborative agreements, consortium agreements, memoranda of understanding, confidentiality agreements and material transfer agreements.

2. Existing Review Procedures

The Ethics Code is not intended to replace the Colleges existing established policies and procedures, relating to ethics which should continue to be followed in the first instance. The established policy and procedure for the approval of Research and Research Related Agreements is the [Bid Management, Faculty Approval and College Authorisation of Research Proposal and Research Related Agreements](#) and as part of this process, Faculty Approval requires that a **Relationship Review** be carried out to assess ethical issues and any reputational risk to the College, before approval is given and College Authorisation is granted.

This policy also contains The Preferred Terms for the College in relation to contractual issues, and the existing escalation route should be used for any contractual issues which may have an ethical implication.

3. Relationship Review.

- 3.1. In order to conduct a relationship review, the reputational risk to the College should be considered before all Research and Research Related Agreements are entered into. In most cases this will be a simple process as the funder and the relationship will be straight forward.
- 3.2. The Organisation itself should be reviewed from an ethical perspective and should have a mission or strategy which is consistent with the College's. There may be more than one organisation involved in any research project, including collaborative partners and sub-contractors etc., and the reputational risk of each should be considered.

To facilitate the Relationship Review, Research Services should review all organisations from an ethical perspective. This will be in addition to the checks which are already carried out for new funders under existing policies and procedures:

- **Table 1** contains the initial organisational checks which should be carried out for all new research partners to the College.
- **Table 2** lists the full due diligence which should be conducted for all organisations in order to assess their reputational risk.

- 3.3. The Research Project. In accordance with [Bid Management, Faculty Approval and College Authorisation of Research Proposal and Research Related Agreements](#) it is the responsibility of individual HoDs to assure themselves that activities being carried out within their dept. should be consistent with the ethical standards expected of the College and should not compromise the Colleges position as an independent entity or present any Conflicts of Interest.

4. Research Services Responsibilities

The roles and responsibilities for reviewing and approving funders from an ethical perspective for Research Services are given below.

- 4.1. Each faculty shall nominate one person to be the Chief Reviewer for the review process.
- 4.2. The Relationship Review requires Research Services to check for potential issues at an organisational level and to verify that ethical considerations have been carried out at the Research Project level.

4.3. Corporate Partnerships (CP) may also carry out due diligence on both the organisation and the research project. Where CP have done so, they will provide Research Services with the formal record of the review undertaken, *which Research Services should then retain as part of the formal record in accordance with 4.9 below.*

4.4. **Organisation.** The senior grants administrator or the contract negotiator should check that the organisation is recorded as either *high or low risk* on the list maintained in the [Ethics Code Due Diligence](#) shared folder. If the organisation is not on the list they should contact the Chief Reviewer for their faculty in order for the due diligence to be carried out – see Table 1 and 2. Discretion may be applied by the Chief Reviewer, as to the most appropriate checks to conduct. The Chief Reviewer will assign a *low* or *high* risk decision for the organisation.

Where an organisation is considered *high risk*, the matter should be raised in accordance with 4.6.

4.5. **Research Project.** In the first instance, Research Services should crosscheck that there are no research activities involving tobacco research or classified research.

The following issues should be raised with the Chief Reviewer in accordance with 4.6:

weapons research or research in the alcoholic beverages or gambling field

potential conflicts of interest which the HoD or the dept. may not be aware of.

*research which is being conducted **outside** of the [EEA](#), North America, Australia, New Zealand, and Japan, refer to the Chief Reviewer to check that there are no restrictions or embargos for that country, see Table 1.*

The Senior Grants Administrator/Contract Negotiator should confirm that the HoD has given Faculty Approval in accordance with the [Bid Management, Faculty Approval and College Authorisation of Research Proposal and Research Related Agreements](#) policy. The HoD confirms that there are no ethical issues as part of Faculty Approval.

4.6. Where a potential ethical issue is identified the Senior Grants Administrator/Contract Negotiator should inform the Chief Reviewer.

The Chief Reviewer should complete the Pro-Forma including details of the organisational and/or project level issues.

The Chief Reviewer should discuss ethical issues with the HoD as soon as possible. The HoD may agree action to resolve or mitigate the issue,

assuming responsibility for any incumbent risks or may elect not to proceed. Any action or further clarification provided by the HoD must be formally recorded on the Pro-Forma by the Chief Reviewer.

- Where the HoD does not feel able to resolve the matter and wishes to proceed with the project, then the issue should be escalated by the Chief Reviewer to the Director of the Research Office and the relevant Dean/Faculty Operating Officer in accordance with 4.8.
- Where the HoD wishes to proceed, but the Chief Reviewer still has specific concerns, the Chief Reviewer may also escalate an issue in accordance with 4.8.

4.7. Where no ethical concerns are raised (or where issues have been escalated and approval has been granted) Research Services should confirm that the ethical review has been conducted as part of College Authorisation. A record of ethics approval should be retained in accordance with 4.9

4.8. **Process for Escalation.**

The form at Appendix B should be submitted to the Dean/FOO and Director of the Research Office setting out the issues. Referrals should be made as early as possible in the process.

Where the Director of the Research Office and the relevant Dean/Faculty Operating Officer cannot resolve the ethical matter [they] shall escalate the issue to the College Cabinet (via the Head of Secretariat).

The College Cabinet shall reach a decision on the ethical issue. Where consensus cannot be reached, a formal reference shall be made by the College Secretary and Registrar to the Audit Committee who will seek further advice from College employees, third parties and the College Council as required.

4.9. **Final Record Keeping.** The following records will be kept by Research Services;

Organisation level review

- Results of due diligence carried should be recorded using Due Diligence Pro Forma Part 1, at Appendix A, and retained in the Ethics Shared Folder [link],
- Pro Forms for organisations with no identified ethical issues, and deemed a *low risk* should be added to the *low risk* folder in the [Ethics Code Due Diligence](#) shared folder, using the naming convention “risk level, organisation name, date of review”, e.g. LowRisk-BHF-10Dec13.

- Pro Formas for organisations with identified ethical issues, and deemed a *high risk* should be added to the *high risk* folder in the Ethics Code Due Diligence shared folder, using the naming convention “risk level, organisation name, date of review”, e.g. HighRisk-RioTinto-10Dec13.

Research Project level review

- Where an InfoEd record has been created HoD approval is the record which confirms that the department has considered reputational risk.
- For contractual matters outside of InfoEd, confirmation by the HoD should be formally recorded in the SharePoint contract record.
- Where an issue has been identified, but through discussion with the HoD, the HoD has resolved or mitigated any risks, this action, and the rationale for the decision should be recorded on the Pro Forma and retained, along with any supporting email chains, and other relevant documentation.
- Pro formas must be held on the Ethics Code Due Diligence shared folder under [Project Relationship Review](#), under the naming convention “PI-organisation-date of review”, and saved under the relevant Faculty folder.
- Where a matter has been escalated for approval in accordance with the procedure in 4.8, a copy of the notification form (Appendix B), as well as confirmation of all approvals received under the escalation procedure should be recorded and retained. Any supporting emails, and other relevant documentation should also be retained.

Table 1 – Initial Organisational Check

The following checks should be carried out for **all new organisations**

Principle	Due Diligence	Responsibility holder	Existing Policy or Procedure
[1]	[2]	[3]	[4]
The organisation is a new research partner at the College (unfunded activity)	Verify the existence of the organisation. e.g. Companies House, Charity Commission, online google search, Dun and Bradstreet (US companies)	Research Services	Bid Mgt, Faculty Approval and Authorisation of Research Agreements
The organisation (and the country in which it is based) should be checked against a list of sanctioned (or restricted) countries or organisations	<p>The UK Government website and the UK Trade and Industry website both provide information by Country.</p> <p>The European Commission website provides an overview of restrictive measures imposed by the EU. The measures in place are listed by country and would highlight regimes or groups which the College may wish to consider carefully before working with.</p> <p>The World Bank provides a searchable list of debarred individuals and firms they have sanctioned under the Bank's fraud and corruption policy.</p>	Research Services	
The organisation is a new research partner funding research at the College. New organisation - integrity check.	<p>A credit check should be carried out by Accounts Receivable (AR) which may include the verification of:</p> <ul style="list-style-type: none"> • The identity of the organisation • The organisational structure and where possible directors and potential links to other companies or individuals • Solvency of the organisation 	AR	Bid Mgt, Faculty Approval and Authorisation of Research Agreements

Table 2 – Due Diligence for all Organisations

Research Services should carry out the following due diligence checks for all organisations except for the organisation types listed below. These are excluded on the basis that they are considered to be a low risk to the College because they are UK government organisations and/or are subject to UK or European legislation or further regulation and are audited on a regular basis, or they are an established research funder/collaborator in UK Higher Education:

All UK Research Councils

All UK Government Depts

Other UK, European, and US universities

All UK Hospitals and NHS Trusts

The European Commission projects where Imperial College is not the co-ordinator.

UK charities registered with the Association of Medical Research Charities (AMRC)

Due Diligence	
<p>Reputational Risk</p> <p>An internet search for recent evidence of illegal activities or ‘bad press’ should be carried out. Online searches using the <u>organisations name</u> and the following terms:</p> <ul style="list-style-type: none"> • Tax Evasion (Only to include unlawful tax evasion not corporate tax avoidance) • Fraud • Human Rights • Falsification of academic research • Bribe/bribery • Crime • Environmental conduct • Health and safety <p>The organisations website should be checked for the following information:</p> <ul style="list-style-type: none"> • Are there any links to other companies or individuals which may affect the reputation of the College? This would include any pressure groups or political organisations or figures. <p><u>Internet Search Guidance:</u></p> <p>The search could produce articles from a variety of sources, ranging from evidence of lawsuits, or criminal convictions to allegations by various pressure groups or individuals. It is recognised that this is a subjective process and the person compiling the information is not expected to come to a decision about whether the organisation is a ‘guilty party’ or not. Sources such as regulatory bodies or watchdogs should be given more credibility, however any news item may have the potential to damage a reputation.</p> <p>In filtering out information which might be of lower risk it may be possible for the following to be ignored:</p> <ul style="list-style-type: none"> • Articles which are more than [five] years old may be ignored [unless the issue is currently being raised in more recent press reports]. • Allegations or court cases involving any wrong-doing of an individual who works for the organisation [unless there is some level of corporate responsibility for which the organisation has been brought to task]. 	<p>Where an internet search has produced a large number of potential concerns the organisations website should be checked for the following information:</p> <ul style="list-style-type: none"> • Does the organisation publish its ethical code of conduct? • Does the organisation have a statement on encouraging diversity? • Does the organisation report health and safety-related incidents, such as recordable injuries or fatalities? • Does the organisation report its sustainability or environmental policy? • Does the organisation report on its regulatory compliance? <p>Whilst this does not override any concerns raised through an internet search it <i>may</i> demonstrate that the organisation has a commitment to tackling such issues.</p>

PART 1 – Organisation review

DETAILS OF INDIVIDUAL MAKING THE NOTIFICATION *(to be completed by the individual making the notification):*

To be completed only where the organisation does not appear in the [Ethics Code Due Diligence](#) shared folder

Mitigating factors to consider:

- Previous activity with the organisation. Have these given rise to any issues?
- Other activity in the UK university sector. Are working with many other universities?

Organisation name (and website, address, contact details)	
Initial Project title (if known)	
Initial Principal investigator(s)	
Name of reviewer	
Signature and Date	
Background comments	

	Outcome Please summarise any issues and provide relevant URLs or
Issues identified from the Initial Organisation Check. <i>Please see Table 1</i> For example: <ul style="list-style-type: none"> • The identity of the organisation • The organisational structure and where possible directors and potential links to other companies or individuals • Where the organisation is based/registered 	
Does the company have a 'poor public image' resulting from company practices, such as poor environmental conduct, health and safety record, human rights record, which may be detrimental to the College's reputation? Has the internet search for recent evidence of illegal activities or 'bad press' raised any concerns? <i>Please see Table 2</i>	
Is the organisation linked to any politically sensitive groups or persons?	

Evaluation

<input type="checkbox"/> No concerns were raised – Low Risk
<input type="checkbox"/> Ethical concerns identified – Consider alongside the Project and complete Part 2 – High Risk

PART 2 – Project level review

DETAILS OF INDIVIDUAL MAKING THE NOTIFICATION *(to be completed by the individual making the notification, being one of the following: HoD, Chief Reviewer):*

Organisation name (and website, address, contact details)	
Project title (if known)	
Principal investigator(s)	
Name of reviewer	
Signature and Date	
Background and comments	

Reputational Risks? e.g. The research activity involves a subject matter which could be seen as politically sensitive such as: <ul style="list-style-type: none"> • gambling • tobacco • alcoholic beverages • weapons manufacturing or biological warfare research 	
Have you identified any identified potential Conflicts of Interest?	
Does the relationship have the potential to compromise the College's status as an independent institution?	
Where research is being conducted outside the EEA , North America, Australia, New Zealand, and Japan does this present any additional risks?	
Does the relationship present any other concerns or issues?	

Evaluation

Have issues been identified?	Yes	No
Organisation (Due diligence form Part 1)	<input type="checkbox"/>	<input type="checkbox"/>
Project (Due diligence form Part 2)	<input type="checkbox"/>	<input type="checkbox"/>
<i>If answer is yes for either the project or the organisation consultation is required</i>		
Ethical concerns identified; Consult with academic department (HoD).	<input type="checkbox"/>	
Outcome:		
Ethical concerns cannot be resolved with department; Escalate	<input type="checkbox"/>	
Outcome:		

**NOTIFICATION OF MATTER FOR ETHICAL CONSIDERATION TO THE DIRECTOR OF THE
RESEARCH OFFICE AND THE FACULTY OPERATING OFFICER/DEAN**

UNDER THE IMPERIAL COLLEGE RELATIONSHIP REVIEW POLICY

DETAILS OF INDIVIDUAL MAKING THE NOTIFICATION *(to be completed by the individual making the notification, being one of the following: HoD, Research Services Manager, Contracts Manager):*

Name:

Position:

Organisation/Party (who issue is being raised for):

DETAILS OF THE ETHICAL ISSUE *(to be completed by the individual making the notification).*

Type of relationship *(i.e. research funder, multi-party collaboration etc)* **[xx]**

Reason for notification *(i.e. ethical concern arising in the course of due diligence or otherwise)* **[xx]**

Detail of the ethical issue and your recommendation as to how the matter should proceed: **[xx]**

Brief history of the matter *(including whether the proposed relationship arises from a solicitation from (or a contact within) Imperial College or from an independent approach):* **[xx]**

Details of any non-standard or potentially onerous conditions proposed in connection with the proposed relationship: **[xx]**

Details of the due diligence that has been carried out and the results of that due diligence: **[Attach Due Diligence Proforma part 1 and 2]**

Status of the relationship and timescales: *(including details of the current status of negotiations/previous contact between the College and relevant individual or organisation/ when it is intended that the relationship will be entered into):* **[xx]**

Further comments and reference to additional documentation provided *(include all further details that you would like to draw to the attention of the decision maker and refer to all supplementary documents included for review)* **[xx]**.

DETAILS OF FURTHER INFORMATION REQUIRED BY DECISION MAKER

Further information required: *(if none, please specify)* **[xx]**

CONFIRMATION OF DECISION AND GUIDANCE *(to be completed by the Director of the Research Office)*

Do you approve the proposed relationship? Yes/No

Details of any conditions attached to an approval: **[xx]**

Any further comments **[xx]**

CONFIRMATION OF DECISION AND GUIDANCE *(to be completed by the Dean/FOO)*

Do you approve the proposed relationship? Yes/No

Details of any conditions attached to an approval: **[xx]**

Any further comments **[xx]**

Appendix C – Map of Research Services Process

Ethical Review – Research Services Process

