

J. David Burch, Epidemiology and Fieldwork
September 19-24, 1998, Kiev, Ukraine, Trip Report

Study of Leukemia and Other Hematological Diseases Among Clean Up Workers in Ukraine
Following the Chernobyl Accident

The purpose of this most recent trip to Ukraine was to finalize, as far as possible, the protocol to be followed in the initiation and implementation of a diagnostic review of retrospectively diagnosed cases with leukemia, lymphoma and related disorders. In this endeavor the majority of the meetings were with Dr. Stuart Finch and the appropriate epidemiologic and hematologic people involved in the study.

I. September 21, 1998 Research Center for Radiation Medicine, Academy of Medical Sciences of Ukraine.

A welcoming meeting was held with Dr. A. Romanyenko, Director of RCRM and Project Director. Other colleagues present were myself and Dr. Finch together with Drs. Bazyka (Administrative Coordinator), V. Bebeshko (Head of the Hematology Department), I. Dyagil (Hematology Group), V. Klimenko (Chief of Hematology Group) Pyatak (Deputy Director of RCRM) and O. Tsvetkova (Consultant).

Dr. Romanyenko welcomed Dr. Finch and myself to Kiev. We (Burch/Finch) informed the group that our primary focus would be on planning the upcoming diagnostic review with emphasis on finalizing the protocol, the clinical record abstract form, miscellaneous other procedures and recommendations for staffing. The finalization of these components of the review process at this time are particularly important in terms of getting the review process off the ground.

Prior to the trip, Dr. S. Kokoreva of the Columbia University technical support team translated the then current version of the protocol and the clinical record abstract form from English to Russian. These documents were presented to Dr. Romanyenko and his colleagues with much appreciation shown on their part.

Dr. Romanyenko informed us that very recently Drs. Bebeshko, Dyagil, Klimenko, and Tsvetkova had travelled to the oblasts of Donetsk, Kharkiv, and Sums kaya at which time the purpose and scope of Phase I and Phase II of the study were presented to each area's Chief of Medical Services (in point of fact usually to his deputy) and other relevant medical staff. During these visits the cooperation of the oblasts' medical personnel in providing case material for the upcoming diagnostic review was attained. The cooperation of medical personnel in Dnipropetrovsk oblast, of course, had been attained some time ago.

Dr. Finch and myself were dutifully informed that in the very near future (i.e. in the next two or three weeks) the same delegation would visit the appropriate medical personnel in Kiev City and Kiev oblast and that it is anticipated that these study areas' cooperation in the review will also be

guaranteed.

At the conclusion of the meeting Dr. Romanyenko presented Dr. Finch and myself with a summary report of the recent meetings held in the three oblasts to date. As the summary report was in Russian, Dr. Tsvetkova presented the material in English to Dr. Finch, myself and our epidemiologic/hematologic colleagues in a subsequent meeting (see below).

II. September 21 - 23, 1998, Clinical Radiology Center

All meetings following the meeting with Dr. Romanyenko and some members of his staff (listed above) involved myself together with Drs. S. Finch, N. Gudzenko (Epidemiology Group), I. Dyagil and V. Klimenko (Hematology Group) and Dr. Tsvetkova (Consultant). These meetings concentrated on: (A) finalization of plans for the upcoming diagnostic review, (B) the summary of the findings made by the delegation from Kiev to the oblasts of Donetsk, Kharkiv and Sumskaya, and (C) discussion of problems encountered in Dnipropetrovsk oblast in the pilot testing of procedures to obtain consent for interview and bleeding amongst a group of 40 liquidators in that oblast

A. Plan for the Diagnostic Review of Retrospectively Diagnosed Case of Leukemia, Lymphoma and Related Disorders for the Chernobyl Liquidator Study

(i) Introduction:

Prior to our meetings Dr. Finch had sent the then current version of the protocol and clinical record abstract form to our colleagues in Kiev. As mentioned above, Russian translations of the two documents were presented in order to facilitate better communication (especially with Dr. Klimenko). The contents of these documents were the result of collaboration between myself and Drs. Beebe, Finch and Reiss (the latter being Columbia's hematological specialist). During our meetings in Kiev the protocol and clinical record abstract form were discussed in detail, paragraph by paragraph.

At the conclusion of our meetings the final (as far as possible) versions of the two documents were agreed upon and a copy of each are attached (Appendix I and Appendix II respectively). The protocol document is in the process of being translated into Russian by Dr. Kokoreva of the Columbia team. The clinical record abstract form has been translated into Russian by Dr. Kokoreva upon my return from Kiev with the special feature, agreed upon in our meetings, that all questions and data entry boxes on the form appear in both Russian (first) and English (second). The completed translations will then be sent to Kiev.

Details of the decisions agreed upon in finalizing the two documents are not given in this report as they can be gleaned from the documents themselves (Appendix I and II). However, certain key decisions were made that are important to highlight here (see below).

(ii) Highlights:

* It was agreed that Dr. V. Klimenko (Head of Hematology Group) will notify the responsible persons at each oblast and Kiev City regarding the procedures and time lines for the random case identification together with the methods for the assembly and review of clinical information and laboratory materials.

* It was agreed that Dr. Natalia Gudzenko (Epidemiology Group) will visit the appropriate hematology departments and out patient clinics of the oblasts and Kiev City to identify in total from each study area 20 retrospectively diagnosed cases with leukemia, lymphoma and related disorders adhering to an agreed upon randomization scheme (see below). Cases will be selected from the population of all males who were between the ages of 20 and 40 years old in 1986, were resident in the study areas and were diagnosed with having developed leukemia, lymphoma and related disorders during or after 1987 up to and including 1998. Once the cases have been identified (from journals stored in each facility) Dr. Gudzenko will notify the appropriate personnel at each facility that a clinical record abstract form will be completed for each such identified case and that the study is requesting ALL histological material for each case be made available for the diagnostic review.

* The randomization scheme, briefly, involves dividing the period 1987 to 1998 into three equal time frames i.e. 1987-1990, 1991-1994 and 1995-1998. The months within each of these time periods will be assigned numbers chronologically from 001 to 048 and cases will be chosen equally (where possible) from each time frame using a randomization of the numbered months to find the appropriate entry page in the journal on which to identify the first case. This process will be repeated for each required case. Further details of this randomization process can be seen in the protocol document (Appendix 1).

* Once the identification is complete the clinical record abstract form will be completed for each case by Dr. Zoya Radtchuk, a hematologist in the Department of Hematology, Institute of Clinical Radiation with another hematologist (as yet unnamed). At this time Dr. Radtchuk and her colleague will also examine the collected histological material for each case to determine if any staining or re-staining of slides is necessary; and, if so, this will be done in Kiev at the Department of Hematology, Institute of Clinical Radiation upon their receipt from the study areas.

*The first objective for the diagnostic review panel is for all members to reach a consensus agreement on diagnostic criteria for each type of disease.

* The major components to be included in the actual review process have been agreed upon. Briefly, these include:

- determination of whether the histological material is or is not diagnostic relative to the quality of the histologic material (e.g. stains etc).
- the review panel will focus on the certainty of diagnosis of leukemia and lymphoma, the

acuteness of disease and the certainty of the type of disease.

- the review evaluation will include a statement of the leukemia and lymphoma classification agreed upon or not agreed upon and the extent to which the cases reviewed are in accord with this system. Details of the necessary review components are in the document protocol (See Appendix I).

* A detailed description of the mechanics of the review process itself will be prepared by Dr. Stuart Finch well in advance of the actual review. Other relevant forms such as individual tabulation forms for the review will be prepared well in advance of the review by Drs. Finch, Gudzenko and myself.

* Practical steps to be taken well before the time of the review were agreed upon such as obtaining at a minimum five microscopes of equal quality, appropriation of desks, excellent lighting, telephone communication, fax, photocopying machine, a good sized room, teaching slides, and personnel (see Personnel below)

(iii) Personnel:

The Review Panel:

The membership of the review panel will be determined as soon as possible. Dr. Stuart Finch will contact potential members (2) from the U.S.A.; Drs. Dyagil and Klimenko in consultation with Dr. Romanyenko will contact potential members (2) in Ukraine and a potential member will have to be contacted in France (by whom?). All potential members will be given two alternative weeks to choose from for participating in the review (the second or third weeks of January, 1999).

Necessary Personnel at the Review:

Plans should be made for the presence of Drs. Dyagil and Gudzenko to work with myself and Dr. Finch (chairperson) as consultants during the actual review process. This will provide bilingual expertise in the fields of hematology and epidemiology and the the presence of persons during the review with experience in similar diagnostic reviews.

(iv) Estimated Costs:

Dr. Stuart Finch asked our Ukrainian colleagues to estimate costs for the review within Ukraine (including transfer of material from and back to the oblast and Kiev City institutions, remuneration for the Ukrainian members of the review panel, costs of staining and re-staining slides etc.) Dr. Finch will provide more details of cost estimations in his trip report.

(v) Time Frame:

The selection of the random sample of retrospectively cases will be complete no later than

November 10, 1998. The completion of the clinical record abstract forms and receipt of all biological material in Kiev should occur no later than December 10, 1998 with the organization of this material being completed by the end of December. The review process itself will take place in Kiev the week beginning January 11 or at the latest the week beginning January 18, 1999 depending on the availability of diagnostic review panel members.

B. Summary Report of Delegation From Kiev to Donetsk, Kharkiv and Sumskaya Oblasts

Drs. Dyagil and Klimenko visited the Chief of Medical Services , the Deputy Chief of Medical Services and other medical personnel of Sumskaya oblast from August 6 to 8, 1998. Drs. Bebeshko, Dyagil and Tsvetkova visited similar senior medical personnel in the oblasts of Donetsk and Kharkiv from September 8 to 12, 1998. Similar visits to the appropriate medical personnel in Kiev oblast and Kiev City will take place immediately.

The purpose of these visits was to explain the overall magnitude of the study (Phase I and II), secure the official cooperation of these study areas in the study and in particular to ensure that these study areas will participate in the upcoming diagnostic review. Dr. Finch and myself were assured that such cooperation was attained and that these particular oblasts will participate in the diagnostic review. In this regard, we were assured by Dr. Bebeshko that the quality of work and skills of the medical and registry personnel in these oblasts are on a par with that in Dnipropetrovsk oblast.

The summary report indicated a number of characteristics particular to these oblasts:

* In the oblasts of Kharkiv and Sumskaya the liquidator registries are located in the dispensaries (which is also true of Dnipropetrovsk oblast) and this should therefore facilitate the identification and follow-up of liquidators.

* In Donetsk oblast the liquidator registry is part of one extensive statistical bureau responsible for the entire populatio of the oblast. We were assured that this fact should not pose any problems.

* In Dnipropetrovsk and Sumskaya oblast liquidators are treated locally or in Kiev City, however, in both Donetsk and Kharkiv a small percentage (percent not available) of the liquidator population chooses to attend clinics in Moscow which is approximately equal in distance from these oblasts as is Kiev.

* In the oblasts of Donetsk, Kharkiv and Sumskaya (like Dnipropetrovsk) there has been very little use of the FAB classification system for leukemias whereas in Kiev and Kiev oblast this system has been and is in use.

*For all oblasts and Kiev City there is no uniform classification system used for lymphoma.

* For all oblasts and Kiev City peripheral blood smears are not kept for long periods of time.

*All oblasts (except for Sumskaya oblast) and Kiev city store bone marrow slides for 10 or more years. Sumskaya oblast stores bone marrow slides for only 3 years.

C. Pilot Work Amongst Liquidators in Dnipropetrovsk Oblast

We very briefly discussed problems which have arisen in the field testing of 20 liquidators selected from the State Registry who were residents of Dnipropetrovsk oblast and had their routine physical examinations in 1997.

Different methods of approaching the potential cohort members were discussed together with the possibility of paying liquidators to secure their cooperation. The amount of payment suggested was \$10 per person. However, both Dr. Finch and myself cautioned our Ukrainian colleagues that once it becomes known that potential respondents will be paid, it is very difficult to return to the methodology of non-payment. The possibility of payment, of course, raises the issue of increased costs in Phase II.

Appendix I

Plan for the Diagnostic Review of Retrospectively Diagnosed Cases of Leukemia, Lymphoma
And Related Disorders for the Chernobyl Liquidator Study

A. Introduction:

In order to evaluate the relationship between ionizing radiation exposure and the development of leukemia, lymphoma and related disorders which have occurred in Ukrainian liquidators since 1986, diagnostic confirmation of their case status is essential. This brief protocol outlines a plan for an expert panel review of the clinical and laboratory information and histologic material from a representative sample of Ukrainian males who developed these disorders in order to determine the feasibility of adequate diagnostic confirmation in the liquidators. The plan is to conduct the review in Kiev in the 5th quarter of Phase I.

B. Persons to be Selected for the Review:

Cases for the diagnostic review will be selected from the population of all males who were between the ages of 20 and 40 years old in 1986, were resident in the city of Kiev or one of the five oblasts in the study and developed leukemia, lymphoma or a related disorder during or after 1987.

There are several reasons for selecting males from the general population of Ukraine rather than restricting the diagnostic review to liquidators. The first reason is that the number of retrospective cases of each type of disease required for the diagnostic review probably is insufficient in the target liquidator population. Secondly, Chernobyl Registry case identification would require a number of cumbersome and time consuming steps in order to identify the specific number of cases of each type of disease in the liquidators in various locations. Thirdly, Chernobyl Registry information for cases amongst the liquidator population may not be sufficiently complete at this time. Lastly, there have been emphatic assurances that the clinical management of males cases in the general Ukrainian population with the diseases of interest has been and is identical to that for the liquidators. Thus, case selection from the general male population meeting the age, residence and temporal occurrence of disease requirements will serve as a surrogate for the liquidator population.

C. Location of Case Information and Biological Tissues:

The major potential sources of information for the identification of retrospectively diagnosed cases of interest in Kiev city and each of the five oblasts are:

1. The hematology departments/outpatient clinics of oblast or city hospitals.
2. Kiev and oblast oncology dispensaries.
3. City and oblast hospital morgues.
4. The State Chernobyl Registry of Ukraine (contains annual registry medical information for liquidators).
5. The Bureau of Lifetime Events (contains information regarding cause of death for all Ukrainian citizens).

Only 1 and 2 above will be utilized for selection of leukemia, lymphoma and related disorders for the review for the following reasons:

- i) All patients in Ukraine who are suspected of having leukemia or a related disorder are directed to the hematology departments of the oblast or city hospitals. There may be some overlap of lymphoma cases but most of these are directed to the oncology dispensaries. The medical records and hematology slides for virtually all retrospective cases will be located in these departments or their clinical laboratories.
- ii) Most patients with suspected lymphoma are referred to the oncology dispensary of the oblast in which they reside for diagnosis and treatment. Thus, the clinical records

and pertinent histological slides will be located in these departments or associated clinical laboratory/pathology departments. As noted above, some lymphoma patients may have been managed in hematology departments and, therefore, will be identified there.

Poor or non-existent diagnostic histologic smears and/or tissue sections may be characteristic of some cases in the hematology and oncology clinical departments. In such instances, if an autopsy was performed at a city or oblast hospital morgue, bone marrow and/or tumor tissue sections could be prepared from autopsy tissue blocks for the review. It should be emphasized, however, that few, if any cases of leukemia, lymphoma or related disorders would have been autopsied without first having been followed in a clinical department so that pathology departments or morgues will not be utilized for primary case identification and requests for special laboratory services should be rare.

D. Number and Types of Cases to be Selected From Each Study Area:

The number of each type of case to be selected (if available) in Kiev city and each of the five oblasts is as follows:

Diagnosis:	Number of Cases
Chronic myelogenous leukemia	2
Chronic lymphocytic leukemia	2
Acute leukemia (any type)	5
Myelodysplasia	2
Myelofibrosis/Hypoplastic anemia	2
Non-Hodgkin's Lymphoma	3
Hodgkin's Disease	2
Multiple Myeloma	2
Total	20

The total number of cases to be reviewed should be a maximum of 120 if each of the six study areas contributes 20 cases.

E. Procedures for Case Selection:

1. An appropriate senior scientist in Kiev (Dr. Victor Klimentko) will notify the responsible persons at each location regarding the procedures and time lines for the random case identification and the methods for assembly and review of clinical information and laboratory materials.
2. Dr. Gudzenko then will identify cases for study at each location from lists (or journals) in accord with a prescribed method of randomization that conforms with the requirements for adequate representation of cases by various types of disease (see D above) and appropriate time periods since 1987 (the 12 year period 1987 to 1998) will be divided into three equal time periods: 1987-90, 1991-94 and 1995-98).

It is absolutely essential to adhere strictly to the randomization process: i.e. in identifying cases who agree with the selection criteria from the journal pages the first name on the relevant page who matches the selection criteria must be chosen. There must absolutely not be any digression from the pre-determined randomization rules.

The method of randomized case selection is as follows:

Lists (or journals) of cases at the oblast and city of Kiev diagnosed from 1987 to 1998 are listed in chronological order by date of diagnosis. This span of years will be divided into three equal time periods: 1987 to 1990, 1991 to 1994 and 1995 to 1998. Within each of the individual time periods numbers will be assigned chronologically (starting at number 1) for each month in that period (the

numbers will run from 1 to 48). In order to ensure that the diagnostic review team has available to them cases diagnosed early and late in the 12 year period 1987 to 1998, whenever two cases of a disease classification are required, one case will be chosen randomly using the randomly identified month from the earliest time period, and the other case, using the same technique will be chosen from the latest time period. Where three cases are required one case from each time period will be selected and in the circumstance where five cases are required, two will be chosen from the earliest time period, one from the middle time period, and two from the latest time period.

In all instances of case selection for each time period the numbers allocated to the 48 months within that period will be computer randomized and the first case will be chosen starting at the beginning of the month selected reading down the journal pages until an appropriate case is identified for that particular type of disease. For the next case of the same disease type, the identical procedure will be followed but rather than reading down the journal pages the pages will be read up from the beginning of the randomly selected month until the first eligible case is identified.

As stated above, there must be no digression of any kind from the established randomization process.

Once a case is identified a request will be made for the following:

1. That each clinical record (if available) be abstracted on a special bilingual form, a copy of which is attached. The abstractor will be Dr. Zoya Radtchuk, a hematologist in the Department of Hematology within the Institute of Clinical Radiology. Ideally, the abstractor should have no vested interest in either the study as a whole or the diagnostic review in particular. The abstract form will be completed for each identified eligible case well before the time of the review.

2. All pre-treatment peripheral blood smears, bone marrow smears, bone marrow sections, tissue sections, touch preparations, cytochemical stained smears, unstained peripheral blood and bone marrow smears be assembled and placed in a slide box or pathology slide folder individually numbered for each case. The assembled materials will then be checked by Dr. Radchuk for their quality.

As noted previously (Section C), if no slides are available or they are of extremely poor quality, and if there were surgical or autopsy blocks the appropriate pathologist at each oblast level will be requested to cut and stain the tissues.

3. The abstracted clinical record and all histologic slides will be identified by the case's name, case number (for each study area this number will be that used at the local level) and a code number for the diagnostic review process (i.e. numbers will run chronologically from 001 through to 120 and will be uniquely assigned to each case by oblast area). Information such as oblast, raion and name of hematologist determining the original diagnosis will be omitted so that anonymity will be provided to the review panel.

4. Assembled slides and completed abstract forms should be in the hands of Dr. Dyagil in Kiev no later than December 10, 1998.

F. Ancillary Tasks to be Completed Well Before the Review

1. A detailed description of the mechanics of the actual review process must be prepared well in advance of the review panel's commencement. During the first day of the review process, review panel members will be given the opportunity to modify the plan where necessary.
2. Individual tabulation forms for the hematologists/pathologists must be prepared well in advance in sufficient numbers so that each reviewer can conveniently and quickly record results for each case.
3. All staining of unstained slides and re-staining of slides must be completed in Kiev at the Institute of Clinical Radiology, Department of Hematology well before the time of the review.

4. An appropriate room in Kiev must be identified as soon as possible where at least 5 tables with good microscopes of equal quality can be located near electrical outlets. Tables should be large enough to accommodate papers for tabulations of results. Substage lighting should be adequate for oil immersion microscopy. Desks should be available for storage of slides, texts, immersion oil, blank forms etc. It is also recommended that the room chosen for the review process be as close as possible to photo copying equipment, fax machines and telephones.
5. An overhead projector, slide projector, large illustration pad and laser slide pointer should be available for the first day of the review.
6. Sets of teaching slides for leukemia, lymphoma and related disorders to be used for agreement on disease classification must be available. Several copies of AFIP atlases on non-Hodgkin's lymphoma and bone marrow disease will be made available for distribution at the beginning of the review process (i.e. on the first day)
7. Plans should be made for the presence of Drs. Dyagil and Gudzenko to work with Drs. Burch and Finch as consultants during the actual review process. This will provide bilingual expertise in the fields of hematology and epidemiology and the presence of persons during the review with experience in similar diagnostic reviews.
8. An interpreter with expertise in Russian and English should be present during the entire review process.

The members of the review panel will be instructed regarding the mechanics of the review process and use of the evaluation/tabulation forms on the first day of the review. If review panel members have suggestions of their own these will be discussed and acted upon at this time. However, the primary focus of the first day of the review will be on reaching a consensus on classification criteria for disease classification.

The use of individual case evaluation/tabulation forms will permit the assessment of inter-reviewer variability. No attempt will be made to assess intra-reviewer variability as it would be virtually impossible to effectively mask repeat clinical information and slides.

G. Essential Objectives and Components of the Review Process

The first objective of the review process is for all members of the review panel to reach a consensus on diagnostic criteria for each type of disease and the classification system to be adopted. It has been agreed to date that only the FAB system will be employed for the acute leukemias but it has been recommended that the NIH Working Classification be used for the classification of non-Hodgkin's lymphoma. This, however, is a topic for discussion and agreement on the first day of the review process.

- For each case the presence/absence of a peripheral blood smear, bone marrow smear/section, tissue slides for lymphomas and completed abstract forms will be noted. In addition, the review panel members will determine whether the available histologic material submitted is or is not diagnostic relative to the quality of the histologic material (ie. staining, tissue thickness, labeling etc.
- Leukemia/Lymphoma Diagnostic Criteria

The review panel will focus on the certainty of diagnosis of leukemia or lymphoma and the certainty of the type of disease.

The review of cases of previously diagnosed leukemia should include:

- certainty of diagnosis of leukemia (definite, probable, possible)
- certainty of type of leukemia (definite, probable, possible)
- final diagnostic category:
 - acute lymphocytic leukemia (FAB type or unclassifiable)
 - chronic lymphocytic leukemia
 - chronic myelogenous leukemia

- acute myelocytic leukemia (FAB type or unclassifiable)
- unclassifiable acute leukemia due to undifferentiation or other reason
- myelodysplastic syndrome (FAB type)
- other type of leukemia (i.e. mixed lineage, T-cell etc.)
- leukemia related disorders (myeloproliferative disorders other than CMLO or myelodysplasia)
- not leukemia giving reason
- no diagnosis possible due to incomplete and/or unsuitable material

The review of cases of previously diagnosed lymphomas must include:

- certainty of diagnosis of lymphoma (definite, probable, possible)
- certainty of type of lymphoma (definite, probable, possible)
- final diagnostic category
 - Hodgkin's Disease with histologic type
 - Non-Hodgkin's lymphoma (NIH working formulation)
 - other types of NHL not included in NIH working formulation
 - unclassifiable lymphoma giving reason
 - not lymphoma giving reason
 - no diagnosis possible due to incomplete and/or unsuitable material
- The review evaluation should include a statement regarding the leukemia and lymphoma classification system agreed on (and why) and the extent to which all cases reviewed are in accord with this system utilizing the above listed parameters. The summary must include tabulations of:
 - The extent of agreement or disagreement by the review panel members on diagnosis of leukemia and/or lymphoma
 - The extent of agreement or disagreement by the review panel members on the type of leukemia and/or lymphoma
 - Material determined to be insufficient for evaluation (no records, poor quality records, inadequate or no slides, mislabeling etc.)
 - Percent of original diagnoses of leukemias and lymphomas confirmed by consensus of review panel as definite or probable
 - Percent of original diagnoses of leukemias and lymphomas confirmed by consensus of review panel as possible or not leukemia or lymphoma
 - The extent of change in the type of leukemia or lymphoma as originally diagnosed.
- The consensus opinions for all cases from each location submitting material for the review should be returned with slides and other material to the appropriate hematologist upon completion of the review. There should be no indication made to the local hematologists that they were inadequate in their original diagnoses stressing that the review panel's opinions are being sent to them for their interest.

H. Membership on the Review Panel

The membership of the diagnostic review panel should be determined as soon as possible so that potential members can be contacted giving them alternate dates for attendance in Kiev for the review which is anticipated to require no more than one working week (i.e. five days). None of the potential members of the review panel should have any connection or involvement with the follow-up cohort studies of liquidators in Ukraine. It has been suggested that the review panel at the very least consist of one hematologist expert in leukemia morphology from both Ukraine and the U.S.A., one hematopathologist expert in leukemia and lymphoma morphology from both Ukraine and the U.S.A. and one hematologist or hematopathologist from France.

I. Time Frame

It is anticipated that the epidemiology group in Kiev will have selected the random sample of cases of leukemias, lymphomas and related disorders from the oblast/study area institutions no later than November 10, 1998. Receipt of all clinical and biological material for the identified cases should be in Kiev by December 10, 1998 with the organization of this material complete by the end of December. The review process itself then will take place during the second week of January, 1999 (the week

beginning January 11) and at the latest, the third week of January, 1999 (the week beginning January 18) depending on the availability of diagnostic review panel members.

Appendix II

ИНФОРМАЦИЯ ИЗ ИСТОРИИ БОЛЕЗНИ
CLINICAL RECORD ABSTRACT

Имя _____ Дата заполнения формы | | | | | | | |
Name Date when form was completed День Месяц Год
Day Month Year

Клинический статус

Clinical status

живой

living

скончался

deceased

(дата смерти | | | | | | | |)

date of death

Месяц

Год

Month

Year

(вскрытие да нет)

autopsy

yes

no

Данные из истории болезни

Clinical Record

да (если пункты, приведенные ниже, полностью
заполнены)

yes (if checked complete all of the following items)

нет (если заполнены только 7-10 из ниже
приведенных пунктов)

no (if checked complete only items 7-10 below)

1) Дата, когда появились первые признаки гематологического заболевания

Date of first symptoms of hematological disorder

| | | | | | | |

Месяц

Год

Month

Year

2) Дата, когда был поставлен диагноз гематологического заболевания

Date of diagnosis of hematological disorder

| | | | | | | |

Месяц

День

Год

Month

Day

Year

3) Симптомы до начала лечения

Pretreatment symptoms

слабость

weakness

утомляемость

tiredness

анорексия

anorexia

кровоточивость

bleeding

лихорадка

fever

- аденопатия ночное потение ломота в костях и суставах
adenopathy night sweats bone pain or joint pain
- головная боль нет ни одного из перечисленных симптомов
headache none of these
- неточные или неполные данные другие симптомы _____
inadequate or poor information other

4) Физикальные данные до начала лечения
Pretreatment physical signs

- бледность пурпура или петехии кровоточивость
pallor purpura or petachiae bleeding
- гингивальная гиперплазия хрупкость костей
gingival hyperplasia sternal tenderness
- значительная лимфоаденопатия гепатомегалия спленомегалия
significant lymphadenopathy hepatomegaly splenomegaly
- нет ни одного из перечисленных признаков
none of these
- неточные или неполные данные
inadequate or poor information
- другие признаки _____
other

5) Диагностические исследования до начала лечения (отметьте все те, которые были проведены)
Pretreatment diagnostic studies (check all performed)

- состав периферической крови
peripheral blood count
- клеточный состав крови
differential blood count
- пунктат костного мозга
bone marrow aspiration
- цитохимические окраски периферической крови или костного мозга
cytochemical stains of peripheral blood or bone marrow

метамиелоциты _____ %
metamyelocytes

миелоциты _____ %
myelocytes

промиелоциты _____ %
prolymphocytes

лимфоциты _____ %
lymphocytes

пролимфоциты _____ %
prolymphocytes

моноциты _____ %
monocytes

плазматические клетки _____ %
plasma cells

бласты (любого типа) _____ %
blasts (any type)

эритроциты с ядрами _____ %
nucleated red cells

другие(пожалуйста, уточните) _____ %
other cells (please, specify)

_____ %

_____ %

7) Препарат(ы), посылаемые для рассмотрения
Slide(s) being sent for review

- мазок периферической крови до лечения
pretreatment peripheral blood smear
- мазок костного мозга до лечения
pretreatment bone marrow aspiration smear
- цитохимические окраски периферической крови или мазков костного мозга
cytochemical stains of peripheral blood or bone marrow smear
- неокрашенный мазок костного мозга
unstained bone marrow smear
- биопсия костного мозга
bone marrow biopsy
- мазок костного мозга
bone marrow touch preparation
- биопсия лимфатического узла
lymph node biopsy
- мазок лимфатического узла
lymph node touch preparation

- биопсия других тканей
other tissue biopsy
 - тканевой препаратный срез (только костного мозга и лимфатического узла)
autopsy tissue sections (bone marrow and lymph node only)
 - ни один из вышеперечисленных
none of the above
- 8) Другие комментарии (а именно: Ph1 или другие опухолевые маркеры, цитохимические окраски, т.д. и т.п.)
Other comments (e.g., Ph1, or other tumor markers, cytochemical stains, etc.)

9) Диагноз
Diagnosis

Клинический _____
Clinical

Вскрытие (если оно проводилось)
Autopsy (if any)
