

Forensic Science Regulator Protocol

Validation – Use of Casework Material FSR-P-300 Issue 2

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PART 1 - INTRODUCTION

1. HISTORY

1.1 Validation in Forensic Science

- 1.1.1 In most industries new or improved techniques and products are subjected to a series of tests before being marketed. These tests tend to culminate in the use of the new technique, or product, in real life situations. Perhaps the clearest example is in the pharmaceutical industry where the last hurdle before approval to market involves clinical trials on humans.
- 1.1.2 There are a number of reasons for this approach to testing but the most important is that if the new product is not subjected to "real life" testing in controlled conditions then there is a significant risk the final testing will actually occur in uncontrolled conditions in the open market.
- 1.1.3 Where methods are not completely validated before use in casework the result may be that the final stages of validation occurs on casework samples but not in the controlled environment normally employed for validation. The release of methods which have not been appropriately tested therefore poses a real and significant risk to the Criminal Justice System (CJS).

1.2 Casework Material Restriction

- 1.2.1 Following the attempted use of a new method in pilot studies the Crown Prosecution Service (CPS) became concerned about the use of casework material within validation, or similar, work.
- 1.2.2 These concerns were related to the following issues.
 - The disclosure requirements created by such use and the possible impact on cases.
 - b. The handling and impact of differences between results obtained with existing and new methods.
 - c. The legal and ethical issues surrounding the use of such material and the impact the use of such material may have on the subsequent deployment of the method which it was used to validate.

- d. Contractual restrictions imposed by the police on the use of exhibits submitted to forensic science laboratories for examination and information derived from them.
- 1.2.3 The CPS was not confident that these issues had been properly addressed by those seeking to use casework material for validation, or similar, work. As a result it concluded that such work posed an unacceptable risk to the CJS and should not be undertaken.

1.3 Protocol

- 1.3.1 This protocol was developed to achieve the following.
 - a. To develop an environment in which the CPS agrees the use of casework material for validation purposes is acceptable.
 - b. To provide an effective system for the use of casework material for validation by simplifying¹ the approval for such by establishing:
 - i. A class of work, and circumstances, for which approval can be presumed; and
 - ii. A simple approval system for a further class or work.
 - c. To establish processes necessary to facilitate the operation of the above system.
- 1.3.2 Where a Forensic Science Provider has applied for, and been granted, approval to operate under this protocol it can, in certain circumstances, use casework materials for validation:
 - a. Without seeking approval (i.e. the presumed approval process), or where this is not possible
 - Use a simplified process for seeking approval (the simplified approval process).
- 1.3.3 The fact that this protocol does not apply to a particular validation exercise does not mean that the use of casework material in that work is prohibited. The use can be authorised through processes other than this protocol.

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In the absence of such a system the approval may require contacting up to 43 police forces, the CPS Headquarters and perhaps CPS local units.

PART 2 – GENERAL

2. PRINCIPLES

- 2.1.1 This protocol operates on the acceptance of, and compliance with, some basic principles that must apply in order that casework material can legitimately be used as part of the final validation process:
 - Casework material is only to be used as part of a documented validation plan that meets the requirements of the Forensic Science Regulator's Codes of Practice and Conduct;
 - Prior to using casework material, validation exercises must provide sufficient data for a documented risk assessment and subsequent risk management plan covering all the identifiable risks that could occur in the use of casework material; and
 - c. Each validation plan must include a plan for resolving any legal and ethical issues identified in relation to the use of casework material in the validation.

3. SCOPE

3.1 Parties

3.1.1 This protocol has been agreed between the CPS, the National Police Chiefs' Council (NPCC) and the Forensic Science Regulator (FSR).

3.2 Forensic Science Providers

- 3.2.1 Forensic science providers² (providers) shall only be able to act under this protocol where the following has been achieved.
 - a. The provider is accredited to ISO 17025 and/or ISO 17020 as is relevant to the validation being performed. ^{3 4}

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The term provider shall be taken to cover all organisations undertaking the scientific examination of exhibits and evidence derived from exhibits – including the police.

This allows the processes discussed in this protocol to be embedded in a quality system and externally audited on a regular basis.

The standard ISO 15189 may be employed for forensic toxicology. Accreditation to ISO 15189 is not covered in this version of the protocol but may be included in future versions.

- b. The provider has quality systems in place which implement the provisions of this protocol.
- c. The FSR, the NPCC and the CPS have agreed that the provider quality systems properly implement the provisions of this protocol.
- d. The provider has not been notified that the FSR, NPCC or the CPS has withdrawn its approval.
- 3.2.2 The process by which the approval noted in paragraph 3.2.1c can be sought is set out in Annex 1.
- 3.2.3 The approval to operate under this protocol may be withdrawn, at any time, by NPCC, the CPS or the FSR.
- 3.2.4 Providers which are not covered by this protocol will be expected to have obtained all necessary permissions from CPS and other relevant bodies directly on a case by case basis (non-protocol approval).

3.3 Limits

- 3.3.1 The police and the CPS are responsible for most criminal investigations and prosecutions in England and Wales. As they are not responsible for all investigations and prosecutions it follows that this protocol only covers material arising from cases submitted by the following organisations.
 - a. The 43 territorial police forces in England and Wales.
- 3.3.2 It is stressed that material arising from the following sources is not covered by this protocol.
 - a. HM Revenue and Customs.
 - The National Crime Agency.
 - c. The Serious Fraud Office.
 - d. UK Border Force.
 - e. Police services outside England and Wales.
 - f. HM Coroners.
 - g. Royal Military Police (and similar military bodies).
 - h. Civil Nuclear Constabulary.
 - The British Transport Police.
 - j. The MoD Police.

- 3.3.3 Although the Police Service of Northern Ireland (PSNI) is a member of NPCC this protocol does not apply to PSNI.
- 3.3.4 There has been no discussion with Police Scotland or the Crown Office and Procurator Fiscal Service. The protocol does not cover material submitted by Police Scotland.
- 3.3.5 The National DNA Database[®] (NDNAD) has processes in place for the use of data held in the NDNAD and samples submitted for DNA profiles to be submitted to the NDNAD^{5 6 7}. There is no intention to circumvent those processes.
- 3.3.6 Therefore this protocol does not apply to data held on the NDNAD, samples taken from individuals for addition to the NDNAD (or in the expectation that the results would be added to the NDNAD) or any data obtained from such samples. However, it does cover data generated from crime scene exhibits.
- 3.3.7 Where approval has been obtained under the NDNAD processes no separate authorisations from NPCC or the CPS is required.

4. MODIFICATION

- 4.1.1 This is the second issue of this document.
- 4.1.2 Significant changes to the text have been highlighted in grey
- 4.1.3 The modifications made to create Issue 2 of this document were to ensure compliance with The Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018. 8
- 4.1.4 The Regulator uses an identification system for all documents. In the normal sequence of documents this identifier is of the form 'FSR-#-###' where (a) the

The National DNA Database is a registered trademark owned by the Secretary of State for the Home Department.

See "The NDNAD Strategy Board Policy for Access and Use of DNA Samples, Profiles and Associated Data" CUSTP-GP-29. Available at: https://www.gov.uk/government/uploads/system/uploads/system/uploads/attachment_data/file/492977/CUSTP-GP-029 Access Use DNA Samples Profiles - Issue 6.pdf.

⁷ The URL was checked on 18 April 2020.

To facilitate compliance with the Regulations significant changes to the document are listed here. The following sections of the document have been altered – 4.1.1, 4.1.2, 4.1.4, 4.15, 4.1.6, 5.1.1, 6.1.1.e and 6.1.1.f. The following footnotes have been altered – 7 and 8.

'#' indicates a letter to describe the type or document and (b) '###' indicates a numerical, or alphanumerical, code to identify the document. For example, the Codes are FSR-C-100. Combined with the issue number this ensures each document is uniquely identified.

- In some cases it may be necessary to publish a modified version of a document (e.g. a version in a different language). In such cases the modified version will have an additional letter at the end of the unique identifier. The identifier thus becoming FSR-#-####.
- 4.1.6 In all cases the normal document, bearing the identifier FSR-#-##, is to be taken as the definitive version of the document. In the event of any discrepancy between the normal version and a modified version the text of the normal version shall prevail.

5. EFFECTIVE DATE

5.1.1 Issue 2 of this protocol became effective on 22 September 2020

PART 3 - PROTOCOL

6. LEGAL ISSUES

6.1 General Provisions

- 6.1.1 The use of material must comply with all legal requirements. These include, but are not limited to, the following.
 - a. The Police and Criminal Evidence Act 1984.
 - b. The Criminal Procedure and Investigations Act 1996.
 - c. The Regulation of Investigatory Powers Act 2000.
 - d. The Human Tissue Act 2004.
 - e. The Data Protection Act 2018.
 - f. The Human Rights Act 1998.
 - g. The Investigatory Powers Act 2016.
- 6.1.2 All contractual obligations must be complied with.
- 6.1.3 Legal privilege must be maintained.

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6.2 Specific Provisions

- 6.2.1 The nature of forensic science is such that providers will deal with material which is subject to legal control or prohibition. Examples include the following.
 - a. Material subject to control or prohibition on possession.
 - b. Material subject to control or prohibition on production
 - Material subject to control or prohibition on use.
- 6.2.2 For many of these areas the legislation contains provisions which allow for the possession and use of the material for use in casework⁹. However, the wording of those provisions may be specific to casework analysis.
- 6.2.3 This issue shall be considered in more detail in the relevant Annexes.
- 6.2.4 It is the responsibility of the provider to ensure that the use of all materials employed in the validation is legal.

6.3 Responsibility

6.3.1 This protocol sets out the process by which use of casework material is authorised. It is the responsibility of the provider to ensure all legal requirements are met.

7. RESTRICTIONS

- 7.1.1 The use of casework material can give rise to issues for the CJS see section 16. Whilst these issues can be dealt with there are classes of case, which tend to be high profile and complex, where the creation of any further complications should be avoided. There are also cases where the use of evidence for any other purpose raises special considerations.
- 7.1.2 There are areas where the use of the material for non-casework purposes may give rise to a risk of adverse publicity for the force involved. In such areas it appears sensible that the force must authorise the work explicitly and on a case by case basis.

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See s39 Human Tissue Act 2004, Misuse of Drugs Regulations 2001, Protection of Children Act 1978 and Criminal Justice Act 1988.

- 7.1.3 Additionally there are areas where the legal restrictions on the use of the certain evidence types that mean individual approval is the appropriate approach.
- 7.1.4 As a result it has been decided to exclude certain classes of case from the protocol. The classes of case which are excluded from the protocol are the following.
 - a. Any case related to terrorist offences.
 - b. Any case involving the murder of, or sexual offence against, a child less than 16 years of age.
 - c. Any case involving indecent images of a person less than 16 years of age.
 - d. Any case involving investigations of financial institutions.
- 7.1.5 The exclusion of these types of case from the protocol does not mean that material arising from such cases can not be used. Such use needs to be specially approved (non-protocol approval) by the force involved and the CPS.

8. POINT OF USE

- 8.1.1 The use of casework material in validation gives rise to issues that have to be dealt with by the CJS. These include:
 - a. The potential undermining of existing inculpatory evidence;
 - b. The potential discovery of additional exculpatory evidence;
 - c. The potential discovery of additional inculpatory evidence;
 - d. The complication that the additional information has originated from a non-validated technique; and
 - e. Disclosure issues related to the use of the material and the results obtained.
- 8.1.2 This is acceptable so long as the risk is reasonable.
- 8.1.3 It follows that use of casework material can only occur at a point where the provider has determined the scientific validity of the technique and is at the final stages of validation.
- 8.1.4 This protocol only applies to the use of casework material at the last stages of validation.

9. CLASSIFICATION

9.1.1 This protocol sets out provisions with regard to use of material on the basis of the type of case, material etc. To do so the terminology must be set out.

9.2 Validation

9.2.1 Validation should be considered to have the same meaning as set out in the document FSR-G-201 Validation Guidance [1].

9.3 Case Types

- 9.3.1 The approval depends, in part, on whether the material relates to a "live" or "closed" case.
- 9.3.2 For the purposes of this protocol the term "live" shall be taken to cover cases which fall within the following classes.
 - a. Cases where a prosecution has yet to conclude.
 - b. Cases where all likely prosecutions have concluded but there is (a) an outstanding appeal or (b) risk that an appeal will be lodged.
 - c. Cases where the Criminal Cases Review Commission has made, or is considering making, a referral.
- 9.3.3 The term "closed" relates to all other cases.
- 9.3.4 Closed cases shall be divided into cases where the retention of exhibits (though not necessarily all exhibits) is required by the Criminal Procedure and Investigations Act 1996 (CPIA) and those where no retention is required.

9.4 Casework Material

<u>Material</u>

- 9.4.1 Casework material that may be used in validation studies extends across the type of exhibits that are submitted for examination, samples that can be derived from such exhibits and data which can be extracted, derived or created from such exhibits and samples.
- 9.4.2 The approval depend, in part, on the nature of the exhibits and samples/data derived from them. There is therefore a need to classify these materials.

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Exhibit Types

- 9.4.3 The exhibits submitted to providers for examination can be classified as physical evidence, biological evidence and electronic evidence.
 - a. Physical evidence refers to material submitted for examination of evidence arising from its chemical or physical properties.
 - Biological evidence refers to material submitted for examination of evidence arising from a biological source.
 - c. Electronic evidence refers to material submitted for examination of evidence held, for example, in electronic data files on or related to the item.
- 9.4.4 Each of these types can be sub-classified this is done in the annex relevant to each evidence type.

Data Types

9.4.5 Providers hold a large amount of data that relates to crime, submitted exhibits and the analysis of such exhibits. The manner in which this data can be used in validation exercises depends on the nature of the data. This is discussed in the relevant annexes.

9.5 Analysis Types

- 9.5.1 The nature of the analysis to be performed as part of the validation has an impact on the approval. In particular, the following types of analysis raise particular concerns.
- 9.5.2 Analysis which either destroys or changes the nature of the material so as to prevent further analysis of the material is defined as "destructive".
- 9.5.3 Analysis which is destructive and results in the quantity of material remaining being less than that required for an analysis (of the type for which the material was submitted to the provider) to be performed is defined as "exhaustive".

10. CASE TYPES

10.1.1 As noted below the use of casework material in validation can give rise to a need to notify the CPS of certain issues and investigate/resolve those issues.

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The use of casework material related to live cases where the trial is imminent increases the risk that these activities can not be completed within the required timeframe.

11. PRESUMED APPROVAL

- 11.1.1 The use of casework materials, by a provider approved to act under this protocol, for validation studies in the circumstances set out in the relevant annexes is allowed, subject to the provisions of paragraph 11.1.3, without approval from the NPCC or the CPS. The relevant annexes are Annex 2 (general provisions) and whichever of Annexes 3-6 (evidence specific considerations) apply to the evidence type.
- 11.1.2 The approval of the FSR is not required for individual validation studies.
- 11.1.3 The presumed approval system only applies when all of the following conditions, in addition to the provisions of 3.2.1, are met.
 - a. The provider has processes in place to ensure the use of casework material is only allowed following the approval of a senior manager familiar with the legal constraints and relevant disclosure requirements.
 - b. The approval of the senior manager is given on the basis of a clear validation plan. This validation plan must meet any standards and/or guidance on validation issued by the FSR.
 - c. The provider has processes in place to ensure records are kept as set out in section 14.

12. SIMPLIFIED APPROVAL

- 12.1.1 This protocol also provides for a simplified approval process for cases where presumed approval is not appropriate but full approval is not required.
- 12.1.2 Annex 2 (general provisions) and Annexes 3-6 (evidence specific considerations) set out the circumstances in which simplified approval is allowed.
- 12.1.3 The process for obtaining such approval is set out in Annex 7.
- 12.1.4 The provisions of paragraph 11.1.3 also apply to this type of approval.

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13. NON-PROTOCOL APPROVAL

- The use of casework materials in circumstances not falling within the presumed or simplified approval system is still possible. In such cases the approval of NPCC¹⁰ and the CPS is required. This may require the approval of each police force and CPS region.
- 13.1.2 The approval of the FSR is not required for individual validation studies.
- 13.1.3 The approval given could be for a specific validation study or a type of validation study.

14. RECORDS

14.1 Presumed Approval

- 14.1.1 The provider must maintain records of the authorisation of casework material for validation studies.
- 14.1.2 The records must include a paper proposing the use of casework material which should set out the following information.
 - a. The nature and purpose of the validation exercise.
 - b. The casework material which is to be employed.
 - c. The nature of the use of the casework material.
- 14.1.3 There must be a record of the approval of a senior manager for the proposed use of casework material.
- 14.1.4 The records referred to at paragraphs 14.1.1 to 14.1.3 should be recorded in an index of unused material. In an active case this must be revealed to the submitting police force and CPS in accordance with CPS Guidance to Experts [2].

14.2 Simplified Approval

14.2.1 Where the use of casework material is approved under the process set out in Annex 7 the following records must be kept.

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Where the work is performed within a force this approval could be from an NPCC ranked officer within the force. However, use of a central approval system may offer a degree of consistency.

- a. The nature and purpose of the validation exercise.
- b. The casework material which is to be employed.
- c. The nature of the use of the casework material.
- d. The formal approval by each party listed in Annex 7.
- The records referred to at paragraph 14.2.1 should be recorded in an index of unused material. In an active case this must be revealed to the submitting police force and CPS in accordance with CPS Guidance to Experts [2].

14.3 Recording Use

- 14.3.1 The nature of the CJS and the adversarial process is such that the inability to account for exhibits and all parts of exhibits could create problems for the CJS.
- 14.3.2 Any provider proposing to use casework material in validation studies must have processes in place to ensure the use of such material and, where relevant, storage and destruction of such material is recorded.
- 14.3.3 These records must allow for the casework records to be linked to the validation study and the use of the material. This does not require the case files to be altered.
- 14.3.4 The records related to the use of the material must be kept at least as long as the case files are retained.

15. Handling

- 15.1.1 Any provider proposing to use casework material in validation studies must have processes in place to ensure appropriate:
 - Security measures are in place;
 - b. Appropriate storage is employed; and
 - c. Destruction/disposal methods are employed where required.
- The presumed approval system does not cover the provision of casework material to any other body. Similarly it does not cover allowing access to such materials by other organisations. The simplified approval system may be used for such work, providing the provisions of this protocol related to such approval are met.

16. REPORTING

16.1 Reporting

- 16.1.1 The fact that casework material has been used in a validation study in the circumstances set out in this protocol does not need to be reported to NPCC or the CPS.
- The validation study may give rise to results which have implications for casework and the provider must have processes in place for dealing with such results. These processes must meet the requirements set out in section 16.2.

16.2 Reporting Differences

- The use of casework material in validation studies gives rise to the possibility that the results obtained in the study raise questions about any previous results obtained in casework. The existence of new information which may affect a case must be reported to the relevant authorities but the timing and form of reporting depend on the nature of the difference.
- 16.2.2 It must be borne in mind that the results obtained in a validation study will, generally, arise from a non-validated method. This method will, often, have been run by staff who are not authorised to undertake relevant analysis of reporting in casework. The confidence that can be held in that result may therefore be limited.

16.3 Anomaly Types

<u>Anomaly 1 – Possible Error</u>

- Some validation studies involve the comparison of a new method with the existing casework method. This may involve the re-analysis of samples with the existing method or the determination of the same result with the new method.
- 16.3.2 The results in the validation study may differ from the results obtained with the existing method and, consequently, suggest the casework result may have been an error.

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Anomaly 2 – Additional Information – Exculpatory

- 16.3.3 The new technique may give rise to additional information (e.g. SGM+ provided allele designations at loci not analysed by the SGM based system). This information may be possibly exculpatory (e.g. the new loci indicate an SGM match would not match in SGM+).
- 16.3.4 In these circumstances the casework results provided correct information to the CJS but the new information suggests the CJS may have received an incomplete picture.

Anomaly 3 – Additional Information – Inculpatory

This is the equivalent of an Anomaly Type 2 but suggests the evidence against the accused is stronger than reported in casework (e.g. a full SGM+ match obtained when only an SGM match has been reported).

Anomaly 4 – Systematic Error

- 16.3.6 It is possible that a validation study raises issues with the reliability of an existing technique. That is the existing technique may have provided information to the CJS which was incorrect and that this was not due to an error in a specific case.
- 16.3.7 It important to stress that this does not mean cases where new method provides additional information or a more discriminating method.

General Improvement

16.3.8 It is possible, and indeed likely, that a validation study will demonstrate a new, or improved, method provides more or better information. This does not, in itself, indicate the existing technique has provided incorrect results to the CJS¹¹.

16.4 Reporting Process

Anomaly 1

16.4.1 Where such a result is obtained from material which relates to a live case the following sequence of actions should be initiated by the provider.

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For example, a DNA profile may be obtained in circumstances where this was, previously, not possible.

- a. The submitting force and, if known, CPS prosecutor should be informed (as soon as practicable and in any event within seven days) of the difference and that additional investigations are being undertaken;
- Appropriate investigations must be initiated, as a matter of urgency, to determine whether the casework result was accurate; and
- c. A report on the difference and the results of any investigations (including a clear statement as to the result considered accurate) must be provided to the submitting force and, if known, the CPS prosecutor. This report is to be provided within a reasonable time and in a format as stipulated by the CPS prosecutor taking into account the date of any trial or order of the court.¹²
- 16.4.2 Where such a result is obtained from material which relates to a closed case the following sequence of actions should be initiated by the provider.
 - Appropriate investigations must be initiated to determine whether the casework result was accurate;
 - b. Where the investigations establish that the casework result is correct no further action is required; but
 - c. Where the investigation suggests the casework result was incorrect a report on the difference and the results of any investigations (including a clear statement as to the result considered accurate) must be provided to the submitting force and, if known, the CPS prosecutor. This report should be submitted as soon as practicable. If submission of the report is not possible within one month of the issue being identified an interim notification should be made.
- In cases where an error has been identified in a casework result the above steps are the first stage of the response. The provider must then initiate the following actions.
 - a. Investigate the sources/causes of the error and determine whether there are likely to be a number of such errors.
 - b. Where it appears that there may have been a significant number of errors, or one error which could have affected a number of cases, this should be

In light of the potential impact on the CJS "reasonable time" should be interpreted as the earliest practicable time.

reported to the FSR, National Policing Lead for Forensic Science and the CPS to allow a plan to be established to deal with the matter.

Anomaly 2

- This type of difference suggests the evidence provided to the CJS may not properly address exculpatory information which is now available. However, the reliability of that exculpatory material is still under consideration¹³.
- 16.4.5 Where such a result is obtained from material which relates to a live case the following sequence of actions should be initiated.
 - a. The submitting force and, if known, CPS prosecutor should be informed (as soon as practicable and in any event within seven days) of the difference, that the new method is the subject of a validation study and, as a result, the reliability is uncertain; and
 - b. On completion of the validation study a report on the difference and the results of any investigations (including a clear statement as to the result considered accurate) must be provided to the submitting force and, if known, the CPS prosecutor. This report is to be provided within a reasonable time and in a format as stipulated by the CPS prosecutor taking into account the date of any trial or order of the court.¹⁴
- 16.4.6 Where such a result is obtained from material which relates to a closed case the following sequence of actions should be initiated.
 - a. The provider should, on completion of the validation study, determine the level of confidence that should be held in the new result; and
 - b. Report the new result, if it is believed the new result is robust, to the submitting force setting out the value of the new results.

Anomaly 3

This type of difference suggests the evidence provided to the CJS may not properly address the value of the evidence which is available. However, the reliability of that material is still under consideration.

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¹³ It is not known whether the new method is sufficiently robust.

In light of the potential impact on the CJS "reasonable time" should be interpreted as the earliest practicable time.

- 16.4.8 Where such a result is obtained from material which relates to a live case the following sequence of actions should be initiated.
 - a. The submitting force and, if known, CPS prosecutor should be informed (as soon as practicable and in any event within seven days) of the difference, that the new technique is the subject of a validation study and, as a result, not considered inherently reliable; and
 - b. On completion of the validation study a report on the difference and the results of any investigations (including a clear statement as to the result considered accurate) must be provided to the submitting force and, if known, the CPS prosecutor. This report is to be provided within a reasonable time and in a format as stipulated by the CPS prosecutor taking into account the date of any trial or order of the court.¹⁵
- 16.4.9 Where such a result is obtained from material which relates to a closed case the following sequence of actions should be initiated.
 - The provider should, on completion of the validation study, determine the level of confidence that should be held in the new result; and
 - b. Report the new result, if it is believed the new result is robust, to the submitting force setting out the value of the new results.

Anomaly 4

- 16.4.10 This type of difference is clearly the most significant. It suggests that the use of the original method may have led to a number of miscarriages of justice.
- 16.4.11 Where a provider has reasonable grounds to believe an Anomaly 4 difference has occurred it should initiate the following actions as a matter of urgency.
 - a. The submitting forces and, if known, CPS prosecutor, in all live cases, should be contacted (as soon as practicable and in any event within fourteen days) to inform them of the issue (further information is to be provided within a time and in a format as stipulated by the CPS prosecutor taking into account the date of any trial or order of the court.);

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In light of the potential impact on the CJS "reasonable time" should be interpreted as the earliest practicable time.

- Investigations should be initiated to determine the source/cause of the error;
- c. Investigations should be initiated to identify the cases which may have been affected by the error; and
- d. The matter should be reported (as soon as practical and in any event within fourteen days) to the FSR, National Policing Lead for Forensic Science and the CPS to determine how the matter should be handled.

General Improvement

- 16.4.12 If a new, or improved, method is being validated it is possible that the validation study shall demonstrate that the new method will provide more, or better, results than the existing method.
- 16.4.13 Where a provider has determined the extent of the improvement provided by the new method it must have processes in place for the following.
 - a. To assess the "added value" provided by the new method.
 - b. Advise customers who have had cases dealt with under the existing technique of the introduction of the new method, the additional capabilities of the new method and the possibility of re-analysis of old cases¹⁶.

Adverse Conclusions

- 16.4.14 If the validation exercise undertaken by a provider establishes issues with a method which may have a significant adverse impact on the CJS these results should be reported to the Forensic Science Regulator.
- 16.4.15 It is expected that a provider encountering such results would either (a) not implement the technique in that form or (b) set out clear warnings to its customers as to the limitations of the technique. This is entirely proper but it leaves the risk that another provider may be using the technique unaware of the risks and, thus, pose a risk to the CJS.

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The Regulator has prepared guidance on validation (see FSR-G-201) [1]. The need for consideration of the impact on the CJS is discussed in that document.

17. PUBLISHING

17.1.1 This protocol does not provide a process for approval of publication of information relating to an identifiable case in publicly available material. Such publication must be authorised through other channels.

18. REFERENCE INFORMATION

- 18.1.1 Providers may collate information to create reference information to assist the interpretation of evidence. Examples may include data collections on the occurrence of particular types of fibre, certain DNA designations or particular features in fingerprints.
- 18.1.2 The use of casework material and information for such purposes is not covered by this protocol.

19. RESERVATION

- 19.1.1 This protocol has been established to facilitate the use of casework material in validation studies for the benefit of the CJS.
- 19.1.2 It does not create any legal rights or establish any legally binding processes/obligations. Further, the parties to the protocol give no guarantee that they will act under the protocol.

20. REVIEW

- 20.1.1 This document is subject to review at regular intervals.
- 20.1.2 If you have any comments please send them to the address or e-mail set out on the Internet at URL: https://www.gov.uk/government/organisations/forensic-science-regulator

21. REFERENCES

- 1 FSR-G-201 Validation Guidance.
- 2 Guidance Booklet for Experts Disclosure: Experts' Evidence, Case Management and Unused Material. Published by the Crown Prosecution Service and the Association of Chief Police Officers of England Wales and Northern Ireland, May 2010.

3 FSR-G-203 Legal Issues in Forensic Pathology and Tissue Retention.

22. ABBREVIATIONS AND ACRONYMS

Text	Meaning			
BE	Biological Evidence			
CJS	Criminal Justice System			
CPIA	Criminal Procedure and Investigations Act 1996			
CPS	Crown Prosecution Service			
D	Data			
DNA	Deoxyribonucleic Acid			
EE	Electronic Evidence			
FSR	Forensic Science Regulator			
HM	Her Majesty's			
ISO	International Organization for Standardization			
MoD	Ministry of Defence			
NDNAD	National DNA Database			
NPCC	National Police Chiefs' Council			
PE	Physical Evidence			
PSNI	Police Service of Northern Ireland			
SGM	Second Generation Multiplex			
SGM+	Second Generation Multiplex Plus			
UK	United Kingdom of Great Britain and Northern Ireland			
URL	Uniform Resource Locator			

ANNEX 1 – APPLICATION FOR PROTOCOL USE

23. APPLICATION

- 23.1.1 The protocol only applies to providers where the CPS, NPCC and the FSR have agreed that it should [see paragraph 3.2]. It follows that there must be a process to seek approval.
- 23.1.2 Providers seeking approval should adopt the appropriate approach set out below.

23.2 Providers – Non-Police

- Any provider, that is not part of a police force, which wishes to operate under this protocol should send an application to the FSR. The FSR will be responsible for provision of information to the CPS and NPCC.
- 23.2.2 The application should set out the following information.
 - a. The name of the provider.
 - b. The contact details of the provider.
 - c. Evidence of accreditation to ISO 17025 and/or ISO 17020 [see paragraph 3.2.1].
 - d. Evidence of quality systems implementing the requirements of the protocol [see paragraph 3.2.1].
 - e. Evidence of systems for approval by a senior manager [see paragraph11.1.3] and the qualifications of the senior manager to undertake that role.
 - f. Evidence of systems to ensure appropriate records are created and maintained [see paragraph 11.1.3].
 - g. A statement that the FSR will be notified of any change which could lead to a reconsideration of approval.
- 23.2.3 The provider should also agree that the FSR (or those nominated by the FSR) may audit the work of the provider under the protocol to ensure it is operating correctly.
- The provider should provide three copies of the material set out at paragraph 23.2.2.

23.3 Providers – Police

Provides Services Outside Own Force

23.3.1 Where a provider is part of a police force and provides services to persons and/or organisations other than that force it should apply following the process set out in section 23.2.

Providing Services To Own Force Only

- 23.3.2 Where a provider is part of a police force and provides services only to that police force it is unnecessary to seek approval from NPCC in relation to this protocol. The approval of the force involved will be sufficient.
- A provider which only provides services to its own force shall use the application process set out in section 23. In addition, it shall provide a letter from an officer of at least the rank of Assistant Chief Constable, or equivalent, (in that force) approving the use of the protocol.

24. PROCESS

24.1 Nominees

- 24.1.1 The CPS shall nominate an individual to be responsible for determination of applications under this protocol. It may also nominate a deputy.
- 24.1.2 NPCC shall nominate an individual to be responsible for determination of applications under this protocol. It may also nominate a deputy.

24.2 Consideration

- 24.2.1 The FSR (or her nominee) shall review any application to determine whether it is one she is minded to support.
- 24.2.2 Where the FSR (or her nominee) is minded to support an application she will provide copies of the application to the nominees of the CPS and NPCC.
 - a. The nominee of the CPS will be asked to make a determination of the application.
 - b. The nominee of NPCC will be asked to make a determination of the application except in cases falling within paragraph 23.3.2.

- c. In cases falling within paragraph 23.3.2 the application shall be provided to the NPCC nominee for information.
- 24.2.3 Where the FSR (or her nominee) is minded to reject an application she (or her nominee) may contact the applicant to seek clarification or modification of the application before providing copies to the CPS and NPCC.
- 24.2.4 The FSR shall inform the provider as to whether the application has been approved.

25. RECORDS

- 25.1.1 The FSR shall maintain records of the application and approval of any application as follows.
 - a. The provider.
 - b. The date on which the application was received.
 - c. The date on which the FSR decided to support/reject the application and the decision.
 - d. The date on which the CPS decided to support/reject the application and the decision.
 - e. The date on which the NPCC, if relevant, decided to support/reject the application and the decision.
 - f. The date on which the application was approved or denied.
 - g. Any restrictions on the approval (e.g. only on material from a specific force).
 - h. The date on which the approval was ended.

ANNEX 2 - USE OF CASEWORK MATERIAL IN VALIDATION STUDIES

26. GENERAL CONSIDERATIONS

- 26.1.1 Casework material may be classified in a number of ways and it is possible that, in any given validation study, the material being used can be described as belonging to more than one class set out in this document.
- To decide what approval route should be applied the following rules should be applied.
 - a. Each classification which could apply to the casework material should be identified.
 - b. Where the consideration of every possible classification indicates approval should be presumed then approval may be presumed for this material.
 - c. Where consideration of any of the possible classifications indicates simplified approval must be sought then it must be sought for this material.
 - d. Where consideration of any of the possible classifications indicates the use of the material falls outside the scope of this protocol then the protocol does not apply and non-protocol approval must be sought for this material.
- In the annexes dealing with specific evidence types the areas are set out where, under this protocol, (a) approval may be assumed or (b) simplified approval must be sought. In areas where neither of these options apply, the use is outside the scope of this protocol and non-protocol approval must be sought from the relevant force and the CPS.

ANNEX 3 – PHYSICAL EVIDENCE

27. LEGAL

- 27.1.1 In this area particular legal issues are likely to relate to use of material subject to legal control as follows.
 - a. Material subject to control or prohibition on possession.
 - i. Controlled drugs (see Misuse of Drugs Act 1971).
 - ii. Firearms and related materials (see Firearms Act 1968).
 - iii. Explosive substances (see Explosive Substances Act 1883).
 - b. Material subject to control or prohibition on production
 - Controlled drugs (see Misuse of Drugs Act 1971).
- 27.1.2 In some cases the legislation provides authorisation for laboratories to perform work for the CJS but this may be restricted to the casework analysis of the material.

28. **DEFINITIONS**

28.1.1 Physical evidence can be sub-divided into a number of classes of relevance to its use in validation.

Physical Evidence Class 1 (PE1)

- 28.1.2 This class covers items seized as evidence from scene of crime over which ownership is unlikely to be claimed.
- 28.1.3 Examples include trace evidence (glass, paint or fibres), footwear marks, toolmarks, fingerprints and weapons.

Physical Evidence Class 2 (PE2)

- This class covers items seized as part of an investigation over which ownership can not or is unlikely to be claimed.
- 28.1.5 Examples include controlled drugs, illegal weapons and items used in the commission of the offence.

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	Physical Evidence Class 3 (PE3)
28.1.6	This class covers items seized (often from suspects) as evidence over which ownership is likely to be claimed.
28.1.7	Examples include clothing, firearms, motor vehicles, tools and suspected stolen goods.
	Physical Evidence Class 4 (PE4)
28.1.8	This class covers items created or derived from exhibits submitted for examination.
28.1.9	Examples include control samples, fibre tapings, test marks and photographs.
29.	USE
29.1.1	The ways in which these classes of evidence can be used in validation (with either presumed approval or protocol approval) is set out below.
29.2	Live Cases
	Presumed Approval
29.2.1	The non-destructive analysis of classes PE1, PE2, PE3 and PE4.
29.2.2	The destructive, but not exhaustive, analysis of classes PE1, PE2 and PE4.
	Simplified Approval Required
29.2.3	None.
29.3	Closed Cases
	Presumed Approval
29.3.1	The non-destructive analysis of classes PE1, PE2, PE3 and PE4.
29.3.2	The destructive, but not exhaustive, analysis of classes PE1, PE2 and PE4.
29.3.3	The exhaustive analysis of classes PE1, PE2 and PE4 where the material is not required to be retained under the provisions of the CPIA.
29.3.4	The destructive and/or exhaustive analysis of class PE3 in circumstances where the material would be destroyed by the provider.

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29.3.5 The destructive and/or exhaustive analysis of classes PE3 in circumstances where (a) the material is not to be destroyed by the provider and (b) it is not to be returned to its owner.

29.4 Flowchart

29.4.1 A flowchart is provided at Annex 8 to assist in the application of the above provisions.

ANNEX 4 - BIOLOGICAL EVIDENCE

30. LEGAL

30.1 General

- In this area particular legal issues are likely to relate to use of material subject to legal control as follows.
 - a. Material subject to control or prohibition on possession.
 - Human tissue (see Human Tissue Act 2004).
 - b. Material subject to control or prohibition on use.
 - Human tissue (see Human Tissue Act 2004).
- 30.1.2 In some cases the legislation provides authorisation for laboratories to perform work for the CJS but this may be restricted to the casework analysis of the material.

30.2 Human Tissue

- In relation to the Human Tissue Act 2004 providers should therefore give careful consideration to any validation exercise which involved the following activities.
 - a. The storage or use of material containing human cells for a purpose set out in Schedule 1 of the Act [see the provisions of s1, s14 and s16 of the Act].
 - The holding of material with the intention to obtain the DNA profile of a human being [see the provisions of s45 of the Act].
- The provisions of the Act are discussed in detail in the annex FSR-G-203 Legal Issues in Forensic Pathology and Tissue Retention [3].

31. **DEFINITIONS**

31.1.1 Biological evidence can be sub-divided into a number of classes of relevance to its use in validation.

Biological Evidence Class 1 (BE1)

This class covers items composed of biological material seized as evidence from scene of crime which can not be directly linked to an individual.

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- 31.1.3 Examples include swabs of blood or other body fluids taken at the scene which originate from the offender, tissue samples from the scene (e.g. blood/hair).
 - Biological Evidence Class 2 (BE2)
- 31.1.4 This class covers items composed of biological material seized as evidence from the scene of crime which can be directly linked to the victim.
- 31.1.5 Examples include swabs of blood or other body fluids taken at the scene, swabs taken from the victim.
 - Biological Evidence Class 3 (BE3)
- 31.1.6 This class covers items composed of biological material seized from an individual for analysis as evidence, including post mortem exhibits.
- 31.1.7 Examples include blood samples for toxicological analysis (e.g. for alcohol or drugs).
 - Biological Evidence Class 4 (BE4)
- 31.1.8 This class covers items composed of biological material seized from individuals for purposes of comparison, including post mortem exhibits.
- 31.1.9 Examples include tissue samples (blood, hair or cells) taken for comparison with material found at the scene of crime.
 - Biological Evidence Class 5 (BE5)
- 31.1.10 This class covers items created or derived from exhibits submitted for examination which can not be linked to an individual.
- 31.1.11 Examples include extracted DNA samples from the scene of crime.
 - Biological Evidence Class 6 (BE6)
- 31.1.12 This class covers items created or derived from exhibits submitted for examination which can be linked to an individual.
- 31.1.13 Examples include extracted DNA samples or extracts from blood samples taken for toxicology.

32. USE

32.1.1 The ways in which these classes of evidence can be used in validation (with either presumed approval or protocol approval) is set out below.

32.2 Live Cases

Presumed Approval

- 32.2.1 The non-destructive and destructive (but not exhaustive) analysis of classes BE1 and BE5.
- The non-destructive and destructive (but not exhaustive) analysis of classes BE2, BE3, BE4 and BE6 where:
 - The analysis will provide no more personal information than is already held by the provider from the casework analysis; or
 - b. As a result of a process of anonymisation, the samples can not (subject to paragraph 32.5) be linked to an individual.

Simplified Approval Required

32.2.3 None

32.3 Closed Cases

Presumed Approval

- 32.3.1 The non-destructive and destructive (but not exhaustive) analysis of classes BE1 and BE5.
- 32.3.2 The non-destructive and destructive (but not exhaustive) analysis of classes BE2, BE3, BE4 and BE6 where:
 - The analysis will provide no more personal information than is already held by the provider from the casework analysis; or
 - b. As a result of a process of anonymisation, the samples can not (subject to paragraph 32.5) be linked to an individual.
- 32.3.3 The exhaustive analysis of classes BE1, BE2, BE3, BE4, BE5 and BE6 in circumstances where retention is not required by CPIA and the material is not to be returned.

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32.3.4 The non-destructive or destructive analysis of classes BE2, BE3, BE4 and BE6 which will provide more personal information about an identifiable individual than is already held by the provider.

32.4 Additional Personal Information

- 32.4.1 The restriction on use which provides additional personal information is to prevent the unauthorised collection of types of information not already in the possession of a provider.
- 32.4.2 The prohibition therefore prevents the provider obtaining information as follows.
 - a. Using a sample to obtain a new class of personal information. Examples include using samples submitted for toxicology analysis for DNA profiling.
 - b. Using a sample to obtain the same class of personal information where the additional information is designed to allow a different class of personal information to be determined. Examples include the use of samples submitted for DNA profiling for additional DNA profiling if that is to determine race or physical characteristics.
- 32.4.3 The prohibition does not prevent samples being analysed to generate the same class of personal information unless it provides a different type of personal information. Therefore:
 - a. The analysis of samples submitted for DNA profiling in one system (e.g. SGM) can be analysed using a different system (e.g. SGM+).

32.5 Anonymised Samples

- In paragraphs 32.2.2 and 32.3.2 there is reference to an anonymisation process. Where such a process is adopted it must be impossible for those undertaking the validation study to link the results from, or employed in, the validation study to link the samples to any named individual.
- In cases where the validation study could give rise to reporting requirements as set out in paragraph 16.4 there must be a record, available to senior managers within the provider, which does allow results to be linked to the cases and

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individuals from which they originate. Such records may only be used for the purpose of reporting anomalies.

32.6 Flowchart

32.6.1 A flowchart is provided at Annex 9 to assist in the application of the above provisions.

ANNEX 5 - ELECTRONIC EVIDENCE

REQUIREMENT

- The nature of electronic evidence is such that it is usually possible to generate effective and comprehensive test data for the validation exercise. The need to use casework material is therefore less likely than in other evidence types.
- It is also important to recognise the use of casework material does not reduce the need for a validation exercise using well designed test data.

34. OVERLAP

In this area the nature of the work means that there will be significant overlap between the requirements for this evidence type and the requirements for data (see Annex 6 below).

35. LEGAL

35.1 General

- In this area particular legal issues are likely to relate to use of material subject to legal control as follows.
 - a. Material subject to control or prohibition on possession.
 - Indecent images of children (see Criminal Justice Act 1988).
 - b. Material subject to control or prohibition on production
 - i. Indecent images of children (see Protection of Children Act 1978).
- In some cases the legislation provides authorisation for laboratories to perform work for the CJS but this may be restricted to the casework analysis of the material.

35.2 Indecent Images of Children

- 35.2.1 This protocol does not apply to casework material from cases related to indecent images of children.
- 35.2.2 The legal provisions related to such images are such that care should be taken that such material is not used, even if it arises from a different type of case, without:

- a. Confirming that such use is legal; and
- b. Obtaining the necessary consent.

36. DEFINITIONS

36.1.1 Electronic evidence can be divided into a number of classes of relevance to its use in validation.

Electronic Evidence Class 1 (EE1)

- This class covers physical items submitted for analysis for electronic evidence.
- This covers any equipment which may retain any information in a digital format. Examples include computers, mobile handsets, cameras, recorders (voice or video), satellite navigation units and personal data assistants.

Electronic Evidence Class 2 (EE2)

- This class covers copies of data taken from items submitted for examination.
- 36.1.5 Examples include mirrors of hard drives and solid state drives.

Electronic Evidence Class 3 (EE3)

- 36.1.6 This class covers items of electronic evidence extracted from submitted items which are believed to contain no personal information.
- 36.1.7 Examples include spreadsheets, transaction records, plans etc.

Electronic Evidence Class 4 (EE4)

- 36.1.8 This class covers items of electronic evidence extracted from submitted items which are believed to contain personal information.
- 36.1.9 Examples of such evidence include data containing names, addresses, phone numbers, images of identifiable people or locations.

Personal Information

36.1.10 The nature of electronic evidence, in particular the number of and variation in files held on media, means it is impracticable to check all of them to determine whether they contain personal information.

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- 36.1.11 It is important that, when assessing whether there is personal information present, the fact that the information may be distributed among a number of different files is considered.
- 36.1.12 When determining the appropriate class that material falls into the provider shall consider it contains personal data if:
 - a. It is known that the material holds personal information;
 - The circumstances of the case suggest it may contain personal information; or
 - c. For some other reason the provider has reasonable grounds to believe it may contain personal information.

37. USE

37.1.1 The ways in which these classes of evidence can be used in validation (with either presumed approval or protocol approval) is set out below.

37.2 Live Cases

Presumed Approval

37.2.1 The non-destructive analysis of class EE3.

Simplified Approval Required

The non-destructive analysis of class EE4 when steps have been taken to anonymise the records. The provisions of paragraph 32.5 apply to this process.

37.3 Closed Cases

Presumed Approval

37.3.1 The non-destructive analysis of class EE3.

Simplified Approval Required

37.3.2 The non-destructive analysis of class EE4 when steps have been taken to anonymise the records. The provisions of paragraph 32.5 apply to this process.

37.4 Flowchart

A flowchart is provided at Annex 10 to assist in the application of the above provisions.

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ANNEX 6 – DATA

38. DEFINITIONS

38.1.1 Data can be sub-divided into a number of classes of relevance to its use in validation.

Data Class 1 (D1)

- 38.1.2 This class covers items of information related to individual criminal offences which is capable of identifying individuals or specific addresses.
- 38.1.3 Examples include details of offences including names, addresses, phone numbers and photographs of individuals or addresses.

Data Class 2 (D2)

- This class covers items of information related to individual criminal offences which is not capable of identifying individuals or specific addresses.
- 38.1.5 Examples include details of offences not including personal data, photographs which do not identify the location.

Data Class 3 (D3)

- This class covers items of information related to or derived from exhibits submitted for examination which does not contain personal information.
- 38.1.7 Examples include descriptions of exhibits, records of examination, results of analytical techniques such as glass refractive index measurement, microspectrophotometry, elemental analysis.

Data Class 4 (D4)

- 38.1.8 This class covers items of information related to or derived from exhibits submitted for examination which does contain personal information.
- 38.1.9 Examples include results such as DNA profiles, photographs of individuals or identifiable addresses.

39. USE

The ways in which these classes of evidence can be used in validation (with either presumed approval or protocol approval) is set out below.

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39.2 Live Cases

Presumed Approval

- 39.2.1 The non-destructive use of classes D2 and D3
- 39.2.2 The non-destructive analysis of classes D1 and D4 where:
 - a. The analysis will provide no more personal information (as discussed at 32.4 above) than is already held by the provider from the casework analysis; or
 - b. As a result of a process of anonymisation, the data cannot be linked to an individual or specific case. The provisions of paragraph 32.5 apply.

Simplified Approval Required

39.2.3 The non-destructive analysis of classes D1 and D4 in circumstances which will provide more personal information that is already held by the provider.

39.3 Closed Cases

Presumed Approval

- 39.3.1 The non-destructive use of classes D2 and D3
- 39.3.2 The non-destructive analysis of classes D1 and D4 where:
 - a. The analysis will provide no more personal information (as discussed at 32.4 above) than is already held by the provider from the casework analysis; or
 - b. As a result of a process of anonymisation, the data can not be linked to an individual or specific case. The provisions of paragraph 32.5 apply.

Simplified Approval Required

39.3.3 The non-destructive analysis of classes D1 and D4 in circumstances which will provide more personal information that is already held by the provider.

39.4 Flowchart

39.4.1 A flowchart is provided at Annex 11 to assist in the application of the above provisions.

ANNEX 7 – APPLICATION FOR SIMPLIFIED APPROVAL

40. APPLICATION

- 40.1.1 In circumstances where the presumed approval process set out in this protocol does not apply the simplified approval system may apply.
- 40.1.2 Providers seeking simplified approval should adopt the appropriate approach set out below.

40.2 Providers – Non-Police

- Any provider, that is not part of a police force, which wishes to operate under this protocol should send an application to the nominees of the CPS and NPCC [see paragraph 41.1]. The application should be sent to the FSR for distribution to the nominees.
- 40.2.2 A copy of the application should be sent to the FSR for information.
- 40.2.3 The application should set out the following information.
 - a. The name of the provider.
 - The contact details of the provider.
 - c. Evidence of approval to operate under this protocol.
 - d. A description of the technique being validated and the validation exercise.
 - i. Information as to the state of validation [see paragraphs 8.1.3 and 8.1.4].
 - ii. The approval of a senior manager for the use of casework material in the validation [see paragraph 11.1.3].
 - e. The validation plan [see paragraph 11.1.3].
- Where the work will involve any organisation other than the provider having access to or control of casework material the following information should be provided.
 - a. The name of the organisation.
 - b. The contact details of the organisation.
 - c. Evidence that the organisation can comply with the provisions of this protocol.

The application and any associated material should be accompanied by a statement setting out whether the information is sensitive and marked, where appropriate, under the Government Security Classification Policy.

40.3 Providers – Police

Provides Services Outside Own Force

40.3.1 Where a provider is part of a police force and provides services to persons and/or organisations other than that force it should apply following the process set out in paragraph 40.2.

Providing Services To Own Force Only

- Where a provider is part of a police force and the validation exercise shall use material sourced only from that police force it is unnecessary to seek approval from the NPCC. The approval of the force involved will be sufficient.
- Where a provider is part of a force and only providing services to that force then the application should be sent to the nominee of the CPS. In addition to the material set out in paragraph 40.2.3 the provider shall include a letter from an officer of at least the rank of Assistant Chief Constable authorising the validation exercise unless the authorisation noted in paragraph 40.2.3d.ii is provided by such a person.
- 40.3.4 A copy of the application should be sent to the FSR and the nominee of NPCC for information.

40.4 Confidentiality

- It is recognised that the research and development activities of providers is likely to be commercially sensitive.
- 40.4.2 Unless the provider clearly states that information is not sensitive the following information will be considered to have been provided in confidence.
 - a. The fact an application has been made.
 - b. The subject matter of the application.
 - c. All information submitted by a provider.
 - d. The outcome of the application.

e. Any information related to the application which could disclose the commercially sensitive activities of the provider.

41. PROCESS

41.1 Nominees

- The CPS shall nominate an individual to be responsible for determination of applications under this protocol. It may also nominate a deputy.
- 41.1.2 NPCC shall nominate an individual to be responsible for determination of applications under this protocol. It may also nominate a deputy.

41.2 Consideration

- The nominees shall make a determination on the application and notify the decision to the FSR. The FSR shall notify the following.
 - a. The provider.
 - b. The other nominee for information.

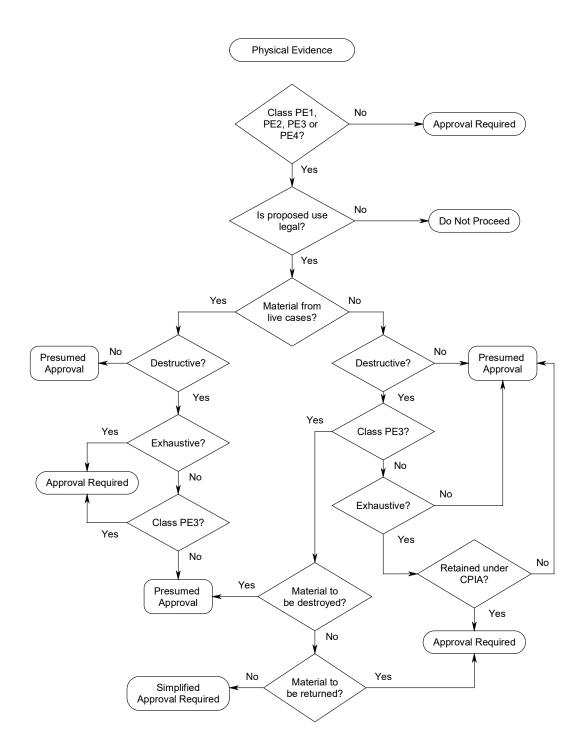
42. RECORDS

Where the application is approved the provider shall retain records of the application and the approvals given.

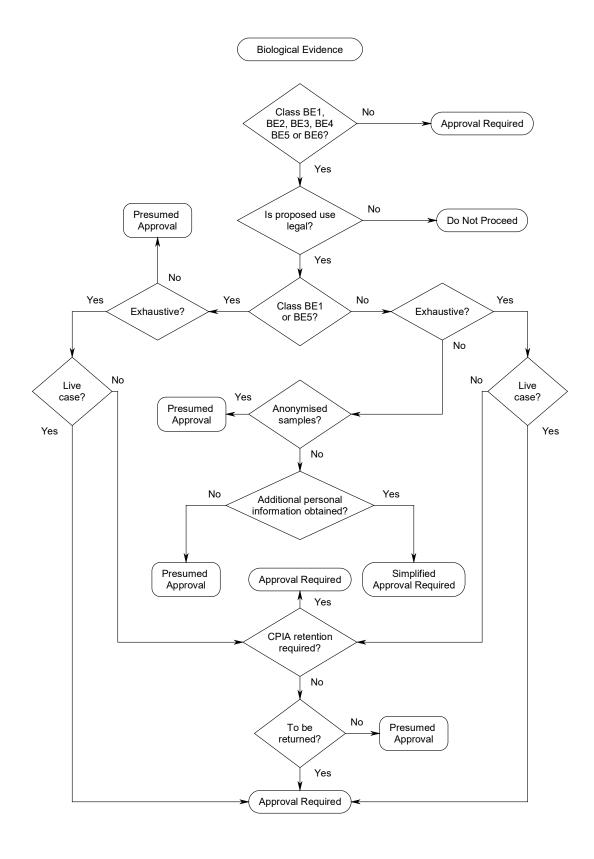
43. NON-PROTOCOL APPROVAL

- Where approval is not provided under the simplified process this does not mean that the use of casework material in the validation exercise is prohibited. It would be possible to seek approval for the use of casework material outside of the systems established by this protocol.
- 43.1.2 It is, however, suggested that in any case where NPCC or the CPS has declined to approve an application it may be more sensible for the provider to address the concerns raised and re-apply.

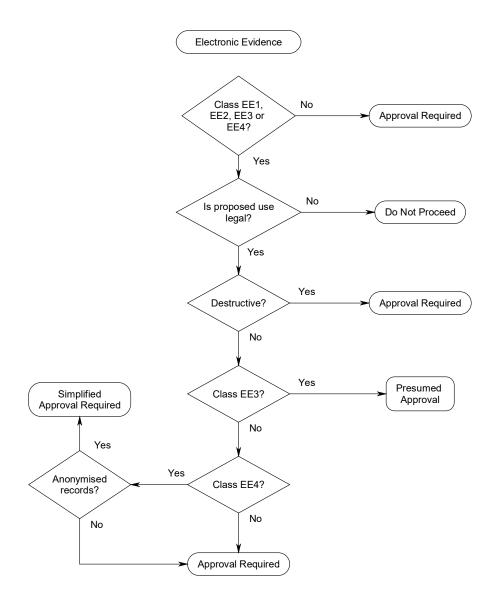
ANNEX 8 - FLOWCHART - PHYSICAL EVIDENCE



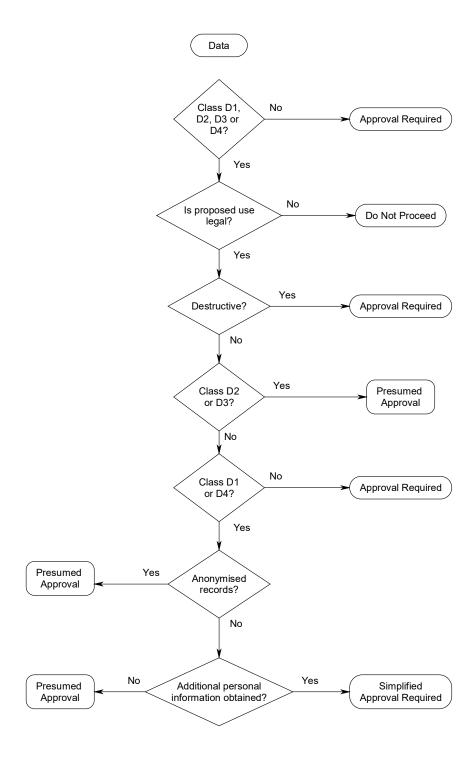
ANNEX 9 - FLOWCHART - BIOLOGICAL EVIDENCE



ANNEX 10 - FLOWCHART - ELECTRONIC EVIDENCE



ANNEX 11 - FLOWCHART - DATA



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