Human Research Ethics Committee for Non-Clinical Faculties

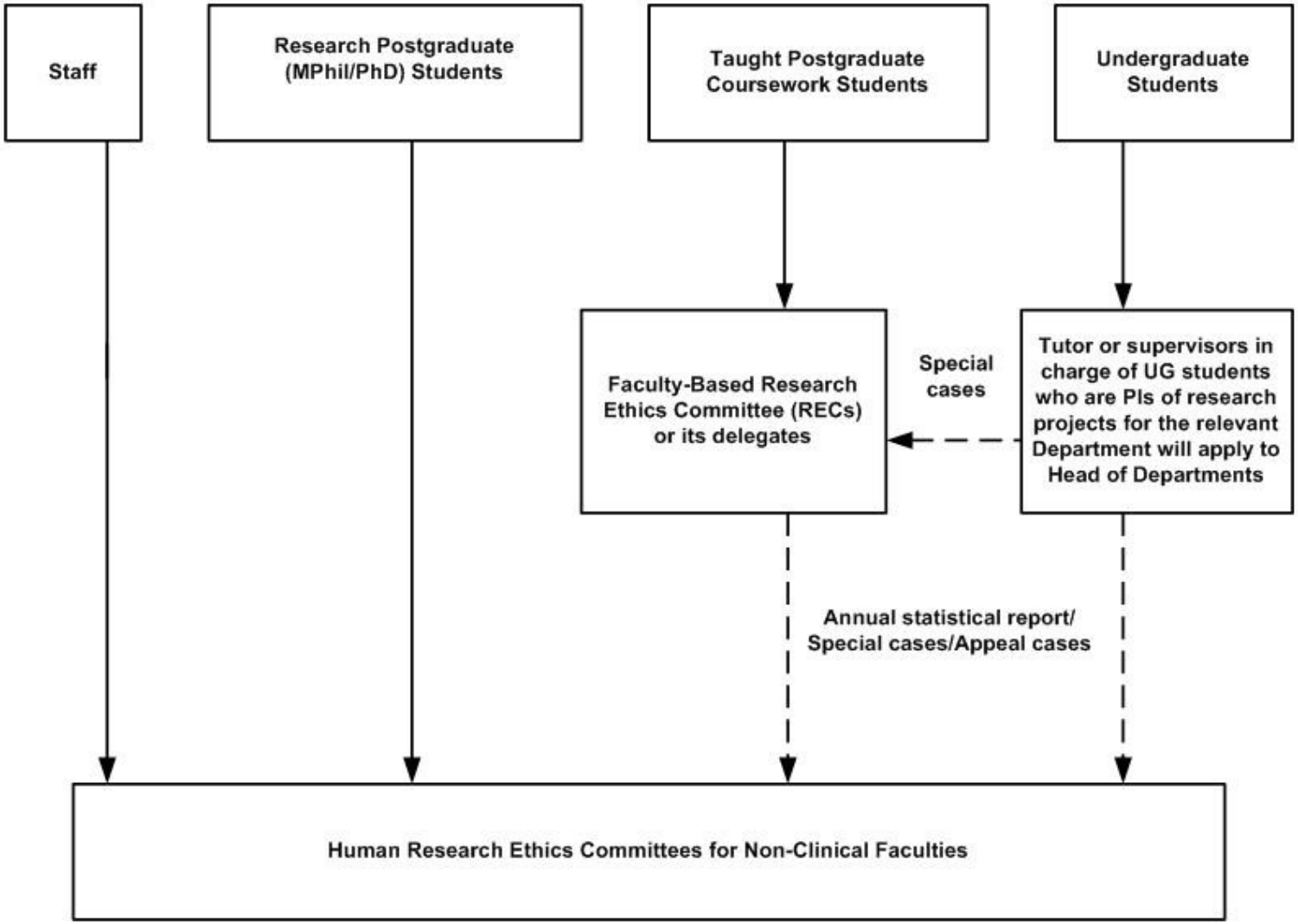
Training Workshop

http://www.hku.hk/rss/HREC.htm

Contents

1. Where to apply for Research Ethical Approval?
2. 3 Basic Principles (Belmont Report)
3. Basic Elements of a Consent Form

Where to apply for Research Ethical Approval?



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3 Basic Principles (Belmont)

1. **Respect for Persons**
2. **Beneficence**
3. **Justice**

Respect for Persons

- **Treated as autonomous agents**
- **Protect those with diminished autonomy**

Application

- **Informed Consent**
  - **Information**
  - **Comprehension**
  - **Voluntary participation**

3 Basic Principles (Belmont)

1. **Respect for Persons**
2. **Beneficence**
3. **Justice**

Beneficence

- **Do no harm**
- **Maximize possible benefits**
- **Minimize possible risks**

Application

- **Assessment of risks and benefits**

3 Basic Principles (Belmont)

1. **Respect for Persons**
2. **Beneficence**
3. **Justice**

Justice

- **The benefits and risks of research must be distributed fairly**

Application

- **Fair Selection of participants**

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3. Basic Elements of a Consent Form

Basic elements of a Consent Form

1. Title of the study
2. Introductory Sentence
3. Purpose of the study
4. Procedures
5. Potential risks/discomforts and their minimization
6. Compensation for participation

Basic elements of a Consent Form (Contd.)

7. **Potential benefits**
8. **Confidentiality**
9. **Participation and withdrawal**
10. **Questions and concerns**
11. **Signature**

Basic elements of a Consent Form

1. Title of the study
2. Introductory Sentence
3. Purpose of the study
4. Procedures
5. Potential risks/discomforts and their minimization
6. Compensation for participation

Title of the study

- **Use a short and informative title without giving away your specific hypotheses.**

Example:

Biosocial Bases of Personality Disorders

Basic elements of a Consent Form

1. Title of the study
2. Introductory Sentence
3. Purpose of the study
4. Procedures
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6. Compensation for participation

Introductory sentence

- **State clearly that this is a research study and who the principal investigator is.**

Example:

You are invited to participate in a research study conducted by Professor [David Chan] in the Department of [Name] at the University of Hong Kong.

Basic elements of a Consent Form

1. Title of the study
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6. Compensation for participation

Purpose of the study

- **Describe in simple, non-technical language what this study is about.**

Example:

This study examines the background factors that might explain why two important personality disorders (schizotypal personality and psychopathic personality) develop. The study also compares levels of these personality disorders in Hong Kong to levels in the United States.

Basic elements of a Consent Form

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Procedures

- **Highlight the main points of the procedure and where it will be done. Be sure to state how long the procedure will last.**

Procedures (contd.)

Example:

You will be invited to fill out some brief self-report questionnaires in Professor [David Chan] lab at the University of Hong Kong to assess schizotypal and psychopathic personality, antisocial and aggressive behavior, early child rearing experiences, social relationships, handedness, history of head injury, and basic social background questions. In addition, we will measure your heart rate and blood pressure using a simple blood-pressure cuff. Altogether, the testing will take on average 25 minutes.

Procedures (contd.)

- **Audiotaping or videotaping**

Example:

You may be audiotaped/videotaped during the procedure.

Procedures (contd.)

- **Mild deception**
  - **Warn participants in advance**
  - **Post-debriefing consent form**

Example:

We may not be able to give you all the information about this study right now. We will however do our best to explain the study to you fully during the debriefing.

Basic elements of a Consent Form

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5. Potential risks/discomforts and their minimization
6. Compensation for participation

Potential risks/discomforts and their minimization

- **Advance warning for mildly upsetting or uncomfortable procedure**

Potential risks/discomforts and their minimization (contd.)

Example:

You may find talking about your personal experience (or watching the videotapes) during the procedure somewhat uncomfortable and upsetting. Such discomforts, however, should be no greater than what we experience in everyday life.

Potential risks/discomforts and their minimization (contd.)

- **If the discomforts may be greater than what is experienced in everyday life, you may be required to offer access to a qualified psychologist/counselor:**

Example:

If you experience discomfort you can stop the research procedure at any time. In addition, you have access to a Psychologist (Professor [David Chan] – see contact information below) who may be able to help.

Potential risks/discomforts and their minimization (contd.)

- **If the risks/discomforts are mild or minimal, you can say so.**

Example 1:

This procedure has no known risks.

Example 2:

You may experience some mild fatigue and discomforts during the procedure. Such fatigue and/or discomforts will be kept to a minimum because the tasks are self-paced and you are free to take short breaks.

Basic elements of a Consent Form

1. Title of the study
2. Introductory Sentence
3. Purpose of the study
4. Procedures
5. Potential risks/discomforts and their minimization
6. Compensation for participation

Compensation for participation

Example 1:

You will receive $30 for your participation in this procedure.

Example 2:

You will receive a small gift for your participation.

Basic elements of a Consent Form (Contd.)

7. **Potential benefits**
8. **Confidentiality**
9. **Participation and withdrawal**
10. **Questions and concerns**
11. **Signature**

Potential benefits

- **State potential benefits to the participants and others. If none to the participants, say so.**

Example 1:

There are no direct benefits to you. However, the research project can provide valuable information on the causes of personality disorders. This information in turn could help inform future treatment of these disorders.

Potential benefits (contd.)

Example 2:

In this study, you will be invited to reflect on your personal experience. Such reflection may give you insights about yourself. In addition, this research project can provide valuable information on….

Example 3:

In this study, you will be taught some learning skills, which may help you become a better learner. In addition, this research project can provide valuable information on….

Basic elements of a Consent Form (Contd.)

7. Potential benefits
8. Confidentiality
9. Participation and withdrawal
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11. Signature

Confidentiality

Example:

Any information obtained in this study will remain very strictly confidential, will be known to no-one, and will be used for research purposes only. Codes, not names, are used on all test instruments to protect confidentiality.

Confidentiality (contd.)

- **If you audiotape or videotape the participants during the procedure, tell the participants that they have the right to review and erase the tapes.**

Example:

You can review the audio/video-recording of the procedure. We will erase the entire audio/videotape or parts of it if you want us to do so.

Basic elements of a Consent Form (Contd.)

7. Potential benefits
8. Confidentiality
9. Participation and withdrawal
10. Questions and concerns
11. Signature

Participation and withdrawal

Example:

Your participation is voluntary. This means that you can choose to stop at any time without negative consequences.

Basic elements of a Consent Form (Contd.)

7. Potential benefits
8. Confidentiality
9. Participation and withdrawal
10. Questions and concerns
11. Signature

Questions and concerns

Example:

If you have any questions or concerns about this research study, please feel free to contact the Principal Investigator Prof./Dr./Mr./Ms. [David Chan] at [Room No, Floor, Building], HKU. Telephone: [1234-5678]; Email: [davidchan@hku.hk]. If you have questions about your rights as a research participant, contact the Human Research Ethics Committee for Non-Clinical Faculties, HKU (2241-5267).

Basic elements of a Consent Form (Contd.)

7. Potential benefits
8. Confidentiality
9. Participation and withdrawal
10. Questions and concerns
11. Signature

Signature

Example:

I _____(Name of Participant) understand the procedures described above and agree to participate in this study.

_____ _____

Signature of Participant Date

Date of Preparation: [Fill in the date]

Expiration date:

Confidentiality

- **Questionnaires about parent-child conflicts will be distributed to children (age 14 to 16) and parents by a researcher and will be collected by teachers.**

Confidentiality

- **Access to Data**
- **Confidentiality Agreement**

Linking Data across Participants or Time

- **Students and their teachers fill out questionnaires on their drinking, smoking, and illicit drug use (if any).**

- **Any relationship?**

Linking Data

- **Identifiers on data sheet/questionnaires?**
- **If not, how to link data?**

Giving Test Results to Participants

- **Participants will be given an IQ test.**
- **One benefit stated in the consent form: Participants will receive a copy of their IQ test report.**

Giving Test Results to Participants

- **Any qualified professional to hand out the test results?**
- **If not, what could go wrong?**

Risks & Discomfort

- **Mood induction**
- **Interviews about traumatic experience**
- **Physical stress**

Risks & Discomfort

- **Any relevant professional on standby?**
- **Any helpful resource information?**

Often Missing from Consent Forms…

- **Duration of participation**
- **Contact information for HRECNCF**
- **Mentioning audio/videotaping**
- **Some procedures mentioned in the Research Plan**

Privacy

- Access to school records?
- Access to medical records?
- Recognized by other focus group members?