

**NOTIFICATION OF DATA BREACH**

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| **PART 1: ADMINISTRATIVE**  *(Blocks will expand to contain the information required, no extra references or pages should be added)* | |
| Ethics Reference Number: |  |
| Study Title: |  |
| Phase of trial: |  |
| Protocol/Project/Study Number: |  |
| Approved Version/No. and Date: |  |
| Amended Version/No. and Date: |  |
| Health product being studied: |  |
| Sponsor/Funder/Donor: |  |
| Applicant: |  |
| Person making report: |  |
| Address: |  |
| Cell No.: |  |
| E-mail address: |  |
| Date of Report: |  |

**PART 2: DETAILS OF REPORT**

This form is for organisations / Investigators that have experienced a data breach and need to report it to the University of the Witwatersrand, Human Research Ethics Committee (Medical). **Please do not include any of the personal data involved in the breach when completing this form**. For example, do not provide the names of data subjects affected by the breach. If we need this information, we will request it later. You should ensure the information provided is as accurate as possible and supply as much detail as possible.

**About your report**

Please answer the following questions, to help us handle your report efficiently and to better understand the risks involved in the data breach.

If you have already spoken to a member of the Wits HREC (Medical) about this breach, please provide their name(s):

**Please indicate report type:**

Initial:

Follow-up:

**ABOUT THE BREACH:**

1. **Please briefly describe what happened and how the incident occurred:**
2. **How did the organization/Investigator discover the breach? e.g. whistleblower, audit, sponsor:**
3. **What preventative measures did you have in place at the time?**
4. **Where and when did the breach happen?**
5. **When did you discover the breach?**
6. **Categories of data included in the breach (tick all that apply)**

**Medical and personal related data:**

Basic personal identifiers, e.g. name, contact details

Health data

Genetic (incl. family history) or biometric data

Official documents, e.g. driving licenses

Location data, eg coordinates

**Gender and Ethnic related**

Data revealing racial or ethnic origin

Sexual orientation data

Sex life data

Gender reassignment data

**Ideology and Religion**

Religious or philosophical beliefs

Political opinions including party membership

Trade union membership

**Legal and criminal**

Identification data, e.g. usernames, passwords

Criminal proceeding

Civil proceeding

Criminal convictions

**Financial**

Economic and financial data, e.g. credit card numbers, bank details, salary, debts, assets

**Other**

Other (please give details below)

Please give additional details to help us understand the nature of the personal data included in the breach. Give a detailed explanation of any health data that has been/may have been compromised:

1. **Number of personal data records concerned**
2. **How many data subjects could be affected?**
3. **If the number of data subjects affected is not known, estimate the maximum possible number that could be affected/total customer base**
4. **Source of breach?**

Verbal

Print

Electronic

Cyber

1. **Categories of data subjects affected (tick all that apply, give details below):**

Trial Participants

Patients

Minors (≤ 18 years)

Pregnant Women

Inmates (offenders when convicted)

Vulnerable Adults (adults with factual incapacity to provide informed consent, persons in dependent relationships, persons highly dependent on medical care, persons with visual, auditory or mobility impairments, collectivities)

Employees and Staff (incl. position of employee/staff)

Research

Admin

Other

Other (please give details below)

1. **Carefully describe any detriment or harm to individuals that has arisen so far, or any detriment you anticipate may arise in the future e.g. physical, psychological, financial, reputational, family, political, academic?**
2. **Is the personal data breach likely to result in risk to the data subjects?**

Yes

No

Not yet known

Please give details:

1. **Cyber incidents only**

**Recovery time (please select)**

We have successfully recovered from the incident with all personal data now at the same state it was shortly prior to the incident

We have determined that we are able to restore all personal data to the same state it was shortly prior to the incident and are in the process of doing this

We have determined that we are unable to restore the personal data to the same state it was at shortly prior to the incident, i.e. backups failed, no current backup, backup encrypted etc.

We are not yet able to determine if personal data can be restored to the same state it was shortly prior to the incident

1. **Had the staff member involved in this breach received data protection and ethics training recently (last 3 years)?**

Yes

No

Do not know

1. **Please describe the data protection and ethics training you provide or intend to provide, including an outline of training content and frequency. (Please do not delay submission of this form to answer this question. The answer can be sent in an additional document within 7 days).**
2. **If there has been a delay in reporting this breach, please explain why and when?**
3. **Action:**
4. Have you taken action to contain the breach or limit its impact? Please describe these remedial actions:
5. Please outline any steps you are taking to prevent a recurrence, and when you expect they will be completed:
6. Describe any further action you have taken, or propose to take, as a result of the breach:
7. **Have you told Data Subjects about the breach? Please select.**

Yes – we have determined it is likely there is a risk to data subjects so we have communicated this breach to data subjects.

Yes – we have determined that it is unlikely there is a risk to data subjects, however decided to tell them anyway

No – but we are planning to because we have determined it is likely there is a risk to data subjects.

No – we determined the incident does not create a risk to data subjects

**18. Have you told, or are you planning to tell any other organisations or groups about the breach? E.g. Sponsor, Applicant, Regulatory Authorities, Other RECs, NDoH, Civil Society**

Yes

No

Do not know

If you answered yes, please specify:

**19. Suspicious websites**

If the breach relates to a suspicious website, please let us know what steps you have taken to report the matter:

**Initial report**

If this is your initial report, please send your completed form in pdf format (password protected), to [**EthicsRegulatory@witshealth.co.za**](mailto:EthicsRegulatory@witshealth.co.za)

**Follow up report**

If this is a follow up report, please *reply to the email we sent you*, attaching this completed form to it. (Make sure you leave the subject line as it is – this will ensure your follow-up gets added to your case).

**What happens next?**

Based on the information you have provided, we will contact you within fourteen (14) calendar days to provide information about our next steps.

If you need any help in completing this form, please contact Prof Victoria Bronstein:

Email: [**Victoria.Bronstein@wits.ac.za**](mailto:Victoria.Bronstein@wits.ac.za)

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| I hereby certify that, to the best of my knowledge, the provided information is true and accurate | |
| Applicant/Principal Investigator:  Signature:  ………………………………………………… | Date  ……………………………………. |